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Review Article

Quality Assurance Guidelines for Breast Imaging – Breast Imaging Society, India

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ABSTRACT

Quality Assurance in Breast Imaging is one of the cornerstones for providing high-quality breast care. It is central to achieving and maintaining high standards of breast radiology services. Uniform guidelines for the entire nation ensures that high standards can be achieved irrespective of geographical location of the imaging center and financial capability of the patient. No consensus document or guidelines focuses on Indian patients and its healthcare infrastructures. In this document, a task group formed by the Breast Imaging Society, India (BISI), sought to formulate quality assurance standards for all breast imaging modalities available in India. A breast imaging framework, practicable for all breast radiologists and institutions, has been provided to establish the minimum quality standards required for breast imaging services. The guidelines encompass all aspects of breast imaging, including mammography, breast ultrasound, breast magnetic resonance imaging, and breast interventions. The recommended reporting format for various modalities is also included. The guidelines also provide the minimum training requirement for all members of the breast imaging service provision team, including radiographers and radiologists. The minimum standards for the equipment, as well as the unit, have also been addressed. The current quality assurance guideline aims to provide a holistic approach to standardize breast care imaging services in India.

Keywords: Indian quality assurance guidelines, Breast imaging, Mammography, Breast ultrasound, Breast MRI, BISI guidelines, BISI QA guidelines

1. MAMMOGRAPHY

Quality assurance (QA) is defined by the Atomic Energy Regulatory Board (AERB), India, as planned and systematic actions necessary to provide adequate confidence that an item or facility will perform satisfactorily in service as per the design specifications.[1] AERB has regulations, and we advise the users of mammography equipment to follow AERB rules and regulations applicable to their respective machines. In this document, the Breast Imaging Society, India (BISI) has advised simple QA measures that are easy to implement at the departmental/hospital level and will improve the quality of patient care. Minimum standards for the radiologist/

mammographer have also been specified to objectively assess and implement reasonable breast imaging standards across India. QA for Digital Breast Tomosynthesis (DBT), stereotactic breast biopsy, and Quality control (QC) tests that are practical and relevant for radiologists have also been discussed and advised. Please refer to 'Best Practice Guidelines of Breast Imaging Society, India' for indications of mammography.[2] At the end of the document, Appendix 4.1 contains details of the AERB documents and QC tests for DBT recommended for the breast radiologist and technologist. There are reporting templates for mammography and stereotactic breast biopsy in [Appendix 4.2 and 4.3], respectively.

1.1 Mammography equipment

Mammography units can be of three types - Digital radiography (DR), Computed radiography (CR), and Traditional film-based mammography. Quality assurance tests are mandatory for all types of mammography units, and mandatory test reports are to be submitted to the Radiological Safety Division of AERB, India, as per the regulations.

The acquisition technique of mammographic images must be monitored with specific attention to radiation dose and technical adequacy of films. The radiation dose must be minimized based on the As Low As Reasonably Achievable (ALARA) principle.[1] Most mammography units have an automatic exposure control (AEC) system, which helps minimize radiation for the given breast thickness and composition. Exposure time must be as low as possible to reduce dose, avoid motion artifacts, and minimize discomfort to the lady being imaged. Optimal compression must be applied.[2]

The regulatory inspection program of AERB includes three types of inspections. There are planned and announced inspections, special regulatory inspections, which are reactive and announced, and surprise regulatory inspections, which are reactive/proactive and unannounced.[3]

At the time of installation, submission of a survey report detailing the radiation survey levels measured around the installation is mandatory.[4] The radiation survey report contains details of the maximum radiation level at various locations, such as the lead glass wall, operator position, entrance door, patient waiting area, front and side walls, and the entrance corridor. The radiation survey report also contains details of the QA tools used, such as kVp and dose meter, survey meter, and imaging phantom.

Typical AERB tests and measurements include performance test verification of safety system/components, radiation protection survey, area monitoring, clinical/product dosimetry, and contamination checks.[3] Personal dosimeters must be given to all radiation workers, including trainees. Any unusual occurrence/incident must be documented, and measures must be taken to avoid recurrence.[3]

Periodic QA test reports must be submitted to AERB at least once every two years and after any repairs with radiation safety implications.[5] Parameters tested for periodic radiation safety performance test reports include accuracy of operating potential, accuracy of timer, linearity of tube current, reproducibility of output, radiation leakage level at 5 cm from the external surface of X-ray tube housing, total filtration and performance of imaging phantom.[5] Image quality is assessed by using a mammography phantom. The manufacturer provides the optimum value for the tests, and the measurements acquired are compared against the provided optimum value and AERB standards.

Digital detectors must be calibrated periodically as per the manufacturer's recommendations for DR Mammography. The CR cassettes must be cleaned and evaluated for artifacts as per the manufacturer's instructions for CR Mammography. In the presence of artifacts that compromise image quality (for example, artifacts that mimic microcalcifications), the CR cassettes must be discarded. Traditional film-based mammography cassettes must be similarly monitored, and darkroom techniques must follow the manufacturer's instructions.

An additional recommendation for Image quality assessment by the Breast Imaging Society, India

Image quality assessment using a mammography phantom is advised at least once a week. However, daily assessment before the first case of the day is ideal, especially for screening mammograms. To pass the mammography image quality standards, at least four fibers, three calcification groups, and three masses must be visible (with no artifacts) at an average glandular dose of less than 3 mGy upon mammography of the phantom.[5] Image quality has been chosen as the continuous assessment method as this is a simple, quick test that the mammographer can perform. This test confirms that the image is of optimal quality and indirectly assesses the factors that affect image quality, such as operating potential, operating tube current, exposure time (msec), effective focal spot size, total filtration, leakage from tube housing, and detector characteristics.[6]

1.2 Mammography image acquisition

Technically adequate Mediolateral oblique (MLO) and Craniocaudal (CC) views are the two standard views of mammography advised for each breast, both for screening and diagnostic mammograms. Additional CC and MLO views with implant displaced optimally are recommended for breasts with implants within. The minimum requirements

for the MLO view include visualization of the pectoralis upto the level of the nipple, convex anterior border of the pectoral muscle, nipple in profile, and inframammary fold, which should be demonstrated and open. The minimum requirements for the CC view include visualization of the nipple in profile and retroglandular fat. The length of the posterior nipple line on CC should be within 1 cm of the length of the posterior nipple line on MLO view. Skin folds are to be avoided in both views.

Additional views (such as spot compression, lateral, laterally extended and medially extended CC) could also be acquired to demonstrate abnormalities better. In the case of palpable masses, special attention must be paid to confirm visualization of the palpable lesion on the mammograms. Repeat films may sometimes be required, but these must be minimized. Clinical needs and the ALARA principle should justify additional views and repeat images. Departmental policy on repeat exposures and other images must be followed. The technologist assesses the acquired images for adequacy of position and artifacts. The degree of autonomy of the mammographer and radiologist's active supervision in these decisions depends on the mammographer's work experience and expertise and should be decided by the supervising radiologist.

CC and MLO markers must be placed as per international practice in the lateral aspect of the CC view and the superior aspect of the MLO view. A skin lesion or mole that may mimic a mass on the mammograms should be marked on the skin with a tiny radiopaque marker, which should be smaller than the skin lesion. The mammographer should identify these at the outset, and mammograms should ideally be acquired after the marker is optimally positioned rather than repeating mammograms. This will avoid increased radiation dose to the patient. Palpable masses also should ideally be marked with a radiopaque marker. This helps identify the palpable mass on the mammograms, which is extremely helpful in cases with multiple focal lesions in the breast.

A review of all mammograms by the radiologist immediately after acquiring images is encouraged to decide the need for additional diagnostic views. However, if the local protocol allows, screening mammograms can be obtained in the absence of the radiologist. In this case, the lady must be recalled for further views.

1.3 Mammography personnel

Specialist Breast Technologist/Mammographer

The mammographer must have a 2 or 3-year diploma or degree, such as a Diploma in Radiography, Diagnostic (DRD) recognized by the state/central government. She should have specific training in Mammography as part of this training program. Performing a minimum of 100 mammograms under supervision before performing mammography independently is strongly recommended. After completion of training, a minimum of 150 procedures should be performed per year to maintain the skills acquired. Mammographers are encouraged to attend periodic educational courses for continued upgradation of technical knowledge. Appropriate training of mammographers should be organized, as this significantly improves the technical adequacy of mammograms and reduces repeat images, thus reducing patient dose significantly.

Mammographers are to take lead in regular radiographic quality control procedures. They are also responsible for maintaining documentation of quality control tests. They are advised to report any breaches/incidents to the radiologist in charge.

The mammographer should counsel the lady about the procedure, especially the importance of compression. She should be able to answer basic questions on radiation dose and the importance of screening. She should be able to help the patient fill out relevant patient questionnaires, check if the mammography requisition is as per the department protocol, and document patient complaints as required. She should record patient contact details to ensure a seamless recall process if needed. She should collect previous mammograms and relevant clinical notes and make these available during reporting. She should also explain the process and time for report collection to the patient.

A mandatory check of name and unique hospital identification number (UHID) must be performed before pressing the radiation button to ensure that the right patient is being imaged. All films must be labeled correctly with the name, UHID number, date, side, and other details as per the local protocol. Repeat mammograms for technical or positioning errors must be less than 3%.[7]

Breast Radiologist

The radiologist should have a medical qualification and hold a degree in Radiology recognized by the National Medical Commission of India. They should have specific training in Mammography as part of their training program. Taking up a breast fellowship course or activity under an experienced Breast Radiologist is strongly recommended before independent reporting of mammograms. This training should also help develop skills for performing mammography-guided procedures such as guided hook wire localization and stereotactic biopsy. Radiologists must attend continuing medical education (CME) courses for upgradation of technical knowledge.

During training, the radiologist is expected to report a minimum of 1500 mammograms under supervision before they start reporting independently. This may be over a 1 to 2-year period, depending on the volume of mammograms in the unit. To maintain skills, the radiologist must report a minimum of 500 mammographic examinations per year. Reporting terminology and format as per ACR BI-RADS lexicon and assessment categories are advised.[8]

The lead breast radiologist oversees the breast unit and should take responsibility for quality-related issues, including equipment selection, staff selection, quality control protocols, and the hospital management team. This also includes interactions with medical physicists, biomedical engineers, vendor application specialists, and the provision of training for mammography technologists. The lead breast radiologist is responsible for planning audits, delegating work to the appropriate person, and applying the lessons learned from the audits to implement changes in the department protocols.

1.4 Radiation dose & safety

In both full-field digital and screen-film mammography, the average glandular dose delivered by a single craniocaudal view of a 4.2 cm thick, compressed breast consisting of 50% glandular and 50% adipose tissue must not exceed 3.0 mGy (0.3 rad), although it is generally much lower.[9] The digital mammography systems automatically calculate the dose, making dose assessment easy. The mammographer and radiologist must endeavor to achieve this by following the ALARA principle. All tests, for example, check mammograms after the machine is serviced, and must be on a mammography phantom, not a patient.

The requisition form must justify mammography; if any doubt exists, the referring doctor should be contacted before radiating the patient. Every patient must be questioned about a recent mammography examination. If mammography has been performed within the last year, mammography should be performed only if clinically justified and after discussion with the radiologist. If good-quality mammograms have been acquired at one hospital, they must not be repeated at the hospital where a second opinion is being given. If a repeat is required, only those views that were suboptimal in the first instance should be repeated. At six month follow up mammography for a BI-RADS 3 lesion, unilateral mammography of the side of concern must be performed rather than bilateral mammography.

