

The American College of Radiology Mammography Accreditation Program: Frequently Asked Questions

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Table of Contents

MQSA, FDA Regulations, and Inspections	2
ACR Mammography Accreditation	3
General	3
New Mammography Facilities	4
Moved Facilities and Units	5
New Units at an Accredited Facility	6
Equipment Evaluations	8
Renewals	9
Full Application and/or Accreditation Testing	9
Application – General	9
Personnel	10
Testing – Clinical	12
Testing – Phantom	15
Testing – QC Documentation	17
Accreditation and Certification	19
FFDM Quality Control – General	23
Monitors and Workstations	26
Data Compression	27
Digitizing Film Mammograms	28
Adverse Accreditation Decisions	28
Reapplying for Accreditation	28
Appealing an Adverse Accreditation Decision	30
Interim Accreditation and MQSA Certificate Extensions	31
Annual Updates	32
Validation Image Checks	32
Loaner and Demo Units	32
The 1999 ACR Mammography QC Manual	34
The ACR Digital Mammography Quality Control Manual	34

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MQSA, FDA Regulations, and Inspections

Q. How many MQSA-certified mammography facilities and units are there in the United States?

A. Current data on the number of MQSA-certified facilities and units, by modality (i.e., FFDM, DBT) may be obtained from the [FDA Web site](#).

Q. Where can I go for assistance or clarification of the FDA mammography regulations?

A. The best source of clarification or assistance regarding the FDA Quality Mammography Standards; Final Rule is the FDA. For policy questions, check the [FDA's Policy Guidance Help System](#). This guidance reflects FDA's current thinking on the final regulations implementing the Mammography Quality Standards Act (MQSA).

You may also call the FDA Facility Hotline at (800) 838-7715, fax question(s) to them at (410) 290-6351 or email them at MQSAhotline@hcmsllc.com

Q. A facility where I interpret mammograms did not have all of my qualification documentation (e.g., initial qualifications, continuing education, or continuing experience) on location during their MQSA inspection. Will this facility be issued a notification of non-compliance for their personnel not meeting MQSA qualifications, and must I stop interpreting mammograms?

A. The answer depends on the circumstance of the MQSA inspection. If you met all initial and continuing MQSA requirements for interpreting physicians (including having taught or completed 15 Category 1 CME in mammography in the previous 36 months and having interpreted or multi-read at least 960 mammographic examinations during the previous 24 months) but the documentation was not present at the time of the facility's MQSA inspection, this may be no more than a paperwork issue.

The FDA recommends that MQSA inspectors give facilities 5 days to provide this documentation; however, inspectors are allowed to use their own discretion in providing this option. Several states have instructed their inspectors to cite facilities if the records are not available at the time of the inspection.) Even if the inspector does give the facility time to get the records, FDA still requires the inspector to give the facility a minor citation (Level 3) for failing to have the records on hand at the time of the inspection. MQSA inspectors must notify facilities at least 5 days in advance of the annual MQSA inspection. It is prudent to use this advance notice to make sure all documents are available in order to avoid the added costs and time spent trying to resolve this citation once it has been issued.

If you do not meet the MQSA requirement for continuing education or continuing experience, **this is not a paperwork issue** and, **you will need to reestablish your qualifications before resuming independent interpretation** at this facility. (Note that if your qualifications and documentation were in order at other facilities that were inspected earlier the same year, you may continue to interpret at those facilities.)The [FDA website](#) has guidance on "Reestablishing the Interpreting Physician Continuing Education Requirements" and/or "Reestablishing the Interpreting Physician Continuing Experience Requirement."

The FDA has written the following useful guide to let facilities know how to get ready for an MQSA inspection: [The Mammography Quality Standards Act Final Regulations: Preparing for MQSA Inspections; Final Guidance for Industry and FDA](#).

Q. Is a radiologist required to be onsite when performing a diagnostic mammogram?

A. No. There is no regulation that requires a radiologist to be present during diagnostic mammography. However, the [ACR Practice Guideline for the Performance of Screening and Diagnostic Mammography](#) recommends that diagnostic mammograms be performed under direct supervision. Direct supervision is defined as the physician being present and immediately available to furnish assistance and direction throughout the performance of the procedure. Direct supervision may also be accomplished via tele mammography as long as the interpreting physician is immediately available. The ACR guidelines are not requirements but are designed as an educational tool to assist practitioners in providing appropriate radiologic care for patients. They are not inflexible rules or requirements of practice and are not intended, nor should they be used, to establish a legal standard of care.

