The American College of Radiology Digital Mammography QC Manual: Frequently Asked Questions

(Revised 05/01/2024, newer items in red)

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General

Q. When was the ACR Digital Mammography Quality Control Manual approved by the FDA?

A. The Food and Drug Administration (FDA) approved the American College of Radiology's (ACR) alternative standard request to allow mammography facilities to use the ACR's 2016 Digital Mammography Quality Control (QC) Manual and Digital Mammography QC Phantom in routine QC of digital equipment in July of 2016. Subsequently, they approved the ACR's DBT supplement in July of 2018. The FDA has historically required digital mammography facilities to perform QC for approved imaging systems according to their respective manufacturers' quality control manuals. Approval of this alternative standard will enable facilities with full-field digital mammography systems with digital breast tomosynthesis (DBT) to use the ACR manual in lieu of manufacturers' quality control manuals.

Q. When was the ACR Digital Mammography QC Manual published?

A. The 2016 ACR Digital Mammography QC Manual was published on July 29, 2016. The 2018 ACR Digital Mammography QC Manual with 2D and Digital Breast Tomosynthesis was published on November 19, 2018. A revised 2nd Edition was published in May of 2020.

Q. How do I access the ACR Digital Mammography QC Manual available?

A. The ACR Digital Mammography QC Manual is publicly available for download at no charge on the ACR's Medical Physics Resources page.

Q. I have tried to download the ACR Digital Mammography Quality Control Manual, and I am unable view or save the manual. What do I do?

A. The ACR Digital Mammography QC Manual is publicly available for download at no charge on the ACR's Medical Physics Resources page. If an old version of the manual is displayed or there is another issue, try the following:

- Refresh the page using the F5 key.
- Clear the browser cache and cookies, and refresh the page.
- Try opening the file with a different browser by copying the link and pasting it into the search bar of the new browser. (We've tested both Chrome and Firefox with good results.)
- If the above suggestions do not work, you may need to reconfigure your browser, which may require assistance from your IT team.

Q. Is the QC manual available in hard copy?

A. No. The manual is only available as an electronic file (PDF). If you would like a hard copy, you may print the PDF file. You may wish to use a commercial office printing company to print the manual double-sided and in color.

Q. The technologist and medical physicist forms in the manual are PDFs. Are the forms available online in a format to allow data entry?

A. Yes. Both the technologist and the medical physicist forms are available for free as downloadable Excel files. These forms have built-in calculations and can be personalized for your facility. Please see the Digital Mammography Quality Control Test Forms section of the ACR Digital Mammography QC Manual Resources web page to download the forms. If the web page does not appear to be updated for 2020 revision, please clear your browser cache and cookies, and reload the web page.

Q. Will the ACR provide training on how to use the ACR Digital Mammography QC Manual?

A. Yes. The ACR Subcommittee on Quality Assurance provided webinars on how to use the 2018 ACR DM QC Manual with 2D and Digital Breast Tomosynthesis for technologists and medical physicists. Check the ACR Digital Mammography QC Manual Resources web page for the recordings and slides.

Applicability

Q. Will the ACR or FDA require that we follow the ACR Digital Mammography QC Manual to be ACR-accredited or MQSA-certified?

A. No. The FDA approved use of the ACR Digital Mammography QC through an alternative standard. This means that the manual may be used instead of using your manufacturer's QC manual as currently required by the FDA regulations. Neither the FDA nor the ACR can require you to use the ACR Digital Mammography QC Manual under the current FDA regulations.

Q. If we choose to use the ACR Digital Mammography QC Manual, must we also perform the QC required by our equipment's manufacturer?

A. No. Because the FDA approved use of the ACR Digital Mammography QC through an alternative standard, if you choose to use the manual, you will no longer be required to

perform QC tests as prescribed in manufacturer's QC manuals. Note that you must still perform any calibrations required by the manufacturer (e.g., Manufacturer Detector Calibration).

Q. Our facility has a digital mammography unit that only performs 2D imaging. Will we be allowed to use the ACR Digital Mammography QC Manual instead of our manufacturer's QC manual for QC on this unit?

A. Yes.

Q. Our facility has a mammography unit that performs 2D imaging using computed radiography (CR). Will we be allowed to use the ACR Digital Mammography QC Manual instead of our CR manufacturer's QC manual for QC on this unit?

A. Yes.

Q. Does the ACR Digital Mammography QC Manual contain QC instructions for contrast-enhanced imaging?

A. No, the manual only includes QC instructions for 2D digital mammography and DBT.

Q. Our facility has a digital mammography unit that performs 2D and/or DBT imaging and contrast enhancement (imaging of an iodinated contrast agent using mammography equipment). Will we be allowed to use the ACR Digital Mammography QC Manual instead of our manufacturer's manual for QC of the 2D and DBT applications of our digital mammography unit and then follow our manufacturer's QC manual for contrast enhancement?

A. Yes. The FDA has determined that facilities may use the manual for QC of the 2D and DBT applications of these units, and recommends that facilities follow manufacturer QC procedures for contrast enhancement applications.

Q Must all units within a facility follow the same QC manual?

A. No. All units within a facility are ***not required*** to use the same QC manual. Each unit within a facility must be evaluated according to a QC manual that has been approved by the FDA, but the QC manuals do not need to be the same.

Q. I received correspondence from the manufacturer recommending new, additional QC Testing, or modifications to their QC testing for their respective unit. Are we required to perform this extra testing if using the ACR DM QC Manual?

A. No. Manufacturer QC tests are not applicable if you are using the ACR DM QC Manual. The ACR DM QC Manual is an approved alternative standard and not subject to manufacturers' QC programs.

Transitioning to the Manual

Q. When may our facility start using the ACR Digital Mammography QC Manual for 2D and DBT and stop using our manufacturer's manual?

A. You may begin using the ACR Digital Mammography QC Manual for QC on all applicable digital mammography units and discontinue using the manufacturer's QC manual on or after November 19, 2018.

Q. When will the ACR start accepting technologist QC and medical physicist reports using the ACR Digital Mammography QC Manual for DBT accreditation purposes?

A. As of November 19, 2018, the ACR started accepting applications with technologist QC and medical physicist reports using the ACR Digital Mammography QC Manual.