To avoid radiation incidents, the mammographer must confirm the patient's name and unique hospital identification number before performing mammography. After obtaining the MLO and CC views, further views should be acquired only if it is expected to add additional information or clarify doubts arising from the basic images.

Routinely wearing a lead shield or apron is not recommended as most of the dose to the organs results from scattering in the breast tissue and entering the trunk through the breast, and this minimizes the benefit of wearing a lead apron.[10]

Pregnancy & Mammography

Women of childbearing age must be checked for pregnancy status, and a pregnancy test is advised if doubt exists. The estimated dose to the uterus from an average bilateral two-view mammography is less than 0.03 μGy (0.003 mrad), which can represent the dose to the fetus in the first trimester.[10] Using a lead shield reduces this dose further by about a factor between two and seven. Therefore, a pregnant patient can reduce the dose to the fetus by at least one-half by wearing a lead apron.[10] If a patient is not aware of her pregnancy status and happens to undergo mammography, the risk to the fetus appears to be minimal.[10] Two types of radiation-related side effects are known: Deterministic and Stochastic. No known in-utero-induced deterministic side effects, such as teratogenic fetal effects, have been reported at radiation less than 50 mGy (5 rad),[11] thus no significant deterministic side effect on the fetus is expected from mammography. Stochastic risks resulting from cellular damage, causing cancer or germ cell mutation, have no threshold dose value, and the severity of radiation-induced stochastic effects is independent of the radiation dose.[12] Therefore, mammography should be carefully used for pregnant patients. However, fear of potential radiation effects on a fetus should not deter us from performing necessary mammographic studies, a case-based approach to decision-making is advised.[13] Although most of the dose to the uterus is from scatter radiation, a lead shield should still be offered to all pregnant patients.[14] Routine screening mammography is not performed during pregnancy.[14]

Staff & Visitors

The radiation safety of staff and visitors to the Department of Radiology is paramount. The mammography unit must be built, maintained, and checked periodically to confirm that AERB regulations are met. An application must be made to AERB for permission to install mammography equipment by the e-Licensing of Radiation Applications (eLORA) System,[4] and the mammography machine must be placed in the hospital with full compliance to AERB regulations.[3] All personnel must wear personal dosimeters, including trainees, at all times. The effective dose received by a radiation worker should not exceed 20 mSv in a year averaged over five consecutive years (calculated on a sliding scale of 5 years),

and the effective dose in any single year should not exceed 30 mSv, as per radiation dose limits specified by AERB for radiation workers. In the case of a pregnant radiation worker, once pregnancy is declared, the equivalent dose limit to embryo/fetus should be 1mSv for the remainder of the pregnancy.[15]

The mammography room must be used for mammography and mammography-guided interventional procedures only. No other investigations, such as breast ultrasounds, should be performed in the mammography room. Only personnel involved in the processes must be in the room during the examinations. This includes trainees who are posted to breast imaging. The mammography machine should be handled only by the mammographer designated for the study. The mammographer's control panel must be behind a protective screen per AERB regulations. The door of the mammography room must be shut and locked at the time of image acquisition, and a red light just outside the door must be switched on so that other members of the department, as well as the patients waiting outside the room, are aware of the risk of radiation.

1.5 Stereotactic biopsy

The stereotactic breast biopsy team should be adequately trained regarding the equipment, procedures, and possible complications. The technologist should be well versed in mammography and preferably undergo three months of observation or supervised training for stereotactic biopsy at a specialized breast unit. Dedicated training by the application specialist of the manufacturer and performance of stereotactic procedure under the supervision of the application specialist before independently performing the biopsy is also acceptable.

The breast radiologist performing the procedure should be trained in stereotactic procedures at a specialized breast unit before performing stereotactic procedures independently. A minimum of 150 supervised image-guided breast procedures (ultrasound and mammography-guided procedures included) must be completed over 1 year to train adequately. A minimum of 60 image-guided breast procedures (both ultrasound and mammography-guided procedures included) per year are recommended to maintain interventional breast imaging skills. The radiologist performing image-guided breast procedures must be well-versed in mammography and breast ultrasound interpretation, as this knowledge is essential for Radiology – Pathology correlation.

A stereotactic biopsy may be performed with a dedicated prone table setup, or with an add-on stereotactic device on the mammography machine and patient sitting on an adjustable chair. All equipment must be calibrated as per the manufacturer's guidelines. Quality control tests for the mammographic unit used to perform stereotactic biopsy are as per the manufacturer's instructions and AERB regulations.

At the time of installation of the stereotactic unit, an initial comprehensive performance test is to be performed by the engineers.[16] Mechanical stability of the free-standing unit, smooth motion of the moving parts, stability of the image receptor holder assembly, adequate support for the needle holders & needle guides, and adequate radiation shielding for the operator/technologist have to be checked and documented at the time of the installation of the unit.[16] This must be repeated each time the mammography machine is serviced or repaired due to any equipment breakdown. Annual quality check by a medical physicist to assess mechanical components of the equipment, collimation, focal spot performance, accuracy of kVp, half-value layer assessment, AEC performance, radiation dose assessment, and image quality evaluation is advised.[16]

Prior to the procedure checks must be performed by the mammographer as per manufacturer's instructions to check the accuracy of stereotaxis. On the accuracy test, each of the indicated needle tip coordinates (x, y and z axes) should be within 1 mm of the actual preset needle tip location. The difference between the preset and computer-determined locations should be less than 1 mm in each direction.[17] If a localization phantom is used, the localization accuracy test should result in the needle tip within 1 mm of the targeted phantom location in each direction.[17]

The operator should obtain written informed consent before the procedure after explaining the steps of the procedure and the possible complications such as hemorrhage, infection, retargeting, and repeat procedure. Instructions about post-procedure care should be duly explained to the patient by the radiologist conducting the procedure. History of allergy to drugs must be checked and documented.

Optimal precautions, such as using sterile gloves for performing the biopsy, are mandatory. The needle length, gauge, and throw should be confirmed before opening the sterile packaging of the core or vacuum-assisted breast biopsy (VABB) device. The VABB equipment must be calibrated before the start of the procedure. The concentration and expiry date of the local anesthetic must be checked while preparing the procedure tray.

During the procedure, images that demonstrate the important steps must be saved. The images should have the patient's name, UHID number, date, indication of right or left breast, name of hospital, and other details as per local protocol. A pre-procedure scout image documenting the lesion that is being targeted (typically microcalcifications), pre-procedure stereotactic pair images, pre-fire, and one set of post-fire stereotactic pair images would be a good set of images to

save for future records. A radiograph of the samples acquired must be saved for microcalcifications to document adequate sampling. As the risk of insufficient sampling is greater if no calcifications are seen on the sample radiograph,[18] further sampling, sometimes after retargeting, should be attempted. A post-procedure scout image (demonstrating partial or complete removal of lesions) is also advised, especially if the lesion biopsied is not calcified and hence, radiography of samples cannot be used to confirm adequate sampling. If a marker clip is deployed (for example, following the complete removal of the targeted lesion), an image demonstrating optimal marker clip placement should also be saved. After the procedure is completed, formal CC and lateral mammograms of the ipsilateral breast are performed to confirm the position of the marker clip.

Special attention must be paid to the disposal of all the sharps used during the procedure per hospital protocol. The biopsy room must have a sharps bin for discarding the needles used during the procedure.

The report should contain details about the lesion targeted, direction of compression, approach, type of biopsy equipment (fully automated core biopsy or vacuum-assisted biopsy), gauge of the needle, number of core specimens obtained, time of obtaining specimen and fixing in formalin, findings of radiograph of samples if any and post-procedure clip position if a marker clip has been positioned. Complications of the procedure, if any, should also be documented in the report. For example, if the post-biopsy mammograms demonstrate displacement of marker clip from the biopsy site, that must be documented.

Explicit mention of the clinical history, pertinent imaging findings, likely imaging diagnosis, name of the procedure (core or VABB), side (right/left breast), and anatomic location depicted by o'clock position, and distance from nipple should be mentioned on the pathology requisition form. Patient name, identification number, examination date, facility name, side (right/left breast), and procedure name should be mentioned on the container where the sample is placed. After the histopathology report is ready, the radiologist should correlate the radiological features with the pathology findings and add an addendum regarding radiology-pathology concordance. If discordance is found, repeat biopsy, follow-up scan, or investigation of the breast with a different modality, such as MR, should be advised as appropriate. Discussion with the referring clinician is of utmost importance in case of discordance.

Other mammography-guided procedures, such as hook wire localization and marker clip placement, should be similarly consented to, documented, and reported. This applies to tomosynthesis-guided procedures as well.

1.6 Digital breast tomosynthesis

Digital Breast Tomosynthesis (DBT) is an active area of research and development with evolving clinical roles. DBT is a quasi-3D imaging technique in which the X-ray tube rotates along an arc around the breast and acquires several low-dose images. The relative positions of structures at different depths in the breast change on the image at different angles. A 3D data set is reconstructed from these projection images and viewed as thin slices. The number of DBT installations in India is on the rise. As India embraces the clinical implementation of this technological advancement, attention to QA parameters is paramount. Due to the wide variation in hardware and processing algorithms used by different manufacturers, adherence to the manufacturer's QC tests becomes even more important with DBT systems. QA guidelines that may be suitable in the Indian context have been recommended in this document. Several international guidelines have been referenced for this purpose.

Indication

DBT is recommended as a complementary method and not a standalone screening technique in the first 6 months to a year of installation to accommodate the mammographer's and the radiologist's learning curve and optimize image quality. DBT has been universally accepted as a diagnostic mammography evaluation tool and used as an adjunct to conventional mammography in those cases requiring further workup.[19] The indications for diagnostic DBT are the same as that for 2D Digital Mammography (DM). DBT may be performed in addition to CC, MLO, and supplemental views to evaluate an area of clinical or imaging concern.[20] When used for screening, complete 2-view DBT acquisitions of each breast are taken in addition to standard DM views. Synthesized 2D image (SM) can be generated from DBT data, eliminating a separate DM exposure. DM+DBT increases the radiation dose by 2.25 compared to DM-only examinations. If DM is replaced with SM, the radiation dose can be reduced by 45%.[21] Studies show that the performance of SM + DBT is equivalent to DM + DBT.[22-24] To image breasts larger than the detector, performing DBT for all routine and additional exposures with synthesized 2D images should be considered. If both DM and DBT acquisitions are required, DBT should be restricted to views that cover the largest portion of the breast to minimize radiation dose.[25] While imaging breasts with implants, DBT should be used only for implant-displaced views.[25]

Reporting terminology and format are similar to the reporting of 2D mammography. It's preferable to use the ACR BIRADS lexicon and assessment categories just as for 2D mammography. The report should include a slice number and

views of findings on DBT. Prints of synthesized images must be labeled as such to distinguish them from a DM exposure. Prints of DBT images must include slice number, thickness, and location relative to the side of the breast.

