BREAST IMAGING SOCIETY, INDIA

QUALITY ASSURANCE GUIDELINES FOR BREAST IMAGING

MAMMOGRAPHY

Quality Assurance (QA) is defined by 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 individual machines. In this document Breast Imaging Society, India (BISI) has advised further simple QA measures that are easy to implement at departmental / hospital level and will further improve the quality of patient care. Minimum standards for the radiologist, technologist/mammographer have also been specified in an attempt to objectively assess and implement good standards of breast imaging across all parts of our country. QA for Digital Tomosynthesis (DBT) as well as stereotactic breast biopsy has also been discussed. 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 very end of the document appendix 1 contains details of AERB documents as well as QC tests for DBT recommended for the breast radiologist and technologist. There are reporting templates for mammography and stereotactic breast biopsy in appendix 2 and 3 respectively.

MAMMOGRAPHY EQUIPMENT

Mammography units can be of three types - Digital Radiography (DR), Computed Radiography (CR) and Traditional Film based mammography units. 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 regulations.

The technique of acquisition of mammographic images must be monitored with specific attention to radiation dose and technical adequacy of films. The dose of radiation must be minimised based on the As Low As Reasonably Achievable (ALARA) principle.(1) Most mammography units have an automated 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, to avoid motion artefact and to minimise discomfort to the lady being imaged. Optimal compression must be applied(2).

Regulatory Inspection Programme of AERB includes three types of inspections. These are planned and announced inspections, special regulatory inspection which are reactive and announced inspections, as well as surprise regulatory inspections which are reactive/pro-active and unannounced inspections.(3)

At the time of installation, submission of Survey Report detailing radiation survey levels measured around the installation is mandatory.(4) The radiation survey report contains details of maximum radiation level at various locations such as the lead glass wall, operator position, entrance door, patient waiting area, front and side walls, entrance corridor, etc. 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 and 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 of the same.(3)

Periodic QA test reports must be submitted to AERB at least once in two years and also after any repairs having radiation safety implications.(5) Parameters tested for periodic radiation safety performance test report 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 optimum values for the tests are provided by the manufacturer and the measurements acquired are compared against the provided optimum values and AERB standards.

For DR Mammography digital detectors must be calibrated periodically as per manufacturer's recommendations. For CR Mammography the CR cassettes must be cleaned and evaluated for artefacts as per manufacturer's instructions. In the presence of artefacts that compromise image quality (for example artefacts that mimic microcalcifications) the CR cassettes must be discarded. In Traditional Film based mammography cassettes must be similarly monitored and darkroom techniques must be as per manufacturer's instructions.

Additional recommendation for Image quality assessment by Breast Imaging Society, India

Image quality assessment by using a mammography phantom is advised at least once a week. However daily assessment prior to the first case of the day is ideal, especially for screening mammograms. To pass the mammography image quality standards at least four

fibres, three calcification groups and three masses must be clearly visible (with no artefacts) at an average glandular dose of less than 3 mGy upon mammography of the phantom.(5) Image quality has been chosen as the method of continuous assessment as this is a simple quick test that can be performed by the mammographer. This test not only confirms that the image is of optimal quality but also indirectly assesses the multiple 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)

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. For breasts with implants within, additional CC and MLO views with implant displaced optimally are advised. The minimum requirements for the MLO view include visualisation of the pectoralis up to the level of the nipple, convex anterior border of the pectoral muscle, nipple in profile, inframammary fold which should be seen and open. The minimum requirements for the CC view include visualisation of the nipple in profile and visualisation of retroglandular fat. Length of the posterior nipple line on CC should be within 1cm of the length of posterior nipple line on the MLO view. Skin folds are to be avoided on both views.

Additional views (such as spot compression view, lateral view, laterally extended CC view and medially extended CC view) could also be acquired for better demonstration of abnormalities. In 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. Additional views and repeat images should be justified by clinical need as well as by ALARA principle. Departmental policy on repeat exposures and additional images must be followed. The technologist assesses the acquired images for adequacy of position as well as artefacts. Degree of autonomy of the mammographer and radiologist's active supervision in these decisions depend on 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 on the CC view and in 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 itself. These should be identified by the mammographer 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 and this is extremely helpful in cases with multiple focal lesions in the breast.

