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## **ACR–AAPM–SIIIM PRACTICE PARAMETER FOR DETERMINANTS OF IMAGE QUALITY IN MAMMOGRAPHY**

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### **PREAMBLE**

This document is an educational tool designed to assist practitioners in providing appropriate radiologic care for patients. Practice Parameters and Technical Standards are not inflexible rules or requirements of practice and are not intended, nor should they be used, to establish a legal standard of care<sup>1</sup>. For these reasons and those set forth below, the American College of Radiology and our collaborating medical specialty societies caution against the use of these documents in litigation in which the clinical decisions of a practitioner are called into question.

The ultimate judgment regarding the propriety of any specific procedure or course of action must be made by the practitioner considering all the circumstances presented. Thus, an approach that differs from the guidance in this document, standing alone, does not necessarily imply that the approach was below the standard of care. To the contrary, a conscientious practitioner may responsibly adopt a course of action different from that set forth in this document when, in the reasonable judgment of the practitioner, such course of action is indicated by variables such as the condition of the patient, limitations of available resources, or advances in knowledge or technology after publication of this document. However, a practitioner who employs an approach substantially different from the guidance in this document may consider documenting in the patient record information sufficient to explain the approach taken.

The practice of medicine involves the science, and the art of dealing with the prevention, diagnosis, alleviation, and treatment of disease. The variety and complexity of human conditions make it impossible to always reach the most appropriate diagnosis or to predict with certainty a particular response to treatment. Therefore, it should be recognized that adherence to the guidance in this document will not assure an accurate diagnosis or a successful outcome. All that should be expected is that the practitioner will follow a reasonable course of action based on current knowledge, available resources, and the needs of the patient to deliver effective and safe medical care. The purpose of this document is to assist practitioners in achieving this objective.

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<sup>1</sup> *Iowa Medical Society and Iowa Society of Anesthesiologists v. Iowa Board of Nursing* 831 N.W.2d 826 (Iowa 2013) Iowa Supreme Court refuses to find that the *ACR Technical Standard for Management of the Use of Radiation in Fluoroscopic Procedures* (Revised 2008) sets a national standard for who may perform fluoroscopic procedures in light of the standard's stated purpose that ACR standards are educational tools and not intended to establish a legal standard of care. See also, *Stanley v. McCarver*, 63 P.3d 1076 (Ariz. App. 2003) where in a concurring opinion the Court stated that "published standards or guidelines of specialty medical organizations are useful in determining the duty owed or the standard of care applicable in a given situation" even though ACR standards themselves do not establish the standard of care.

## I. INTRODUCTION

This practice parameter was developed collaboratively by individuals with recognized expertise in breast imaging, medical physics, and imaging informatics, representing the American College of Radiology (ACR), the American Association of Physicists in Medicine (AAPM), and the Society for Imaging Informatics in Medicine (SIIM), primarily for technical guidance. It is based on a review of the clinical and physics literature on digital mammography and the experience of experts and publications from the Image Quality Collaborative Workgroup [1-3]. Additionally, this practice parameter includes input from industry, radiologists, and other interested parties in an attempt to represent the consensus of the broader community. It received further input from another working group of the Integrating the Healthcare Enterprise (IHE) Initiative [4].

For the purposes of this practice parameter, mammography is defined as the radiographic and tomographic examination of the breast by using dedicated electronic detectors to record the image and having the capability for image display on computer monitors. This practice parameter in mammography image quality does not pertain to computed tomography (CT) mammography. Image quality for stereotactic/tomosynthesis-guided breast biopsy is not explicitly addressed in this document, although much of what is discussed in this document applies to biopsy units as well. For further information on breast biopsy, see the [ACR Practice Parameter for the Performance of Stereotactic/Tomosynthesis-Guided Breast Interventional Procedures](#) [5].

In many parts of this practice parameter, the level of technical detail regarding the determinants of image quality for mammography is advanced. It is intended to provide an expanded knowledge of the issues pertinent to assessing and maintaining mammography image quality from acquisition, to display, and then to the data storage aspects of the process. Personnel directly involved in clinical implementation and oversight, such as Radiologists, Qualified Medical Physicists, mammography technologists, and regulators, will benefit from this guidance. Where basic technical requirements for mammography overlap with those for digital radiography in general, users are directed to consult the referenced ACR articles [6,7]. All interested individuals are encouraged to review the [ACR–AAPM–SIIM–SPR Practice Parameter for Digital Radiography](#) [8]. Furthermore, the ACR Subcommittee on Quality Assurance in Mammography has developed a Digital Mammography Quality Control (QC) Manual [9].

Analysis of image quality has meaning primarily in the context of a particular imaging task [10]. This practice parameter has been developed with reference to specific imaging tasks required by mammography, using the information available in the peer-reviewed medical literature regarding mammography acquisition, image processing and display, storage, transmission, and retrieval. Specifically, the imaging tasks unique to mammography that determine the essential characteristics of a high-quality mammogram are its ability to visualize the following features of breast disease.

