Revised 2012 (Resolution 36)*

ACR–AAPM–SIIM PRACTICE GUIDELINE FOR DETERMINANTS OF IMAGE QUALITY IN DIGITAL MAMMOGRAPHY

PREAMBLE

These guidelines are an educational tool designed to assist practitioners in providing appropriate radiologic and radiation oncology care for patients. They are not inflexible rules or requirements of practice and are not intended, nor should they be used, to establish a legal standard of care. For these reasons and those set forth below, the American College of Radiology cautions against the use of these guidelines 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 physician or medical physicist in light of all the circumstances presented. Thus, an approach that differs from the guidelines, 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 the guidelines when, in the reasonable judgment of the practitioner, such course of action is indicated by the condition of the patient, limitations of available resources, or advances in knowledge or technology subsequent to publication of the guidelines. However, a practitioner who employs an approach substantially different from these guidelines is advised to document in the patient record information sufficient to explain the approach taken.

The practice of medicine involves not only the science, but also 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 these guidelines 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 sole purpose of these guidelines is to assist practitioners in achieving this objective.

I.   INTRODUCTION

This guideline 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].

For purposes of this guideline, digital mammography is defined as the radiographic examination of the breast utilizing dedicated electronic detectors to record the image (rather than screen-film) and having the capability for image display on computer monitors. This guideline is specific to 2-dimensional (2D) digital mammography since the vast majority of digital mammography performed in the United States is 2D. Although some 3-dimensional technologies are in use, they are not addressed in this guideline since they continue to evolve and are not yet in widespread clinical use.

In many parts of this guideline, the level of technical detail regarding the determinants of image quality for digital mammography is advanced, and is intended to provide radiologists, Qualified Medical Physicists, regulators, and other support personnel directly involved in clinical implementation and oversight an expanded knowledge of the issues pertinent to assessing and maintaining digital mammography image quality from the acquisition, display, and data storage aspects of the process. Where basic technical requirements for digital mammography overlap with those for digital radiography in general, users are directed to consult the referenced ACR practice guidelines [4,5]. All interested individuals are encouraged to review the ACR digital radiography guidelines. Additionally, this guideline includes input from industry, radiologists and other interested parties in an attempt to represent the consensus of the broader community. It was further informed by input from another working group of the Integrating the Healthcare Enterprise (IHE) Initiative [6]. Furthermore, the ACR Subcommittee on Digital Mammography is developing a Quality Control (QC) Manual for Digital Mammography.

Analysis of image quality has meaning primarily in the context of a particular imaging task [7]. This guideline has been developed with reference to specific imaging tasks required by mammography, using the information available in the peer-reviewed medical literature regarding digital 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 cancer:

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 to prior studies.

The primary goal of mammography is to detect breast cancer, if it exists, 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 digital mammography system using current technology depends on several factors and is the major focus of this guideline.

II.   QUALIFICATIONS AND RESPONSIBILITIES OF PERSONNEL

Interpreting physicians, Qualified Medical Physicists, and radiological 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) [8]. Those personnel must have at least 8 hours of training in digital mammography before beginning to use that modality. See the ACR Practice Guideline for the Performance of Screening and Diagnostic Mammography [9].

III.   DIGITAL MAMMOGRAPHY IMAGE ACQUISITION

In digital mammography, the processes of image acquisition, display, and storage are performed by separate systems, each of which can be optimized. The digital detector has a well characterized response to the fluence of incident X-rays over a very wide range. It can be 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 two-dimensional matrix, where each element 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, it will demonstrate the key features required for mammographic interpretation.

Technical descriptions of digital radiography image acquisition devices and specifications are available in [5]; 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 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's regulations. Currently, the responsibility for the development and provision of QC testing procedures for the image acquisition system is the specific manufacturer of the image acquisition device.

For all digital acquisition systems overall image quality and the probability that relevant anatomical detail or pathology is displayed is affected by tissue coverage, spatial resolution, contrast, latitude or dynamic range, noise, and artifacts.

A. Tissue 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 items 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 for digital mammography, breast tomosynthesis, and stereo mammography, just as for screen-film mammography.

2. Inactive regions of the image receptor along the chest wall will result in missed breast tissue, and therefore the gap between the chest wall edges of image receptor and breast support should be minimized; in no case should this gap exceed 7 mm. Typical digital units provide coverage for all but 4 mm to 7 mm of tissue along the chest wall [3,10]. The image receptor should be large enough to image most women without loss of breast tissue on edges other than the chest wall edge.

3. Clinical assessment of positioning in digital mammography match**es** that required for screen-film and evaluates the retromammary 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 no more than 1 cm less (approximately) than 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 about 45 degrees on the MLO image.

4. 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 one image in the same view projection. Standard tiling methods that double expose the least possible amount of breast tissue should be used. A larger FOV lowers the need for multiple-section imaging**.**

B. Spatial resolution [5] of an imaging system refers to its ability to depict two adjacent structures as being separate, or to an edge in the image (i.e., sharpness). Measurement is performed by qualitative or quantitative methods [5]. Spatial resolution losses occur because of blurring caused by geometric factors such as the size of the X-ray tube focal spot and the magnification of a given structure of interest. Other factors include unsharpness due to light diffusion in the receptor (although this does not apply to amorphous selenium [a-Se] systems), scintillator, detector element effective aperture and pitch, and relative motion of the X-ray source, the breast or the image detector during the exposure. 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. Detection, 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.

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, un-sharp 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 of the denser parts of the image. Contrast-limited adaptive histogram equalization also brings out edge information of lesions but, at the same time, 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.

Motion blurring can have a particularly strong impact on limiting spatial resolution and image sharpness. In digital mammography, motion blurring is caused by movement of the breast during exposure and is minimized by using a short exposure time and appropriate breast compression.

1. Tube voltage (kVp) may be increased for thick, dense breasts to allow reduction of exposure time. Image processing compensates for contrast losses to the extent allowed by the background noise and the image signal-to-noise ratio (SNR).
2. Magnification techniques with small focal spots and lower tube current (mA) require longer exposure times. The amount of blurring depends on object motion speed, exposure duration, and degree of magnification.
3. For scanned slot systems, motion causes misregistration artifacts between the anatomy imaged both before and after motion occurs.