Review of all mammograms by the radiologist immediately after acquisition of images is encouraged to decide need for additional diagnostic views. However screening mammograms can be acquired in the absence of the radiologist if local protocol allows. In this case the lady will need to be recalled for further views as required.

MAMMOGRAPHY PERSONNEL

Specialist Breast Technologist / Mammographer

The mammographer must have a 2 or 3 years diploma or degree such as Diploma in Radiography, Diagnostic (DRD) recognized by the state / central government. She should have specific training in Mammography as part of this training programme. Performing a minimum number 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 organised as this significantly improves 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 during the procedure. She should be able to answer basic questions on radiation dose and importance of screening. She should be able to help the patient fill relevant patient questionnaires, check if the requisition for mammography is as per department protocol and document patient complaints as required. She should record patient contact details to ensure a seamless recall process if required. She should collect previous mammograms and relevant clinical notes and make these available during reporting. She should also explain to the patient the process and time for report collection.

Mandatory check of name and unique hospital identification number (UHID) must be performed before pressing the button that activates radiation to ensure that the right patient is being imaged. All films must be correctly labelled with the name, UHID number,

date, side and other details as per local protocol. Repeat mammograms done for technical or positioning errors must be kept to less than 3%. (7)

Breast Radiologist

The radiologist should have a medical qualification and should hold a degree in Radiology that is recognized by the Medical Council of India. She/he should have specific training in Mammography as part of her/his training programme. Taking up a breast fellowship course or training under an experienced Breast Radiologist is strongly recommended before independent reporting of mammograms. This kind of training should also help develop skills for performing mammography guided procedures such as guided hookwire localization and stereotactic biopsy. Radiologist must attend periodic continued medical activity (CME) courses for continuing upgradation of technical knowledge.

During training the radiologist is expected to report a minimum of 1500 mammograms under supervision before he/she starts 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 is expected to report a minimum of 500 mammographic examinations per year. Reporting terminology and format in accordance with ACR BI-RADS lexicon and assessment categories is advised.(8)

The lead breast radiologist is in charge of the breast unit and should take responsibility for quality related issues including equipment selection, staff selection and quality control protocols along with the hospital management team. This also includes interactions with medical physicist, biomedical engineer, vendor's application specialist and provision of training for mammography technologists. Responsibility of planning audits, delegating related work to the appropriate person and applying the lessons learnt from the audits to implement changes in the department protocols rests with the lead breast radiologist.

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 dose making dose assessment an easy process. 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, must be on a phantom and not a patient.

The requisition form must justify mammography and if any doubt exists the referring doctor should be contacted before radiating the patient. Every patient must be questioned about 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 second opinion is being given. If 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.

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

Routine wearing of lead shield or apron is not recommended as most of the dose to the organs is as a result of scatter in the breast tissue and enters the trunk through the breast and this minimizes the benefit of wearing a lead apron.(10)

Pregnancy & Mammography

Women of child bearing 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 0.03µGy (0.003 mrad) and this can be representative of the dose to the fetus in the first trimester.(10) The use of a lead shield reduces this dose further by about a factor of 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 which are the result of 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 in pregnant patients although fear of potential radiation effects on a fetus should not deter us from performing necessary mammographic studies and 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

Radiation safety of staff and visitors to the department of Radiology is of utmost importance. The mammography unit must be built, maintained and checked periodically to confirm that AERB regulations are met. Application must be made to AERB for permission of installation of mammography equipment by the e-Licensing of Radiation Applications (eLORA) System (4) and mammography machine must be placed in the hospital with full compliance with AERB regulations(3). Personal dosimeters must be worn by all personnel, 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 five years) and 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/foetus should be 1 mSv for the remainder of the pregnancy.(15)

The mammography room must be used to perform mammography and mammography guided interventional procedures only. No other investigations, such as breast ultrasound should be performed in the mammography room. Only personnel involved in the procedures must be present 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 situated behind a protective screen as 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.