Training and certification requirements for Mammographer and Radiologist

Basic training requirements listed in the mammography section for technicians and radiologists working in breast imaging centers must be met. Specific training for DBT may be obtained during residency or fellowship in Breast imaging for radiologists and as part of the radiography curriculum for radiographers. However, it is expected that most breast radiologists and radiographers practicing today are unlikely to have been exposed to this imaging technique. Due to wide variation in technology, training is advisable from individual DBT manufacturers through training courses and observerships in units with the same equipment run by qualified peers. A minimum of 8 hours of initial training with documentation in the form of a training certificate or letter is advisable before independently using this new mammographic modality.[26] Over and above basic training, mammographers, and radiologists are encouraged to update their knowledge and skills continuously. The lead radiologist is responsible for recognizing additional staff training requirements to maintain and improve the quality standards of the unit.

Image Acquisition & Archiving

As in DM, the QA of DBT aims to acquire the best possible quality images with the lowest radiation dose per the ALARA principle. The testing procedures and requirements specified for DBT units are consistent with those set in the DM section per AERB guidelines. It should be noted that the manufacturers may advise some machine-specific QA testing to be done that is additional to these tests.[19] Working conditions and image display requirements are also the same as DM. Many international guidelines are available on DBT, and the reader is urged to study these and apply necessary QA measures at departmental and hospital levels as required.[19,25,27] DBT images, if generated in a proprietary format, should be converted to the DICOM standard of Breast Tomosynthesis Object (BTO) before transfer.[25] The archive device should support DICOM receipt of MG images and DBT data sets. Storage of "for presentation" or processed images is required to ensure the ability of radiologists to reproduce the original images used for interpretation. Storage of images "for processing" or raw data is encouraged but is not mandatory. The archive device should be able to query and retrieve DM and DBT data sets.

DBT-guided biopsy equipment

It is recommended but not mandatory. Procedure-related QA and documentation of images for DBT biopsy are similar to the steps mentioned in the stereotactic biopsy section. If DBT guidance is not available for a tomosynthesis-only finding, performing a stereotactic biopsy using adjacent tissue landmarks for guidance is acceptable. However, a biopsy marker should be placed with post-procedure DBT images in two projections to demonstrate that the original finding was targeted correctly.

1.7 The reporting station

Luminance of the viewing light box should be a minimum of 3,000 candelas per square meter (cd/m^2) for screen-film mammography and the display of digital images printed on films.[28] Ideally, viewing boxes of appropriate size are required to allow comparison with previous mammograms. All tubes may need simultaneous replacement to ensure they are of the same color and intensity, maintaining uniformity.

Ambient lighting must be conducive to reporting. Room lighting should be indirect, and care should be taken to ensure that no illumination from room lighting falls directly on the reporting monitor. The ambient lighting must not exceed 20 lux and should be assessed as part of Mammography QA.[19] The visual inspection of ambient lighting should be done daily by a designated QA technologist.

Two 5-megapixel monitors are advised to display images at the radiologist's reporting workstation. The monitors must be checked annually by the medical physicist or a biomedical engineer, per local protocol. One 3-megapixel monitor should be available for technologists close to the image acquisition area. This can include the acquisition station itself.[18]

At the radiologist's workstation, multiple layouts of image display can be arranged, and a hanging protocol for image display can be set up per the radiologist's preference. It is advisable to print the right and left MLO images side-by-side with the posterior part of the images facing each other to optimize the detection of asymmetries. CC images should be displayed similarly to printed images. Comparison of current studies with prior examinations is strongly recommended. To facilitate meaningful comparison, the printed images should have the magnification factor documented on them so that comparison of the size of abnormalities is possible even at other centers if required. Mammographic displays should allow fast and easy navigation between previous and current studies and between 2D and DBT images.[28] Therefore, storage requirement estimates should consider the need to store and access current and prior images. Prior examinations may be imported from portable media. Digital

mammogram image compression can provide more efficient transmission and storage. Wherever picture archiving and communications system (PACS) is used, it must be ensured that the quality of patient images is maintained in the PACS system and 5-megapixel mammography display systems are used for reporting. A lossless compression must be used during image storage or transfer. Thereby, by definition, there is no impact on the image; thus, optimum image quality is ensured for interpretation.[19]

Routine cleaning of monitors and viewing boxes with cleaning agents as per manufacturer's choice is advised. Cleaning the monitor to keep it dust-free is recommended at least once a week.

Images should be printed using films and printers compatible with the mammography machine as the manufacturer recommends and per the local hospital regulations.

DR and CR facilities should maintain mammography images and reports in the patient's permanent medical record for a period not less than five years.[29] Traditional film-based mammography units may save reports only for the same duration as the printed images are given to the clients.

1.8 Audits

An audit of mammography acquisition is advised once a year for each mammographer. This should include an audit of retakes due to suboptimal positioning or other factors. A good example is categorizing mammography positions as perfect/good/moderate/poor (PGMI) and auditing to see if each mammographer achieves 50% or greater P or G ratings in a PGMI evaluation of 50 randomly selected image sets.[30]

An audit of radiation dose per mammogram should also be performed at least once a year in the unit.

An audit of breast radiologists' performance should be conducted annually. This should include a review of appropriate clinical indications, accuracy of reports, and correlation with pathology reports to check the adequacy of sampling in cases of stereotactic procedures.

An audit of stereotactic procedures should be performed in the unit annually. The total number of stereotactic biopsies performed, the total number of cancers detected, benign lesions detected, inconclusive results requiring repeat biopsy, and complications should be analyzed.[31]

In units with DBT, additional dedicated DBT medical audits are advised, particularly in screening settings, to distinguish between the two modalities concerning performance. Examinations should be systematically reviewed and evaluated as part of the overall quality improvement program at the facility. Monitoring should include evaluating the accuracy of interpretation and the appropriateness of the examinations. Complications and adverse events or activities that may have the potential for sentinel events must be monitored, analyzed, reported, and periodically reviewed to identify opportunities to improve patient care.

Records of all audits and training activities must be maintained in the department. The lead radiologist oversees planning the audits as well as applying the findings of the audits to enhance patient care.

1.9 Teamwork & multidisciplinary meetings

For QA measures to be effective, all team members must understand their roles and participate actively in the program. Radiologists, radiographers, breast care nurses, medical physicists, information technologists, and healthcare managers must work together for a good QA program to make a difference for our patients.

Each mammography unit should develop policies and procedures for quality control and assurance, infection control, and patient safety. These should be documented and kept in the breast imaging and intervention department. These should be readily available to all team members. Audits to check compliance with local policies should be encouraged.

Regular multidisciplinary meetings (MDM) should be held so that clinical features, imaging findings, and results of biopsies can all be well correlated and appropriate decisions on the next best step for the patient can be taken on a case-to-case basis. Participation in the MDMs must be mandatory for all doctors and breast care nurses. Representation from consultant-level team members of all specialties must be required at any given meeting.

1.10 Nuclear medicine

Centers with PET CT and sentinel lymph node biopsy facilities must follow AERB rules for nuclear medicine facilities. Radioisotopes handled, handling facilities, imaging equipment, availability of operating personnel and their monitoring, measuring instruments/protection level equipment (such as radiation survey meter, contamination monitor, dose calibrator, dosimeters), availability of documents (such as minutes of local safety committee meetings, patient information data), are all checked during the AERB regulatory inspection, the frequency of which depends on the nuclear medicine equipment available on site.[3]

2. BREAST ULTRASOUND

Breast ultrasound is a well-established investigation of breast diseases in women and men. Being widely available across

our country, both in large institutions and small diagnostic centers, the Indian radiologist is well versed in this modality. It is especially invaluable as a primary imaging tool in symptomatic women less than 30 years of age. It is also the modality of choice for pregnant and lactating women. Quality assurance guidelines have been formulated in this document to ensure that optimum equipment for ultrasound breast is used all over the country, as well as to encourage uniformity and standardization of reporting templates.[32] At the document's end is a suggested reporting template for normal and abnormal breast ultrasound studies [Appendix 4.4]. Reporting templates for ultrasound-guided core biopsy, hook wire localization, marker clip placement, and fine needle aspiration cytology [Appendix 4.5, 4.6, 4.7, and 4.8] are also available in numerical order.

Ultrasound is the imaging technique of choice in women under 30 and pregnant and lactating women. A combination of breast ultrasound and mammography is the basic set of investigative tools used to investigate breast complaints for women over 30. Ultrasound helps evaluate and characterize palpable masses and other breast symptoms such as nipple discharge, dimpling of the skin, retraction of the nipple, and focal non-cyclical mastalgia. It can be used as a supplement to mammography for screening women with heterogeneously dense or extremely dense breasts. However, ultrasound of the breasts on its own is not advisable for breast screening.[33] Ultrasound is the modality of choice for assessment of the axilla. Please refer to the 'Best Practice Guidelines' of the Breast Imaging Society, India, for indications of breast ultrasound in detail.[34]

2.1 Equipment and technical settings

A high-resolution probe (such as 12 – 5 MHz, 18 – 6MHz) with a center frequency of at least 10 MHz is required to perform breast ultrasound.[8,18] However, a convex probe may sometimes be used depending on the breast size and the lesion's depth.

The patient is examined in a supine or oblique position. The medial portion of the breast is imaged in a supine position with the arm placed above the head. The side being examined is lifted (the lady turns to the opposite side – semi-lateral decubitus position), and the arm is placed above the head to ensure that the breast is flattened over the chest wall while scanning the lateral aspect of the breast. Applying a coupling agent such as gel on the skin is mandatory for ultrasound studies. A focal thick layer of gel on the skin at the site of a superficial lesion helps bring the superficial lesion into the focal zone and improves visualization of the abnormality.[8] A similar technique can be used to visualize structures in the nipple-areolar complex. Scanning obliquely also helps visualize lesions in the nipple-areolar complex region. Gentle pressure while scanning allows better visualization of structures in the breast.

Optimization of grayscale settings is the first step towards obtaining good-quality representative and diagnostic images.[18] The focal zone should be set at the level of the lesion being assessed. Gain should be set such that subcutaneous fat appears medium gray.[8] Depth is considered optimal when most of the screen is occupied by breast tissue and the chest wall is seen at the posterior margin of the screen.[18] Tissue harmonics, spatial compound imaging, color, and power Doppler should be used when required. The color box should be placed over the region of interest, and only gentle pressure must be applied while scanning to get the best results in color flow imaging.

Equipment performance monitoring should follow the manufacturer's instructions and local departmental protocol.

Both strain elastography, and shear wave elastography are useful as adjunct to grayscale ultrasound. Elastography findings aid diagnosis but should not be used in isolation to evaluate a lesion. Using a linear probe, it is assessed in the same standard patient positions as those for grayscale ultrasound. While performing elastography, it is essential to ensure that the lesions of interest and the surrounding normal breast parenchyma are included within the elastography box, thus enabling the comparison of elasticity parameters. Different vendors and machine settings offer variable color coding methods (varying from hard to soft). Therefore, this has to be annotated in the image to avoid confusion.

2.2 Training requirements of doctor performing breast ultrasound

Radiologists who supervise, perform, and interpret breast ultrasound examinations should hold a degree in Radiology recognized by the National Medical Commission of India. A breast fellowship course or training under an experienced breast radiologist is strongly recommended before performing breast ultrasound and ultrasound-guided interventional procedures independently. The radiologist should have a thorough knowledge of the indications for ultrasound examinations and should direct each examination per the indication. For example, in a patient with nipple discharge, intraductal lesions should be vigilantly looked for. The radiologist should also be able to correlate an abnormality seen on ultrasound with findings seen on mammograms and breast MRI, considering clinical findings, if any.