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 [5]. Achieving high radiographic contrast is especially important due to subtle differences in soft-tissue densities of normal and pathologic structures of the breast, the concurrent need to detect and characterize minute microcalcifications (governed more by spatial resolution), and the structural characteristics of the margins of masses (governed more by contrast resolution).

1. Subject contrast is the relative difference between the X-ray transmission at the entrance plane of the image receptor through different parts of the breast. Attenuation, and therefore subject contrast, depend strongly on the X-ray energy spectrum, which is determined by the target material, kVp, and on filtration (either inherent in the tube or added).

   a. Molybdenum (Mo) target X-ray units generate characteristic radiation at 17.9 and 19.5 keV. A Mo filter 0.025 to 0.03 mm thick strongly suppresses photon energies less than 15 keV and those greater than 20 keV, yielding high subject contrast and avoiding excess radiation dose for 2 to 5 cm breasts imaged at typical voltages of 25 to 28 kVp.

   b. Incident X-ray beams with higher effective energy are used for thicker and/or denser breasts (5 cm to 7 cm). These beams are achieved with higher voltage (>28 kVp) on a Mo target with either a Mo filter (0.030 mm) or a rhodium (Rh) filter (0.025 mm). For denser breasts, an Rh filter preferentially transmits energies from 15 to 23 keV, including Mo characteristic radiation.

   c. A more penetrating beam is obtained with an Rh target emitting 20 and 23 keV characteristic X-rays combined with a Rh filter (0.025 mm), operated at 28 kVp or higher. For very dense, difficult-to-penetrate breasts, the resulting spectrum preserves subject contrast and reduces dose to a practical level.

   d. Tungsten (W) target materials permit longer exposures than molybdenum (Mo/Mo) exposures, allow for higher effective energy, better tube heat loads, and, in some cases, lower dose. Without useful characteristic radiation, the energy spectrum of W targets is optimized for mammography with Mo, Rh, and silver (Ag) filters, typically of 0.05 mm thickness or greater. Greater filter thickness is necessary to attenuate useless L X-rays emanating from the W target. Careful choice of kVp and filter material can yield excellent results in terms of contrast and breast dose.

2. The properties of digital detectors and image processing adjustment of display contrast allow the use of higher energy X-rays (25 to 35 kVp and above) for digital systems compared to screen-film systems (where 22 to 32 kVp is more typical). Dose is reduced for the same image SNR by using higher energy X-rays, especially for large or dense breasts.

3. Grids [5] designed for mammography reduce scattered radiation and improve subject contrast at the cost of higher breast dose [13,14]. Grids are used for contact (non-magnification) 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.

4. Breast compression is as important for digital mammography as it is for screen-film mammography. It contributes to digital image quality by immobilizing the breast and shortening exposure times (reducing motion unsharpness), producing a more uniform, thinner tissue (less scattered radiation, more even penetration of X-rays, less magnification or geometric blurring, less anatomical super-position), and lowering breast radiation dose.

5. Any technique adjustments should be performed in consultation with and verified by the radiologist in charge of the digital mammography program and the Qualified Medical Physicist.

D. In digital mammography, it is important to discuss noise as well as contrast [5]. Radiographic image noise is the unwanted random (uncorrelated), nonrandom (correlated), or static (e.g., detector defect) variation in signal in a radiograph that has been given a uniform X-ray exposure [17-19]. Using fewer quanta increases random noise or quantum mottle (for a fixed signal) or decreases SNR and reduces the ability to discern subtle differences in 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 output SNR is inversely related to the DQE (detective quantum efficiency), and systems with high DQE are usually more dose efficient. "Appropriate" X-ray exposure depends on the system's DQE, and requisite SNR can be achieved with a calibrated automatic exposure control (AEC) system.

IV. DIGITAL MAMMOGRAPHIC IMAGE DISPLAY

Although it is possible to display digital images in a hardcopy format, the advantages of digital mammography may not be fully realized without softcopy display [26]. The quality of the display 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 [27,28].

Many aspects of display technologies and uniform practice have been addressed by standards-setting groups [6,29-33]. The Medical Imaging and Technology Alliance (MITA) has published two 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 [34] as well as hardcopy printing devices [35] for full-field digital mammography (FFDM). As new display technologies emerge, it is important to ensure that the technical specifications of the device are reviewed and compared to the image specifications to ensure adequate presentation of image details on the display for efficient and accurate diagnoses. For example, hand-held displays are currently available with software applications approved for viewing certain types of radiographic images under certain explicit conditions (e.g., ambient light requirements). At this time, these devices do not have the spatial resolution required for viewing mammograms and thus should not be used.

A. Hardcopy Printing

Despite the move to digital acquisition of mammographic images, some are still printed to hardcopy for display and interpretation. MQSA requires facilities to have the ability to print images. Thus, hardcopy mammographic image quality remains an important issue and must be included in any effort to address digital image quality in mammography. 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 [36]. The ACR also strongly recommends that only FDA-cleared printers be used for digital mammography. Quality assurance issues for hardcopy display have been set forth in a number of publications [35,37,38]. While there are no recommendations regarding the use of hardcopy versus softcopy display for interpretation, the FDA requires the ability to print FFDM images of final interpretation quality to film if so requested by patients or their health care providers [36]. When FFDM images are printed to film, the manufacturer's guidelines should be followed.

1. Printer operation recommendations
   a. The printer to be used should be cleared for mammography applications by the FDA.
   b. Printer pixel pitch should not exceed the detector element (del) size, so the printing device should not limit the spatial resolution of the printed image. Images should be printed to match the "true" size of the imaged anatomy [6].
   c. Conformance to the Digital Imaging and Communications in Medicine (DICOM) Grayscale Standard Display Function (GSDF) standard is desirable. The GSDF provides a mechanism to standardize the appearance of images on monitors of different inherent brightness and with different response curves. Pixel values undergo a transformation to ensure that pixel values that increase linearly appear that way to the human visual system, which is inherently non-linear.
   d. All FDA rules for laser printers must be followed and quality control (QC) procedures adhered to. Existing recommendations for hardcopy printing should be used uniformly when printing digital images [8].
   e. The FDA requires that all printers used with an FFDM unit comply with a quality assurance program that is substantially the same as that recommended by the manufacturer of the unit's detector and that they pass the phantom and clinical image review process of the facility's accreditation body. At the present time, no accreditation body reviews softcopy images, so the FDA recommends that the softcopy images be of such quality that if they were submitted, they would pass the phantom and clinical image review process of the facility's accreditation body [36].