1. The characteristic morphology of a mass
2. The shape and spatial configuration of calcifications
3. Distortion of the normal architecture of the breast tissue
4. Asymmetry between images of the left and right breast
5. The development of anatomically definable changes when compared with prior studies

The primary goal of mammography is to detect breast cancer by accurately visualizing these features. At the same time, it is important that these signs of breast cancer not be falsely identified if breast cancer is not present. Two aspects of digital image quality can be distinguished: technical and clinical. It is possible to make technical measurements describing the above attributes, and it may be possible to infer a connection between these technical measures and clinical image quality. The extent to which these features are rendered optimally with a mammography system using current technology depends on several factors and is the major focus of this practice parameter.

## II. QUALIFICATIONS AND RESPONSIBILITIES OF PERSONNEL

Interpreting physicians, Qualified Medical Physicists, and radiologic technologists who work in mammography must meet the requirements of the Mammography Quality Standards Act (MQSA) final rule as published by the Food and Drug Administration (FDA) [11]. Under MQSA, personnel need to receive 8 hours of initial training prior to

independently using any new mammographic modality, defined as a modality in which the person has not previously been trained. See the [ACR Practice Parameter for the Performance of Screening and Diagnostic Mammography](#) [12]. This includes full-field digital mammography (FFDM) and digital breast tomosynthesis (DBT). For further information see the FDA's [Frequently Asked Questions about DBT and MQSA Training Requirements](#) [13].

### III. MAMMOGRAPHY IMAGE ACQUISITION

In FFDM and DBT, the processes of image acquisition, display, transmission, and storage are performed by separate systems, each of which can be optimized. The digital detector is designed to efficiently absorb X-rays, produce an electronic signal, digitize the signal, and store the results in computer memory. The output image is saved as a 2-D matrix, in which each picture element (pixel) represents the X-ray transmission corresponding to a particular path through the breast. This image can be digitally processed such that when it is displayed in softcopy form on a high-resolution display device or printed on laser film, the key features required for mammographic interpretation can be visualized.

Technical descriptions of digital radiography image acquisition devices and specifications are available in Williams et al [7], and individual device specifications are available on request from the specific equipment manufacturers. Once a system has been purchased, calibrated, and acceptance tested, regularly scheduled quality control (QC) procedures performed by the technologist and annual testing (or as needed) by the Qualified Medical Physicist are required to maintain compliance with the FDA regulations. These regulations allow mammography quality assurance programs the option to follow the system specific QC testing procedures for FFDM and DBT systems required to be prescribed by the image acquisition device manufacturer, or those found in the recently-approved ACR Digital Mammography Quality Control Manual [9].

For digital acquisition systems, accurate representation of anatomical detail and pathology requires adequate anatomic coverage and image quality. Image quality can be described in terms of spatial resolution, image contrast, noise, and artifacts. Any technique adjustments should be performed in consultation with and verified by the radiologist in charge of the mammography program and the Qualified Medical Physicist.

- A. Anatomic coverage depends on the chosen view (projection) and positioning of the breast. The goal is to project as much of the breast tissue as possible onto the image detector to maximize breast disease detection. The following factors affect tissue coverage:
1. The geometrical relationship of the X-ray source, collimation, compression device, patient, grid, and image detector requires the X-ray beam and image receptor to come as close to the chest wall edge of the breast support as possible.
  2. The image receptor should be large enough to image the entire breast of most women. Along the edge of the detector nearest the chest wall, inactive regions of the image receptor will result in missed breast tissue. Consequently, the gap between the chest wall edge of the image receptor and the breast support should be minimized and in no case should exceed 7 mm. Typical digital units have a gap of 4 to 7 mm [3,14]. On all other sides of the detector, there should be complete coverage of the breast tissue.
  3. Large breasts may require imaging of the breast in sections, particularly for smaller field of view (FOV) detectors. The resulting multiple images in the same projection must be viewed together to form the complete mammogram. An increase in radiation dose occurs to regions of the breast that are exposed to X-rays in more than 1 image in the same projection. Standard tiling methods that minimize double exposure should be used. A larger FOV detector lowers the need for multiple-section imaging.
  4. Clinical assessment of positioning in FFDM evaluates the retroglanular aspects of the breast between the craniocaudal (CC) and mediolateral oblique (MLO) views. On the CC view, the posterior nipple line of the breast (the distance between the nipple and the posterior edge of the image) should be within 1 cm (approximately) of that on the MLO view (the distance between the nipple and the anterior edge of pectoralis muscle). The anterior edge of the pectoralis muscle on the MLO view should be convex, and it is desirable

for the muscle to extend to the level of the nipple. The posterior nipple line should be drawn at an angle perpendicular to the muscle, usually at approximately 45 degrees on the MLO image.

- B. Spatial resolution [7] of an imaging system refers to its ability to depict 2 adjacent structures as being separate, or the distinctness of an edge in the image (ie, sharpness). Measurement is performed by qualitative or quantitative methods [7]. The effects of spatial resolution on clinical image quality are most easily observed when imaging fine detail in the breast such as spiculations radiating from a mass or microcalcifications. Shape and margins help differentiate a benign from a malignant process. However, one may not isolate spatial resolution effects on clinical image quality from effects due to quantum mottle and electronic noise under typical digital image acquisition conditions.