The radiologist is expected to perform at least 1,500 breast ultrasound examinations under supervision over 1 to 2-year period, depending on the caseload of the institute, to complete

adequate training. A minimum of 500 breast ultrasound studies per year is recommended to maintain their skill.

2.3 Reporting and documentation

Ideally, the request form for breast ultrasound should provide relevant history, clinical examination findings with a diagrammatic representation of any lump if palpable, and a provisional diagnosis. A standard requisition form approved by the hospital/radiology department is encouraged.

If available, ultrasonography has to be correlated with other breast imaging studies, such as mammograms or MRIs. Comparison with previous breast imaging should be performed. The findings of correlation with other imaging modalities and comparison to prior images must be documented in the report. Correlation with physical examination directed to the area of concern should be made.

Breast ultrasound includes an assessment of the axilla. The ipsilateral supraclavicular fossa, infraclavicular fossa (level 3 axillary lymph nodes), and internal mammary lymph nodes should also be checked for newly diagnosed breast cancer to quantify locoregional lymph node disease.[35,36] Lesion characterization with documentation of sonographic characteristics of the lesion, such as size, shape, margin, orientation, echo pattern, posterior acoustic features, and surrounding tissue should be performed. Color flow and Doppler findings, if applicable, should also be reported. Each lesion should be identified and described. If there are multiple lesions with similar characteristics, they can be described collectively. Lesion description should be followed by the most likely diagnosis and the likely nature of the lesion, such as benignity or the possibility of malignancy. Of the established reporting systems, the most widely used system in our country is the Breast Imaging Reporting and Data System (BI-RADS) of the American College of Radiologists (ACR), and usage of such established reporting systems helps uniformity of lexicon in ultrasound reporting.[8] If elastography is performed, findings should be documented. In strain elastography, size ratio and strain ratio values should be documented. In shear wave elastography, elasticity value should be documented in kilopascals (kPa) or meters/second (m/s).[37]

Images showing relevant findings should be recorded and saved to be reviewed later.[38] Image of a lesion should have documentation of its anatomic location (breast/axilla/chest wall), side (left/right), orientation of the transducer (radial/antiradial/transverse/longitudinal), quadrant and o'clock position, distance from the nipple in centimeters. Recording the depth from the skin is very useful if two lesions with similar appearance are at the same o'clock position in the breast. Abnormality should be recorded in two perpendicular projections. Two sets of images with and without calipers are preferable, especially for tiny abnormalities, as the cursor may obscure the lesion.[8] Measurements of masses should be taken in three dimensions. Color Doppler images assessing the vascularity of the lesion should also be recorded separately.

Ultrasound images should have details of the hospital's name, UHID, the date of examination, the patient's first and last name, and date of birth. A radiologist's identification number or initials should also be preferably recorded.

The minimum number of recorded, saved, and printed images should be as per the departmental protocols. A negative whole breast ultrasound should be documented with representative images of all quadrants, retroareolar region, and axilla. Important findings of targeted ultrasound of an area, such as assessing a mammographic asymmetry, should also be documented.

2.4 Ultrasound-guided breast biopsy (and other procedures)

Radiologists who perform breast interventions should hold a degree in Radiology recognized by the National Medical Commission of India. The radiologist should perform ultrasound-guided interventional procedures under supervision until they can perform interventions independently. They must be trained regarding equipment, procedures, and potential complications, preferably at a specialized center performing breast imaging and interventions. A minimum of 150 supervised image-guided breast procedures (ultrasound and mammography-guided procedures included) should be performed over 1 year to train adequately. A minimum of 60 image-guided breast procedures per year (ultrasound and mammography-guided procedures included) are recommended to maintain interventional breast imaging skills. The radiologist performing image-guided breast procedures must be well-versed in mammography and breast ultrasound interpretation, as this knowledge is essential for Radiology – Pathology correlation. The personnel assisting the radiologist should also be adequately trained and aware of the steps of the procedure and possible complications of the procedure.

Written informed consent must be obtained before the procedure. Explanation of the steps of the procedure and possible complications in lay terms for better understanding of the patient and their family members is mandatory before obtaining consent. History of allergy to drugs must be checked and documented.

Optimal precautions, such as using sterile gloves and drapes for the procedure are mandatory. The needle length, gauge, and throw should be confirmed before opening the sterile packaging of the core biopsy device. The concentration and

expiry date of the local anesthetic must be checked while preparing the procedure tray.

Ultrasound-guided breast interventional procedures such as core biopsies, vacuum-assisted biopsies, cyst aspirations, hook wire localizations, marker clip insertions, and fine needle aspiration cytology (FNAC) should be recorded with images and a formal report.[39] Documentation of the lesion biopsied, number of core specimens obtained, time of obtaining specimen and fixing in formalin, should be made. Complications, if any, at the time of performing the procedure should be documented in the procedure report.

A thorough ultrasound examination of the area of concern should be performed before the intervention to confirm that the correct lesion is being targeted and to decide the intervention approach.[40] Patient name, identification number, examination date, facility name, right or left breast designation, anatomic location depicted by clock position, and distance from nipple should be mentioned on the clinical images. Before the procedure, two orthogonal images of the lesion to be biopsied should be obtained for clinical record keeping. Pre-fire and post-fire images with the needle on the long axis should be obtained. A post-fire image in the orthogonal plane is also to be obtained to confirm the presence of the needle within the lesion.[39,41,42] If a core biopsy of calcifications is performed under ultrasound guidance, specimen radiography must be performed to confirm sampling of calcifications.[43]

For hook wire localizations and marker clip insertions, post-procedure mammograms must be performed to confirm the optimum position of the wire and marker clip on both craniocaudal and lateral views.

Following the procedure, sharps must be disposed of in separately assigned sharps bins as per institutional protocol. Instructions about post-procedure care should be duly explained to the patient by the radiologist conducting the procedure.

The pathology requisition form should mention the clinical history, pertinent imaging findings, and likely imaging diagnosis. Patient name, identification number, examination date, facility name, and right or left breast designation should be mentioned on the container where the sample is sent to the pathology department.[41]

There should be a process for obtaining the pathology department's cytology/histopathology report. It is considered good practice to add an addendum report stating whether the cytology/histopathology report is concordant or discordant with the imaging findings and communicate the final report to the patient and referring physician.[41]

Annual audit of the total number of ultrasound biopsies performed (FNAC and core biopsy), the total number of cancers detected, benign lesions detected, inconclusive results requiring repeat biopsy, and complications (hematoma, infection, pneumothorax) post-biopsy is encouraged.[41]

3. MRI BREAST

Magnetic Resonance Imaging (MRI) Breast is a valuable tool in breast imaging as it has a very high sensitivity. The specificity depends on various factors such as imaging equipment, radiologist expertise, and patient cohorts. Indications for breast MRI have been explained in the Best Practice Guidelines of Breast Imaging Society, India.[44] These include inconclusive findings on conventional imaging, pre-operative staging in some cases, perioperative evaluation to assess residual disease, metastatic axillary lymph nodes when the primary site is not demonstrated on conventional imaging, screening of young women at high risk of breast cancer, and assessment of implant integrity. Quality assurance guidelines have been formulated in this document to ensure that optimum equipment for MRI breast is used nationwide and to encourage uniformity and standardization of reporting templates. At the end of the paper is a suggested reporting template for normal and abnormal breast MRI studies [Appendix 4.9], followed by a template for an MR-guided Breast biopsy report [Appendix 4.10].

3.1 Equipment specifications

It is widely acknowledged that a magnetic strength of at least 1.5 Tesla is required to acquire good-resolution images. The minimum requirement is an 8-channel dedicated diagnostic breast coil to perform a quality breast MRI.[45] Simultaneous bilateral breast imaging is advised as this allows better detection of abnormal, asymmetric morphology and enhancement.

It is essential to acquire images of high spatial and temporal resolution so that the abnormality can be morphologically differentiated from normal breast tissue and assessed optimally by the kinetics of the lesion after contrast injection. A slice thickness of 3mm or less is required, and in-plane pixel resolution should be 1 mm or less as this reduces volume-averaging effects to the minimum.[46] To achieve a pixel size of not more than 1 x 1 mm, a matrix of at least 300 x 300 in a 300 mm field of view (FOV) is required.[47] To detect lesions ≥ 5 mm in size, voxel size should be less than 2.5 mm in any direction.[47]

The contrast in a 0.1 mmol/kg body weight dose should be administered as a bolus using a power injector followed by at least 10 ml of saline flush. It may be omitted if the study is performed solely to check implant integrity. As peak enhancement in breast cancer usually occurs within the first 2 minutes of contrast injection, the post-contrast sequences

should be able to acquire data from the entire breast quickly, preferably 1 – 2 minutes per volume acquisition. Washout of contrast from malignant masses may be as early as 2 – 3 minutes post-contrast. Hence, a dynamic sequence must aid the measurement of contrast uptake at least at three-time points, i.e., a precontrast, 1-2 minutes, and a delayed volume acquisition of breast is necessary.[47] The number of acquisitions can be more, depending on the local protocol. Apart from visual assessment, time-intensity curves must be calculated in regions of interest (ROI) for quantitative analysis of lesion kinetics. ROI should be 3 - 4 pixels maximum to reduce volume averaging.

Subtraction techniques are used for the assessment of enhancement of breast abnormalities. However, these are prone to misregistration artifacts due to patient motion between image acquisitions. Misregistration may result in nonvisualization of the lesion. Hence, it is crucial to incorporate fat suppression (FS) in the sequences acquired after contrast injection, which reduces fat signal and helps better visualization of the lesion. Protocols incorporating both fat suppression and subtraction can be used. Assessing the lesions on post-contrast subtraction images and the FS sequence images is important. Motion correction algorithms are advised to reduce motion artifacts in subtraction sequences.[46]

3.2 Timing & technique

Studies have shown significant lower background parenchymal enhancement (BPE) in menstrual cycle days 7-20 than in days 21-6.[48] It is also advised that a dynamic breast MRI should be performed during the first half of the menstrual cycle (days 3-14) so that interpretative difficulties related to gadolinium uptake due to normal hormonal fluctuations during the menstrual cycle can be minimized.[49] Breast MRI should be performed as per the departmental protocol. One suggestion is that breast MRI is performed between days 7–14 of the menstrual cycle.[18]

A dedicated bilateral breast coil must be used. The patient is positioned prone with the breasts hanging in the coil loops. Supporting the breast helps reduce motion artifacts, but breast compression should be avoided.[47]

Several sequences help the characterization of breast abnormalities. T2 weighted sequence (2D/3D), with or without fat saturation, is beneficial for analyzing cysts, edema, and fluid. T1 weighted sequence without fat suppression to assess the morphology of the lesion, fat signal intensity within the lesion, architectural distortion, and clips after biopsy/surgery is recommended. STIR silicone selective axial/sagittal sequence with water saturation demonstrates hyperintense silicone and helps assess implant integrity. Also, a suppressed sequence on which water is hyperintense is useful for implant evaluation. Dynamic contrast T1 Gradient echo (GRE) sequence is essential to assess tumor kinetics. Pre-contrast T1 FS sequences followed by at least two post-contrast T1 FS sequences with subtraction images are advised.[47] A suggested protocol of each acquisition period of not >60 seconds (preferably not >45 seconds) for a total acquisition time of five minutes gives a good number of time points to draw the time-intensity curves.[45]

Diffusion-weighted imaging (DWI) is a promising MR technique that gives insight into the functional aspect of the lesion. This may be used depending on the equipment capability and experience of the radiologist. It helps to differentiate between benign and malignant lesions based on the diffusivity of water molecules. Malignant lesions show less diffusivity due to increased cellularity and desmoplastic reaction than benign lesions. Thus, these are hyperintense on higher b values and have low values on ADC (Apparent Diffusion Coefficient) images. The high b-value images should always be seen in correlation with the ADC maps. A minimum of two sets of images are acquired with different b values; the recommended b values are 0 and 800.[50] The higher b value applied can vary from b800-1000 according to magnet strength.[45] The ADC value is obtained by drawing an ROI on the lesion on the ADC map (or the b = 800 s/mm^2 image when the workstation allows propagation of the ROI to the ADC map). The ROI should fall completely within the lesion, contain at least 3 voxels, and avoid the lesion's artifacts and necrotic or hemorrhagic parts.[50] DWI is performed before contrast administration to reduce artifacts.