2. Lightbox considerations
   a. Luminance: A minimum of 3,000 candelas per square meter (cd/m^2) is the standard for screen-film mammography [38]. The same guidelines should be used for display of digital images printed on film. A "hot light" (focal or lightbox) will be of limited value for digital mammograms printed to film.
   b. Uniformity: No specific standards address spatial uniformity of lightbox luminance or of intralightbox luminance uniformity. Luminance variations should be minimized.
   c. Shutters and masking: The FDA requires that masking materials be available for interpreting physicians [8,36]. 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.

B.   Softcopy Display Devices

Many factors contribute to image quality in softcopy radiographic and mammographic display [39-42]. Although the FDA recommends that monitors used for interpretation be specifically cleared for FFDM use by the FDA, the use of others is also legal under MQSA [36]. The ACR also recommends that only FDA-cleared monitors be used for digital mammography. In addition, softcopy displays for mammography should meet minimum quality specifications for acquisition, interpretation, and review workstations [4]. The AAPM Task Group 18 documentation on assessment of display performance for medical imaging systems provides test images [39], an executive summary of tests [43], and a complete overview [44] that are very useful for specifying and verifying performance for display of medical images, including mammography. Details for most of the display parameter specifications can be found in [4]. Individual device specifications 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 review workstation prior to its clinical use.

1.   Minimum and maximum luminance
a.   Monitor luminance, L, is characterized by minimum (L_{min}) and maximum (L_{max}) values. Ideally, the maximum luminance of monitors used for primary interpretation should be at least 400 cd/m^2 while greater than 450 cd/m^2 is recommended for optimized contrast.
b.   Smaller ranges might lead to an inadequate level of contrast in the displayed mammograms. The human eye is more sensitive to contrast and high spatial resolution details with increased luminance.

2.   Contrast
a.   Within the applicable luminance range of the mammographic display device, the device should render the image details with a consistent grayscale that should be measured and maintained over time. The contrast response of mammographic displays should comply with the AAPM Task Group 18 recommendations [43,44].

3.   Bit depth
a.   A display device must render mammographic details with sufficient luminance and grayscale range to prevent the loss of contrast details and eliminate contour artifacts.
b.   A minimum of 8-bit output luminance resolution is required. At the time of publication, relatively few data have been reported in the literature to address possible advantages with higher bit-depth display devices. However, 9-bit or higher is recommended if the "For Processing" image data is greater than 8-bits.

4.   Digital image matrix size and display size
a.   A 5 megapixel monitor (2,048 x 2,560 pixel samples in the horizontal and vertical directions for portrait orientation) requires less zoom/pan for image interpretation when the mammography radiologist desires to view the full resolution image dataset compared to a lower resolution display [45]. Display device specifications should match the acquisition matrix size as closely as possible.
    i.   For a standard viewing distance of approximately 67 cm, the diagonal dimension of the display should be 21 inches (53 cm), with a total viewing field of about 32 x 42 cm.
b.   Mammographic displays should render images with a pixel density sufficient to enable viewing of a full or partial (50% or greater area of the breast image) mammogram with sufficient spatial detail at a normal viewing distance of 15 to 60 cm. Panning through a reduced subset of the entire image at full spatial resolution without excessive magnification should be easily available to the reader. Zoom/pan functions should be used rather than moving closer to the display or using a magnifying glass to view details. A magnifying glass is generally inappropriate, as it simply magnifies the pixels rather than increasing the magnification of the image details.
c.   During image interpretation, all images should be viewed at 1:1 or 100% size. Routine viewing at 2:1 (or 200% size increase) with zoom/pan function to examine the entire image may also be useful [45]. When viewed at a size that is "fit to viewport," images are not necessarily reduced by a factor of 1:2 or 50%, and reduction will vary depending on the image size. Some displays scale the fit to viewport to maximize the scale of the mammogram.

Hanging protocols and viewing modes for evaluation and comparison of longitudinal studies are important to maintain consistent viewing conditions, particularly for mammograms from different acquisition devices. The IHE Mammography Image profile [6] should be consulted for recommendations and implementation of digital mammography image display for interpretation.

    d. Monochrome vs. color
- i. No clinical specifications require color rather than monochrome displays for mammography.
- ii. With technological advances, newer color LCD monitors may deliver the required performance, and thus might be considered for such applications.

5. Other softcopy display characteristics
- a. Image displays must be able to display mammography 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 in "true" size [6]. This is critical since the sizes of features in the image are generally judged visually, and not having this feature could distort the appearance of features and hence the judgment of interpreting mammographers.
- c. Image displays must be able to display images at the "same" physical size on the display (e.g., 18 x 24 cm) even though they might be from different acquisition stations with different pixel sizes and detector dimensions.
- d. Image displays must be capable of annotating image information, image identification, and technical factor information [36].
- e. Image displays must be capable of displaying simultaneously a set of current and prior conventional four-view screening mammograms (left and right CC and MLO views).
- 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 background outside the breast is maintained as black if contrast adjustments are performed during interpretation. Otherwise,

the background may be lighter as the window width and level are increased.
- h. Additional guidelines for viewing images can be found in the ACR–AAPM–SIIM Technical Standard for Electronic Practice of Medical Imaging.

C. Digital Image Presentation Issues

The IHE initiative has specified a consistent presentation of image integration profile that specifies a number of transactions to maintain the consistency of grayscale images and their presentation state information (including user annotations, shutters, flip/rotate, display area, and zoom). It also defines a standard contrast curve (the GSDF) against which different types of display and hardcopy output devices can be calibrated. Thus it supports display in hardcopy, softcopy, and mixed environments [6].

1. The time it takes to bring up an image on a workstation from online local storage media should be 3 seconds or less. Times for retrieval of images from hierarchical storage management 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.

3. Hanging protocols should be flexible and tailored to user preferences, specifically for mammography with proper labeling and orientation of the images.