Q. When will the ACR start accepting images from the ACR Digital Mammography Phantom for mammography accreditation for 2D and DBT?

A. As of November 19, 2018, the ACR started accepting applications with images from the ACR Digital Mammography Phantom for mammography accreditation.

Q. If a facility chooses to use the ACR Digital Mammography QC Manual for their digital mammography unit, do they need to notify the ACR?

A. No. They may do so without notifying the ACR. Facilities should submit the appropriate documentation and testing materials using the QC manual during their normal accreditation cycle.

Q. If a facility chooses to use the ACR Digital Mammography QC Manual for their digital mammography unit, do they need to notify their MQSA inspector?

A. No. However, the facility should document the date they transitioned to the ACR Digital Mammography QC Manual in their QC records (e.g., their Corrective Action Log).

Q. After November 19, 2018, may our facility begin using the ACR Digital Mammography QC Manual for 2D and DBT and stop using our manufacturer's manual?

A. Yes, but please note that before the facility QC technologist may start using the DMQC Manual on a unit, the medical physicist must first conduct an ***annual survey*** of the digital mammography unit for 2D and DBT and display devices using the manual and phantom. This is important to provide testing techniques and procedures for the QC technologist to use during routine QC. After this is done, the QC technologist may start performing routine QC using the manual.

Q. Is a full mammography equipment evaluation (MEE) required to begin using the ACR Digital Mammography QC Manual for 2D and DBT?

A. No, an ***annual survey*** is required for facilities transitioning from a manufacturer's QC program to the ACR DM QC Manual. ***However***, **MEE** test data obtained under the facility's previous QC program should be maintained and available for baseline, comparison, and troubleshooting purposes until those tests are performed for the first time under the ACR Digital Mammography QC procedures. If data for the MEE tests are not available for baseline, comparison, and troubleshooting purposes, a full MEE must be done in order to make those data available.

Q. Must the initial medical physicist's annual survey using the manual and phantom be performed on the digital mammography unit and display devices on the same day?

A. No. The medical physicist may choose to perform the digital mammography unit and display device annual surveys on the same day or on different days. The QC technologist should perform the routine QC on the digital mammography unit using the manual and phantom after the medical physicist's testing is complete on the unit. Likewise, the QC technologist should perform the routine QC on the display devices using the manual and phantom after the medical physicist's testing is complete on the display devices. However, it is preferable that

mammography units and display devices located at the same geographical location be tested by the medical physicist on the same day.

Q. Our facility has several digital mammography units in one location and several radiologist workstations at different locations in several states. We intend to switch to the ACR Digital Mammography QC Manual for all devices. How long does our facility have to transition QC testing for all devices (units and workstations) to the new manual once we begin this transition with one device?

A. The ACR does ***not*** require that all devices within a facility be transitioned to the ACR Digital Mammography QC Manual within a specific timeframe. However, for ease of QC management, we encourage that this transition take place as soon as possible.

Q. Our facility has display devices that are geographically distant from the mammography units. Is there a time limit between transitioning our mammography units to the ACR Digital Mammography QC Manual program and these distant display devices?

A. Yes. The display devices must have annual surveys performed for transition at the next regularly scheduled annual survey, or earlier. The existing manufacturer's QC program for the distant display devices must be followed until the transition annual survey is completed, and clear documentation should be kept to identify transition dates for each device.

Q. Our radiologist practice interprets mammography images for multiple facilities. These facilities have adopted different QC procedures that include one or more facilities that has/have implemented the ACR DM QC manual alternative standard. Can we continue to follow the Radiologist Workstation manufacturer's QC procedures and elect to not use the ACR DM QC manual for our display devices that are used to interpret mammograms for facilities that have implemented the ACR DM QC manual alternative standard?

A. No. All Radiologist Workstations (display devices) that are used to interpret mammography images for facilities that have adopted the ACR DM QC manual must also implement the ACR DM QC manual for all applicable Radiologist Workstations (RWS, display devices). They must also perform the manufacturer's QC for the facilities that have not adopted the ACR DM QC manual. It is important to note that for most Radiologist Workstation manufacturers, the Technologist QC tests required by the ACR DM QC manual are also required by their QC manuals. In many cases, the only additional QC test required by the ACR DM QC manual will be the ACR phantom image evaluation on a monthly frequency. It may be valuable to work with your medical physicist to assist in detailing the tests and frequencies of tests for these scenarios.

Q. When transitioning from the manufacturer's QC manual to the ACR Digital Mammography QC Manual, must the medical physicist's annual survey include both the tests in the ACR QC manual AND all the tests in the manufacturer's QC manual?

A. No. The medical physicist is only required to perform the tests that are in the ACR Digital Mammography QC Manual.

Q. We will be performing a mammography equipment evaluation (MEE) on a new digital mammography unit using the ACR Mammography QC Manual. Must the medical physicist's MEE include both the tests in the ACR QC manual AND all the tests in the manufacturer's QC manual?

A. No. The medical physicist is only required to perform the tests that are in the ACR Digital Mammography QC Manual.

Q. Our QC technologist prefers the manufacturer's testing procedures; our medical physicist prefers following the procedures in the ACR Digital Mammography QC Manual? May the QC technologist and the medical physicist follow the testing procedures each prefers even if they are different?

A. No. The facility, in consultation with their medical physicist, should decide which manual they will follow for each unit. This is especially important for accreditation purposes. For any given digital mammography unit, the QC technologist and the medical physicist must use the same QC manual.

Q. If our QC technologist starts following the testing procedures in the ACR Digital Mammography QC Manual may she switch back to the manufacturer's procedures if she prefers them?

A. Yes. However, the QC technologist may ***only*** switch back to the manufacturer's procedures
- ***After consultation with the facility's medical physicist, and***
- ***After an annual survey is conducted by their medical physicist*** (where the manufacturer's procedures are followed for the annual survey).

It is important to note that if the facility wishes to switch back before their normally-scheduled annual survey, the medical physicist must conduct the annual survey earlier and before the switch takes place.

Q. We like some of the tests in the ACR Digital Mammography QC Manual. Others we would prefer not to do. May we perform some of the tests from the manual and others from our manufacturer's QC manual?

