ACR Mammography Accreditation

Q. FDA regulations require an Equipment Evaluation after a new processor is installed and before it is used to process patient films. Must the facility also submit the results of this Equipment Evaluation to the ACR whenever a new processor is installed and before it is used for mammography?

A. No. Although an Equipment Evaluation must be performed and all items must pass before a new processor is used to develop patient films, a facility does not need to notify the ACR or submit this information for a new or replacement film processor.

Q. Must the clinical images we submit for accreditation be performed on 18 x 24 cm film only?

A. No. The ACR accepts clinical images on both the 18 x 24 cm and 24 x 30 cm film sizes. As described in the 1999 ACR Mammography Quality Control Manual, it is important that the appropriate size film be selected to match the size of the breast. ACR clinical image reviewers will evaluate the images accordingly.

Q. Does the ACR require automatic flashing of films by the mammographic unit?

A. No. The FDA requires that the image identification be permanent and legible but does not require a flash ID system to do it. The ACR strongly recommends a flash card since it is the most permanent method for image identification (see 1999 ACR Mammography Quality Control Manual, page 26).
The 1999 ACR Mammography QC Manual

General

Q. Does the ACR require a facility to meet all of the performance criteria specified in the 1999 ACR Mammography Quality Control Manual in order to pass accreditation?

A. Under the MQSA Final Rules, the ACR cannot require facilities to meet accreditation standards that differ from MQSA regulations. That means the ACR Mammography Quality Control Manual is not a regulatory document; it is a guidance document. It contains recommendations on how things should be done for quality improvement as well as to meet MQSA regulations, clearly differentiating between what is required by the FDA and performance criteria that are suggested by the ACR (guidelines). Although facilities must only meet FDA requirements to be accredited, the ACR recommends that facilities consider implementing the guidelines to further improve the quality of their mammography.

Q. How can I access the quality control forms from the 1999 ACR Mammography Quality Control Manual on the ACR Web site?

A. The Technologist’s QC Charts, the Medical Physicist’s Summary Report and Data Recording and Analysis Forms and the MQSA Requirements for Equipment form are available in the accreditation section. The technologist’s forms are in a Word format and the medical physicist’s forms are in Excel. You must download the files as follows to your own computer (or disk) in order to use them:

1. From www.acr.org, right click on “ACCREDITATION”
2. Click on “Mammography”
3. Click on “Testing and QC Forms”
4. Select the form under “Radiologic Technologist’s Quality Control Forms”
5. On the pop-up menu, click “open” to print the form immediately, or “save” to designate where the file should be downloaded.

Q. Can all technologists contribute to performing QC?

A. Yes, but 1 technologist must be assigned the responsibilities of quality control. Other qualified individuals may perform specific QC tests but they must be reviewed and evaluated by the designated QC technologist. The designated QC technologist is responsible for ensuring that tasks are done properly by standardizing test methodology, reviewing all data, overseeing repeat testing before calling the medical physicist or service personnel, etc. (see page 121 of the manual).

Q. How long must we maintain our QC records?

A. FDA rules require that quality control records be “maintained until the next annual inspection that would verify compliance or until an individual test has been performed 2 additional times at the required frequency, whichever is longer. Verifying compliance implies that if QC records for a given test were found to be deficient and the facility was cited during an annual inspection, these records must be kept until the facility corrects the problem to FDA’s satisfaction. This also means that records for semiannual tests may have to be kept longer than the period between 2 successive annual inspections, and records for annual tests must include the most recent 2.” (See FDA’s Policy Guidance Help System.)