4. Workstation software tools must include window/level and zoom/pan at a minimum. Tool use generally increases reading time, so there is a trade-off between increased tool use, performance, and workflow.

5. Specific recommendations regarding the types of tools that should be used with softcopy mammography display and how to use them most effectively do not exist. Further research on the ergonomics of tool use is encouraged.

6. 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.

7. An interpreting physicians or "primary interpretation" workstation is one that is used to render an "official" or "final" interpretation of a study.

8. A "technologist's workstation" is one used by the technologist during the acquisition and QC process of an examination. It should also comply with and be calibrated to the DICOM GSDF standard [32]. Since technologists will perform QC on mammographic images at the acquisition or QC workstation to ensure that the radiologist has images of adequate quality, these displays must be of high quality.

a. When checking for positioning, contrast, and patient motion, the technologist should use a monitor having the same maximum luminance (e.g., 400 cd/m^2) as the one used by the interpreting physician.

b. A high-resolution monitor similar to the one at the primary interpretation workstation is desirable.

9. A "clinician workstation" is one used to review images as an adjunct to the official interpretation by a radiologist and may not need the high-resolution displays necessary for final interpretation.

10. Monitors used to display images acquired in the process of needle localization must provide sufficient spatial resolution compared to final image interpretation monitors, so there should be the means to provide zoom and pan features allowing the user to view images at full spatial resolution in the acquisition room.

D. Computer-Aided Detection

1. Studies of mammography CAD alone (without a human observer) suggest that mammography CAD detects some types of lesions very well (especially calcifications, although possibly less well with amorphous forms). Mammography CAD is designed to be used in conjunction with human observers, and a human reader would not be expected to recall all mammography CAD marked lesions for further workup. In most cases, that is appropriate since the marked lesions are not cancers. More research is needed to ascertain how to allow human observers to better distinguish between false positives and true positives with mammography CAD.

2. Specialized breast imagers seem to benefit less from mammography CAD (at least in its current form in which lesions are simply pointed out and the likelihood of malignancy is not provided) than do nonexpert mammographers or general radiologists.

3. All mammography CAD algorithms should use "for processing" rather than "for presentation" image data, as many mammography CAD algorithms already apply various levels of processing. Processed image data may alter the effectiveness of the mammography CAD algorithms if processing effects are not taken into account.

4. The mammography CAD prompt may influence performance [56-58].

a. A prompt that completely encircles the potential lesion may be more effective than one that simply points to or is over the general area.

b. Using color or altering the brightness or size of the prompted region may be more effective than traditional prompts.

c. Visual search behaviors can change with mammography CAD, potentially affecting workflow as well as the detection of other unprompted lesions.

d. The number of false-positive prompts on the displayed image can affect performance, with larger numbers reducing true-positive detection rates.

E. Image Processing Considerations

Image processing has great potential to improve image quality and secondarily diagnostic accuracy and even to reduce the radiation dose necessary to achieve an image of acceptable quality [59-61]. 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 [48].

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. Image processing steps (spatial frequency restoration and deblurring) are then carried out 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 and global latitude reduction increase the relative signal in underpenetrated areas and reduce the signal in highly transmissive regions. Fourier filters or spatial convolution kernels of large spatial extent create a low frequency blurred image that is then subtracted from the nonblurred image.

5. 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.

6. Differently processed versions of the same digital mammogram are preferred, depending on the task and lesion type, suggesting that workstations might implement multiple processing options for use during interpretation [48].

7. Desired processing parameters may vary with radiographic factors such as tube target, kVp, 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.

8. 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 "Archive" for further information on this subject.

9. Application of image processing at the reading station (or by a separate processing box located separately from the primary interpretation workstation) requires image processing software that is applicable to the images from any digital mammography system. This requires an understanding of the characteristics of the image data from the digital mammography system or other input devices (e.g., film digitizers) as well as storage of image data in the DICOM format intended "for processing."

F. 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 [4,62,63]. Some of the more critical considerations include the following:

1. Impact of ambient light
   a. Ambient light should be low and consistent, particularly in a hybrid viewing environment where stray light from bright lightboxes can be detrimental when displaying softcopy images. The amount of ambient light (illuminance) should be approximately equal to the level of the average luminance of a clinical image being displayed [63], generally in the 20 to 45 lux range; total darkness is not recommended.
   b. Distracting glare and reflections occur from the display surface, even when antiglare coatings are applied.
   c. Variations in the adaptation of the human eye affect the contrast sensitivity and hence the ability to detect low-contrast targets.
   d. Fatigue levels and eyestrain increase and interpretation accuracy decreases with higher levels of ambient light [63].

2. Other environment factors [63]
   a. Heat and noise
      i. Improved air handling is especially important to maintain optimal temperature and humidity levels.
      ii. Radiologists are vulnerable to increased heat and poor ventilation. Consider

direct and individually adjustable air conditioning vents for each workstation area and computers, using technology that can reduce ambient noise.

    b. Ergonomic and connectivity requirements

       i. Prevention of debilitating injury and permanent impediments is essential.

      ii. Chairs with lumbar support and adjustable height (including armrests), workstation table (with height adjustment), keyboard, mouse, and monitors should all be designed to maximize comfort and efficiency.

     iii. Workstations should be designed to be scalable (to accommodate one or more radiologists) and flexible enough to evolve with changing technologies and institutional requirements.

     iv. Dictation tools, internet access, and other facilitators of the radiologic interpretation task should be readily accessible and easy to use while viewing images.

     v. Keyboards that allow the user to adjust their height and angle, and ergonomically designed alternatives to the more traditional mouse and trackball interfaces should be considered.

     vi. Monitor bases should allow adjustment of the monitor angle, and the radiologist should be close enough to the monitor to optimize the ability to discern detail yet far enough from the monitor to prevent eyestrain. This distance will vary depending on the individual radiologist's near and intermediate visual acuity and preferences and the type of imaging study, but is generally in the range of 50 to 100 cm from the monitor. Optimal viewing occurs with the monitor center placed 15 to 20 degrees below a horizontal marking the line of sight.