STEREOTACTIC BIOPSY

The team performing stereotactic breast biopsy should be adequately trained with regards to the equipment, procedure and possible complications of the procedure. The technologist should be well versed with 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 supervision of application specialist before independently performing the biopsy is also acceptable.

The breast radiologist performing the procedure should be trained in stereotactic procedures at a specialised breast unit prior to performing stereotactic procedures independently. A minimum of 150 supervised image guided breast procedures (both ultrasound and mammography guided procedures included) are recommended to be

performed over a period of 1 year to train adequately. A minimum of 60 image guided breast procedures (both ultrasound and mammography guided procedures included) per year are recommended for maintaining interventional skills in breast imaging. The radiologist performing image guided breast procedures must be well versed with mammography and breast ultrasound interpretation, as this knowledge is essential for Radiology – Pathology correlation.

Stereotactic biopsy may be performed with a dedicated prone setup or with an add-on device and adjustable chair. All equipment must be calibrated as per the manufacturer's guidelines. Quality control tests for the mammographic unit used to perform stereotactic biopsy are as per manufacturer's instructions as well as 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 break down of equipment. 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, assessment of radiation dose and evaluation of image quality 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. That is, the difference between the preset location and the computer determined location 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 being within 1 mm of the targeted phantom location in each direction.(17)

Written informed consent should be obtained by the operator prior to the procedure after explaining the steps of procedure and the possible complications such as haemorrhage, 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 use of 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 (VAAB) device. The VAAB equipment must be calibrated before start of procedure. The concentration and expiry date of the local anaesthetic must be checked while preparing the procedure tray.

During the procedure images that demonstrate the important steps of the procedure must be saved. The images should have patient's name, UHID number, date, indication of right or left breast, name of hospital and other details as per local protocol. Pre-procedure scout image documenting the lesion that is being targeted (typically microcalcifications), pre-procedure stereotactic pair images, prefire and one set of post fire stereotactic pair images would be a good set of images to save for future record. A radiograph of the samples acquired must be saved in the case of 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 calcifications and hence radiography of samples cannot be used as confirmation of adequate sampling. If a marker clip is deployed (for example following complete removal of the targeted lesion), image demonstrating optimal placement of marker clip should also to be saved. After the procedure is completed formal CC and lateral mammograms of the ipsilateral breast are performed to confirm position of the marker clip.

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

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 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 procedure if any should also be documented in the report. For example if the post biopsy mammograms demonstrate displacement of marker clip from the site of biopsy, that must be documented.

Clear mention of the clinical history, pertinent imaging findings, likely imaging diagnosis, name of procedure (core or VAAB), side (right/left breast), 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), name of procedure should be mentioned on the container in which the sample is placed. After 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 investigating 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 a hookwire localization and marker clip placement should also be similarly consented, documented and reported. This applies to tomosynthesis guided procedures as well.

DIGITAL BREAST TOMOSYNTHESIS

Digital Breast Tomosynthesis (DBT) is an active area of research and development with evolving clinical role. In principle 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. From these projection images a 3D data set is reconstructed and viewed as thin slices. The number of DBT installations in India is on the rise. As India embraces clinical implementation of this technological advancement, attention to QA parameters is of paramount importance. Due to the wide variation in hardware as well as processing algorithms used by different manufactures, adherence to 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. In the absence of international consensus about some of the QA protocols, several international guidelines have been referenced for this purpose.

Indication

DBT is recommended as a complimentary method and not a standalone screening technique in the first 6 months to a year of installation to accommodate the learning curve of the mammographer and the radiologist and also for optimization of 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 for 2D Digital Mammography (DM). DBT may be performed in addition to CC, MLO and/or 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 dataset allowing for elimination of a separate DM exposure. Use of DM+ DBT increases the radiation dose by a factor of 2.25 compared with that for DM only examinations. If DM is replaced with SM, the radiation dose can be reduced by 45%.(21) Studies show that 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 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 in accordance with reporting of 2D mammography. It's preferable to use ACR BIRADS lexicon and assessment categories just as for 2D mammography. Slice number and views of findings on DBT should be included in the report. Prints of synthesized images must be labeled as such to distinguish 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 centres must be met with. 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 technique of imaging. Due to wide variation in technology it is advisable that training is acquired from individual DBT manufacturers in the form of training courses and observerships in units who have 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 prior to independently using this new mammographic modality.(26) Over and above the basic training, mammographers and radiologists are encouraged to continuously update their knowledge and skills. The lead radiologist has the responsibility of recognizing additional training requirements of the staff in order to maintain and improve the quality standards of the unit.