Q. I just had my MQSA inspection. My inspector informed me that I needed to update our Consumer Complaint Policy to provide a timeframe for reporting complaints to the ACR. Does the ACR have a time limit in which we have to report complaints to the ACR?

A. No. The ACR does not specify a timeframe for facility's to report unresolved serious consumer complaints because we realize that every complaint is different. The amount of time facility staff will need to spend resolving a complaint varies considerably; however, facilities should report unresolved serious consumer complaints to the ACR **as soon as possible**. See the [Mammography Accreditation Program Requirements](#) for ACR's consumer complaint policy.

ACR Mammography Accreditation

General

Q. How many mammography facilities and units are accredited by the ACR?

A. You can view or download a list of ACR Accredited facilities using the Accredited Facility Search function of the new ACR Accreditation website, found here: www.acraccreditation.org.

Q. I have questions about my facility's accreditation. Where can I go for help?

A. Visit www.acraccreditation.org today! With just a click of the mouse you have 24/7, user-friendly access to the complete array of the ACR's highly respected accreditation programs, from easy-to-use applications, testing and quality control forms for each modality, to a list of the most frequently asked questions. If our on-line information does not address your specific question, please call the Breast Imaging Accreditation Programs at (800) 227-6440. Our phone lines are open business days from 8:30 AM – 5PM eastern time.

Q. Is Mammography Accreditation available through the ACR's online application?

A. Yes, the online system, ACredit became available July 29, 2013. It is available at <https://acredit.acr.org/>.

Q. I consult with a mammography facility that just failed accreditation. I would like to obtain details on why they failed accreditation so that I may assist them in their next application. May I obtain that information directly from the ACR?

A. No. The ACR cannot discuss facility-specific information with individuals outside the facility. In our accreditation information to the facility we state that all facility accreditation information is "privileged and confidential under the Code of Virginia 8.01-581.17" regulations. The ACR is legally bound to respect this and must not discuss facility accreditation issues with outside individuals. However, in

unique cases, a facility may wish an outside entity (such as an attorney or consultant) to communicate with the ACR on behalf of the facility. In these cases, the ACR will ask the facility's lead interpreting physician to send a letter formally requesting this. However, it is critical in all cases that the facility's staff receives direct communication from the ACR on all accreditation issues since they have the ultimate responsibility for meeting ACR requirements.

Q. The application asks for our facility's EIN number. What is it, and where do I find it?

A. An Employer Identification Number (EIN, also known as "Federal Tax ID Number") is a 9-digit number that the IRS assigns in the following format: 12-3456789. The IRS uses the number to identify taxpayers who are required to file various business tax returns. You must also use your EIN when filing a CMS (Medicare) claim. EINs are used by employers, sole proprietors, corporations, partnerships, nonprofit organizations, trusts, estates of decedents, government agencies, certain individuals, and other business entities. You should ask your business office for your facility's EIN number.

New Mammography Facilities

Q. When should I notify the ACR that we are opening a new facility?

A. You must access the ACR online accreditation system, [ACRedit](#), and start an application at least **two weeks** before you expect to start performing mammography. If your facility has an existing online accreditation account, you may log in, and create your new mammography facility. If you have never logged into the ACRedit database for other modalities, click "Register" to create a new account. This will give you time to download the [additional application materials](#) that must be completed prior to submission. If you need assistance call us at (800) 227-6440.

Q. When can my new facility start performing mammography?

A. A new mammography facility may perform mammography on patients **only after receiving a valid provisional MQSA certificate**. The FDA (or state certifying body) will send you a 6-month provisional MQSA certificate within two business days of receiving the ACR notification. Expect to wait **four business days from the time you submit all required documentation to the ACR and when you receive the provisional MQSA certificate**.

When scheduling your medical physicist's Equipment Evaluation for your new unit, be sure to allow enough time for any possible corrective action and the accreditation application process described above. The ACR typically recommends scheduling an Equipment Evaluation **at least one week** prior to performing mammography on patients. You cannot use the unit to examine patients even during "applications" training until you meet the above conditions.

Finally, you should contact your state radiation control agency to determine if they have their own special requirements for operating new equipment that you must meet.