V. 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 computed tomography (CT) and magnetic resonance imaging (MRI). The goal of DICOM transmission and storage standards is to provide a standard for storage and transmission, while the IHE mammography profile [6] provides a recommendation for best practice implementation and work flow. Relevant standards are the DICOM DX Image Information Object, the DICOM Digital Mammography X-Ray Image Information Object (MG), and the DICOM Mammography CAD Structured Report. Any of these information objects can be stored for later retrieval.

A. Digital Mammography Image and Data Types

1. The MG information object descriptor includes a specification for two types of image information. "For processing" represents image data that is 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 requires 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 is 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. 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.

3. Digital 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).

4. Since many mammography CAD systems require "for processing" images, vendors of digital mammography acquisition devices should ensure that the devices support DICOM transmission of both "for presentation" and "for processing" MG images.

5. Telemammography demands high speed networks and/or compression (see below). Reasonable transmission speeds may make the difference between an efficient, successful service and failure.

6. 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 datasets.

Figure 1. Flowchart of image data distribution.
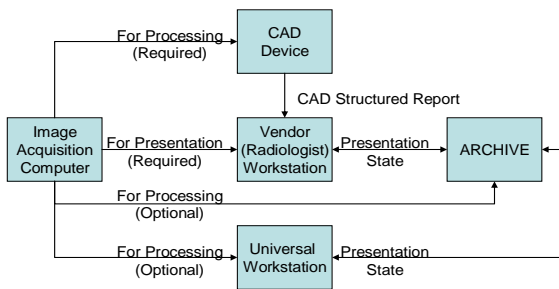
B. Workstation Retrieval Requirements

1. The mammography display workstation must support receipt of DICOM-compatible MG images and mammography CAD structured reports "for presentation."

2. Display of new data "for processing" should be optional and configurable for digital mammography workstations.

3. The display system should support DICOM query and retrieve of digital 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 [6]).

6. Universal workstation
   a. Should properly display "for processing" and "for presentation" MG data, with mammography-specific hanging protocols and support for the IHE Mammography Image Profile.
   b. Should provide user-defined processing algorithms for digital mammograms as well as display acquisition-defined "for presentation" algorithms and Look up Tables (LUTs).
   c. Should allow multimodality image viewing of associated breast imaging studies (e.g., ultrasound, MRI, CT, PET/CT, biopsy

specimens, stereotactic images, surgical specimens, and other pertinent studies).

C. Archive

1. The archive device for digital mammography must support DICOM receipt of MG images.

2. Storage of "for presentation" images is required to insure 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 datasets should not be required for technical reasons, but may be required for local medical-legal ones.

4. Storage of mammography CAD structured reports (SR) 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 should be documented.

5. The archive device should be able to query and retrieve digital mammograms.

6. Prior examinations
   a. If possible, comparison of current studies to prior examinations is strongly recommended. See the ACR Practice Guideline for the Performance of Screening and Diagnostic Mammography [9]. 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 about 150,000 examinations per year would produce 25 GB of data per day, assuming non-storage 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 [36] 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 mammogram 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. Mammography images are suitable for compression (lossless or not) because of large black areas outside the breast that do not contain diagnostically relevant information.

Compression may be defined as mathematically reversible (lossless) or irreversible (lossy). 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 type of image, the modality, and the objective of the study will determine the amount of compression that can be tolerated. The term diagnostically acceptable irreversible compression (DAIC) is mathematically irreversible compression that does not affect a particular diagnostic task [64]. DAIC may be used under the direction of a qualified physician or practitioner, with no reduction in clinical diagnostic performance by either the primary image interpreter or the decision makers reviewing the images.

The ACR and this practice guideline make no general statement on the type or amount of compression that is appropriate to any particular modality, disease or clinical application to achieve the diagnostically acceptable goal. The scientific literature and other national guidelines may serve to assist the responsible physician in choosing appropriate types and amounts of compression, weighing the risk of degraded performance against the benefits of reduced storage space or transmission time. The type and the amount of compression applied to different imaging studies transmitted and stored by the system should be initially selected and periodically reviewed by the responsible physician to ensure appropriate clinical image quality, always considering that it may be difficult to evaluate the impact on observer performance objectively and reliably [65]. Lossy compression is not justified solely by the small cost savings to be realized. The benefits and costs of using lossy compression need to be carefully considered, and compression schemes should be used that preserve the high frequency content of microcalcifications.

If reversible or irreversible compression is used, only algorithms defined by the DICOM standard such as JPEG, JPEG-LS, JPEG-2000 or MPEG should be used, since images encoded with proprietary and nonstandard compression schemes reduce interoperability, and decompression followed by recompression with a different irreversible scheme (such as during migration of data) will result in significant image quality degradation [64]. DICOM does not recommend or approve any particular compression scheme for any particular modality, image type or clinical application. The U.S. Food and Drug Administration (FDA) requires that when an image is displayed, it be labeled with a message stating if irreversible compression has been applied and with approximately what compression ratio [66]. In addition this technical standard recommends that the type of compression scheme (JPEG, JPEG 2000, etc.) also be displayed, since this affects the interpretation of the impact of the compression. The DICOM standard defines specific fields for the encoding of this information, and its persistence even after the image has been decompressed.

The FDA does not allow irreversible compression of digital mammograms for retention, transmission, or final interpretation, though irreversibly compressed images may be used as priors for comparison [67]. For other modalities, the FDA does not restrict the use of compression, but it does require manufacturers of devices that use irreversible compression to submit data on the impact of the compression on quantitative metrics of image quality (such as peak signal-to-noise ratio [pSNR]) [66]. Since it is known that such simple metrics do not correlate well with human assessment of quality or performance for diagnostic tasks [68], the claim of the manufacturer that irreversible compression is satisfactory may not be sufficient, and the burden remains on the responsible physician to assure that the image quality is sufficient to achieve a diagnostically acceptable goal.

E. Legal Challenges

The legal requirements for digital mammography are established by the FDA Final Rule [8] 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 one state as well as for the practice that receives images from more than one 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.

VI. QUALITY CONTROL RECOMMENDATIONS

A. Acquisition

1. Manufacturer-specific QC procedures are required under the current FDA rules for digital mammography and must be followed. 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 Subcommittee on Mammography QA, consisting of clinical, MITA, and ACR representatives is currently working on developing a phantom and QC manual for digital mammography. The charge of the subcommittee is to design an accreditation phantom and write a QC manual that will work with all FDA-approved full-field digital mammography systems. The goals are to standardize all QC tests for all digital mammography manufacturers, standardize all test frequencies, standardize all performance criteria, and have the QC manual apply to all manufacturers.