The FDA requirements for mammography QC test image retention are outlined in the following table:
<table>
<thead>
<tr>
<th>QC Images</th>
<th>Retention</th>
</tr>
</thead>
<tbody>
<tr>
<td>Daily QC</td>
<td>previous 30 days</td>
</tr>
<tr>
<td>Weekly QC</td>
<td>previous 12 weeks</td>
</tr>
<tr>
<td>Monthly QC</td>
<td>until the next annual inspection has been completed and FDA has determined that the facility is in compliance with the quality assurance requirements</td>
</tr>
<tr>
<td>Quarterly QC</td>
<td>until the next annual inspection has been completed and FDA has determined that the facility is in compliance with the quality assurance requirements</td>
</tr>
<tr>
<td>Semi-annual QC tests</td>
<td>until the next annual inspection has been completed and FDA has determined that the facility is in compliance with the quality assurance requirements or until the test has been performed 2 additional times at the required frequency, whichever is longer</td>
</tr>
<tr>
<td>Annual QC tests</td>
<td>not required by FDA; the ACR recommends that images documenting test failures be provided to the facility to assist them in making corrective actions</td>
</tr>
<tr>
<td>Mammography Equipment Evaluations</td>
<td>not required by FDA; the ACR recommends that images documenting test failures be provided to the facility to assist them in making corrective actions</td>
</tr>
</tbody>
</table>

Individual state laws may impose more stringent requirements for QC record retention. Facilities should check with their state for any requirements.

**Q. How should we cite the 1999 ACR Mammography Quality Control Manual in articles and books?**

**A.** Cite the manual as follows:


**The Accreditation Phantom**

**Q. Must the disc be placed in a specific location on the phantom for the weekly screen-film phantom QC and density difference measurement?**

**A.** In the 1999 ACR Mammography Quality Control Manual, the ACR recommends placing the disc *between and slightly below the first and second largest fibers*. However, any location is acceptable as long as it is in a consistent location in the image area so it will not obscure details in the phantom and where it cannot cast a shadow on any portion of the AEC detector. With current equipment, significant variability in film optical density can result from placing the disc along the central anode-cathode axis, where a varying fraction of the AEC detector area might be covered by the disc’s shadow, depending on the position of the detector. To ensure consistency, glue such as “SuperGlue” may be used to attach the disc permanently to the phantom as long as it does not produce artifacts.
Q. Do I have to compress the phantom to a 4.2 cm thickness? I really cannot do this without damaging my paddle.

A. No. The phantom represents a compressed breast thickness of 4.2 cm. Just lower the paddle so it just touches the phantom. See page 169 of the manual.

Q. How do I establish new operating levels for phantom controls? I can find reasons to establish new phantom operating levels in the ACR QC Manual but not how.

A. The FDA has an article on Establishing and/or Changing the Phantom Image Test Operating Levels on their website. Be sure to consult with your medical physicist regarding your specific situation.

Q. On pages 171 and 173 of the current mammography quality control manual, the mAs graph of the Phantom Control Chart indicates a permissible variance of ±15%. The y-axis of the graph indicates a variance of ±15 points, but no units are given. Is this intended to be ±15% of the baseline mAs or ±15 mAs?

A. The intent was to have the mAs remain as close to ±15% as possible but also to make this data as easy as possible for the QC tech to plot. Assuming that most mAs values obtained with the phantom will be around 100, the ±15% will be equal to ±15 mAs (85 mAs to 115 mAs). If the phantom's baseline mAs is 90, then ±15% becomes 76.5 mAs to 103.5 mAs. This is more difficult for the tech to plot without 10 divisions per grid. Using ±15 mAs (75 mAs to 105 mAs) in this case will be easier for the tech to plot and still provide reasonable control limits. With very low or high baseline mAs values, the upper and lower levels should be modified to be as close to ±15% as possible but still make it easy for the staff to plot.

Finally, the ±15% is not a MQSA or ACR requirement but is an ACR recommendation to help facilities determine possible causes for density changes on the phantom image.

Radiologic Technologist’s Tests

Q. I noticed in the Processor Quality Control Comments on the last page of our accreditation final report, that it states, “The ACR Subcommittee on Mammography Physics recommends that the processor quality control operating levels (“aims”) fall within the following ranges.” Ranges are then given for the MD, DD, and B+F. I have never seen this before: is this new?

A. No. The ACR Committee on Quality Assurance in Mammography established practices and standards for QC in screen-film mammography starting with the 1990 version of the original Mammography QC manual. Since then, it has been updated and revised several times to reflect improvements in mammographic technology and QC procedures.

It is necessary to establish operating levels and control limits when a QC program is started. The operating level is that level that is normally expected. Normally, if the control limits are reached or exceeded, the test is repeated immediately to confirm the problem. (See page 134 of the 1999 ACR Mammography QC Manual for more information.)