Spatial resolution losses occur because of blurring caused by geometric factors such as the size of the X-ray tube focal spot and the amount of applied compression. Magnification is used to improve spatial resolution, but it will introduce magnification-dependent focal spot blur; therefore, a smaller focal spot size is required. Other factors that affect spatial resolution include detection methods used (direct or indirect detection); detector material; detector element effective aperture and pitch; and relative motion of the X-ray source, breast, or image detector during the exposure. For DBT systems, tube motion, the number of projections acquired, the angular range, and the angle of incidence will affect the in-plane and z-axis spatial resolution. Geometric optimization techniques are vendor-specific, resulting in variability in image quality of DBT systems [15].

Motion blurring can have a particularly strong impact on limiting spatial resolution and image sharpness. In FFDM, motion blurring is caused by movement of the breast during exposure and is minimized by using a short exposure time and appropriate breast compression. Magnification techniques with small focal spots and lower tube current (mA) require longer exposure times and are therefore more susceptible to motion blur.

1. Applied kilovoltage (kV) may be increased for thick, dense breasts to allow reduction of exposure time. Image processing may compensate for contrast losses to the extent allowed by the background noise and the image signal-to-noise ratio (SNR).

- C. Contrast resolution (radiographic contrast) refers to the magnitude of the signal difference between the structure of interest and its surroundings in the displayed image and is influenced by subject contrast and display (image) contrast [7]. High radiographic contrast is needed to visualize the subtle differences in soft-tissue densities of normal and pathologic structures, including structural characteristics of the margins of masses and the detection and characterization of minute microcalcifications.

1. Subject contrast is the relative difference between the X-ray transmissions at the entrance plane of the image receptor through different parts of the breast. Attenuation, and therefore subject contrast, depends strongly on the X-ray energy spectrum, which is determined by the target material, tube potential, and filtration (either inherent in the tube or added). In mammography, low tube potentials (~24-35 kV) are employed. Target and filtration materials are vendor-specific, but generally include molybdenum, rhodium, and tungsten targets and molybdenum, rhodium, silver, and aluminum filters. In general, a molybdenum target/filter with a low tube potential will only be used for imaging smaller breasts (thickness of 2 to 5 cm). For thicker and/or denser breasts, a higher-energy X-ray beam is needed to achieve adequate tissue penetration. The properties of digital detectors and adjustment of display contrast through image processing allow the use of higher energy X-rays as a means of dose reduction without compromising image SNR. The subject contrast may be increased by the use of a contrast agent. Contrast-enhanced mammography (CEM) is a technique that uses iodinated contrast and dual-energy digital mammography to enhance visualization of tumor neovascularity [16].
2. Grids [7] designed for mammography reduce scattered radiation and improve radiographic contrast with the trade-off of higher breast dose [17,18]. Linear and cellular grids are used for contact (nonmagnification) imaging to reduce noise contributed by scatter. With geometric magnification views, the increased air gap between the breast and detector eliminates the need for a grid. Mammography systems may use image processing instead of a grid to reduce the effects of scattered radiation on image contrast. Some DBT systems do not use a grid because of the low exposure available per projection and the moving X-ray source position

during acquisition.

3. Breast compression produces thinner, more uniform tissue, which results in less scattered radiation, more even penetration of X-rays, less magnification or geometric blurring, less anatomical superimposition, and lower breast radiation dose.
- D. Radiographic image noise is the unwanted random (uncorrelated), nonrandom (correlated), or static (eg, detector defect) variation in signal in an image acquired from a uniform x-ray exposure [19-21]. Using fewer X-rays (quanta) increases random noise or quantum mottle (for a fixed signal), decreases SNR, and reduces the ability to discern subtle differences in image contrast. Fine calcifications or subtle masses that can be the first signs of cancer may not be visible in a noisy (underexposed) image. The exposure required to achieve a desired SNR is inversely related to the detective quantum efficiency (DQE). Consequently, as DQE increases, so does the dose efficiency. “Appropriate” X-ray exposure depends on the system’s DQE, and requisite SNR can be achieved with a calibrated automatic exposure control system.

Anatomical noise is another common source of noise in mammography. Mammographic breast density is the amount of radiopaque tissue relative to the amount of radiolucent tissue present in the breast. Dense breasts, with high amounts of glandular and fibrous tissues, can produce abundant anatomic noise in the image, leading to challenges in interpretation by masking underlying pathology [22]. DBT, CEM, breast CT, breast MRI, molecular breast imaging, and breast ultrasound are also useful as supplemental tools to aid in breast cancer detection for women with dense breasts.

- E. Artifacts in FFDM images can lead to errors in interpretation by either mimicking or obscuring abnormalities in the breast. There are a number of sources of these artifacts related to the patient, machine, detector, image processing, and data storage [23].

