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

(Revised 8/16/17; updated questions 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. The FDA requires 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 mammography QC technologists and medical physicists to use the 2016 ACR manual in lieu of manufacturers' quality control manuals when it becomes available. The FDA alternative standard specifies that the 2016 manual may be used ***only*** for full-field digital mammography systems ***without*** advanced imaging capabilities (e.g., tomosynthesis and contrast enhancement).

Q. When was the 2016 ACR Digital Mammography QC Manual published?

A. The ACR Digital Mammography QC Manual was published on July 29, 2016.

Q. Is the 2016 ACR Digital Mammography QC Manual available to all ACR-accredited facilities at no charge?

A. Yes. A link to download the 2016 ACR Digital Mammography QC Manual at no charge was emailed on August 1, 2016 to accreditation facility contacts at all ACR-accredited mammography facilities. They were instructed to share this link with their colleagues at the facility, including their medical physicists. ***Corrections and updates will periodically be sent to all accredited facility contacts as they become available.*** Consequently, it is important to check that all your facility's contact information, including email addresses, are up to date in the ACR accreditation database (ACRedit). Go to http://www.acraccreditation.org/Login to log in.

Q. I am a technologist and the ACR accreditation contact at our mammography facility and did not receive an email with the link to download the 2016 manual. What should I do?

A. First, go online (http://www.acraccreditation.org/Login) to check that your facility's contact information, including email addresses) is up to date in the ACR accreditation database (ACRedit). (If you do not maintain your facility's ACR Mammography Accreditation log-in information, check with the person at your facility who does.) Make any necessary corrections or updates online to ensure accuracy.

Then contact the Mammography Accreditation Hotline at (800) 227-6440 or email mamm-accred@acr.org and let us know you did not receive the 2016 ACR Digital Mammography Quality Control Manual. They will forward your request and email address to the appropriate person at ACR to send you the download link.

Q. I am the medical physicist for several ACR-accredited mammography facilities. Can ACR directly send me the link to download the 2016 ACR Digital Mammography Quality Control Manual?

A. No. You must obtain the link to download the 2016 ACR Digital Mammography Quality Control Manual from one of your ACR-accredited facilities. A link to download the manual at no charge was emailed to accreditation facility contacts at all ACR-accredited mammography facilities. They were specifically instructed to share this link with their medical physicists. Contact your mammography facility and ask them to send you the link.

Q. I have tried to download the 2016 ACR Digital Mammography Quality Control Manual from the link that the ACR sent, and I am unable view or save the manual. What do I do?

A. There are several possible solutions to this problem:

- First, 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 this does not work, you may need to reconfigure your browser. (This may require assistance from your IT team).

Q. I am not affiliated with an ACR-accredited facility. How may I obtain a copy of the 2016 manual?

A. Individuals not associated with ACR-accredited facilities may purchase the manual from the ACR catalog.

Q. I am on the faculty at an educational institution. Is there volume discount pricing to obtain the 2016 QC manual?

A. Yes. Please send an email to DMQC@acr.org for volume discount pricing.

Q. Is the 2016 QC manual available in hard copy?

A. No. The 2016 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 on line 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 2016 ACR Digital Mammography QC Manual Resources web page to download the forms.

Q. Will the ACR provide training on how to use the 2016 ACR Digital Mammography QC Manual?

A. Yes. The ACR Subcommittee on Quality Assurance has developed a series of webinars on how to use the 2016 QC manual for technologists and medical physicists. Please visit the December 2016 ACR Digital Mammography QC Manual Webinars section of the 2016 ACR Digital Mammography QC Manual Resources web page to view the recordings or see the slides.

Applicability

Q. Will the ACR or FDA require that we follow the 2016 ACR Digital Mammography QC Manual to be ACR-accredited or MQSA-certified?

A. No. The FDA approved use of the 2016 ACR Digital Mammography QC through an alternative standard. This means that the 2016 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 2016 ACR Digital Mammography QC Manual under the current FDA regulations.

Q. If we choose to use the 2016 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 2016 ACR Digital Mammography QC through an alternative standard, if you choose to use the 2016 manual, you will no longer be required to perform any of the manufacturer's QC tests. Note that you must still perform any calibrations required by the manufacturer (e.g., Manufacturer Detector Calibration).

Q. Does the 2016 ACR Digital Mammography QC Manual contain QC instructions for tomosynthesis or contrast-enhanced imaging?

A. No, the 2016 manual only includes QC instructions for 2D digital mammography.

Q. Our facility has a digital mammography unit that only performs 2D imaging. Will we be allowed to use the 2016 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 2016 ACR Digital Mammography QC Manual instead of our CR manufacturer's QC manual for QC on this unit?

A. Yes.

Q. Our facility has a digital mammography unit that performs both 2D imaging and tomosynthesis. Will we be allowed to use the 2016 ACR Digital Mammography QC Manual instead of our manufacturer's manual for QC of the 2D applications of our digital mammography unit and then follow our manufacturer's QC manual for tomosynthesis?

A. No. Since the manufacturer's QC of tomosynthesis is typically built on their 2D digital mammography QC, to ensure that no gaps in testing occur, facilities with these systems must follow ***all*** the manufacturer's quality control procedures for both 2D and tomosynthesis imaging.