When establishing processor QC operating levels, as recommended in the 1999 ACR Mammography QC Manual, the MD step should be the step that has an average density closest to but not less than 1.20. The HD step should be the step that has an average density closest to 2.20, and the LD step should be the step that has an average density closest to but not less than 0.45. B+F is derived from the average of the densities from step 1 or any clear region or the unexposed area of the 5 strips used when establishing the processor QC.
When doing the daily processor QC, MQSA requires that the B+F density shall be within +0.03 of the established operating level, the MD shall be within ±0.15 of the established operating level, and the DD shall be within ±0.15 of the established operating level.

The information provided in our final report, under Section IV, which you are referring to reflects the above information. As indicated in this particular section, the ranges shown are recommendations for processor QC operating levels. Therefore, because the recommended range for B+F is ≤ 0.25, with a control limit of +0.03, the B+F could be 0.28; although that is on the high end of the control limit and should be investigated. As you may have already noticed, even though you find in the latest version of the QC manual that the MD should not be less than 1.20, with today's newer, faster mammography film, the MD can be much higher. The reason for this is that the background densities (mid-densities) of most mammograms (both phantom and patient) have been increasing over the years to take advantage of the higher contrast obtained at these densities.

Q. The processing chart no longer shows a daily temperature chart. The small temperature block at the bottom of the page is not large enough for daily recordings of temperature for 1 month. Is this an oversight or a change in policy?

A. The 1999 manual (like the 1994 manual) does not have a chart for daily plotting of temperature. The temperature only needs to be measured (and recorded) when establishing operating levels, when problems are suspected (if points show a trend or go out of limits), or at other critical times, (e.g., during “crossover”). Some film and chemistry manufacturers have included a temperature chart in their control charts. The facility is free to track temperature on a daily basis if staff feels it provides a benefit to operations.

Q. If we are re-establishing our quality control operating levels and are in the process of obtaining our 5-day averages, may we perform mammography?

A. Yes. We recommend that you continue to monitor and plot the data from your processor for those five days using your old chart to check for stability. At the end of the 5 days, determine the new operating levels and plot the values over the past five days on the new chart. Be sure to note in the remarks section why the operating levels were re-established.

Q. Do we have to send our sensitometer and densitometer out for preventive maintenance? If so, how often?

A. The ACR manual recommends that you follow the manufacturer instructions for preventative maintenance and calibration of these devices. See page 158.

Q. If our sensitometer is out for repairs, may we still use the processor to develop mammography films?

A. Yes. The FDA has approved an “alternative standard” that may be used for a period up to 2 weeks in this situation. Under the alternative standard, processor performance is considered satisfactory if:

- The optical density of the film at the center of an image of a standard FDA-accepted phantom is at least 1.20 when exposed under typical clinical conditions
- The optical density of the film at the center of the phantom image changes no more than ±0.20 from the established operating level
- The density difference between the background of the phantom and an added test object, used to assess image contrast, is measured and does not vary by more than ±0.05 from the established operating level
In addition:

- To evaluate base + fog, an additional measurement of density must be made, either of a shielded portion of the phantom image film or of an unexposed film. In accordance with 21 CFR 900.12(e)(1)(i), the base plus fog density must be within + 0.03 of the established operating level.

This alternative test must be conducted “each day clinical films are processed, but before processing of clinical films.” All results must be recorded and charted. If processor performance fails to meet any part of the alternative test, the problem must be corrected before processing is resumed.

Q. What if our densitometer is out for repairs? May I still perform mammography?

A. No. Without a densitometer, you cannot measure the optical densities or degree of blackening of film. The daily QC is required to be conducted prior to processing patient films. No alternative is currently available to verify processor performance without a densitometer. If your facility plans to use a loaner densitometer, reintroduce one into service after repair/calibration, or obtain a new densitometer, you should contact your medical physicist for assistance on how to proceed.