There are specific artifacts associated with DBT imaging that can enhance or impede object visibility. High-contrast objects can cause out-of-plane ghosting or result in shadowing that appears as dark, “embossed” regions in the direction of the tube movement. Both are due to incomplete sampling that results from the limited angular range and the reduced number of acquisition angles [24,25]. These artifacts can be minimized via image post processing, either by reconstructing thicker slices or by viewing multiple slabs or stacked thin slices. Each vendor has reconstruction algorithms for artifact reduction and enhancement. Training is imperative for understanding individual vendor reconstruction characteristics.

#### **IV. MAMMOGRAPHY IMAGE PROCESSING**

Image processing has great potential to improve image quality and diagnostic accuracy and even to reduce the radiation dose necessary to achieve an image of acceptable quality [26-28]. Digital mammograms typically have a wide dynamic range and the ability to process the image data provides an opportunity to display the data more effectively. Storage of “for processing” image data provides greater flexibility for subsequent postprocessing using different algorithms. Systematic variations in intensity can be equalized, local contrast can be enhanced, and the sharpness of calcifications can be restored. Enhanced visualization of subtle structures is suggested as a possible contributor to the improved performance of digital mammography in patients with dense breast tissue [29].

1. Segmentation of the breast from the region of the direct beam is the first step for defining the areas to be processed, using edge detection algorithms and grayscale adjustment to equalize apparent tissue thickness. Artifacts near the skin line can occur in the equalized image, and the potential for this improper segmentation requires the ability to turn off the algorithm.
2. Spatial frequency restoration and deblurring are used to render microcalcifications with greater detail and higher conspicuity.
3. Selective (adaptive) noise reduction attempts to reduce noise only in regions where tissue contrast does not have noticeable fine detail. Difficulty arises in reducing noise and preserving high spatial resolution with the

same process. In some cases, noise reduction might not improve detection performance if the reduced noise texture is similar to that of target objects.

4. Unsharp masking sharpens images by using Fourier filters or spatial convolution kernels of large spatial extent to create a low frequency blurred image that is then subtracted from the nonblurred image.
5. Global latitude reduction increases the relative signal in underpenetrated areas and reduces the signal in highly transmissive regions.
6. Adaptive local contrast enhancement and multiscale processing are other methods that have been used. When applying global latitude equalization or adaptive contrast enhancement, there is always some risk that subtle tissue characteristics of potential diagnostic significance may be diminished in relation to the detail that is enhanced.
7. Differently processed versions of the same mammogram may be preferred depending on the task and lesion type, suggesting that workstations might implement multiple processing options for use during interpretation [29].
8. Desired processing parameters may vary with radiographic factors such as tube target, kV, and tube filter type and thickness. One must be careful to ensure that the processing being used is appropriately matched to the techniques used to obtain the mammogram.
9. A synthetic 2-D mammogram can be reconstructed from DBT projections and has the potential to replace 2-D FFDM. Use of synthetic mammography allows for a reduction in radiation dose and a shorter total examination time and may result in better conspicuity of high-contrast calcifications and architectural distortions relative to 2-D FFDM. Synthetic mammography images have been shown to underperform in terms of spatial resolution, the potential for false-positive calcifications, and synthetic-mammography-specific artifacts [30].
10. Comparison of images from prior mammography examinations is essential in the interpretation of a new study. However, variations in the processing of prior and current images may make such comparisons difficult. See the discussion below under section VI. C. "Archive" for further information on this subject.
11. Application of image processing at the reading station (or by a processing box located separately from the primary interpretation workstation) requires image processing software that is applicable to the images from any mammography system. This requires an understanding of the characteristics of the image data from the mammography system or other input devices (eg, film digitizers) as well as storage of image data in the DICOM format intended "for processing."

It should be noted that although image processing has a number of beneficial aspects, the user must also be aware of the potential deleterious consequences of using certain image processing tools with digital mammography. For example, unsharp masking can enhance the sharpness of mass lesion borders, but it can make indistinct masses appear more circumscribed. Histogram-based intensity windowing can improve the conspicuity of edges but at the potential cost of losing detail outside the denser parts of the breast. Contrast-enhanced adaptive histogram equalization brings out edge information of lesions but also enhances the visibility of distracting nonlesion features, potentially leading to false-positive reports. Peripheral equalization brings out lesion detail while preserving peripheral information in the surrounding breast, but the downside is possible flattening of image contrast in nonperipheral areas.

## **V. MAMMOGRAPHIC IMAGE DISPLAY**

Although it is possible to display digital images in a hardcopy format, the advantages of FFDM may not be fully realized without softcopy display [31]. The quality of the display used to view mammographic images has a direct effect on radiologic interpretation. A faulty, inadequately calibrated, or improperly set-up display device can compromise the overall quality of the mammography examination [31,32]. Since DBT provides the radiologist with a

series of images through the breast that are scrolled through, rather than viewed as single images as with FFDM, there are added display requirements (eg, temporal resolution or frame rate). Many display manufacturers have DBT specific displays to counteract motion blur during scrolling.