A. No. The facility, in consultation with their medical physicist, should decide which manual they will follow for each unit. This is especially important for accreditation purposes. For any given digital mammography unit, the QC technologist and the medical physicist must use the same QC manual. However, if the facility is using the ACR Manual, they may also choose to perform additional tests from their manufacturer's QC manual if they believe that would be of benefit.

Q. We really like some of the Management Forms in the Radiologic Technologist Section (e.g., ACR Technique and Procedure Summaries, Corrective Action Log, Facility Offsite Display Locations). May we use these forms even if we do not use the ACR Digital Mammography QC Manual and remain with our manufacturer's QC manual?

A. Yes. You may use the forms that do not involve testing even if you do not use the ACR Digital Mammography QC Manual.

Q. We really like some of the new "tests" and forms that are in the Radiologic Technologist Section (e.g., Facility QC Review, System QC for Radiologist and Radiologist Image Quality Feedback). These tests are not currently part of our manufacturer's QC manual. May we use these tests and forms to complement our manufacturer's QC manual even if we do not use the ACR Digital Mammography QC Manual?

A. Yes. However, you may need to modify some of the forms to be applicable to your manufacturer's QC manual's tests.

Q. For a facility with multiple units whose annual test dates are spread throughout the year, is it acceptable to do the transition surveys when annual surveys come due?

A. Yes. Each unit (and display device) must be evaluated according to an FDA-approved QC manual at all times. Transitioning each unit on its own annual survey schedule is acceptable.

Q. What if radiologists reading from remote workstations do not want to transition to the new ACR QC manual?

A. If your facility will be switching to the new QC manual and the images are going to be reviewed offsite, those offsite display devices must be evaluated according to the ACR DM QC Manual, including the Technologist's QC. This is why it is so important that the lead interpreting physician be involved with the facility's decision to transition (or not to transition) to the ACR manual. The ACR manual offers a streamlined and standardized QC program.

Q. MQSA requires that the AGD delivered during a single cranio-caudal view of an FDA-accepted phantom be less than 3.0 mGy. Are the 2D and DBT views of a clinical "combo mode" acquisition considered separate views?

A. Yes. The 2D and DBT views are considered separate, and therefore ***each view is individually subject to the 3.0 mGy limit***, even in a "combo mode" acquisition.

Q. Can the medical physicist, during an annual survey, conduct and report failed tests normally performed during MEEs (e.g. kVp, collimation, etc.), or is the facility allowed to ignore the failures because they are not required for an annual survey?

A. The MEE tests are also troubleshooting tests for medical physicists to use as they see fit. If a medical physicist performs a test which results in a failure for the tested item, then the ***failure must be reported and corrective action initiated***.

Q. For AEC test ROI measurements, do I need to use the radiologist review workstation or can I use the images at the acquisition workstation?

A. Either workstation is fine for this analysis, as long as "for processing" images are used and ROI tools are available.

Q. If we do not switch to the ACR phantom for QC and continue with the manufacturer QC, do we still need to do reject or repeat tests?

A. If your facility chooses to follow the manufacturer's QC manual, and the manual requires that a reject or repeat analysis be performed, you must perform it.

Q. How do I know which vendor "tests" are necessary calibrations that must be continued if we choose to use the ACR QC manual?

A. Equipment ***calibrations*** are procedures that are used to detect ***and automatically correct*** equipment problems. For example, digital detector manufacturers create calibration procedures that optimize detector performance by compensating for dead or over-responding pixels, structured or other noise, nonlinear response, and other technical performance parameters. ***QC tests*** are procedures that detect problems but ***the procedure itself does not correct the problem***. Manufacturers should clearly identify the calibration procedures necessary to keep their detectors in optimal operating condition. If you have questions regarding which manufacturer tests are "calibrations" as opposed to QC tests, you should contact your equipment manufacturer.

Q. Should the medical physicist stop subtracting from the phantom image quality score due to artifacts for both the small ACR Mammography Phantom as well as the large ACR Digital Mammography Phantom used with the new ACR QC manual?

A. No. If the unit is using the manufacturer's QC manual with the small ACR Mammography Phantom, artifacts should be subtracted from the test object scores as described in these manuals. ***For units using the new ACR QC manual with the large ACR Digital***

Mammography Phantom, there is no subtraction from the phantom test object scores due to artifacts. However, at the discretion of the technologist or medical physicist performing the test, artifacts in the phantom image can cause failure of the unit's phantom image quality test.

Q. Why can't we use the new phantom for compression thickness test? Can we use the old phantom instead of tape rolls?

A. The new ACR DM Phantom will not allow paddles to flex due to its size, so it cannot be used for evaluating compression thickness. The old ACR mammography phantom allows paddle flex, so yes, it may be used for the compression thickness test. It is more accurate and relevant clinically to measure compression thickness accuracy toward the chest wall.

Q. While performing AEC testing during my survey I noticed a discrepancy in the 2018 DM QC Manual. The Performance Criteria and Corrective Actions section states that "The SNR *must* be ≥ 40.0 for the 4.0 cm phantom in the DBT mode." However, the Precautions and Caveats section also states, "It is recognized that the SNR is not strictly defined for DBT images." Which is correct?

A. The ACR recognizes that this is a typographical error in the manual, and it was corrected in the 2020 revision. The SNR Performance Criteria and Corrective Actions now state, "The SNR *must* be ≥ 40.0 for the 4.0 cm phantom in the 2D Contact mode." For DBT, the SNR is not strictly defined. Please download the May 2020 revision of the 2018 DM QC Manual.

Q. When performing the Phantom Image Quality test, what settings should be used to acquire the phantom image?

A. Some manufacturers have historically included in their QC manual phantom image quality test procedure a step to fix the AEC "sensor" position, or to fix automatic segmentation features, or fix kVp settings, in order to ensure the phantom image quality acquisitions are consistently performed. With ACR's QC manual and the new, larger phantom, this accommodation is unnecessary. For facilities using the ACR manual, the phantom image quality test must be performed using the same image acquisition settings that are used in routine patient screening mammography exams.