Spectroscopy may be used depending on the equipment capability and experience of the radiologist. Choline is the metabolite detected and measured in single-voxel spectroscopy and is used to differentiate between benign and malignant lesions. It is also used to predict response to neoadjuvant chemotherapy in malignant lesions.[51]

3.3 Quality assurance of the equipment

Quality assurance assessments should be performed per the manufacturer's instructions and hospital protocol. Evaluation of the quality of the images for spatial resolution, fat suppression, and testing of the breast coil should be performed by qualified medical physicists at regular intervals. The MRI breast examination should also be systematically examined and evaluated for quality control and improvement. Any adverse reactions or complications during the procedure should be reported and analyzed as a part of the quality control program in the hospital. For reporting standards and image output, in-house and external periodic auditing should be done.

3.4 MRI guided biopsy

Suspicious findings seen only on MRI with no correlating abnormality on second look breast ultrasound must be biopsied under MRI guidance. A vacuum-assisted breast biopsy (VABB) device should be used. The breast should be immobilized between the grid plates. Too much compression should be avoided to prevent nonvisualization of the lesion. A marker clip placement is mandatory following a biopsy. The marker position must be confirmed on post-procedural mammography in two orthogonal planes.[52]

The operator should obtain written informed consent before the procedure after explaining the steps and the possible complications, such as hemorrhage, infection, and procedure cancellation due to the nonvisualization of the lesion. Instructions about post-procedure care should be duly explained to the patient by the radiologist conducting the procedure. History of allergy to drugs must be checked and documented.

Optimal precautions, such as using sterile gloves for performing the biopsy, are mandatory. The needle length, gauge, and throw should be confirmed before opening the sterile packaging of the VABB device. The VABB equipment must be calibrated before the start of the procedure. The concentration and expiry date of the local anesthetic must be checked while preparing the procedure tray. Special care must be taken to use MR-compatible equipment for the procedure.

Images that demonstrate important steps of the procedure must be saved during the procedure. The images should have the patient's name, UHID, date, an indication of right or left breast, name of the hospital, and other details per the local protocol. Special attention must be paid to the disposal of all the sharps used during the procedure as per the hospital protocol.

The report should contain details about the lesion targeted, the type of biopsy equipment, gauge of the needle, the number of core specimens obtained, the time of obtaining the specimen and fixing in formalin, and the post-procedure clip position. Complications of the procedure, if any, should also be documented in the report. For example, if the post-biopsy mammograms demonstrate displacement of marker clip from the biopsy site, this must be documented.

Clear mention of the clinical history, pertinent imaging findings, likely imaging diagnosis, name of the procedure (VABB), side (right/left breast), the anatomic location depicted by the o'clock position, and distance from the nipple should be mentioned on the pathology requisition form. Patient name, identification number, examination date, facility name, side (right/left breast), and procedure name should be mentioned on the container where the sample is placed.

The cancellation rate for MR-guided biopsy due to the inability to visualize the targeted breast lesion at the time of biopsy after intravenous contrast injection ranges from 8% to 13%.[53] Nonvisualization of the target is an absolute contraindication to MRI-guided breast biopsy. Before canceling the procedure, it should be verified that the patient received a successful bolus of contrast and that excessive breast compression does not impede blood inflow. As there is a 0%–10% malignancy rate for lesions not visualized at the time of attempted biopsy, a follow-up diagnostic MRI should be obtained within six months to ensure the lesion is absent.[53,54]

The radiologist performing MR-guided breast biopsies must be well-versed in breast MRI, mammography, and breast ultrasound interpretation, as this knowledge is essential for correlating MRI findings with mammography and ultrasound findings. This knowledge is critical for performing second-look ultrasound for MRI-only lesions. After the histopathology report is ready, the radiologist should correlate the radiological features with the pathology findings and add an addendum regarding radiology-pathology concordance. If discordance is found, appropriate advice must be given. Discussion with the referring clinician is of utmost importance in case of discordance.

3.5 Qualifications and responsibilities of the radiologist

The radiologist should hold a degree in Radiology recognized by the National Medical Commission of India. Interpreting radiologists should have broad knowledge of imaging and diagnosis of breast disease and, thereby, should be able to correlate MRI findings with Mammography and Breast Ultrasound. The slightly different positions in which a lesion may be demonstrated on a prone MRI, supine ultrasound, and an erect mammogram are best appreciated with a good knowledge of all three breast modalities. Additional training in breast MRI under supervision should be obtained before the radiologist reports breast MRI independently. Reporting a minimum of 150 MRI breast cases under supervision over 1 to 2 years, depending on the caseload of the institute is recommended before independent reporting.[18] Taking up a breast fellowship course or training under an experienced Breast Radiologist is strongly recommended before performing breast MRI and MRI-guided interventional procedures independently. Subsequently, the radiologist is expected to report at least 50 breast MRI studies in a year to maintain reporting skills. Breast MRI should ideally be practiced in a facility having a capacity for mammography, ultrasound, and breast interventions, including MRI-guided biopsy. If very few studies are performed in a center or are not performed for lack of technology, such as a dedicated breast coil, the radiologist is encouraged to visit a center that performs a higher volume of breast MRI and stay in touch

with the MR images and reporting. The radiologist must regularly attend educational courses to stay updated about MR technology and reporting techniques. If the center does not offer MRI-guided biopsy, a referral center with the facility should be accessible to the patient. The results of biopsies initiated on MRI findings require radiology-pathology correlation that should be tracked by the radiologist recommending the biopsy and the radiologist performing the biopsy at the referral center.

The Radiologist should review and validate clinical indications for the examination, set MRI protocol, use an adequate dose of contrast, ensure an emergency physician is available when contrast is given, interpret the breast MRI, including a review of pertinent prior breast imaging studies, and provide a report with recommendations. Established reporting systems such as the BI-RADS of the American College of Radiologists are encouraged for uniformity and standardization of reports.[8] The salient features to be covered in the report have been enumerated in Appendix 4.9 of this document. All printed films and softcopies of the MRI images must be correctly labeled with the name, UHID number, date, side, and other details as per local protocol. Selected MR images that are printed are to be decided by the radiologist and should include time-intensity curves of significant lesions.

3.6 Qualifications and responsibilities of the technologist

The technologist must have a 2 or 3-year diploma or degree such as Diploma in Radiography, Diagnostic (DRD) recognized by the state/central government and have specific training in MRI as part of this training program. The technologist is expected to perform 20 breast MRI scans under supervision before performing a breast MRI independently. The supervised scans may be performed in a different center that has been performing breast MRI or can be in the technologist's center under the supervision of a senior MRI technologist in the department or the application specialist of the MR manufacturer if breast MRI service is being newly set up in the hospital. The technologist should be able to manage the overall safety of the patient, staff, and equipment during the procedure. The contraindications for any routine MRI also apply to breast MRI, and it is the technologist's responsibility to check for any contraindication based on the MRI questionnaire filled out by the patient. They should be able to produce high-quality images and adjust protocols as required. Technologists are encouraged to attend periodic educational courses for continuing upgradation of technical knowledge.

DISCLAIMER

The above-mentioned quality assurance guidelines are purely recommendatory and general-purpose only. Actual decisions for investigating and managing the patients should be individualized according to the caregiver's judgment and tailored on a case-to-case basis. As scientific knowledge is continuously improving, a regular update by the caregiver is essential. Failure to do so may result in untoward patient management or outcome, and members of Breast Imaging Society, India, or Breast Imaging Society, India, as the organization cannot be held responsible for that in any manner.

Declaration of patient consent

Patient's consent not required as there are no patients in this study.

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Use of artificial intelligence (AI)-assisted technology for manuscript preparation

The authors confirm that there was no use of artificial intelligence (AI)-assisted technology for assisting in the writing or editing of the manuscript and no images were manipulated using AI.

REFERENCES

1. Atomic Energy Regulatory Board. Government of India. Radiation Safety In Manufacture, Supply And Use Of Medical Diagnostic X-Ray Equipment, AERB Safety Code No. AERB/RF-MED/SC-3 (Rev. 2), March 2016. Available at: https://www.aerb.gov.in/images/PDF/RF-MED-SC-3.pdf [Last accessed on 2023 July 30].
2. Chakrabarthi S, Shikha P, Tulika S, Shilpa L, Jwala S, Niranjan K, Sanjeev M, Sanjay T. Best Practice Guidelines for Breast Imaging, Breast Imaging Society, India. Annals of the National Academy of Medical Sciences, Vol. 58 No. 2/2022. DOI: 10.1055/s-0042-1742586
3. Atomic Energy Regulatory Board. Government of India. AERB Safety Manual, Regulatory Inspection And Enforcement In Radiation Facilities; AERB/RF/SM/G-3; Atomic Energy Regulatory Board, India; December 2014. Available at: https://www.aerb.gov.in/storage/images/PDF/13-January-20151.pdf [Last accessed on 2023 July 30].
4. Atomic Energy Regulatory Board. Government of India. e-Licensing of Radiation Applications (eLORA) System Guidelines, Medical Diagnostic-Radiology Module, Atomic Energy Regulatory Board, India; July 14, 2016. Available at: https://www.aerb.gov.in/images/PDF/DiagnosticRadiology/e-LORA-Diagnostic-Radiology-Guidelines.pdf [Last accessed on 2023 July 30].