Many aspects of display technologies and uniform practice have been addressed by standards-setting groups [33-38]. The Medical Imaging and Technology Alliance (MITA) has published 2 standards that include templates and describe a minimum set of QC tests that should be included as part of the quality assurance plan for displays and workstations [39] as well as hardcopy printing devices [40] for FFDM. As new display technologies emerge (eg, workstations for viewing DBT images), it is important to verify that the technical specifications of the device are reviewed and compared to the specifications required to provide adequate image quality for efficient and accurate diagnosis. For example, hand-held displays are currently available with software applications approved for viewing certain types of radiographic images under certain explicit conditions (eg, ambient light requirements). At this time, these devices do not have the spatial resolution required for viewing mammograms.

#### A. Hardcopy Printing

Despite the adoption of FFDM, some facilities may print images for hardcopy display and interpretation. MQSA gives the decision of maintaining a printer and/or the ability to print hardcopy images to each individual facility. MQSA states, “If a facility chooses to maintain a printer, it must follow all the QC requirements that are prescribed by the manufacturer of the printer and mammographic unit. The manufacturer’s quality control program benefits the facility that wants to provide the best possible quality in any hardcopy mammography images it prints. Although the FDA’s MQSA inspection program has removed printer QC questions from its inspection procedures, if a facility decides to maintain a printer, medical physicists must continue to include that printer QC in the mammography equipment evaluation upon installation, after a major repair, and annually, if required by the printer’s or image receptor’s manufacture quality control program” [41].

#### Lightbox considerations

1. Luminance: A minimum of 3,000 candelas per square meter (cd/m<sup>2</sup>) is the standard for screen-film mammography [42]. The luminance used for display of digital images printed on film should be sufficiently bright to view the darkest image. A “hot light” (focal or lightbox) will be of limited value for digital mammograms printed to film.
2. Uniformity: No specific standards address spatial uniformity of lightbox luminance or of intralightbox luminance uniformity. Luminance variations should be minimized.
3. Shutters and masking: The FDA requires that masking materials be available for interpreting physicians [11,43]. Viewscopes are allowed as long as the illuminated area can be limited to a region equal to or smaller than the exposed portion of the film. The average ambient light conditions should be adjusted relative to the average luminance of the displayed images (properly masked). Care should be taken to avoid any direct reflections on image surfaces. Darker images require a darker environment to interpret properly.

Although the FDA recommends that only printers specifically cleared for FFDM use by the FDA be used, the use of other printers is also legal under MQSA [41]. The ACR also strongly recommends that only FDA-cleared printers be used for FFDM. Quality assurance issues for hardcopy display have been set forth in a number of publications [40,42,44]. When FFDM images are printed to film, the manufacturer’s guidelines should be followed.

#### B. Softcopy Display Devices

Many factors contribute to image quality in softcopy radiographic and mammographic display [45-48]. Although the FDA recommends that monitors used for interpretation be specifically cleared for FFDM/DBT use by the FDA, the use of other monitors is permitted under MQSA [49]. Softcopy displays for mammography should meet minimum quality specifications for acquisition, interpretation, and review workstations [6]. Displays for DBT should incorporate technology to compensate for image blur during scrolling via optimized frame rates. The AAPM Task Group 18 documentation on assessment of display performance for medical imaging systems provides test images [45], an executive summary of tests [50], and a complete overview [51], which are very useful for specifying and verifying adequate performance for displays used in medical images. Descriptions of most of the display performance metrics



can be found in Krupinski et al [6]. The AAPM Task Group 270 report provides more specific recommendations for flat-panel displays, including both liquid crystal displays and organic light-emitting diode displays that are used for acquisition and diagnostic review [49].

Individual device specifications and expected performance criteria can be requested from display manufacturers. Once a display has been purchased and calibrated, it should be tested regularly by a Qualified Medical Physicist, a biomedical engineer, or a qualified technologist to ensure compliance. MQSA requires that a Qualified Medical Physicist test the diagnostic review workstation prior to its clinical use. Facilities should refer to their FFDM or DBT system QC manuals or the ACR Digital Mammography Quality Control Manual [9] for details and requirements pertaining to ongoing and annual testing for their image displays [52].

1. Luminance response

The brightness and contrast of grayscale medical images result from the luminance in relation to the image gray level values [50]. The reader is referred to the [ACR–AAPM–SIIM Technical Standard for Electronic Practice of Medical Imaging](#) [53] for current guidance regarding ambient luminance, minimum and maximum luminance, and display contrast response for displays.

2. Contrast

Within the applicable luminance range of the mammographic display, the device should render the image details with a consistent grayscale that should be measured and maintained over time. The contrast (luminance) response of mammographic displays should comply with the AAPM Task Group 18 and Task Group 270 recommendations. Guidance is also provided in the [ACR–AAPM–SIIM Technical Standard for Electronic Practice of Medical Imaging](#) [53].

3. Bit depth

For further information on bit depth, please see the [ACR–AAPM–SIIM Technical Standard for Electronic Practice of Medical Imaging](#) [53].

4. Digital image matrix size and display size

For further information on digital image matrix size and display size, please see the [ACR–AAPM–SIIM Technical Standard for Electronic Practice of Medical Imaging](#) [53].