Image Acquisition & Archiving

As in DM, the aim in QA of DBT is to acquire the best possible quality images with lowest radiation dose as per ALARA principle. The testing procedures and requirements specified for DBT units are consistent with those specified in the DM section as 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.

There are many international guidelines available on DBT and the reader is urged to study these and apply necessary QA measures at departmental and hospital level as required. (19,25,27)

DBT images if generated in 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, it is acceptable to perform a stereotactic biopsy using adjacent tissue landmarks for guidance. However a biopsy marker should be placed with post procedure DBT images in two projections to demonstrate that the original finding was properly targeted.

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 for display of digital images printed on films.(28) Viewing boxes of appropriate size, ideally to allow comparison with previous mammograms, are required. All tubes may need simultaneous replacement to ensure they are of the same colour and intensity, therefore maintaining uniformity.

Ambient lighting must be conducive to reporting. Room lighting should be indirect and care should be taken to make sure 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 designated QA technologist.

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

At the radiologist's work station multiple layouts of image display can be arranged and a hanging protocol for image display can be set up as per 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 detection of asymmetries. CC images should be displayed similarly on 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 size of abnormalities is possible even at other centres if required. Mammographic displays should allow fast and easy navigation between previous and current studies as well as between 2D and DBT images.(28) Storage requirement estimates should therefore take into account 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 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 and 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 recommended by the manufacturer and also as per local hospital regulations.

It is advisable for DR and CR facilities to maintain mammography images and reports in the permanent medical record of the patient for a period of not less than 5 years.(29) Traditional film based mammography units may save reports only for the same duration as the printed images are given to the clients.

AUDITS

Audit of mammography acquisition is advised once a year for each mammographer. This should include audit of retakes due to suboptimal positioning or other factors. A good example to follow is categorizing mammography position 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)

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

Audit of breast radiologists’ performance should be conducted annually. This should include review of appropriate clinical indication, accuracy of reports and correlation with pathology reports to check adequacy of sampling in cases of stereotactic procedures.

An audit of stereotactic procedures should be performed in the unit annually. Total number of stereotactic biopsies performed, total number of cancers detected, benign lesions detected, inconclusive results requiring repeat biopsy and complications should be analysed.(31)

In units with DBT additional dedicated DBT medical audits are advised, particularly in screening setting to distinguish between the two modalities with respect to performance. Examinations should be systematically reviewed and evaluated as part of the overall quality

improvement program at the facility. Monitoring should include evaluation of the accuracy of interpretation as well as 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 is in charge of planning the audits as well as applying findings of the audits to enhance patient care.

TEAM WORK & MULTIDISCIPLINARY MEETINGS

For QA measures to be effective it is important that all members of the team understand their role and participate actively in the programme. Radiologists, radiographers, breast care nurses, medical physicists, information technologists and healthcare managers need to work as a team for a good QA programme to make a difference to our patients.

Each mammography unit should develop policies and procedures related to 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 decision on the next best step for the patient can be taken on a case to case basis. The participation in the MDMs must be mandatory for all doctors and breast care nurses and at any given meeting representation from consultant level team members of all specialities must be mandatory.

NUCLEAR MEDICINE

Centres which have 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)

DISCLAIMER

Above mentioned Quality Assurance Guidelines is purely recommendatory and general purpose only in nature. Actual decisions for investigation and management of the patients should be individualized according to own judgment of the caregiver and tailored on case-to-case basis. As scientific knowledge is continuously improving, a regular update of the same 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.