5. Atomic Energy Regulatory Board. Government of India. Format for periodic quality assurance test report for Mammography equipment, Atomic Energy Regulatory Board, India. Available at: https://www.aerb.gov.in/images/PDF/Diagnostic Radiology/3-FORMAT-FOR-PERIODIC-QUALITY-ASSURANCE-TEST-REPORT-FOR-MAMMOGRAPHY-EQUIPMENT.pdf [Last accessed on 2023 July 30].
6. Atomic Energy Regulatory Board. Government of India. Radiation Safety Training Module: Diagnostic Radiology; Quality Assurance in Diagnostic Radiology; Radiology Safety Division, Atomic Energy Regulatory Board, India. Available at: https://www.aerb.gov.in/images/PDF/Diagnostic Radiology/QUALITY-ASUURANCE-OF-DIAGNOSTIC-X-RAY-EQUIPMENT.compressed.pdf [Last accessed on 2023 July 30].
7. Perry N, Broeders M, de Wolf C, Törnberg S, Holland R, von Karsa L. European guidelines for quality assurance in breast cancer screening and diagnosis. Fourth edition--summary document. Ann Oncol 2008;19:614–622.
8. American College of Radiology. ACR BI-RADS Atlas® 5th Edition, Breast Imaging Reporting and Data System. 2013 Available at: https://www.acr.org/Clinical-Resources/Reporting-and-Data-Systems/Bi-Rads [Last accessed on 2023 July 30].
9. American College of Radiology. ACR Practice Parameter For the Performance of Screening and Diagnostic Mammography. Revised 2023 (Resolution 10). Available at: https://www.acr.org/-/media/ACR/Files/Practice-Parameters/Screen-Diag-Mammo.pdf [Last accessed on 2023 July 30].
10. Sechopoulos I, Suryanarayanan S, Vedantham S, D'Orsi CJ, Karellas A. Radiation Dose to Organs and Tissues from Mammography: Monte Carlo and Phantom Study. Radiology 2008;246:434–43.
11. American College of Radiology. ACR–SPR Practice Parameter For Imaging Pregnant Or Potentially Pregnant Adolescents And Women With Ionizing Radiation. Revised 2018 (Resolution 39). Available at: https://www.acr.org/-/media/ACR/Files/Practice-Parameters/Pregnant-Pts.pdf [Last accessed on 2023 July 30].
12. Wieseler KM, Bhargava P, Kanal KM, Vaidya S, Stewart BK, Dighe MK. Imaging in pregnant patients: examination appropriateness. Radiogr Rev Publ Radiol Soc N Am Inc 2010;30:1215–29; discussion 1230-1233.
13. Wagner LK, Applegate KE. Re: More cautions on imaging of pregnant patients. Radiogr Rev Publ Radiol Soc N Am Inc 2011;31:891; author reply 891-892.
14. Vashi R, Hooley R, Butler R. Geisel J, Philpotts L. Breast Imaging of the Pregnant and Lactating Patient: Imaging Modalities and Pregnancy-Associated Breast Cancer: Am J Roentgenol 2013;200: 321-328.
15. Atomic Energy Regulatory Board. Government of India. Right To Information, Queries & Responses, Atomic Energy Regulatory Board India. Available at: https://www.aerb.gov.in/hindi/transparency-open-government/rti/rti-faq-s [Last accessed on 2023 July 30].
16. American College of Radiology. Quality Control: Stereotactic Breast Biopsy (Revised 12-12-19), Accreditation Support American College of Radiology. 2019 Available at: https://accreditationsupport.acr.org/support/solutions/articles/11000064161-quality-control-stereotactic-breast-biopsy-revised-12-12-19- [Last accessed on 2023 July 30].
17. American College of Radiology. Stereotactic Biopsy, Quality Control Manual, 1999, American College of Radiology Committee on Stereotactic Breast Biopsy Accreditation, Subcommittee of Stereotactic Breast Biopsy Quality Assurance. 1999 Available at: https://www.acr.org/-/media/ACRAccreditation/Documents/Stereotactic/1999-ACR-SBBAP-QC-Manual.pdf [Last accessed on 2023 July 30].
18. Canadian Association of Radiologists .CAR Practice Guidelines and Technical Standards for Breast Imaging and Intervention, September 17, 2016. Available at: https://car.ca/wp-content/uploads/Breast-Imaging-and-Intervention-2016.pdf [Last accessed on 2023 July 30].
19. Heggie JCP, Barnes P, Cartwright L, Diffey J, Tse J, Herley J, *et al*. Position paper: recommendations for a digital mammography quality assurance program V4.0. Australas Phys Eng Sci Med 2017;40:491–543.
20. Skaane P, Bandos AI, Gullien R, Eben EB, Ekseth U, Haakenaasen U, *et al*. Comparison of Digital Mammography Alone and Digital Mammography Plus Tomosynthesis in a Population-based Screening Program. Radiology 2013;267: 47–56.
21. Tirada N, Li G, Dreizin D, Robinson L, Khorjekar G, Dromi S, *et al*. Digital Breast Tomosynthesis: Physics, Artifacts, and Quality Control Considerations. RadioGraphics 2019;39: 413–26.
22. Zuckerman SP, Conant EF, Keller BM, Maidment AD, Barufaldi B, Weinstein SP, *et al*. Implementation of Synthesized Two-dimensional Mammography in a Population-based Digital Breast Tomosynthesis Screening Program. Radiology 2016;281:730–6.
23. Zuley ML, Guo B, Catullo VJ, Chough DM, Kelly AE, Lu AH, *et al*. Comparison of Two-dimensional Synthesized Mammograms versus Original Digital Mammograms Alone and in Combination with Tomosynthesis Images. Radiology 2014;271:664–71.
24. Aujero MP, Gavenonis SC, Benjamin R, Zhang Z, Holt JS. Clinical Performance of Synthesized Two-dimensional Mammography Combined with Tomosynthesis in a Large Screening Population. Radiology 2017;283:70–6.
25. American College of Radiology .ACR Practice Parameter For The Performance Of Digital Breast Tomosynthesis (DBT), Adopted 2018 (Resolution 36). Available at: https://www.acr.org/-/media/ACR/Files/Practice-Parameters/DBT.pdf?la=en [Last accessed on 2023 July 30].
26. U.S. Food and Drug Administration. MQSA facility certification extension requirements for Digital Breast Tomosynthesis (DBT) System. 2017 Available at: https://www.fda.gov/radiation-emitting-products/facility-certification-and-inspection-mqsa/digital-breast-tomosynthesis-dbt-system [Last accessed on 2023 July 30].
27. National Health Service. Routine quality control tests for breast tomosynthesis (Radiographers) NHSBSP Equipment Report 1406, August 2014, NHS Cancer Screening Programmes, National Health Service, UK. Available at: https://assets.publishing.service.gov.uk/government/uploads/system/

uploads/attachment_data/file/442730/nhsbsp-equipment-report-1406.pdf [Last accessed on 2023 July 30].
28. American College of Radiology. ACR–AAPM–SIIM Practice Parameter for Determinants of Image Quality In Digital Mammography, Revised 2017 (Resolution 42). Available at: https://www.acr.org/-/media/ACR/Files/Practice-Parameters/Dig-Mamo.pdf [Last accessed on 2023 July 30].
29. U.S. Food and Drug Administration. Mammography Record Retention: What Should I Keep, and For How Long? 2018 Available at: https://public4.pagefreezer.com/browse/FDA/27-12-2022T08:32/https://www.fda.gov/radiation-emitting-products/mqsa-insights/mammography-record-retention-what-should-i-keep-and-how-long [Last accessed on 2023 July 30].
30. Breastscreen Australia. National Accreditation Standards, BreastScreen Australia Accreditation Review Committee, 16 March 2022. Available at: https://www.health.gov.au/sites/default/files/2023-04/breastscreen-australia-national-accreditation-standards-nas.pdf [Last accessed on 2023 July 30].
31. American College of Radiology. ACR Practice Parameter for the Performance of Stereotactic/Tomosynthesis-Guided Breast Interventional Procedures, Revised 2020 (Resolution 3). Available at: https://www.acr.org/-/media/ACR/Files/Practice-Parameters/stereo-breast.pdf [Last accessed on 2023 July 30].
32. American College of Radiology. ACR BI-RADS® Atlas Fifth Edition, Quick Reference. Available at: https://www.acr.org/-/media/ACR/Files/RADS/BI-RADS/BIRADS-Poster.pdf [Last accessed on 2023 July 30].
33. Evans A, Trimboli RM, Athanasiou A, Balleyguier C, Baltzer PA, Bick U, *et al*. Breast ultrasound: recommendations for information to women and referring physicians by the European Society of Breast Imaging. Insights Imaging 2018;9:449-461.
34. Breast Imaging Society. Best Practice Guidelines on Breast Ultrasound. Breast Imaging Society, India. Available at: https://www.bisi.co.in/guidelines/breast-ultrasound/ [Last accessed on 2023 July 30].
35. Lane DL, Adeyefa MM, Yang WT. Role of sonography for the locoregional staging of breast cancer. AJR. American Journal of Roentgenology 2014;203:1132-1141.
36. Iyengar P, Strom EA, Zhang YJ, Whitman GJ, Smith BD, Woodward WA, *et al*. The value of ultrasound in detecting extra-axillary regional node involvement in patients with advanced breast cancer. Oncologist 2012;17:1402-1408. doi: 10.1634/theoncologist.2012-0170
37. Youk JH, Gweon HM, Son EJ. Shear-wave elastography in breast ultrasonography: the state of the art. Ultrasonography 2017;36:300–9.
38. American College of Radiology. ACR Practice Parameter for the Performance of a Breast Ultrasound Examination, Revised 2016 (Resolution 38). Available at: https://www.acr.org/-/media/ACR/Files/Practice-Parameters/US-Breast.pdf [Last accessed on 2023 July 30].
39. American College of Radiology. ACR Breast Ultrasound Accreditation Program Requirements, Revised: 6/14/19. 2016 Available at: https://www.acraccreditation.org/-/media/ACRAccreditation/Documents/Breast-Ultrasound/Requirements.pdf?la=en [Last accessed on 2023 July 30].
40. American Institute of Ultrasound in Medicine; American Society of Breast Surgeons. AIUM practice guideline for the performance of a breast ultrasound examination. J Ultrasound Med. 2009;28:105-109. Available at: https://pubmed.ncbi.nlm.nih.gov/19106368/[Last accessed on 2023 July 30].
41. American College of Radiology (2013). ACR Practice Parameter for the Performance of Ultrasound-Guided Percutaneous Breast Interventional Procedures, Revised 2016 (Resolution 37). Available at: https://www.acr.org/-/media/ACR/Files/Practice-Parameters/us-guidedbreast.pdf [Last accessed on 2023 July 30].
42. Harvey JA, Moran RE.Ultrasound-guided core needle biopsy of the breast: technique and pitfalls.RadioGraphics 1998 18:4, 867-877.
43. Lee J. Practical and illustrated summary of updated BI-RADS for ultrasonography. Ultrasonography 2017;36:71-81.
44. Breast Imaging Society. Best Practice Guidelines – MRI Breast. Breast Imaging Society, India. Available at: https://www.bisi.co.in/guidelines/breast-mri/ [Last accessed on 2023 July 30].
45. The Royal College of Radiologists. Guidance on screening and symptomatic breast imaging, Fourth edition, November 2019, The Royal College of Radiologists, UK. Available at: https://www.rcr.ac.uk/system/files/publication/field_publication_files/bfcr199-guidance-on-screening-and-symptomatic-breast-imaging.pdf [Last accessed on 2023 July 30].
46. American College of Radiology. ACR Practice parameter for the performance of contrast enhanced magnetic resonance imaging (MRI) of the breast, Revised 2018 (Resolution 34). https://www.acr.org/-/media/ACR/Files/Practice-Parameters/mr-contrast-breast.pdf [Last accessed on 2023 July 30].
47. Mann RM, Kuhl CK, Kinkel K, Boetes C. Breast MRI: guidelines from the European Society of Breast Imaging. Eur Radiol 2008;18:1307-1318.
48. Müller-Schimpfle M, Ohmenhaüser K, Stoll P, Dietz K, Claussen CD. Menstrual cycle and age: influence on parenchymal contrast medium enhancement in MR imaging of the breast [published correction appears in Radiology 1997 Aug;204(2):583]. Radiology 1997;203:145-149.
49. Delille JP, Slanetz PJ, Yeh ED, Kopans DB, Garrido L. Physiologic changes in breast magnetic resonance imaging during the menstrual cycle: perfusion imaging, signal enhancement, and influence of the T1 relaxation time of breast tissue. Breast J 2005;11:236-241.
50. Baltzer P, Mann RM, Iima M, Sigmund EE, Clauser P, Gilbert FJ, *et al*. Diffusion-weighted imaging of the breast—a consensus and mission statement from the EUSOBI International Breast Diffusion-Weighted Imaging working group. Eur Radiol 2020;30:1436-1450.
51. Bartella L, Huang W. Proton (1H) MR Spectroscopy of the Breast. RadioGraphics 2007 27:suppl_1, S241-S252.
52. American College of Radiology. ACR practice parameter for the performance of magnetic resonance imaging-guided breast interventional procedures. Revised 2016, (resolution 35). Available at: https://www.acr.org/-/media/ACR/Files/Practice-Parameters/MR-Guided-Breast.pdf [Last accessed on 2023 July 30].