Q. How can I obtain a provisional MQSA certificate?

- A. Submit to the ACR:
- A completed online New Facility Application
 - A Survey Agreement signed and dated by your Lead Interpreting Physician and president/CEO
 - An MQSA Information Release Authorization signed by your Lead Interpreting Physician
 - The results of your Equipment Evaluation (showing all required tests have passed) signed and dated by your medical physicist
 - The appropriate application fee

The ACR will review your application and Equipment Evaluation and, **if complete**, transmit the information on your new facility to the FDA within two business days. The FDA (or state certifying body) will send your facility a 6-month provisional MQSA certificate within two business days of receiving the ACR notification. Expect to wait a total of four business days from the time you submit all required documentation to the ACR until you receive the provisional MQSA certificate. **You may not legally perform mammography without this certificate.**

Q. We are opening a new site and will be accrediting with the ACR. How and when will I receive a Mammography Quality Control Manual?

A. The ACR will email a new facility applying for accreditation a link to download the *ACR Digital Mammography Quality Control Manual* after a complete new Facility Application and fee are received and processed. If you would like to start setting up your QC program before you receive the manual, all of the [QC forms](#) in the manual are available on the [ACR Web site](#).

Q. We are opening a new site and will be accrediting with our state accrediting body. Will ACR send me a Mammography Quality Control Manual?

A. No. You may purchase the manual from the ACR. Visit the [ACR Web Store](#) for more information.

Q. My facility is getting a new mobile mammography unit. Does the unit have to have its own MAP ID number?

A. Possibly. The new mobile unit can be added to an already accredited and certified mobile or fixed facility as long as the owner and the Lead Interpreting Physician are the same for both. However, if the owner and/or Lead Interpreting Physician are different, the new mobile unit must apply as a separate facility and obtain unique MAP ID and FDA ID numbers. See “Special Situations” in the [Mammography Accreditation Program Requirements](#) for more information.

Q. We are a facility that is located at two different sites. One of our sites does screening, the other diagnostic imaging. We presently have two ID numbers. Can we consolidate our separate sites under a single accreditation?

A. No. They may not be combined under one accreditation. Because of their separate physical locations and addresses, these two facilities must have their own MAP ID numbers. Mammography equipment physically located at different addresses must be accredited and certified as though they belong to separate facilities even though ownership and/or staffing may be the same.

Moved Facilities and Units

Q. We will stop performing mammography at our current location and move to a new building at a different address. We will remain under the same ownership, keep the same personnel, and the same equipment. Can we keep our accreditation status when we move?

A. Yes. However, in order to maintain accreditation you must notify the ACR **prior** to moving your facility to a new address. You will use the [online accreditation system](#) to update the facility information. Click on “My Modalities” then “Modality Details” and click the “Change” button next to the facility location address. You are required to submit the completed application and the Equipment Evaluation report conducted by the medical physicist on the relocated mammography unit(s) **after** the move. These completed materials will let the ACR know if your units still meet all MQSA requirements after the move, and allow both the ACR and the FDA to ensure that essential, time-dependent accreditation and certification notices reach your new location.

Q. We will be moving one of our accredited mammography units from an existing site to a new facility we are opening at a different address. (The old site will remain open.) Since the

new mammography facility is under the same ownership and uses the same radiologists and technologists, do we need our own MQSA certificate prior to examining patients?

A. Yes. Your new facility must be certified separately from the old one. A unit's accreditation does not transfer to a new facility. Furthermore, an MQSA certificate cannot be used to cover two separate physical locations—even temporarily. In order to operate legally, your medical physicist must first perform an **Equipment Evaluation** that indicates compliance with all MQSA requirements. Second, you must apply for mammography accreditation of this new facility. Upon acceptance of your **complete** application, the ACR will notify your certifying body (either the FDA or the state) that you have begun the process of accreditation. **You may not perform mammography until you receive a 6-month provisional MQSA certificate or an interim notice from your certifying body.**

Q. We will be moving our mammography unit to another existing, certified site affiliated with our facility. Do we have to inform the ACR?

A. Yes. Since this moved unit would be “new” to an existing, separately accredited and certified facility it is considered a “new” unit and must undergo appropriate testing. You will use the [online accreditation system](#) to add the new unit to the other existing certified site, click on “My Modalities: then “Units/Modules” and “Add New Unit”. You may use the unit after your medical physicist has performed an **Equipment Evaluation** that indicates compliance with all MQSA requirements **and** you have submitted the appropriate application materials to the ACR. If you need assistance call us at (800) 227-6440.