Q. Our facility has a digital mammography unit that performs both 2D imaging and contrast enhancement (imaging of an iodinated contrast agent using mammography equipment). Will we be allowed to use the 2016 ACR Digital Mammography QC Manual instead of our manufacturer's manual for QC of the 2D applications of our digital mammography unit and then follow our manufacturer's QC manual for contrast enhancement?

A. No. Since the manufacturer's QC of contrast enhancement is typically built on their 2D digital mammography QC, to ensure that no gaps in testing occur, facilities with these systems must follow ***all*** the manufacturer's quality control procedures for both 2D and contrast enhancement imaging.

Q. Our facility has one digital mammography unit with tomosynthesis and another unit that does not have tomosynthesis capability. Will we be allowed to follow the 2016 ACR Digital Mammography QC Manual for the unit without tomosynthesis and the manufacturer's manual for the one with tomosynthesis?

A. Yes.

Transitioning to the 2016 Manual

Q. When may our facility start using the 2016 ACR Digital Mammography QC Manual and stop using our manufacturer's manual?

A. You may begin using the 2016 ACR Digital Mammography QC Manual for QC on all applicable digital mammography units and discontinue using the manufacturer's QC manual on July 24, 2017.

Q. When will the ACR start accepting technologist QC and medical physicist reports using the 2016 ACR Digital Mammography QC Manual for accreditation purposes?

A. The ACR will start accepting technologist QC and medical physicist reports using the 2016 ACR Digital Mammography QC Manual for applications submitted on or after July 24, 2017.

Q. When will the ACR start accepting images from the 2016 ACR Digital Mammography Phantom for mammography accreditation?

A. The ACR will start accepting images from the 2016 ACR Digital Mammography Phantom for mammography accreditation for applications submitted on or after July 24, 2017.

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 2016 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 2016 ACR Digital Mammography QC Manual in their QC records (e.g., their Corrective Action Log).

Q. After July 24, 2017, may our facility begin using the 2016 ACR Digital Mammography QC Manual and stop using our manufacturer's manual?

A. Yes, but please note that before the facility QC technologist may start using the 2016 DMQC Manual on a unit, the medical physicist must first conduct an ***annual survey*** of the digital mammography unit and display devices using the 2016 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 2016 manual.

Q. Must the initial medical physicist's annual survey using the 2016 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 and display devices using the 2016 manual and phantom after the medical physicist's testing is complete.

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 2016 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 2016 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. When transitioning from the manufacturer's QC manual to the 2016 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 2016 ACR Digital Mammography QC Manual.

Q. We will be performing a mammography equipment evaluation (MEE) on a new digital mammography unit after July 2017 using the 2016 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 2016 ACR Digital Mammography QC Manual.

Q. Our QC technologist prefers the manufacturer's testing procedures; our medical physicist prefers following the procedures in the 2016 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 2016 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 2016 ACR Digital Mammography QC Manual. Others we would prefer not to do. May we perform some of the tests from the 2016 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, the facility may choose to perform additional tests from their manufacturer's QC manual if they believe it 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 2016 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 2016 ACR Digital Mammography QC Manual.

Q. We really like some of 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 2016 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.

ACR Digital Mammography Phantom

Q. May I use our old ACR phantom to perform the tests in the 2016 ACR Digital Mammography QC Manual instead of obtaining the new ACR Digital Mammography Phantom?

A. No. The 2016 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 2016 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 2016 ACR Digital Mammography Phantoms?

A. The ACR posts the name and contact information for approved vendors of the 2016 ACR Digital Mammography Phantom on the 2016 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 the same time as 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 Appendix III of the 2016 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 2016 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 question for more information.

Q. For the 2016 manual's Compression Thickness Indicator test, may we use our old ACR phantom instead of stacked rolls of tape as shown in the 2016 manual?

A. Yes. The 2016 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 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 2016 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 2016 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 2016 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.

Medical Physicist's Section

Q. Will the ACR require medical physicists to use the forms provided in the 2016 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; different formats can slow down this review process for facilities. The other forms in the 2016 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 2016 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 question for more information.

Q. In the Average Glandular Dose procedures, Table 6 (s-factors or Acrylic and BR-12) appears to have an error. Shouldn't the s-factor for W/Ag be 1.042 (and not 1.072)?

A. Yes. The s-factor for W/Ag should be 1.042 [Dance DR, Young KC, van Engen RE. Further factors for the estimation of mean glandular dose using the United Kingdom, European and IAEA breast dosimetry protocol. PhyMedBio 54 (2009).] This will be corrected in a future revision of this edition of the QC manual.

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 2016 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 that the film printer is not used clinically.

Q. Since the 2016 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.

Tomosynthesis

Q. Will the ACR update the Digital Mammography QC Manual to include tests for tomosynthesis?

A. Yes. The ACR Subcommittee on Quality Assurance is currently working on an appendix for technologist and medical physicist tests of tomosynthesis features. Once completed, the appendix will be reviewed by tomosynthesis equipment manufacturers for applicability. The ACR draft must be reviewed and approved by the FDA before it becomes final. We hope the approved appendix will be available in 2017.

Q. Will the use of the pending tomosynthesis QC appendix require the purchase and use of another phantom?

A. At this time, we do not believe a new phantom will be needed. The ACR Subcommittee on Quality Assurance is designing the tomosynthesis tests to be performed using the current ACR Digital Mammography Phantom.

Q. Will there be a training webinar after the tomosynthesis QC appendix is published?

A. Yes.

Miscellaneous

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.