5. Other softcopy display characteristics

- a. Image displays must be able to display mammography computer-aided detection (CAD) marks (when CAD is implemented) and to apply marks on the displayed image corresponding to all findings encoded in the DICOM mammography CAD structured reporting (SR) objects.
- b. Image displays must be able to display images at the same size as the imaged object [48]. This is critical because the sizes of objects in the image are generally judged visually and limitations in the size of the displayed image could distort the appearance of anatomy and negatively affect the interpretation of mammograms.
- c. Displays must be able to show images at the “same” physical size on the display (eg, 18 × 24 cm) even though they might be from different acquisition stations with different pixel sizes and detector dimensions.
- d. Displays must be capable of showing image information, including patient identification, image information, and acquisition technique [43].
- e. Image displays must be capable of displaying a set of current and prior 4-view mammograms (left and right CC and MLO views) simultaneously.
- f. Image displays should be able to display a ruler on the screen as a visual clue to indicate physical size.
- g. Image displays should ensure that the luminance of the image background (outside the breast) is maintained at  $L_{min}$  as window width and level are adjusted during interpretation.
- h. Additional guidelines for viewing images can be found in the [ACR–AAPM–SIIM Technical Standard for Electronic Practice of Medical Imaging](#) [53].



### C. Image Presentation Issues

The IHE initiative has defined a presentation of image integration profile that provides a standard method for storing grayscale images and information about their presentation state, including user annotations, shutters, flip/rotate, display area, and zoom [48].

1. It should not take more than 3 seconds to retrieve an image from online local storage and display it on a workstation. Times for image retrieval from storage archives and from remote sites will vary significantly depending on prefetching rules, management of image routing, and network speeds, among other issues.
2. Mammographic displays should allow fast and easy navigation between old and new studies. This is especially critical when there is a mix of FFDM and DBT images.
3. Hanging protocols should be specific to mammography, have proper labeling and orientation of the images, and be flexible and tailored to user preferences.
4. Workstation software tools must include window/level and zoom/pan. Use of image display tools can aid in image interpretation but increases reading time. There are no specific recommendations regarding which tools should be used with softcopy mammography displays and how they can be used effectively. Further research on the ergonomics of using image display tools is encouraged.
5. Multimodality datasets and interoperability:
  - a. To ensure that a workstation is capable of displaying digital mammograms correctly, it should conform to the IHE MAMMO profile. If it does not, then it is possible that the workstation will fail to show all digital mammograms as they are intended to be displayed by the acquisition system manufacturer.
  - b. Mammography workstations should accommodate and display images from several modalities.
  - c. Vendor-specific workstations form part of the “vertical industrial stack,” making image sharing among different workstations difficult. For those who seek best-of-breed solutions tailored to imaging needs, current capabilities are limited.
  - d. New workstations should also be capable of displaying DBT examinations correctly (eg, proper frame rates) and should conform to the IHE DBT profile as well as the IHE MAMMO profile. If it does not, then it is possible that the workstation will fail to show all DBT examinations as they are intended to be displayed by the acquisition system manufacturer.

### D. Computer-aided detection (CAD)

1. The purpose of CAD is to help radiologists detect malignancies. Studies of mammography CAD alone (without a human observer) suggest that mammography CAD detects some types of lesions well (especially calcifications, although possibly less well with amorphous forms). Mammography CAD is used to supplement routine image evaluation, and a human reader would not be expected to recall all or even most of mammography CAD marked lesions for further workup.
2. CAD may potentially play a role with DBT [54]. The increased number of images along with the subsequent time needed for review can have a significant impact on workflow. Because DBT is still fairly new, more research needs to be done before recommendations can be made for the particular properties associated with the various CAD programs designed for DBT. The current research suggests that DBT CAD software is comparable in sensitivity and false-positive rates when compared with other commercial CAD systems used with FFDM [54].

### E. Reading Environment

Factors as diverse as ambient light, temperature, noise, posture fatigue, and poor ergonomics may have significant effects not only on radiologist comfort but also on the quality, accuracy, and consistency of image interpretation [6,55-

58]. A more detailed discussion of factors affecting the reading room environment can be found in the AAPM Task Group 270 report and the [ACR–AAPM–SIIM Technical Standard for the Electronic Practice of Medical Imaging](#) [49,53].