As of January 1, 2012 the ACR Subcommittee has completed the design of the digital mammography accreditation phantom and is near completion on the digital QC manual draft. The next steps are to have the QC manual draft made available to participating MITA members, the FDA, and other invited groups and individuals to review and provide feedback to the Subcommittee before final submission to the FDA for approval as an alternative standard. The ACR Subcommittee hopes to have this digital phantom and QC manual ready for implementation by the end of 2012 pending FDA approval.

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 [32]. Specific manufacturer 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 [34,35].

B. Image Display and Processing

1. QC guidelines for display monitors include implementation of the DICOM GSDF standard [32] and the mammography-specific recommendations of AAPM Task Group 18 [43]. These recommendations are outlined in the ACR harmonized full-field digital mammography documents (not yet available at the time of publication).

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.

ACKNOWLEDGEMENTS

Collaborative Committee – members represent their societies in the initial and final revision of this guideline

ACR
Kalpana M. Kanal, PhD, Co-Chair
Eric A. Berns, PhD
William R. Geiser, MS
Martha B. Mainiero, MD
Samir B. Patel, MD
Judith A. Wolfman, MD, FACR

AAPM
Andrew Karellas, PhD
Melissa C. Martin, MS, FACR
Jon D. Shepard, MS

SIIM
Elizabeth Krupinski, PhD, Co-Chair
Daniel L. Rubin, MD, MS
Eliot L. Siegel, MD, FACR

ACR Guidelines and Standards Committee – Medical Physics – ACR Committee responsible for sponsoring the draft through the process.
Tariq A. Mian, PhD, FACR, Chair
Maxwell R. Amurao, PhD, MS
Chee-Wai Cheng, PhD
Laurence E. Court, PhD
Richard A. Geise, PhD, FACR
Nicholas J. Hangiandreou, PhD
Bruce E. Hasselquist, PhD
Ralph P. Lieto, MS
Jeffrey P. Limmer, MSc
Janelle Lira Park, MD
Doug Pfeiffer, MS
Christopher J. Watchman, PhD
Gerald A. White, Jr., MS, FACR
John W. Winston, MS
James Hevezi, PhD, FACR, Chair, Commission

Committee on Breast Imaging – ACR Committee responsible for sponsoring the draft through the process
Mary C. Mahoney, MD, FACR, Chair
Mary S. Newell, MD, Vice-Chair
Lisa Bailey, MD

Lora D. Barke, DO
Carl J. D'Orsi, MD, FACR
Bruce G. Haffty, MD
Jennifer A. Harvey, MD, FACR
Mary K. Hayes, MD
Phan T. Huynh, MD, FACR
Peter M. Jokich, MD
Su-Ju Lee, MD
Constance D. Lehman, MD, PhD, FACR
Martha B. Mainiero, MD
David A. Mankoff, MD, PhD
Samir B. Patel, MD
Handel E. Reynolds, MD, FACR
M. Linda Sutherland, MD
Barbara S. Monsees, MD, FACR, Chair, Commission

Comments Reconciliation Committee
Mahadevappa Mahesh, MS, PhD, FACR, Co-Chair
Debra L. Monticciolo, MD, FACR, Co-Chair
Kimberly E. Applegate, MD, MS, FACR
Eric A. Berns, PhD
Laurie L. Fajardo, MD, MBA, FACR
Howard B. Fleishon, MD, MMM, FACR
William R. Geiser, MS
R. Edward Hendrick, PhD, FACR
James M. Hevezi, PhD, FACR
Andrew Karellas, PhD
Kalpana M. Kanal, PhD
Elizabeth Krupinski, PhD
Paul A. Larson, MD, FACR
Mary C. Mahoney, MD, FACR
Martha B. Mainiero, MD, FACR
Melissa C. Martin, MS, FACR
Tariq A. Mian, PhD, FACR
Barbara S. Monsees, MD, FACR
Samir B. Patel, MD
Daniel L. Rubin, MD, MS
Jon D. Shepard, MS
Eliot L. Siegel, MD, FACR
Julie K. Timins, MD, FACR
Judith A. Wolfman, MD, FACR

REFERENCES

1. Avrin D, Morin R, Piraino D, et al. Storage, transmission, and retrieval of digital mammography, including recommendaitons on image compression. *JACR* 2006;3:609-614.
2. Siegel E, Krupinski EA, Samei E, et al. Digital mammography image quality: image display. *JACR* 2006;3:615-627.
3. Williams MB, Yaffe MJ, Maidment AD, Martin MC, Seibert JA, Pisano ED. Image quality in digital mammography: image acquisition. *JACR* 2006;3:589-608.
4. Krupinski EA, Williams MB, Andriole K, et al. Digital radiography image quality: image processing and display. *J Am Coll Radiol* 2007;4:389-400.

---

14 / Digital Mammography   PRACTICE GUIDELINE

5. Williams MB, Krupinski EA, Strauss KJ, et al. Digital radiography image quality: image acquisition. *J Am Coll Radiol* 2007;4:371-388.

6. *Ergonomic Requirements for Office Work with Visual Display Terminals. Part 2: Ergonomic Requirements for Flat Panel Displays*. Geneva: International Organization for Standardization; ISO 13406-2; 2001.

7. *Medical Imaging: the Assessment of Image Quality*. Bethesda, Md: International Commission on Radiation Units and Measurements; ICRU Report 54; 1996.

8. Department of Health and Human Services. *FDA Mammography Quality Standards, Final Rule.* : Federal Register, Vol 62, No. 208; Tuesday, October 28, 1997.

9. American College of Radiology. ACR Practice Guideline for the Performance of Screening and Diagnostic Mammography. http://www.acr.org/SecondaryMain MenuCategories/quality_safety/guidelines/breast/Scr eening_Diagnostic.aspx. Accessed Aug. 16, 2011.

10. Bloomquist AK, Yaffe MJ, Pisano ED, et al. Quality control for digital mammography in the ACRIN DMIST trial: part I. *Med Phys* 2006;33:719-736.