Q. I am performing the annual survey for my facility and need clarification on Collimation Assessment. Am I required to perform the test annually on all available anode tracks and field sizes, or is this only required at MEE?

A. For 2D-only units, you only need to perform the ***full*** 2D collimation test (with all anode tracks and both small and large FOV) at MEE or after relevant service or component replacement. There is no requirement in the manual for annual Collimation Assessment for 2D-only units. For units that are 2D and DBT or DBT-only, you need to perform the ***full*** 2D collimation test at MEE and after relevant service or component replacement. Additionally, for units that are 2D and DBT or DBT-only, you must perform the Collimation Assessment annually, for only the largest FOV and the most clinically used anode track. This annual test for collimation must be done in 2D mode, not in DBT mode.

Q. For the quarterly Facility QC Review, the manual states, "The lead mammography radiologist lead interpreting physician), along with the facility manager, must review the QC test results…" and, "QC data/notebooks must be reviewed by both the lead interpreting radiologist and facility manager." What if we have a facility that does not have a manager?

A. The QC technologist must have supervision and support from a leader who is or serves as management with oversight at the facility. In some smaller practices, there may not be a

dedicated manager for the mammography clinic; in cases like this it is appropriate for the lead mammography radiologist (LIP) to function as the facility manager for mammography QC.

ACR Digital Mammography Phantom

Q. May I use our old ACR phantom to perform the tests in the ACR Digital Mammography QC Manual instead of obtaining the new ACR Digital Mammography Phantom?

A. No. The ACR Digital Mammography QC Manual procedures were designed around the new ACR Digital Mammography Phantom. The old ACR phantom ***cannot*** be used to conduct the tests in the manual.

Q. If our facility does not want to purchase the new ACR Digital Mammography Phantom, can we continue to use the old phantom and follow the manufacturer's QC manual?

A. Yes.

Q. Where do I obtain the ACR Digital Mammography Phantoms?

A. The ACR posts the name and contact information for approved vendors of the ACR Digital Mammography Phantom on the ACR Digital Mammography QC Manual Resources web page. For a manufacturer to sell the new phantom, they must have it reviewed and approved by the ACR.

Q. How much is the new ACR Digital Mammography Phantom?

A. Please contact the phantom manufacturers for their pricing.

Q. How does the new ACR Digital Mammography Phantom differ from the old one?

A. The main differences are as follows:

- The new phantom is large enough to cover most of the detector. This enables artifact evaluation to be done at the same time that the phantom image quality is evaluated.
- The largest test objects have been removed and smaller ones have been added. The gradations between test objects are also smaller so that the phantom is more sensitive to changes.
- The tolerances for test object size and location are much tighter ensuring minimal phantom-to-phantom variation.
- A filter has been included under the wax insert so that the signal throughout the phantom is much more uniform.

Q. How do the test object sizes of the new ACR Digital Mammography Phantom compare to those of the old ACR mammography phantom?

A. See the table:

Old and New ACR Phantom Test Object Visual Equivalency (Green are Passing)

Fiber (mm)		Speck Groups (mm)		Masses (mm)	
Old	**New**	**Old**	**New**	**Old**	**New**
1.56					
1.12		0.54		2.00	
0.89	0.89	0.40		1.00	1.00
0.75	0.75	0.32	0.33	0.75	0.75
	0.61		0.28	0.50	0.50
0.54	0.54	0.24	0.23		0.38
0.40	0.40		0.20	0.25	0.25
	0.30	0.16	0.17		0.20
			0.14		

Q. How does the scoring of the new ACR Digital Mammography Phantom compare to that of the old ACR mammography phantom?

A. See the table:

# of Test Objects That Must Be Visible to Pass

Test Object	Old ACR Mammography Phantom	New ACR Digital Mammography Phantom
Fibers	4	2
Speck Groups	3	3
Masses	3	2
Artifacts	Subtract scores for artifacts	Fail if clinically significant artifact present in a location that could impact clinical imaging

Q. What is the biggest change in evaluating the new ACR Digital Mammography Phantom image relative to the old phantom?

A. The biggest change is ***failing the phantom image for artifacts***. QC technologists, medical physicists and ACR phantom reviewers should fail the phantom image if there is a clinically significant artifact in a location that could impact clinical interpretation, even if all fibers, speck groups and masses pass. This change was made since phantom reviewers noted that phantom images submitted for accreditation would occasionally contain clinically-significant artifacts that would not prompt failure since they did not obscure test objects in the old phantom.

Q. Can my unit fail accreditation if the ACR phantom reviewers fail my ACR Digital Mammography Phantom image submitted for accreditation due to clinically-significant artifacts?

A. Yes.

Q. I am still using the old, small ACR Mammography Phantom for routine QC using the manufacturer's QC manual and am submitting that phantom's image for accreditation. Will the ACR phantom reviewers fail my phantom image if clinically-significant artifacts are present but all fibers, speck groups and masses pass?

A. No. At this time, ACR phantom reviewers will continue to use the scoring protocol outlined in the 1999 ACR Mammography Quality Control Manual. This means they will not fail the old phantom images for artifacts if all fibers, speck groups and masses pass. However, they will note that the artifacts are "unacceptable" and provide possible causes. If this occurs, the facility should work with their medical physicist to further diagnose and eliminate the artifact.

Q. What are clinically-significant artifacts?

A. Clinically-significant artifacts may be broad-area artifacts (e.g., non-uniformities, blotches, and streaks) or detailed artifacts (e.g., black or white pixels, clusters of pixels, lines, or dust particles). This aspect of the test fails if any artifacts are in a ***location*** that could impact clinical interpretation and the artifacts:

- Are as prominent as (or more prominent than) the visible test objects in the phantom image, or
- Obscure test objects in the phantom, or
- Could affect clinical interpretation.

For more information, see the Artifact Evaluation Guide in the ACR Digital Mammography QC Manual.

Q. Should the new ACR Digital Mammography Phantom image fail for clinically-significant artifacts if any speck-like artifacts appear on the image?

A. Phantom image failure will depend on the number of artifacts that appear and where they are located:

- If only ***1 to 3 speck-like artifacts appear in a location that could impact clinical interpretation, the image should <u>not</u> fail***. However, the artifacts should be evaluated and eliminated if possible.
- If speck-like artifacts are more ***widespread and appear in a location that could impact clinical interpretation***, these are probably clinically significant and the image should fail. These artifacts must be eliminated in order for the phantom image to pass.