53. Chesebro AL, Chikarmane SA, Ritner JA, Birdwell RL, Giess CS. Troubleshooting to Overcome Technical Challenges in Image-guided Breast Biopsy. Radiographics 2017;37: 705-718.
54. Sung JS, Lee CH, Morris EA, Comstock CE, Dershaw DD. Patient follow-up after concordant histologically benign imaging-guided biopsy of MRI-detected lesions. AJR Am J Roentgenol 2012;198:1464-1469.

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APPENDIX 4.1

QA Mammography/DBT - Suggestions to the Radiologist

1. It is expected that the Indian breast radiologist will be well versed with mammography-related QA aspects of the following documents of the Atomic Energy Regulatory Board, India:
   - e-Licensing of Radiation Applications (eLORA) System Guidelines, Medical Diagnostic-Radiology Module, Atomic Energy Regulatory Board, India; July 14, 2016. https://www.aerb.gov.in/images/PDF/DiagnosticRadiology/e-LORA-Diagnostic-Radiology-Guidelines.pdf (accessed on 5 September 2020)
   - AERB Safety Manual, Regulatory Inspection And Enforcement In Radiation Facilities; AERB/RF/SM/G-3; Atomic Energy Regulatory Board, India; December 2014. https://www.aerb.gov.in/storage/images/PDF/13-January-20151.pdf (accessed on 5 September 2020)
   - Format for periodic quality assurance test report for Mammography equipment, Atomic Energy Regulatory Board, India. https://www.aerb.gov.in/images/PDF/DiagnosticRadiology/3-FORMAT-FOR-PERIODIC-QUALITY-ASSURANCE-TEST-REPORT-FOR-MAMMOGRAPHY-EQUIPMENT.pdf (accessed on 5 September 2020)
   - Radiation Safety In Manufacture, Supply And Use Of Medical Diagnostic X-Ray Equipment, AERB Safety Code No. AERB/RF-MED/SC-3 (Rev. 2), March 2016, Atomic Energy Regulatory Board, India. https://www.aerb.gov.in/images/PDF/RF-MED-SC-3.pdf(accessed on 5 September 2020)
2. BISI Recommendation (additional to above): Image quality assessment using a mammography phantom is advised at least once a week. However, a daily review before the first case of the day is ideal, especially for screening mammograms.
3. DBT Quality control tests to be performed by the mammographer (in addition to 2D mammography tests): These tests have been chosen as they are simple and can be performed in the department by the mammographer and radiologist, with relative ease[19,27]. These may be altered as per local protocol after discussion with the medical physicist of the hospital. These tests do not replace the tests performed per the manufacturer's instructions or local protocol. [Table 1]

Table 1: DBT Quality control tests to be performed by the mammographer.

Test	Frequency	Method	Look for
System check (Uniformity of field)	Daily	Expose phantom under Automatic Exposure Control (AEC) in Digital Breast Tomosynthesis (DBT) mode and check reconstructed image slices (not the projections)	Abnormal artifacts or variations in noise pattern
Automatic Exposure Control (AEC)	Monthly	Expose each thickness of Perspex in turn under AEC in Tomosynthesis mode and check reconstructed image slices	Abnormal artifacts or variations in noise pattern
Image quality check	Weekly	Expose the phantom in Tomosynthesis mode and find the slice at which the image of the test object appears sharpest and record that slice number. Send the image to a reporting workstation. Evaluate the image, using the slice recorded as having the sharpest image. Compare the image with a baseline image and look for significant changes in the appearance of the in-focus and out-of-focus slices	The number of the sharpest slice should be within baseline ± 2 slices[a]

[a]Clear visualization of the minimum number of fibers, specks, and masses depends on the phantom used

APPENDIX - 4.2

Template for Mammography Report[8,32]

1. Indication
2. Pertinent physical exam details
3. Date of comparison mammograms/correlating ultrasound/ MRI
4. Scope and Technique: unilateral/bilateral, routine views acquired, additional views
5. Short description of composition:
   a. The breasts are almost entirely fatty
   b. There are scattered areas of fibroglandular density in both breasts
   c. The breasts are heterogeneously dense, which may obscure small masses
   d. The breasts are extremely dense, which lowers sensitivity of mammography.
6. Clear description of significant findings
   (a) MASS
   Location: laterality (left/right), quadrant, depth (anterior/mid/posterior)
   Size:
   Shape: oval/round/irregular
   Margin: circumscribed/obscured/microlobulated/ indistinct/spiculated
   Density: high/equal/low/fat-containing
   Ultrasound correlation:
   Associated Features: architectural distortion/ calcification/skin and nipple changes (thickening/ retraction), trabecular thickening
   (b) ARCHITECTURAL DISTORTION
   Laterality
   Quadrant
   Size
   Ultrasound correlation
   (c) ASYMMETRIES
   Laterality
   Quadrant
   Size
   Ultrasound correlation
   Asymmetry
   Global asymmetry
   Focal asymmetry
   Developing asymmetry
   (d) CALCIFICATIONS
   Location: laterality (left/right), quadrant, depth (anterior/mid/posterior)
   Size:
   Morphology: round or punctate/amorphous/coarse heterogeneous/fine pleomorphic/fine linear or fine-linear branching
   Distribution: diffuse/regional/grouped/linear/segmental
   Associated Features: mass/architectural distortion/ skin and nipple changes (thickening/retraction), trabecular thickening
   (d) AXILLARY LYMPH NODES
   (e) OTHERS: If multiple significant findings are present, all findings must be mentioned and described
   (f) CONTRALATERAL BREAST: Findings, if any
7. Impression: BI-RADS Assessment Category & Management Recommendation
   BI-RADS: 0 (Complete assessment of breasts is not possible based on mammography alone. Bilateral breast ultrasound/comparison with previous breast imaging studies is advised.)
   BI-RADS: 1 (within normal limits)
   BI-RADS: 2 (within benign limits)
   BI-RADS: 3 (probably benign. Needs follow up in 6 months' time)
   BI-RADS: 4A (Low suspicion for malignancy. Core biopsy is advised)
   BI-RADS: 4B (Moderate suspicion for malignancy. Core biopsy is advised)
   BI-RADS: 4C (High suspicion for malignancy. Core biopsy is advised)
   BI-RADS: 5 (Highly suggestive of malignancy. Core biopsy is advised)
   BI-RADS: 6 (known biopsy-proven malignancy)
8. Other important information/advice that you wish to communicate – Some examples:
   (a) when there may be a mismatch between the BI-RADS category and management recommendation, a clear explanation for your decision should be given
   (b) Clear recommendation should be given about follow-up: after 6 months/1 year & the appropriate imaging modality (mammography/ultrasound)
   (c) Screening breast ultrasound study (as a supplement to mammographic screening in dense breasts) is advised. (Note: Breast ultrasound should not be used as a standalone breast screening test).
9. Normal examination: Important negative findings should be mentioned. An example:
   (a) No mass, architectural distortion, significant focal asymmetry, suspicious calcification, or skin thickening is demonstrated in either breast
   (b) No abnormal axillary lymph node is demonstrated bilaterally
   (c) Regular screening mammography is advised if ≥ 40 years of age
10. A composite report with one overall BIRADS assessment is advised if Mammogram and Ultrasound studies are jointly performed. The most worrisome feature from either or both exams should decide the final BI-RADS assessment category and management recommendation.

APPENDIX - 4.3

Template for Stereotactic Breast Biopsy Report

PROCEDURE: Stereotactic Biopsy of right/left breast microcalcification/mass/focal or developing asymmetry/ architectural distortion

Target: right/left breast microcalcification/mass/focal or developing asymmetry/architectural distortion in _____ quadrant measuring _____

Consent: Informed consent was obtained after explaining the steps of the procedure and possible complications (such as hemorrhage, infection, retargeting, and repeat procedure)

Technique: The report should have the following points:

Patient position: prone/sitting upright

Compression: craniocaudal/lateral/oblique

Approach: vertical/lateral

Type of biopsy: 14 gauge core biopsy/VABB of ____gauge

Local anesthesia: name and quantity

Number of cores obtained:

Specimen Radiography obtained: If yes, mention the findings

Clip placement: If yes, mention findings of post-procedure check mammograms

Complications: mention if any

Post-procedure instructions: rest to ipsilateral arm, analgesics, care of dressing

Contact telephone number: in case of emergency or concern

Addendum to report after Radiology-Pathology correlation: after the histopathology report, establish concordance/discordance and advise accordingly

APPENDIX 4.4

Template for Breast Ultrasound Report[8,32,43]

1. Indication
2. Pertinent Physical exam details
3. Dates of comparison/correlation exams
4. Scope and Technique: Handheld/Automated, Unilateral/ Bilateral, Whole Breast/Targeted
5. Type of probe used. Special techniques
6. Short description of composition (screening studies only):
   a. The breasts have homogeneous background echotexture – predominantly fatty
   b. The breasts have homogeneous background echotexture – predominantly fibroglandular tissue
   c. The breasts have heterogeneous background echotexture
7. Clear description of significant findings with images

MASS:

Location: Laterality (left/right), o'clock position, Distance from nipple and depth from skin Shape: oval/round/irregular Orientation: parallel/not parallel Margin: Circumscribed/ Not circumscribed (indistinct/angular/microlobulated/ spiculated)

Echo pattern: anechoic/hyperechoic/complex cystic and solid/hypoechoic/isoechoic/heterogeneous

Posterior features: no posterior features/enhancement/ shadowing/combined pattern

Associated Features: architectural distortion, duct changes, skin changes (thickening/retraction), edema, vascularity (absent/internal vascularity/vessels in the rim), elasticity (soft/intermediate/hard)

Calcifications: in a mass/outside a mass/intraductal calcifications

SPECIAL CASES: Simple cyst, clustered microcysts, complicated cyst, mass in or on the skin, foreign body including implants, intramammary lymph nodes, axillary lymph nodes, vascular anomalies (arteriovenous malformations/ pseudoaneurysms/Mondor's disease), postsurgical fluid collection, fat necrosis