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Appendix 1

BREAST IMAGING SOCIETY, INDIA

QUALITY ASSURANCE GUIDELINES FOR BREAST IMAGING

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 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 by using a mammography phantom is advised at least once a week. However daily assessment prior to 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. These may be altered as per local protocol after discussion with medical physicist of the hospital. These tests do not replace the tests that are to be performed as per manufacturer's instructions or local protocol

Test	Frequency	Method	Look for
System check (Uniformity of field)	daily	Expose phantom under AEC in DBT mode and check reconstructed image slices (not the projections)	abnormal artefacts or variations in noise pattern
AEC thickness check	monthly	Expose each thickness of perspex in turn under AEC in tomosynthesis mode and check reconstructed image slices	abnormal artefacts 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	Number of sharpest slice should be within baseline ± 2 slices*

* Clear visualization of minimum number of fibres, specks and masses depends on the phantom used

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Appendix - 2

BREAST IMAGING SOCIETY, INDIA
QUALITY ASSURANCE GUIDELINES FOR BREAST IMAGING

MAMMOGRAPHY REPORT TEMPLATE
(Based on ACR BI-RADS)

1. Indication
2. Pertinent physical exam details
3. Dates of comparison mammograms / correlating ultrasound / MRI
4. Scope and Technique : unilateral/bilateral, routine views acquired, additional views
5. Short description of composition :
    - The breasts are almost entirely fatty.
    - There are scattered areas of fibroglandular density in both breasts
    - The breasts are heterogeneously dense, which may obscure small masses
    - The breasts are extremely dense, which lowers sensitivity of mammography.
6. Clear description of significant findings

    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 / fatty

    Ultrasound correlation:

    Associated Features: architectural distortion / calcification / skin and nipple changes (thickening / retraction), trabecular thickening

    ARCHITECTURAL DISTORTION: laterality, quadrant, size, ultrasound correlation

    ASYMMETRIES : Asymmetry / global asymmetry / focal asymmetry / developing asymmetry

    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

    AXILLARY LYMPH NODES

    OTHERS : If multiple findings are present, all findings must be mentioned and described

CONTRALATERAL BREAST: Findings if any

7. Impression : BIRADS Assessment Category & Management Recommendation
    - BIRADS - 0 (Complete assessment of breasts is not possible based on mammography alone. Bilateral breast ultrasound / comparison with previous breast imaging studies is advised)
    - BIRADS - 1 (within normal limits)
    - BIRADS - 2 (within benign limits)
    - BIRADS - 3 (probably benign. Needs follow up in 6 months' time)
    - BIRADS - 4A (Low probability for malignancy. Core biopsy is advised)
    - BIRADS - 4B (Moderate probability for malignancy. Core biopsy is advised)
    - BIRADS - 4C (High probability for malignancy. Core biopsy is advised)
    - BIRADS - 5 (Highly suggestive of a malignant mass. Core biopsy is advised)
    - BIRADS - 6 (Biopsy proven malignant mass)
8. Other important information / advice that you wish to communicate – Some examples:
    - when there may be a mismatch between BIRADS category and management recommendation, a clear explanation for your decision should be given
    - Clear recommendation should be given about follow up: after 6months / 1 year & the appropriate imaging modality (mammography /ultrasound)
    - Screening breast ultrasound study (as a supplement to mammographic screening in dense breasts) is advised. (Note: Breast ultrasound is not to be used as a standalone breast screening test).
9. Normal examination : Important negative findings should be mentioned. An example:
    - No mass, architectural distortion, significant focal asymmetry, suspicious microcalcification or skin thickening is demonstrated in either breast
    - No abnormal axillary lymph node is demonstrated bilaterally
    - Regular screening mammography is advised, if ≥ 40 years of age
10. If Mammogram and Ultrasound studies are jointly performed , a composite report with one overall BIRADS assessment is advised. The most worrisome feature from either or both exams should decide the final BIRADS assessment category and management recommendation.

REFERENCE:

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Appendix - 3

BREAST IMAGING SOCIETY, INDIA
QUALITY ASSURANCE GUIDELINES FOR BREAST IMAGING

STEREOTACTIC BREAST BIOPSY REPORT TEMPLATE

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 obtained after explaining the steps of procedure and possible complications (such as haemorrhage, infection, retargeting, 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 / VAAB of ____gauge
Local anaesthesia : 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 histopathology report, establish concordance/ discordance and advice accordingly