Q. What technique should I use when exposing the new ACR Digital Mammography Phantom? Should I use a fixed or manual technique?

A. Use the imaging mode and technique that you would normally use for a patient with a 4.2 cm thick compressed breast consisting of 50% glandular and 50% adipose tissue. If you normally use automatic exposure control (AEC) for patients, AEC should be used for the phantom. If you do not used fixed or manual techniques when imaging patients, do not use them for the phantom.

Q. Are 5-day startup averages required for setting performance levels for the new ACR Digital Mammography Phantom?

A. No. The phantom is only evaluated against pass/fail criteria.

Radiologic Technologist's Section

Q. We are using cushion pads when performing mammograms on some of our patients. Do we have to include the pad when performing the phantom QC tests under the manual?

A. When performing the routine phantom QC tests, you must simulate as closely as possibly your typical clinical conditions. Thus, if you are not using a cushion pad for more than half of your patients, you do not have to include the cushion pads when performing the phantom QC tests. However, if you are using a cushion pad for more than half of your patients, you must include the cushion pad when performing these QC tests. If you routinely use the cushion pad on both the bucky and the compression paddle, you must use two layers of the cushion pad when performing the phantom QC tests. See the FDA Policy Guidance Health System for more information.

Q. For the manual's Compression Thickness Indicator test, may we use our old ACR phantom instead of stacked rolls of tape as shown in the manual?

A. Yes. The manual specifies that "any commonly available object that is 10 cm long by 10 cm wide (or less) and 4 to 6 cm in thickness" may be used. The old ACR mammography phantom would qualify. However, it is important that any protruding objects, such as the small acrylic disk or screws, be removed to prevent damage to the compression paddle.

Q. For the Acquisition Workstation (AW) Monitor QC test, we cannot bring up a test pattern on the AW monitor. What do we do?

A. Just indicate "NA" on the QC form. We understand that not all systems allow the display of a test pattern on AW monitors. The QC manual indicates to perform that aspect of the test "if available".

Q. Our facility does not use a film printer for digital mammography. We do not interpret images on film; we do not provide images to referring physicians, surgeons or patients on film (we only provide CDs). Our film printer has been permanently shut down. Are we required to perform QC on this film printer?

A. No. QC on film printers is only required if they are used clinically for mammography (i.e., for interpretation and to provide images to referring physicians, surgeons or patients). It is important that the facility documents in their QC logs that the film printer is not used clinically.

Q. The QC manual for my mammography unit contains some activities that they call "calibrations" instead of "QC tests." Do I have to perform these calibrations if we are using the ACR DM Manual?

A. Yes. "Calibration" usually refers to the checking ***and rectification*** of an equipment component. Many manufacturers include automatic calibrations in their software to check and automatically correct any deficiencies in their detector's performance. Because this is an important task specific to each manufacturer, the Technologist's Section of the ACR manual includes a test called "11. Manufacturer Detector Calibration." If the manufacturer requires certain calibrations for their digital mammography detector, such as the "Detector Flat Field Calibration" required by Hologic or "Detector Calibration" required by Siemens, you must continue to perform these calibrations.

Q. Is the detector calibration performed by the technologist or by the service representative during routine preventative maintenance?

A. It depends on the manufacturer. If your equipment manufacturer specifies that the technologist performs this routine activity, you must perform it.

Q. In the manual, why is the Repeat Analysis an optional test and not required as before?

A. The ACR Subcommittee on Quality Assurance in Mammography believed that the Repeat Analysis better serves the mammography community as an optional, rather than a mandated, test and that each facility should decide if the time and effort it takes to correctly perform the test generates useful information. (Even though the system is digital, collecting accurate, relevant data is difficult and time-consuming.) The Subcommittee also believed that there were more effective ways to promote clinical improvement such as the use of the Radiologist Image Quality Feedback form.

Q. If we chose to perform the optional Repeat Analysis test under the manual, may we use the data provided by our digital mammography unit?

A. Maybe. Some equipment manufacturers provide an automated system to collect, record and analyze repeated clinical images. These systems may be used if the system includes the following 2 key elements:

- Count of the total # of exposures made during the evaluation period
- % repeats during the same period: (# Repeat Exposures/Total # Exposures)*100%TBD

(See the Optional – Repeat Analysis test in the manual.)

Q. We really like the Radiologist Image Quality Feedback form and think it may help us document some of the FDA's new EQUIP requirements. May we use it for EQUIP?

A. You may use the Optional - Radiologist Image Quality Feedback form to help meet ***part (a) of the MQSA inspector's EQUIP question 1***:

> *1. Does the facility have procedures for corrective action (CA) when clinical images are of poor quality?*
>
> *(a) Do the procedures include a mechanism for providing ongoing IP feedback on image quality to RT's or other designated facility personnel?*
>
> *(b) Do the procedures require documenting any corrective actions taken and documenting the effectiveness of any corrective actions taken?*

Visit the FDA EQUIP webpage and the FDA's FAQs for complete and current information.

Q. We would like to use the Radiologist Image Quality Feedback form in our evaluation of image quality as described in the EQUIP question 2. However, we are concerned that our inspector may not accept this since the form does not include the exact language used by FDA to describe the eight image quality attributes that must be evaluated. May we use this form in our evaluation of image quality for EQUIP?

A. You may use the Optional - Radiologist Image Quality Feedback form to ***partially*** meet the MQSA inspector's EQUIP question 2, part (a):

> *2. Does the facility have procedures to ensure that clinical images continue to comply with the clinical image quality standards established by the facility's accreditation body?*
>
> *(a) Do the procedures include a mechanism for regular reviews of image quality attributes of a sample of mammograms performed by each active RT and a sample of mammograms accepted for interpretation by each active IP?*
>
> *(b) Is there documentation of such review since the last inspection?*

There are eight image quality attributes listed in the MQSA regulations, 900.4(c)(2)(i-viii), that must be evaluated by accrediting bodies. They are: positioning, compression, exposure level, contrast, sharpness, noise, artifacts, and examination identification. These attributes were developed in the days of screen-film mammography. The ACR Digital Mammography QC manual is designed for the modern clinical setting. Though most of these attributes are still valid as we know them from the screen-film days, exposure level, contrast and noise are all interrelated. Consequently, the new form evaluates all the historic attributes but uses terms more relevant to digital imaging. This relationship is outlined in the table below.