Q. Why, how, and when do you perform the crossover procedure?

A. The purpose of the crossover procedure is to “recalibrate” your control chart to reflect the slightly different sensitivity of the film emulsion of the new QC film compared with the old. (It’s analogous to weighing yourself on one bathroom scale that gives your true weight, and another one that reads high by 2 pounds…you would adjust the second scale down 2 pounds to read the correct value.) When your box of QC film is almost empty (at least 5 sheets left), the crossover procedure should be performed using film from both the old and new boxes. The control chart is then adjusted to compensate for the differences. This procedure should be performed on the same day. See page 161 of the 1999 manual for detailed instructions.

Q. Do I still need to do a crossover if the new batch of film has the same emulsion number as the old batch of film?

A. Yes. A crossover needs to be performed whenever a new box of film is opened. Even though the new and old batch of film have the same emulsion number, film aging and storage conditions can affect the sensitometric characteristics of the film.

Q. In our version of the 1999 ACR Mammography QC Manual, the processor QC chart is missing a line (9 instead of 10). Will corrected versions be mailed out to all facilities?

A. The ACR is aware of the processor chart error. Corrected forms are available and can be printed from our Web site.

Q. There is a mistake on Page 211 of the QC Manual. The performance criteria for fixer retention of the second paragraph reads “if the stain indicates that there is more than 0.05 μg/m² residual hypo in the film, the test should be repeated.” In the paragraph above, it states “0.05 g/m².” Which is correct?

A. It should say “0.05 g/m²” in both paragraphs.
Q. On page 205 of the Radiologic Technologist’s Section, there’s an example of a completed Mammography Report – Reject Analysis form. The numbers and percentages in the “Repeats” and “Rejects” columns appear to be reversed. (The number of repeats is larger than the number of rejects.) Is this an error?

A. Yes. The repeats should be the sum of items 1-11 (23) for a percentage of 1.9%; the rejects should be the sum of all the rows (1-14) for a percentage of 3.2%.

Q. The 1999 ACR Mammography Quality Control Manual and the FDA regulations state that “the maximum compression force for the initial power drive shall be between 111 newtons (25 pounds) and 2000 newtons (45 pounds).” Does this mean I should be using between 25 and 45 pounds when I compress the breast during mammography?

A. No. The regulations do not require that this amount of compression be used for each mammogram but rather that your mammography unit be capable of providing this maximum amount of compression force.

Medical Physicist’s Section

Q. On our mammography unit, the collimation on the anterior side of the film results in a much greater “white gap” than the -4% allowed by the ACR Performance Criteria. The equipment manufacturer’s service representatives say they cannot decrease the size of that white gap to meet the ACR criterion. What is the purpose of that criterion and is it a requirement?

A. On page 236 of the manual ACR is recommending that the field not be within -4% SID on the anterior side of the film. The purpose is to minimize the amount of unattenuated light that reaches the reader’s eyes that can cause a decrease in perceived contrast. However, it is a “recommendation” and not a “requirement” for accreditation. As an FDA-approved accrediting body, we can only require for accreditation what is required under MQSA.

Q. This question pertains to the “Deviation Between X-ray Field and Edges of the Image Receptor” part of the Collimation Assessment test. In the ACR/MQSA part of the action limit, the form sets the limit as ± (plus or minus) 2% of the SID. What is not made clear at this point is that the MQSA limit is + (plus) 2% and the ACR recommendation limit is - (minus) 2%. As stated, the implication is that the MQSA rule requires x-ray alignment to the film within ±2% of SID and this is not the case. Is this a mistake?

A. Yes. The ± sign under ACR/MQSA Action limit should be a plus (+) sign only. (Hopefully, readers will figure this out since the rest of the test says “If X-ray field exceeds image receptor...” It’s hard to “exceed” something with a “-” sign.) This has been corrected in the forms available on the Web site.

Q. I am having difficulty performing the artifact test on a mammography system using a film processor with a daylight loader. The 1999 ACR Mammography Quality Control Manual specifies that 2 exposed films must be processed orthogonally to each other in order to differentiate processor-caused artifacts from other causes. How do I do this with a daylight processing system?