Q. Our facility is remodeling, and we are moving our accredited mammography unit to another room in the same building. What are the ACR requirements regarding post-move accreditation or QC?

A. Since your unit is not moving to another address or facility, you do **not** need to notify the ACR or submit accreditation testing. If your unit is disassembled and reassembled as part of this move, the FDA requires your medical physicist to conduct an Equipment Evaluation to ensure that the unit works properly. If the move consists of rolling the unit into a different room (with no disassembly and reassembly), an Equipment Evaluation may not be necessary. You should consult with your medical physicist. In either case, the FDA requires you to perform a phantom image quality test before use on patients per their guidance, “[Mobile Units Equipment Quality Control](#)”.

New Units at an Accredited Facility

Q. What does the ACR consider to be a “new” unit?

A. For accreditation purposes, a “new” unit is any mammography unit that is new to the facility. This includes previously owned units, previously accredited units moved from one site to another, and new units replacing previously accredited units.

Q. When can my facility start using a new unit to examine patients?

A. A facility with a current MQSA certificate may begin examining patients with a new unit **only after:**

- The medical physicist has provided the facility with the written results of his or her Equipment Evaluation showing that all required tests have passed, **and**
- The facility has submitted the complete new unit application (with the Equipment Evaluation results) to the ACR. You must access the ACR [online accreditation system](#), to start the process, click on “My Modalities: then “Units/Modules” and “Add New Unit”. Please call the Mammography Accreditation Program at (800) 227-6440, if you need assistance.

Once approved, the ACR will notify the FDA (or the state certifying body) within two business days that an accreditation application has been accepted for the new unit. These facilities are **not required to wait for a response** from the ACR to begin clinical use of the new unit since they are operating with a current MQSA certificate.

For facilities applying for accreditation on their first FFDM or DBT system, the Center for Medicare and Medicaid Services (CMS) **will not reimburse** for examinations performed that new modality **unit until the FDA has received notification** that your new unit has applied for accreditation. In order to ensure appropriate reimbursement, we recommend that MQSA-certified facilities do the following before using their new FFDM (DBT) unit to examine patients:

- Submit the online accreditation application,
- **Fax** the application materials with the Equipment Evaluation results to the ACR at (703) 648-9176,
- After three business days, **log** into ACRedit, go to the My Application tab, and confirm that the ACR has accepted your new unit application, and
- **Do not** submit your mammography claims for 14 days (as recommended by CMS) to ensure that your local payer has the most current MQSA file.

When scheduling the medical physicist's Equipment Evaluation for your new unit be sure to allow enough time for any possible corrective action and the accreditation application process described above. The ACR typically recommends scheduling an Equipment Evaluation **at least one week** prior to performing mammography on patients. You cannot use the unit to examine patients even during "applications" training until you meet the above conditions.

Finally, you should **contact your state radiation control agency** to determine if they have their own special requirements for operating new equipment that you must meet.

Q. What accreditation testing is required when a facility purchases a new (or previously owned) unit?

A. If your facility has **over 13 months** left on its current accreditation when the new unit is installed, ACR staff will advise you of two options:

1. **New Unit Addendum** – This option primarily applies to a facility with other fully accredited units. The facility pays a **reduced fee** and only the new unit goes through accreditation testing. Once accreditation is approved for the new unit, **its expiration date will be the same as the expiration dates for the other units at the facility (less than three years)**.
2. **New Unit Reinstatement** – This option primarily applies to a facility with only one unit. The facility voluntarily surrenders its current MQSA certificate and submits a reinstatement application at the **full fee**. The facility will immediately obtain a 6-month provisional MQSA certificate that provides them with adequate time to complete the accreditation process. Once approved, **the facility will receive a full 3-year accreditation from the date of approval**. (If the facility has multiple accredited units, these units must be withdrawn and apply for accreditation at the same time as the new unit.)

If the facility has **less than 13 months** left on its accreditation when the new unit is installed, the ACR will instruct the facility to begin **early renewal** on all units at the usual renewal fee. Facilities should contact the ACR for the appropriate instructions and applications prior to installation of any new units. Once accreditation is approved, all units at the facility will have an expiration date that is three years from the old expiration date.