11. *Measurements of Dimensions and Properties of Focal Spots of Diagnostic Tubes*. District of Columbia, DC: National Electrical Manufacturers Association; NEMA XR 5; 1992.

12. Samei E, Flynn MJ, Reimann DA. A method for measuring the presampled MTF of digital radiographic systems using an edge test device. *Med Phys* 1998;25:102-113.

13. Rezentes PS, de Almeida A, Barnes GT. Mammography grid performance. *Radiology* 1999;210:227-232.

14. Wagner AJ. Contrast and grid performance in mammography. In: Barnes GT, Frey GD, eds. *Screen Film Mammography: Imaging Considerations and Medical Physics Responsibilities*. Madison, Wis: Medical Physics Publishing; 1991:115-134.

15. Barnes GT, Brezovich IA. The intensity of scattered radiation in mammography. *Radiology* 1978;126:243-247.

16. Barnes GT, Brezovick IA. Contrast: effect of scattered radaition. In: Logan WW, ed. *Breast Carcinoma: the Radiologists Expanded Role*. . New York, NY: Wiley Publisher; 1977:73-81.

17. Barnes GT. Radiographic mottle: a comprehensive theory. *Med Phys* 1982;9:656-667.

18. Nishikawa RM, Yaffe MJ. Signal-to-noise properties of mammographic film-screen systems. *Med Phys* 1985;12:32-39.

19. Swank RK. Absorption and noise in X-ray phosphors. *J Appl Phys* 1973;44:4199-4203.

20. Bunch PC, Huff KE, Van Metter R. Analysis of the detective quantum efficiency of a radiographic screen-film combination. *J Opt Soc Am A* 1987;4:902-909.

21. Rossmann K. Effect of quantum mottle and modulation transfer on the measurement of radiographic image quality. In: Thomas CC, Moseley RD, Rust JH, eds. *Diagnostic Radiologic Instrumentation*. Springfield, Mo; 1965:350.

22. Maidment AD, Yaffe MJ. Analysis of the spatial-frequency-dependent DQE of optically coupled digital mammography detectors. *Med Phys* 1993;21:721-729.

23. Wagner RF. Physical performance and diagnostic imaging modalities. *Acad Radiol* 1999;1:69.

24. Yaffe MJ, Nishikawa RM. X-ray imaging concepts: noise, SNR, and DQE. In: Seibert JA, Barnes GT, Gould RG, eds. *Specification, Acceptance Testing and Quality Control of Diagnostic X-Ray Imaging Equipment*. Woodbury, NY: American Institute of Physics; 1994:109-144.

25. Critten JP, Emde KA, Mawdsley GE, Yaffe MJ. Digital mammography image correction and evaluation. In: Doi K, Giger ML, Nishikawa RM, Schmidt RA, eds. *Digital Mammography >96*: Excerpta Medica International Congress Series; 1996:1119-1455.

26. Badano A, Flynn MJ, Kanicki J. *High-Fidelity Medical Imaging Displays*. Bellingham, Wash: SPIE Press; 2004.

27. Badano A, Flynn MJ, Martin S, Kanicki J. Angular dependence of the luminance and contrast in medical monochrome liquid crystal displays. *Med Phys* 2003;30:2602-2613.

28. Baker JA, Rosen EL, Crockett MM, Lo JY. Accuracy of segmentation of a commercial computer-aided detection system for mammography. *Radiology* 2005;235:385-390.

29. *Specifications for Medical Diagnostic Imaging Test Pattern for Television Monitors and Hard-Copy Recording Cameras*. New York, NY: Society of Motion PIcture and Television Engineers; 1991.

30. *Ergonomic Requirements for Office Work with Visual Display Terminals. Part 3: Visual Display Requirements*. Geneva: International Organization for Standardization; ISO 9241-3; 1992.

31. *Flat Panel Display Measurements Standard*. Milpitas, Calif: Video Electronics Standards Association; Version 1.0; 1998.

32. *Digital Imaging and Communications in Medicine (DICOM) Part 14: Grayscale Standard Display Function*. Rosslyn, Va: National Electrical Manufacturers; 2001.

33. *Imaging Quality Assurance in X-Ray Diagnostics, Acceptance Testing for Image Display Devices*. Munich, Germany: Deutsches Institute for Normung; 2001.

34. *Quality Control Manual Template for Manufacturers of Displays and Workstations Devices Labeled for Final Interpretation in Full-Field Digital Mammography*. Rosslyn, Va: National Electrical Manufacturers Association; XR 22-2006; 2006.

35. *Quality Control Manual Template for Manufacturers of Hardcopy Output Devices Labeled for Final*

Interpretation in Full-Field Digital Mammography. Rosslyn, Va: National Electrical Manufacturers Association; XR 23-2006; 2006.

36. Samei E, Wright SL. Viewing angle performance of medical liquid crystal displays. *Med Phys* 2006;33:645-654.

37. Gray JE, Anderson WF, Shaw CC, Shepard SJ, Zerembra LA, Lin PJ. Multiformat video and laser cameras; history, design consideration, acceptance testing, and quality control. . *Med Phys* 1993;20:427-438.

38. Hendrick RE, Bassett L, Botso MA, et al. *The ACR Mammography Quality Control Manual*. Reston, Va: American College of Radiology; 1999.

39. *Assessment of Display Performance for Medical Imaging Systems*. College Park, Md: American Association of Physicists in Medicine; AAPM Report 003; 2005.

40. Burgess AE, Kang H. Incomplete skin representation in digital mammograms. *Med Phys* 2004;31:2834-2838.

41. Goo JM, Choi JY, Im JG, et al. Effect of monitor luminance and ambient light on observer performance in soft-copy reading of digital chest radiographs. *Radiology* 2004;232:762-766.

42. Gray JE. Use of the SMPTE test pattern in picture archiving and communication systems. *J Digit Imaging* 1992;5:54-58.

43. Samei E, Badano A, Chakraborty D, et al. Assessment of display performance for medical imaging systems: executive summary of AAPM TG18 report. *Med Phys* 2005;32:1205-1225.