## VI. TRANSMISSION, STORAGE, AND RETRIEVAL

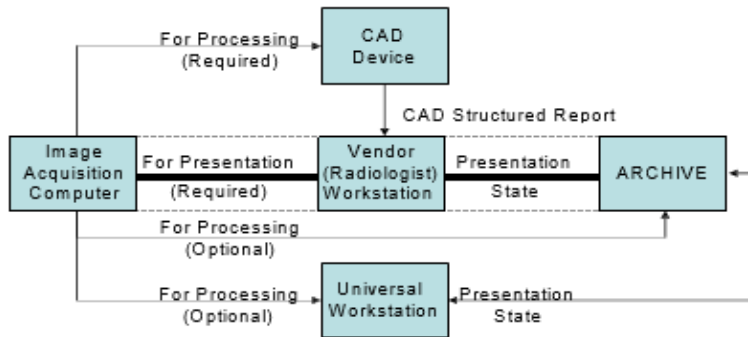
The development of tools for image storage and retrieval has emphasized the isolated silo concept, with each manufacturer optimizing its own system, at the expense of the PACS interoperability common for other imaging technologies, such as CT and MRI. The goal of DICOM is to provide a standard for storage and transmission, whereas the IHE mammography profile [48] provides a recommendation for best practice implementation and work flow. Relevant standards of DICOM Information Object Definitions (IOD) are the Digital Mammography X-Ray Image (MG), Mammography CAD SR, X-Ray Radiation Dose SR, Breast Tomosynthesis Image, and Breast Projection X-Ray Image. Any of these information objects can be stored for later retrieval.

### A. Mammography Image and Data Types

1. The MG information object descriptor includes a specification for 2 types of image information. “For processing” represents image data that are corrected for detector acquisition but not processed for interpretation. “For presentation” image information has been processed by vendor-specific algorithms and is ready to be displayed on a workstation.
  - a. “For processing” image data require mammography-specific algorithms to produce a high quality image for interpretation. Mammography CAD devices most commonly use “for processing” image data.
  - b. “For presentation” image data are processed for display on any DICOM-compliant and calibrated monitor acceptable for mammography viewing. DICOM presentation state information enables the reproduction of the appearance of the image on different display devices or media.
2. For DBT, the following 2 or 3 types of image data are created:
  - a. A sequence of low-dose 2-D projection images, conceptually similar to 2-D mammograms but acquired at different X-ray tube angles and using a lower dose per image. These projections may be stored for future reference in a DICOM standard format but are generally only used at the time of acquisition to form reconstructed DBT images.
  - b. DBT images or “slices” are a stack of 2-D mammogram-like images that make up the DBT volume. In general, the DBT images are oriented parallel to the detector surface. DBT images are stored as a DICOM breast tomosynthesis object (BTO), or sometimes as a proprietary DICOM secondary capture object (SCO).
  - c. A synthetic mammogram (optional), which is generated from the DBT projection and/or volume data by use of a proprietary algorithm. The synthetic mammogram should be stored as a DICOM MG “for presentation” image or DICOM BTO.
3. Mammography CAD devices produce a DICOM mammography structured report and presentation state that may be used by other mammography workstations to display the results of the mammography CAD process.
4. Mammography acquisition devices may transmit all types of image data to other storage devices, display devices, or postprocessing devices such as mammography CAD systems (see Figure 1).
5. Since many mammography CAD systems require “for processing” images, vendors of mammography acquisition devices should ensure that the devices support DICOM transmission of both “for presentation” and “for processing” MG images.
6. Tele mammography demands high speed networks and/or compression (see below). Reasonable transmission speeds may make the difference between an efficient service and an unsuccessful one.

7. Other considerations regarding image datasets
  - a. File sizes of stereotactic biopsy unit images are typically 0.5 to 2 MB per image.
  - b. Breast MRI, breast ultrasound, breast CT, and DBT are modalities that typically produce a large number of images and, for breast CT and DBT, very large data sets.

**Figure 1. Flowchart of image data distribution**



## B. Workstation

1. The mammography display workstation must support receipt of DICOM-compatible MG images, DBT data sets, and mammography CAD structured reports “for presentation.”
2. Display of new data “for processing” should be optional and configurable for mammography workstations.
3. The display system should support DICOM query and retrieve mammograms from a DICOM archive.
4. Support for DICOM presentation states for displaying images with the ability to save and retrieve various presentation states as specified by the user is required.
5. Mammography workstations should support the IHE Consistent Presentation of Images Integration Profile and the IHE Mammography Image Profile (see the IHE Radiology Technical Framework, Supplement 2006-2007 [48]).
6. A universal workstation should:
  - a. Properly display “for processing” and “for presentation” MG data, with mammography-specific hanging protocols and support for the IHE Mammography Image Profile.
  - b. Provide user-defined processing algorithms for mammograms as well as display acquisition-defined “for presentation” algorithms and Lookup Tables.
  - c. Allow multimodality image viewing of associated breast imaging studies (eg, ultrasound, MRI, CT, PET/CT, biopsy specimens, stereotactic images, surgical specimens, and other pertinent studies).

## C. Archive

1. The archive device for mammography should support DICOM receipt of MG images and DBT data sets.
2. Storage of “for presentation” images is required to ensure the ability of radiologists to reproduce the original images used for interpretation. The “for presentation” image set must be archived to PACS and be viewable with comparable quality on different but suitable workstations.
3. Storage of images “for processing” is encouraged but is not required. The “for processing” image data storage

is optional, with the possible exception of mammography CAD, which might require storage of the “for-processing” data. Each facility should carefully consider the ramifications of archive space necessary for additional storage of the “for processing” images as well as the potential downstream benefit and legal implications of reprocessing these data to create new “for-presentation” image sets for future comparisons. Storage of these data sets should not be required for technical reasons but may be required for local medical-legal ones.