AXILLA: Lymph nodes and any other pathology to be mentioned

SUPRACLAVICULAR FOSSA: if findings suspicious for malignancy

8. Impression: BI-RADS Assessment Category & Management Recommendation
   BI-RADS: 0 (Complete assessment of breasts is not possible based on ultrasound alone. Bilateral mammography or comparison with previous breast imaging studies is advised)
   BI-RADS: 1 (negative - within normal limits)
   BI-RADS: 2 (within benign limits)
   BI-RADS: 3 (probably benign. Needs follow up in 6 months' time)
   BI-RADS: 4A (Low suspicion for malignancy. Core biopsy is advised)
   BI-RADS: 4B (Moderate suspicion for malignancy. Core biopsy is advised)
   BI-RADS: 4C (High suspicion for malignancy. Core biopsy is advised)
   BI-RADS: 5 (Highly suggestive for malignancy. Core biopsy is advised)
   BI-RADS: 6 (Known biopsy-proven malignant mass)
9. Other important information/advice that you wish to communicate – For example:
   (a) when there may be a mismatch between the BI-RADS category and the management recommendation, a clear explanation for your decision should be given
   (b) Clear recommendation should be given about the next follow-up/screening test after 6 months/1 year, whether mammography or ultrasound
10. Normal examination: Important negative findings should be mentioned. An example:
   (a) No mass is demonstrated in the breasts
   (b) No abnormal duct is demonstrated
   (c) No skin thickening is seen
   (d) No abnormal lymph node is demonstrated in the axillae
   (e) Documentation with images: all quadrants, retroareolar region, and axilla
11. A composite report with one overall BI-RADS assessment is advised if Mammogram and Ultrasound studies are jointly performed. The most worrisome feature from either or both exams should decide the final BI-RADS assessment category and management recommendation.

*Short description of composition is for screening breast ultrasound studies only (as a supplement to mammographic screening in dense breasts). Breast ultrasound is not to be used as a standalone breast screening test.

APPENDIX 4.5

Template for Ultrasound Guided Core Biopsy Report

PROCEDURE: Ultrasound-guided Core Biopsy of right/left breast mass/duct/lymph node

Target: Right/Left Breast mass located in _____ quadrant at ___ o'clock position, demonstrated on ultrasound dated _____.

Consent: Informed consent was obtained after explaining the procedure steps and possible complications (such as hemorrhage, infection).

Technique: Skin was cleaned and draped. Under ultrasound guidance, _____ ml of _____ (local anesthesia – name, and quantity) was injected for local anesthesia. A 2 mm skin incision was made. _____ (number of cores) were acquired under ultrasound guidance with a 14 gauge fully automated biopsy gun. The dressing is done (mention the type of dressing, such as SteriStrips, if required). No complication of procedure noted (mention complications here, if any).

Aftercare: rest to ipsilateral arm, adequate pain relief, care of dressing, as per local protocol

Contact phone number in case of emergency or concern:

Radiology-Pathology correlation: appropriate recommendation after correlation.

APPENDIX 4.6

Template for Ultrasound-guided Hook Wire Localization Report

PROCEDURE: Ultrasound-guided hook wire localization of right/left breast mass

Target: Right/Left Breast mass located in _____ quadrant at ___ o'clock position, demonstrated on ultrasound dated _____.

Consent: Informed consent was obtained after explaining the procedure steps and possible complications (such as bleeding, inappropriate positioning of wire, migration of wire, and repeat procedure).

Technique: Skin was cleaned and draped. Under ultrasound guidance, _____ ml of _____ (local anesthesia – name, and quantity) was injected for local anesthesia. Under ultrasound guidance, ____ gauge hook wire localization needle was inserted. The fine wire within the needle was deployed once the needle was in the correct position. Once the satisfactory position of the wire was confirmed on ultrasound, the needle was removed from the breast and discarded. The wire was gently strapped to the adjacent chest wall. No complication of procedure noted (mention complications here, if any).

Check mammograms: Post-procedure mammograms confirmed the optimum position on craniocaudal and lateral views. These mammogram images were made available to the surgeon.

Aftercare: rest to ipsilateral arm, adequate pain relief, care of dressing, as per local protocol.

Specimen radiograph: The targeted abnormality was demonstrated on the postsurgical specimen radiograph (for mammography occult lesions specimen should be scanned on ultrasound).

Radiology-Pathology Correlation: Addendum after histopathology report of the excised tissue is available.

APPENDIX 4.7

Template for Ultrasound-guided Marker Clip Insertion Report

PROCEDURE: Ultrasound-guided marker clip insertion into right/left breast mass

Target: Right/Left Breast mass located in _____ quadrant at ___ o'clock position, demonstrated on ultrasound dated _____.

Consent: Informed consent was obtained after explaining the steps of the procedure and possible complications (such as hemorrhage, infection, inappropriate positioning of clip, migration of clip, repeat procedure).

Technique: Skin was cleaned and draped. Under ultrasound guidance, _____ ml of _____ (local anesthesia – name, and quantity) was injected for local anesthesia. Under ultrasound guidance, ____ gauge needle was inserted. Once the needle was in the correct position, the marker clip within the needle was deployed. Once the satisfactory position of the clip was confirmed on ultrasound, the needle was removed from the breast and discarded. Dressing done. No complication of procedure noted (mention complications here, if any).

Check mammograms: Post-procedure mammograms confirmed the optimum position of the marker clip on both craniocaudal and lateral views.

Aftercare: rest to ipsilateral arm, adequate pain relief, care of dressing, as per local protocol

Contact phone number in case of emergency or concern:

Note: During surgery, ultrasound or mammography of the excised tissue is advised to confirm that the clip has been removed.

APPENDIX 4.8

Template for Ultrasound Guided Fine Needle Aspiration Cytology (FNAC) Report

Note: FNAC should be considered only if core biopsy is not possible. Core biopsy is the procedure of choice for sampling of breast lesions. If core biopsy expertise is locally unavailable, the patient should be referred to higher centers for core biopsy.

PROCEDURE: Ultrasound-guided FNAC of right/left breast cyst/mass/duct/lymph node

Target: Right/Left Breast mass located in _____ quadrant at ___ o'clock position, demonstrated on ultrasound dated _____.

Consent: Informed consent was obtained after explaining the procedure steps and possible complications (such as hemorrhage, infection).

Technique: Skin was cleaned and draped. Under ultrasound guidance, _____ ml of _____ (local anesthesia – name and quantity) (this is optional and as per local protocol) was injected for local anesthesia. Under ultrasound guidance, a ____ gauge needle was used, and aspiration was performed. _____ (number) slides were drawn with the aspirate and sent for cytological analysis. Dressing done. No complication of procedure noted (mention complications here, if any).

Aftercare: rest to ipsilateral arm, adequate pain relief, care of dressing, as per local protocol

Contact phone number in case of emergency or concern:

Radiology-Pathology correlation: appropriate recommendation after correlation. A core biopsy of the target should be advised if there is any doubt.

APPENDIX 4.9

Template for Breast MRI Report[8,32]

1. Indication
2. Technique: Magnet strength, coil type, sequences used, contrast details, correlation with mammography and ultrasound
3. Last Menstrual Period
4. Overall Breast Composition: Type a,b,c,d (choose one of the below):
   a. Almost entirely fat
   b. Scattered fibroglandular tissue
   c. Heterogeneous fibroglandular tissue
   d. Extreme fibroglandular tissue
5. Background Parenchymal Enhancement: (also look for symmetry)
   a. Minimal
   b. Mild
   c. Moderate
   d. Marked
6. Clear description of significant findings:

MASS

Size:

Location: laterality (left/right), o'clock position, distance from nipple/skin/chest wall

Shape: oval/round/irregular

Margins: circumscribed/non-circumscribed (irregular/spiculated)

Enhancement Characteristics: homogeneous/heterogeneous/rim enhancement/dark internal septations

Kinetics: Initial enhancement phase: slow/medium/fast

Delayed Phase: persistent/plateau/wash-out

Type of Time Intensity Curve

NON-MASS ENHANCEMENT (NME):

Location: laterality (left/right), o'clock position, distance from nipple/skin/chest wall

Distribution: Focal/Linear/Segmental/Regional/Multiple regions/Diffuse

Enhancement Patterns: homogeneous/heterogeneous/clumped/clustered ring

Kinetics

FOCUS: Location, number, symmetry, kinetics

OTHER FINDINGS: cysts/non-enhancing mass/dilated ducts/skin thickening/nipple retraction/chest wall invasion/intramammary lymph nodes

IMPLANTS: Material, location, integrity

SECOND LOOK ULTRASOUND FINDINGS

AXILLARY LYMPH NODES

INTERNAL MAMMARY LYMPH NODES

FINDINGS IN THE OTHER BREAST (similarly described in detail)

7. Comparison with previous MR Breast studies
8. Impression: BI-RADS Assessment Category & Management Recommendation
   BI-RADS: 0 (Incomplete. Need Additional Imaging) BI-RADS: 1 (negative - within normal limits)
   BI-RADS: 2 (within benign limits)
   BI-RADS: 3 (probably benign. Needs follow-up in 6 months)
   BI-RADS: 4 (suspicious for malignancy. Core biopsy is advised)
   BI-RADS: 5 (Highly suggestive of malignancy. Core biopsy is recommended)
   BI-RADS: 6 (Known biopsy-proven malignancy)
9. **Other important information/advice** you wish to communicate: for example, a clear explanation should be given when there may be a mismatch between the BI-RADS category and the management recommendation. Also, important negative findings should be mentioned in the report in relevant clinical scenarios.

APPENDIX 4.10

Template for MRI-guided Breast Biopsy Report

Informed Consent: Includes explanation of steps of the procedure, the possibility of complications such as pain, bleeding, and infection, including cancellation of the procedure due to nonvisualization of the targeted suspicious abnormality.

Indication: Suspicious finding on MRI with no clinical/other imaging (Mammogram/USG) correlate.

Method: Grid/post & pillar method.

Description of abnormality: mass/non-mass enhancement/ focus

Location of abnormality: right/left breast, quadrant, 0' clock position, distance from nipple.

Approach: Medial/lateral/both

Type of biopsy: Vacuum-assisted biopsy, needle gauge used.

Patent position: Prone

Procedure: Preprocedural contrast MRI (type and amount of contrast used) was performed, and the lesion to be biopsied was visualised. Under local anesthesia (type and ___ ml of local anesthetic used), after localizing the target, a biopsy was performed using VABB with ___ gauge needle, and about 12 (minimum) cores were obtained from the target. Post-procedure MRI showed a cavity at the target site. A marker clip (type and name) was placed at the biopsy site. Post-procedure check mammograms were obtained for confirmation, which demonstrated optimum clip position.

Documentation of procedure:

(a) MRI of target finding, MRI of coaxial needle position in prefire, MRI of VABB needle, post-biopsy cavity.
(b) Mammogram in two orthogonal planes post-biopsy after clip placement
(c) If more than one lesion is biopsied, separate reports must be given for each procedure

Complications: Significant bleeding/pain – Yes/No

Post-procedure instructions: Ice packs for pain, analgesics, care of dressing.

Emergency contact no:

Addendum to the report after histopathology result:

Radiology – Pathology concordance

Advice/Recommendation after biopsy results