Once you have decided the option that works best for your facility, go to the ACR [online accreditation system](#), click on "My Modalities: then "Units/Modules" and "Add New Unit". If you need assistance call us at (800) 227-6440.

Equipment Evaluations

Q. What is a Mammography Equipment Evaluation?

A. FDA regulations requires the facility to have a **medical physicist** perform a Mammography Equipment Evaluation **when a new unit or processor is installed**, a unit or processor is disassembled and reassembled in the same or a new location, or major components of a mammography unit or processor equipment are changed or repaired. This Equipment Evaluation must determine whether the new or changed equipment meets the **applicable MQSA requirements for mammography equipment** [section 900.12(b) of the FDA regulations] **in addition to the applicable quality assurance requirements** for equipment listed in section 900.12(e). **All problems must be corrected before the new or changed equipment is put into service for examinations or film processing and before the facility may apply for accreditation of a new mammography unit.** All new mammography facilities and all ACR-accredited facilities installing new mammography units must submit a copy of their medical physicist's Equipment Evaluation results with their initial accreditation application and fee to the ACR **before the units may be used to examine patients.**

Q. How should the medical physicist summarize the results of the Equipment Evaluation?

A. In order to expedite the application review process for a new unit, the ACR requires the facility to submit only the following ACR forms, completed by the medical physicist:

1. [MQSA Requirements for Mammography Equipment](#). The medical physicist should complete all applicable sections of the checklist, indicating "Not Applicable" where appropriate. If "Not Applicable" is marked, a reason should be provided.
2. [Medical Physicist's Mammography QC Test Summary](#). Because an Equipment Evaluation is performed before a mammography unit is used clinically, a medical physicist is **not required to complete the "Evaluation of Site's Technologist QC Program" section** of the form at this time. Your medical physicist will need to evaluate your facility's QC program and complete this section of the QC Test Summary as part of the new unit's Annual Survey report submitted to the ACR with the full application and/or testing materials.

These ACR forms can be downloaded from the [ACR Web site](#). **It is important to note that summaries submitted in different formats (or summaries from manufacturer QC manuals) will delay the ACR's review even if they contain all of the required information.**

The medical physicist should provide these summaries to the facility **as soon as possible** for inclusion with your application to the ACR. (Handwritten or faxed summaries are acceptable.) You do not need to submit the entire Equipment Evaluation report at this time, only the summaries described above. **Also, be sure that all requirements pass before submitting the application.**

Q. Must my medical physicist leave a copy of his or her Equipment Evaluation results before he or she leaves my facility after the survey?

A. No. Although some medical physicists may be able to provide you with written, preliminary Equipment Evaluation results before leaving your facility, others may need to take the raw test data and images back to their office for analysis. In this case, your medical physicist must provide you with the written pass/fail Equipment Evaluation summary as soon as possible so that you can include it with your application to the ACR. The medical physicist may fax or e-mail this summary to you.

If this is a new unit at an existing MQSA-certified facility, you may **not** start using the unit until you have received written Equipment Evaluation results from the medical physicist showing that all items have passed **and** you have sent the Equipment Evaluation results to the ACR with all required application materials. You may **not** start using the equipment to examine patients based on a verbal indication from the medical physicist that all items passed.

Q. Who reviews the Equipment Evaluations and what is evaluated?

A. ACR staff who are experienced mammography technologists with advanced registries in mammography review the medical physicist's pass/fail Equipment Evaluation summary. They check to verify that the Equipment Evaluation was performed no earlier than 6 months before the date of application, that the medical physicist has evaluated each applicable FDA-required item, and that each item has passed. If the medical physicist fails an item, ACR staff will check that the facility has provided appropriate documentation of corrective action (e.g., the medical physicist's re-evaluation, a service ticket, etc.). If the required item was not evaluated by the medical physicist or if the item failed and no corrective action was provided, ACR staff will call and/or contact the facility in writing for the missing information. ***The application will not be processed until all information is complete.***

Q. Am I required to notify the ACR if we replace the x-ray tube in our mammography unit?

A. No. However, you must have your medical physicist conduct a Mammography Equipment Evaluation (and all applicable tests must pass) before you may use the mammography unit to examine patients.