It is important to note that ***use of the form alone does not fully address EQUIP question 2*** since it does not address the latter part of part (a) or part (b). Visit the FDA EQUIP webpage and the FDA's FAQs for complete and current information.

Image Quality Attributes Outlined in FDA Regulations	ACR Digital Mammography QC Manual Radiologist Image Quality Feedback Form Attributes
1. Positioning	**Positioning**
	Missing tissue
	Nipple not in profile
	Skin fold
	Pectoralis not down to PNL
	Tissue droopy (camel nose)
	Narrow/concave pectoralis
	Inframammary fold
	Centering not correct
	Technical Issues
2. Compression	Not enough compression
3. Exposure level 4. Contrast 5. Noise	Exposure Too Low (Excessive Noise)
	Exposure Too High (Image Saturation)
6. Sharpness	Patient Motion
7. Artifacts	Artifacts
8. Examination identification	Incorrect Patient ID

Q. In the header of the Facility Display Device QC Summary Checklist form there is a space for recording the Physical Location at Facility/ID Designation. We have several remote sites that have just a single workstation. How do I record workstations at multiple locations?

A. There are two ways that this can be handled. The first is to use one copy of the form for each location. This is useful if you have multiple workstations at several sites. In the situation you describe, it would also be acceptable to enter "Multiple" in the Facility line and then, in the table below, include a site identifier along with the device ID and room.

Q. The ACR DM QC manual discusses monitor cleaning in the Technologist Section for both the Acquisition Workstation (AWS) Monitor QC and the Radiologist Workstation (RWS) Monitor QC tests. Are we required to record, or provide documentation, that the display devices have been cleaned and if so, at what frequency must they be cleaned?

A. No. The ACR DM QC manual procedure instructs the facility to evaluate the monitor condition and clean only when indicated, or warranted, specifically using a method approved by the monitor manufacturer. There is no requirement to document that monitor cleaning was performed. The intent of this QC procedure is to document that the monitor is evaluated at least monthly. If it is determined that the monitors contain "blemishes" due to the cleanliness

condition of the monitor or any other cause, then the result should be recorded as Pass/Fail during the monthly evaluation.

Q. Our practice includes Radiologist Workstations (Display Devices) that are distant/remote away from our mammography units. Are the Technologist QC tests described in the ACR DM QC manual required to be performed by a qualified Mammography QC Technologist or can these QC tests be performed by the qualified radiologist?

A. The technologist is not required to be the one who performs these tests. The qualified radiologist may perform and document the RWS QC and must provide the results to all facilities that have clinical exams interpreted using that specific RWS. See the following MQSA PGHS regulation and guidance on other "qualified individuals" and documentation of training:

https://www.accessdata.fda.gov/cdrh_docs/presentations/pghs/Quality_Control_Technologist_Responsibilities.htm

Q. The ACR DM QC manual Technologist QC section AWs & RWs QC includes a requirement to perform the display device automated QC if available and that the Technologist must review the results monthly. It also states that all automated QC must "Pass" The automated QC for our display device(s) is to be performed weekly per the manufacturer's manual. If this is evaluated at a monthly frequency and the weekly QC results fails in the weeks preceding the monthly evaluation, are we out of compliance?

A. No. The ACR DM QC Manual requires this test monthly. If you discover the test did not pass during your monthly evaluation, it must be recorded as a failure at that time and corrective action must be completed within 30 days of discovery of the failed automated QC test. The facility would only be considered out of compliance if the test is not performed monthly and if a failure that exists was not corrected within 30 days of discovery of the failure. The physicist is not required to re-run or perform the automated QC tests, only to verify that the most recent results passed.

Q. We have adopted the ACR DM QC Manual for our QC program. As part of the program we are required to perform a monthly evaluation of an ACR phantom image on each of our Radiologist Workstations. Are we required to evaluate a phantom image from every digital mammography unit that is interpreted on the Radiologist Workstation?

A. No. The phantom images used for evaluation should have been acquired from any digital mammography unit(s) within the past month.

Medical Physicist's Section

Q. Will the ACR require medical physicists to use the forms provided in the ACR Digital Mammography QC Manual?

A. The medical physicist must complete the following 2 forms provided in the QC manual:
- "Medical Physicist's DM QC Test Summary" form to summarize the Medical Physicist's QC Tests and the Tech QC Evaluation results and corrective action.
- "Mammography Equipment Evaluation (MEE)" form to assess compliance with MQSA equipment regulations during MEEs.

The FDA requires the ACR to review these forms during the accreditation process; using any other form can slow down this review process for facilities. The other forms in the ACR Digital

Mammography QC Manual correlate with the new phantom and testing instructions and are provided as a convenience for the medical physicist. The ACR encourages their use but cannot require it.

Q. When I image the ACR Digital Mammography Phantom in magnification mode, I cannot see the entire insert so it is impossible for me to measure the dimension as required in the ACR DM Phantom Image Quality test. What should I do?

A. Depending on the magnification used, the field of view in the chest wall-nipple direction might be too small to see the entire insert. If this happens, first try repositioning the phantom so that the front edge of the insert is closer to the chest wall. This may provide enough room to see the entire extent without impacting the exposure. If this still is not adequate, first expose the phantom as described in the manual and score the phantom in that image. Now, rotate the phantom 90° so that the short dimension of the insert is perpendicular to the anode-cathode direction. Make another exposure and measure the dimension of the insert in that image.

Q. We are using cushion pads when performing mammograms on some of our patients. Do we have to include the pad when performing the phantom QC and dose tests under the manual?

A. When performing the phantom and dose tests, you must simulate as closely as possibly your typical clinical conditions. Thus, if the facility is not using a cushion pad for more than half of their patients, you do not have to include the cushion pads when performing the phantom and dose QC tests. However, if the facility is using a cushion pad for more than half of their patients, you must include the cushion pad when performing these QC tests. If the facility routinely uses the cushion pad on both the bucky and the compression paddle, you must use two layers of the cushion pad when performing the phantom and dose QC tests. See the FDA Policy Guidance Health System for more information.