4. Storage of mammography CAD SRs is recommended but should be optional. However, those who choose to discard the mammography CAD information on which they based their interpretations should understand that the only way to reproduce the original mammography CAD data is to retain the original report. Reprocessing may yield different results. If CAD SR is not stored, the CAD version used at the time of the original interpretation may be documented.
5. The archive device should be able to query and retrieve FFDM images and DBT data sets.
6. Prior examinations
  - a. If possible, comparison of current studies to prior examinations should be performed (see the [ACR Practice Parameter for the Performance of Screening and Diagnostic Mammography](#) [12]). Storage requirement estimates should therefore take into account the need to store and access current and prior images.
  - b. Prior examinations may be imported from portable media. Prior examinations may have been obtained using a screen-film system, and these can be digitized for softcopy display. Currently, a digital practice of approximately 150,000 examinations per year would produce 25 GB of data per day, assuming nonstorage of the “for processing” images. If the “for processing” images are stored, the data storage requirements will be considerably higher.
  - c. Although the FDA does allow the digitization of prior film examinations for comparison purposes, its current guidelines [43] do not allow digitized film images to be the sole source for archival purposes. The original film images must be maintained.

#### D. Image and Data Compression

Digital image compression can provide more efficient transmission and storage. The digital image is an exact representation of an inexact noisy signal, with finite limits to the amount of compression that can be applied. Compression may be defined as mathematically reversible (lossless) or irreversible (lossy). Mammography images are suitable for compression (lossless or not) because of large black areas outside the breast that do not contain diagnostically relevant information. Reversible compression may always be used, since by definition there is no impact on the image. Irreversible compression may be used to reduce transmission time or storage space only if the quality of the result is sufficient to reliably perform the clinical task. The FDA does not allow irreversible compression of digital mammograms for retention, transmission, or final interpretation, although irreversibly compressed images may be used as priors for comparison [59]. The reader is referred to the [ACR-AAPM-SIIM Technical Standard for Electronic Practice of Medical Imaging](#) [53] for current guidance regarding image compression in mammography.

#### E. Legal Challenges

The legal requirements for digital mammography are established by the FDA Final Rule [11] and by the state that has appropriate jurisdiction.

1. For acquisition and interpretation, the legal requirements are the same as those for film mammography.
2. Current FDA regulations require that facilities maintain mammography films and reports in a permanent medical record of the patient for a period of not less than 5 years or not less than 10 years if no additional mammograms of the patient are performed at the facility, or a longer period if mandated by state or local law. The record retention requirements may differ from state to state.

3. Security requirements for disaster recovery of digital imaging are greater than those for film-based imaging. A physically separated redundant archive increases safety of the data and may actually be required in some jurisdictions.
4. Circumstances become more complex for the patient who is seen in more than 1 state as well as for the practice that receives images from more than 1 state. Clearly, the requirements of each jurisdiction must be analyzed carefully.
5. Use of lossy compression for data storage, transmission, and retrieval is not allowed by the FDA.

## VII. QUALITY CONTROL RECOMMENDATIONS

### A. Acquisition

1. Manufacturer-specific QC procedures are approved by the FDA as an alternative standard under the FDA rules for digital mammography. Documents provided by the manufacturer of the digital mammography system define the procedures and limits for corrective action for periodic tests (daily, weekly, monthly, quarterly, and semiannually) performed by a designated QC technologist and for annual tests by a Qualified Medical Physicist. These documents are periodically updated, so the technologist and Qualified Medical Physicist need to stay abreast of updated versions of the documents.
2. The ACR Digital Mammography Quality Control Manual [9] for FFDM and DBT systems has been approved by the FDA as an alternative standard to the manufacturer's recommended quality assurance program. See the Mammography Quality Standards Act and Program [60].
3. Other requirements regarding the overall QA program mandated by the FDA must be carefully followed. QC for hardcopy devices used for printing of digital mammograms should include implementation of the DICOM GSDF standards for printers [37]. Specific manufacturer or ACR QC test procedures, frequencies, and corrective action limits must be followed for digital mammography displays, workstations, hardcopy devices, and verification of proper grayscale rendition of printed images compared to displayed images is necessary. MITA standards and document templates are available to assist in the recording of these processes [39,40].

### B. Image Display and Processing

1. QC guidelines for display monitors include implementation of the DICOM GSDF standard [37] and the mammography-specific recommendations of AAPM Task Groups 18 and 270 [49,50]. Recommendations are also provided in the ACR Digital Mammography Quality Control Manual [9] and the [ACR–AAPM–SIIM Technical Standard for Electronic Practice of Medical Imaging](#) [53].
2. QC for image processing of digital mammograms should include interaction with radiologists and verification of reproducible image processing characteristics and proper rendition of images and correct functioning of task-dependent processing.

### C. Storage and Archiving

Optimal components of digital storage and archiving include the following:

1. Verification of DICOM metadata in header and accuracy of information
2. Security and privacy protection
3. Backup and disaster recovery testing

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