A. Generally, you cannot. Daylight processing systems will only accept cassettes to unload in one direction. Furthermore, attempting to “trick” the system by loading an 18 x 24 cm film crosswise in a 24 x 30 cm cassette may result in error messages or jam the system. Remember, the purpose of this maneuver is to help you localize the source of the artifact. Fortunately, many processor-caused artifacts have characteristic appearances (e.g., roller marks, pi lines, runback, etc.). If you cannot readily identify the artifact based on its appearance, try sequentially removing (or changing) various components of the x-ray system (such as the filter, compression paddle, bucky, or cassette) to see if
the artifact goes away. If there are several mammography units at the facility, you can also check if the same artifacts appear on all the films. If they do, the processing system is most likely the cause. Finally, check with the daylight loader/processor manufacturer for any recommendations for this test that are specific to their unit.

Q. Is the wording about screen uniformity on page 308 of the 1999 ACR Mammography Quality Control Manual wrong? It reads that if the standard deviation of control cassette densities is less than 0.05, and the density range exceeds 0.3, then corrective action is needed. Are we then to assume that if the standard deviation of control cassette densities is greater than 0.05, but the density range exceeds 0.3, then corrective action is NOT needed? I think the action limit means to say that the standard deviation should be less than 0.05, and the density range should be less than 0.3. Is this correct? Should this say, “If the standard deviation of control cassette densities is greater than 0.05, or the density range exceeds 0.3, then corrective action is needed”?

A. Both the 1994 and the 1999 manuals are correct. This test is designed to evaluate the uniformity of the screens and cassettes. However, the procedure is only valid if the processing and x-ray generator remain constant. If the standard deviation of the control cassette densities exceeds 0.05, it means that there is another problem not associated with the cassettes. This variability should be evaluated and reduced before the cassettes are evaluated. (See page 247 under Data Analysis and Interpretation.) Corrective action on the cassettes should only be taken if the standard deviation of the control cassette does not exceed 0.05 and the optical density exceeds 0.03. In other words, don’t blame the cassettes if it’s an x-ray unit or processor problem.

Q. Our Siemens unit has 49 density settings, from -24 to +24 in steps of 1. If I test at the station -3, -2, -1, 0, etc., it would fail since neither the mAs nor the optical density increase by 12-15%, nor the optical density by 0.15, but a much smaller number. Siemens has recommended that I test at the stations -12, -8, -4, 0, +4, +8, +12 in order to get the above increments in mAs and optical density. Is it OK for me to jump up the density stations in steps of 4? The ACR manual specifies that the test be performed at each integer density setting.

A. The intent of the ACR recommendation was to ensure that there are fine enough steps in density control to make small adjustments to film optical density. The Siemens recommendation for testing is acceptable.

You should also note that the density control test you describe is not an MQSA requirement. It is ACR guidance and applies to most of the equipment that was in use at the time the QC manual was published. The ACR does not require that facilities meet our guidance/recommendations to pass accreditation. However, they must meet MQSA requirements/regulations.

Q. According to the 1999 manual, the luminance of viewboxes for mammography must be 3000 cd/m2 (nit). Is this a requirement or a recommendation?

A. This measurement or performance criterion is not required under the FDA’s Final Rules nor is it required for ACR accreditation. This test is recommended to ensure viewboxes have adequate luminance to view the high-density mammograms that are commonly recommended. See the Medical Physicist’s Mammography QC Test Summary and page 290 in the test section of the 1999 manual. Also note that, based on more recent data, the 3000 cd/m2 recommended in the 1999 manual has been reduced from the 3500 cd/m2 recommended in the 1994 manual.
Q. Although the text in step 6 on page 287 states “take the following illuminance measurements with the viewbox lights of the viewbox being evaluated turned OFF,” figure 13 on page 289 specifies that illuminance “measurements should be made with the viewbox lights ON.” Which is correct?

A. Figure 13 is in error. The caption should read, “measurements should be made with the viewbox lights OFF.”

Q. The ACR-recommended performance criterion for illumination levels in a reading room is 50 lux. This seems high. Is it correct?

A. On page 288 of the QC manual, it states “the illumination levels should be 50 lux, or preferably less.” Much more is known now about the importance of low ambient lighting than at the time the manual was written. Even though the authors could not specify a lower number at the time, they did indicate that they would prefer the illuminance to be less than 50 lux.