44. Samei E, Badano A, Chakraborty D, et al. *Assessment of Display Performance for Medical Imaging Systems*. Madison, Wis: Medical Physics Publishing; Task Group 18; 2005.

45. Haygood TM, Arribas E, Brennan PC, et al. Conspicuity of microcalcifications on digital screening mammograms using varying degrees of monitor zooming. *Acad Radiol* 2009;16:1509-1517.

46. Kallergi M, Heine JJ, Berman CG, Hersh MR, Romilly AP, Clark RA. Improved interpretation of digitized mammography with wavelet processing: a localization response operating characteristic study. *AJR* 2004;182:697-703.

47. Kimme-Smith C. New digital mammography systems may require different X-ray spectra and, therefore, more general normalized glandular dose values. *Radiology* 1999;213:7-10.

48. Kobayashi M. *Image Optimization by Dynamic Range Control Processing*. Springfield, Va: Society for Imaging Science and Technology; 47th Annual Conference; 1993.

49. Lee JS. Digital image enhancement and noise filtering by use of local statistics. *IEEE Transactions on Pattern Analysis and Machine Intelligence*. District of Columbia, DC: IEEE; 1980:13-25.

50. Pisano ED, Cole EB, Hemminger BM, et al. Image processing algorithms for digital mammography: a pictorial essay. *Radiographics* 2000;20:1479-1491.

51. Flynn MJ, Badano A. Image quality degradation by light scattering in display devices. *J Digit Imaging* 1999;12:50-59.

52. Krupinski EA, Johnson J, Roehrig H, Nafziger J, Lubin J. On-axis and off-axis viewing of images on CRT displays and LCDs: observer performance and vision model predictions. *Acad Radiol* 2005;12:957-964.

53. Roehrig H, Krupinski EA, Furukawa T. Evaluation of a flat CRT monitor for use in radiology. *J Digit Imaging* 2001;14:142-148.

54. Badano A, Fifadara DH. Goniometric and conoscopic measurements of angular display contrast for one-, three-, five-, and nine-million-pixel medical liquid crystal displays. *Med Phys* 2004;31:3452-3460.

55. Samei E, Wright SL. Effect of viewing angle response on DICOM compliance of liquid crystal displays. *Proc SPIE* 2004;5371:170-177.

56. Freer TW, Ulissey MJ. Screening mammography with computer-aided detection: prospective study of 12,860 patients in a community breast center. *Radiology* 2001;220:781-786.

57. Gur D, Sumkin JH, Rockette HE, et al. Changes in breast cancer detection and mammography recall rates after the introduction of a computer-aided detection system. *J Natl Cancer Inst* 2004;96:185-190.

58. Zheng B, Swensson RG, Klyn AH, et al. Classification of breast abnormalities under different detection cueing environments. *Proc SPIE* 2004;5372:211-217.

59. Diekmann F, Diekmann S, Bick U, Hamm B. Reduced-dose digital mammography of skin calcifications. *AJR* 2002;178:473-474.

60. Krupinski EA, Nodine CF, Kundel HL. A perceptually based method for enhancing pulmonary nodule recognition. *Invest Radiol* 1993;28:289-294.

61. Obenauer S, Hermann KP, Grabbe E. Dose reduction in full-field digital mammography: an anthropomorphic breast phantom study. *Br J Radiol* 2003;76:478-482.

62. Horii SC, Horii HN, Mun SK, Benson HR, Zeman RK. Environmental designs for reading from imaging work stations: ergonomic and architectural features. *J Digit Imaging* 1989;2:156-162.

63. Siddiqui KM, Chia S, Knight N, Siegel E. Design and ergonomic considerations for the filmless environment. *JACR* 2006;3:456-467.

64. Usability of irreversible image compression in radiological imaging. A position paper by the European Society of Radiology (ESR). http://www.sor.org/news /files/images/fulltext_0.pdf.

65. Rockette HE, et al. Relationship of subjective ratings of image quality and observer performance (Proceedings Paper). In: Kundel HL, ed. *Medical Imaging 1997: Image Perception*. Bellingham, WA SPIE Medical Imaging; 1997:152-159.

66. U.S. Food and Drug Administration Center for Devices and Radiological Health. Guidance for the submission of premarket notification for medical imaging management devices.

16 / Digital Mammography　　　　　　　　　　PRACTICE GUIDELINE

http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm073721.pdf. Accessed July 12, 2011.

67. U.S. Food and Drug Administration. Mammography Quality Standards Act (MQSA) Policy Guidance Help System. http://www.fda.gov/Radiation-EmittingProducts/MammographyQualityStandardsActandProgram/Guidance/PolicyGuidanceHelpSystem/default.htm. Accessed July 12, 2011.

68. Brennan PC, McEntee M, Evanoff M, Phillips P, O'Connor WT, Manning DJ. Ambient lighting: effect of illumination on soft-copy viewing of radiographs of the wrist. *AJR* 2007;188:W177-180.

69. Foos DH, Muka E, Slone RM, et al. JPEG 2000 compression for medical imagery. *Proc SPIE* 2000;3980:85-96.

70. Good WF, Sumkin JH, Ganott M, et al. Detection of masses and clustered microcalcifications on data compressed mammograms: an observer performance study. *AJR* 2000;175:1573-1576.

71. Kocsis O, Costaridou L, Varaki L, et al. Visually lossless threshold determination for microcalcification detection in wavelet compressed mammograms. *Eur Radiol* 2003;13:2390-2396.

72. Penedo M, Pearlman WA, Tahoces PG, Souto M, Vidal JJ. Region-based wavelet coding methods for digital mammography. *IEEE Trans Med Imaging* 2003;22:1288-1296.

73. Suryanarayanan S, Karellas A, Vedantham S, Waldrop SM, D'Orsi CJ. A perceptual evaluation of JPEG 2000 image compression for digital mammography: contrast-detail characteristics. *J Digit Imaging* 2004;17:64-70.

---

*Guidelines and standards are published annually with an effective date of October 1 in the year in which amended, revised or approved by the ACR Council. For guidelines and standards published before 1999, the effective date was January 1 following the year in which the guideline or standard was amended, revised, or approved by the ACR Council.

Development Chronology for this Guideline
2007 (Resolution 35)
Revised 2012 (Resolution 36)