Q. Is a medical physicist required to be on site to test a new monitor that has been replaced in a radiologist workstation?

A. Yes. The manual considers this to be a major repair requiring an equipment evaluation. See Table 2 in the Medical Physicist's Section.

Q. A facility does not use a film printer for digital mammography. They do not interpret images on film; they do not provide images to referring physicians, surgeons or patients on film (they only provide CDs). The film printer has been permanently shut down. Is the medical physicist required to test the film printer during equipment evaluations and the annuals surveys?

A. No. Testing film printers during equipment evaluations and annual surveys is only required if they are used clinically for mammography (i.e., for interpretation and to provide images to referring physicians or patients). It is important that the facility documents in their QC logs that the film printer is not used clinically.

Q. Since the manual specifies that the Half-Value Layer Assessment only needs to be done during MEE or troubleshooting, should I use the HVL obtained during the unit's MEE to determine the annual average glandular dose? Should I use that value if I suspect that the tube is degrading and the HVL has changed?

A. Normally, you should use the HVL obtained during the unit's MEE to determine the annual average glandular dose. However, if you suspect that the tube is degrading and the HVL has changed, you should troubleshoot and confirm the situation by conducting a new HVL Assessment.

Q. The 2018 revised 2nd edition, May 2020 ACR DM QC manual includes a phantom evaluation form to record phantom QC results during the annual medical physics survey. This form includes columns for phantom image evaluations for multiple imaging modes including phantom scoring. Is the medical physicist required to perform phantom image evaluations in all imaging modes used by the facility?

A. No. The medical physicist is only required to perform phantom scoring for a single 2D imaging mode used for clinical imaging and if applicable, a single DBT mode used for clinical imaging. The columns for the additional image modes were intended to be used for artifact evaluation only. The 2016 1st edition version had the phantom scoring area shaded out. The additional phantom image scoring area was inadvertently left unshaded in the 2nd edition May 2020 version of this form. While a facility could elect to evaluate the phantom using different imaging modes on this form, only a single clinically used modes for 2D and a single clinically used DBT are required. If the mammography unit uses an add-on DBT device to acquire 2D images as well as DBT images, then a phantom image evaluation is required to be performed using 2D, 2D using add-on DBT, and DBT clinical imaging modes. The ACR will revise the form in the next revision of the manual.

Q. Our accredited facility has adopted the ACR DM QC manual program. We have multiple remote mammography reading locations which are not convenient to our main location. We have implemented a process where we transfer these remote Radiologist Workstations (RWS) to our main facility. These are set up in a reading room where the annual survey is performed by the medical physicist. The RWS is then transferred back to the remote reading location where a Mammography Equipment Evaluation (MEE) following relocation is performed under MP Oversight as described on page 138 of the ACR DM QC manual. A report is generated to document these results. This is completed prior to clinical use. Is this an acceptable procedure?

A. No. The medical physicist's annual survey of the RWS must be performed at the location where mammographic images are interpreted. Even though the RWS equipment can be easily relocated, this does not mean that it should be, unless there is a definitive need. It is not the intent that the RWS annual survey be performed in "any" location and under "any" conditions. True relocation means that the RWS equipment is moved to a new permanent or temporary location where the RWS will be used for final interpretation of mammographic images, not for the purposes of convenience for equipment evaluation. If an annual survey is to be performed following true relocation, then the survey must be performed with the medical physicist onsite. The medical physicist's RWS annual survey includes evaluation of viewing conditions where the RWS is used for the final interpretation of images. MP oversight for an MEE following true relocation is permitted. However, an annual survey is still required within 12-14 months from the previous one.

Q. When performing the annual Automatic Exposure Control System Performance, my results do not meet the pass/fail criterion of ≥ 40.0.

A. The ≥ 40.0 pass/fail criterion no longer applies to the annual AEC Performance test. It has come to ACR's attention that material composition and their resulting noise properties can vary significantly across and within attenuator manufacturers. This test is intended to track AEC performance both during the annual survey and over time, so the MP should take care to use the same attenuator material from year to year after establishing a baseline. If the attenuator material changes, establish a new baseline.

Q. The ACR DM QC Manual only requires that the collimation test be performed during the initial MEE, annually for DBT units, and following relevant repair or if additional troubleshooting is needed to diagnose a potential problem. If collimation is evaluated by an MQSA inspector during an MQSA inspection and it fails, is the facility required to have the medical physicist troubleshoot collimation onsite?

A. No, because the ACR DM QC Manual is an approved alternative standard and such a requirement is not in the manual. However, if the MQSA inspector is performing the collimation test under their state regulations, then the state regulatory requirement pathway must be followed. Under current MQSA requirements, the medical physicist and service engineer ***should*** be notified and consulted for corrective action. If the service engineer adjusts the collimation, the medical physicist is not required to perform an onsite evaluation. If the collimation assembly is replaced, then the medical physicist would be required to perform an onsite evaluation (MEE) prior to clinical use.

Q. For the DBT Z Resolution, DBT Volume Coverage, DBT Spatial Resolution, DBT DM Phantom Image Quality, DBT Volume Coverage, and DBT Automatic Exposure Control (AEC) tests, the acquisition workstation (AW) does not always have appropriate capabilities to perform the required data analysis and interpretation. What options do I have for data analysis and interpretation?

A. If the AW does not have ROI or display capability for data analysis and interpretation for these tests, the medical physicist should use one of the following alternatives to complete the test(s):

- Perform data analysis and interpretation on a radiologist workstation (RW). An RW is any workstation that has undergone the initial medical physicist's MEE and meets all RW QC testing and performance requirements, as outlined in the ACR DM QC Manual, regardless of whether it is used by radiologists for interpretation.
- Use image viewing and analysis software on an external computer system to perform data analysis and interpretation. If either the DM Phantom Image Quality or spatial resolution test(s) fail using an external computer system, analysis and interpretation must be repeated on an RW.

(**Note:** These additional options for data analysis and interpretation already exist in the manual for AEC; see Note box on page 169.)

Miscellaneous

Q. Our unit manufacturer would like to install a software update in the form of a patch or bug fix. Is the medical physicist required to perform an onsite MEE after this software update?

A. The ACR DM QC Manual does state that MP involvement must be on-site following FFDM software upgrades or modifications, however, this was not intended to include software patches or other minor updates (e.g., "bug fixes") that do not affect the unit's functionality, such as AEC performance, radiation output, or image quality, as indicated by the manufacturer. It is acceptable to provide MP oversight for such minor software updates that do not affect the system's functionality, as described in MQSA Alternative Standard #6. Under MQSA Alternative Standard #6, it is very important that the manufacturer must receive an acknowledgement from the FDA of the receipt of the upgrade software notification before beginning the upgrade software installation. The FDA's acknowledgement means that none of the necessary tests after the software upgrade need to be performed by the medical physicist. The medical physicist may use their discretion based on communication with the manufacturer regarding the conditions of the software change.

Q. I understand that there is no Clinical Image Quality Section in the new ACR Digital Mammography QC Manual. May I still access the Clinical Image Quality Section that was in the 1999 ACR Mammography QC Manual?

A. Yes. The Clinical Image Quality Section of the 1999 ACR Mammography QC Manual is located at on the ACR Mammography Accreditation web page.

Q. We noticed that the Detector Calibration test requirements were corrected in the May 2020 revision of the ACR DM QC manual medical physicist section, but not the Technologist QC section. Does this change also apply to the Technologist QC section?

A. Yes. This will be revised in the next QC manual revision.

Updated Medical Physicist Involvement Requirements for Display Devices

Q. When is the medical physicist required to perform an on-site MEE after service or replacement of various components of our display devices?

A. As a result of questions from the medical physics community regarding display devices and when an in-person MEE is required, the ACR submitted the table on the following page to the FDA, who subsequently approved it. The changes in the table are effective immediately and are only applicable to facilities that use the ACR DM QC Manual.

Q. I am the medical physicist for an accredited facility that has adopted the ACR DM QC manual as their QC program. The facility has replaced the entire computer that supports the RWS. The ACR DM QC manual FAQ that addresses MP involvement following major repairs or service includes guidance for individual components, but not the entire computer. If the entire computer is replaced, is onsite MP involvement required or can this be conducted under MP Oversight?

A. The replacement of the entire computer used for the RWS does not require MP onsite involvement and can be resolved under MP oversight since the entire computer contains the individual components listed in this FAQ. This does not mean that it cannot be performed with onsite MP involvement if the MP deems it necessary to properly assess the RWS performance.

ACR DM QC Medical Physicist Involvement for Display Devices (Review Workstations and Components)			
Item	**Component**	**Major Repair**	**Medical Physicist Involvment**
Display Devices	Installation of new RWS	Y	**On-site**
	RWS replacement	Y	**On-site**
	RWS that is currently being used by an accredited mammography facility and being added to another accredited MAP (with different MAP ID and not a new facility) and following the manufacturer's recommended QC program*	N	Oversight
	New video card replacement (equivalent or new make & model)	N	Oversight
	Monitor replacement	N	Oversight
	CPU replacement	N	Oversight
	Monitor power supply replacement	N	Oversight
	Hard drive replacement	N	Oversight
	Operating system (OS) software upgrade (e.g. OS upgrade or reinstallation)	N	Oversight
	OS software update, no impact on image display (e.g. OS security updates and patches)	N	Oversight
	Software upgrade (QC Software)	N	Oversight
	Software replacement (QC software)	N	Oversight
	Software upgrade (PACS, video card drivers, etc.)	N	Oversight
	QC software reinstallation (no change in software)	N	Oversight
	Software replacement (PACS, video card drivers, etc.)	N	Oversight
	System (monitors) recalibration after repair	N	Oversight
	RWS relocation same facilty and MAP ID, different room***	N	Oversight
	Minor change in positioning of RWS within the room***	N	Oversight
	RWS relocation to different physical address, same Mammograpy Accreditation Program Identification Number***	N	Oversight

Objectives: To ensure that mammography equipment meets Section 900.12(b) of FDA's Final Rule for Mammography and complies with MEE-only required tests.

Frequency: As part of the MEE of new units, after relevant service, and after component replacement.

MEE Guidance Table for Display Devices (Display Devices and Components)

This table is available to provide guidance for Display Devices in MQSA Certified Facilities following installation of new units, after relevant services and after component replacement. Display devices, as used in this table, are defined as those display devices that are used for the final interpretation of clinical mammography images.

The first column of the table identifies the item that was serviced or replaced. This table only addresses the Display Devices. The second column of the table identifies the component of that item that was serviced or replaced. The third column indicates whether or not the serviced or replaced component would be considered a major repair or not by the ACR DM QC manual. The fourth column identifies the physicist involvement if the site uses the ACR DM QC Manual as their QC program.

If the facility does not adopt the ACR DM QC manual, then the site must follow current MQSA requirements stating that facilities follow the QC guidance provided by the DM/DBT Unit Manufacturer QC Manual first, then, the Monitor/Display/RWS Manufacturer QC Manual. It is recommended that the facility consult with their medical physicist after any unit or component replacement or relevant service or the installation of a new unit.

*If a RWS has already had an initial MEE or annual survey as part of an accredited mammography facility, and will be used by a different mammography accredited facility (different MAP ID), the evaluation of the RWS for this "new existing" MAP ID can be performed under MP oversight by a qualified individual as defined by MQSA. The MP must perform the in-person evaluation on-site at the next annual survey.

**Oversight is defined as performed where the results are reviewed in consultation with the medical physicist prior to clinical use. Important Note: Ensure manufacturer's automated tests & frequencies are properly configured and results meet requirements.

***The medical physicist's annual survey of the RWS must be performed at the location where mammographic images are interpreted. MP oversight for an MEE following true relocation is permitted. This would still require an annual survey after 12-14 months from the previous one. If an annual is to be performed following true relocation, then the survey must be performed with the medical physicist onsite. The medical physicist's annual survey of RWS includes evaluation of viewing conditions where the RWS are used for final interpretation of images.