Q. We recently installed a new processor. Is an Equipment Evaluation by our medical physicist necessary before we start using the unit for mammography?

A. Yes. This is required under the FDA's Final Rules. See [FDA's Policy Guidance Help System](#) for specific guidance on appropriate tests.

Renewals

Q. Our facility is currently accredited by the ACR. How will we be notified that it is time to renew? When will this occur?

A. In order to provide timely service, the ACR will notify you by email when it is time to renew your accreditation. It is important that your facility activate its online accreditation account to receive these email notifications. Once this is completed the ACR will email your facility's contact and Lead Interpreting Physician renewal notification approximately 8 months prior to your ACR accreditation certificate expiration. If you do not hear from us, please call our office so we may follow up on this for you.

Q. Do we have 6 months to return the renewal application to the ACR?

A. No. To ensure that there is adequate time to process your application and evaluate images before your MQSA certificate expires, you must submit your completed Renewal Application and fee within 60 days. Facilities should allow at least 6 months for the reaccreditation process to be completed. For this reason, the ACR notifies each facility 8 months before their accreditation expires that it is time to Renew. ***You may not legally perform mammography if your FDA certificate expires.***

Full Application and/or Accreditation Testing

Application – General

Q. I just received my testing packet from the ACR and it appears to be missing the full application and testing instructions. Can you help?

A. Yes. Your facility will not fill out most of the testing packet that you use to receive in a paper format online, in ACredit. Log into the ACredit, click "My Testing Package", click "Modify", and follow the prompts to complete the application.

Q. How long do I have to submit the full application and testing materials to the ACR?

A. You have 45 calendar days from the date the testing materials are sent to submit the completed application and testing materials to the ACR. If you are having a problem meeting this deadline, you should contact the Mammography Accreditation Program Information Line at (800) 227-6440 for assistance.

Please note that your submission contains HIPAA data, so we strongly recommend that you send your submission via a traceable method with a signature required for delivery.

Q. Our facility's accreditation will expire in 6 months. Since receiving our testing package for renewal, we do not think that we will be able to make the 45-day deadline for submitting the completed application and testing materials. Can we get an extension?

A. No. If you cannot meet the 45-day time limit, the ACR cannot guarantee completion of the accreditation process (this includes reviewing all submitted testing and application materials as well as issuing a final report) before your MQSA certificate expires. Consequently, the ACR does not grant extensions to the 45-day time limit. We recommend that you keep the ACR informed of the reasons for the delay and submit your completed materials as soon as possible.

Q. We submitted our testing material three weeks ago. When are we going to receive the results?

A. The accreditation review process takes approximately 60 days. You should receive your results soon after that.

Q. Why can't the ACR give facility results over the phone or by fax?

A. FDA requires accrediting bodies to report the results of the accreditation process to facilities in writing. Further, the ACR's Mammography Accreditation Program is a peer-review process; the information we receive is considered privileged and confidential. This includes information received or developed during the accreditation process.

Q. Will the ACR report our facility's results to anyone else?

A. The ACR will provide this information to your certifying body (either the FDA or the state) only as is required by MQSA.

Q. Will the ACR accept faxed signatures for the application and/or verification of mammography personnel qualifications?

A. Yes, the ACR does accept faxed signatures. These will be considered legally binding.

Q. Will the ACR accept electronic or digital signatures for accreditation applications, medical physicist's reports, and/or verification of mammography personnel qualifications?

A. Yes, the ACR accepts electronic or digital signatures. These will be considered legally binding.

Personnel

Q. Our Lead Interpreting Physician/Supervising Radiologist just left. Do we need to designate a new one?

A. Yes. FDA regulations require each facility to "identify a Lead Interpreting Physician who shall have the general responsibility of ensuring that the quality assurance program meets all requirements."

Q. We are changing our Lead Interpreting Physician/Supervising Radiologist. Do I need to report this to the ACR?

A. Yes. Your new Lead Interpreting Physician/Supervising Radiologist must complete several forms so that we know that he or she is aware of his or her responsibilities as a Lead Interpreting Physician/Supervising Radiologist. You may update the Lead Interpreting physician in ACredit and print the necessary forms from the application. Once completed, please mail or fax them to the ACR. (The address and fax number are on the form.)

You may contact the ACR Mammography Accreditation Program Information Line at (800) 227-6440 for more assistance.

Q. We have hired several new radiologists, technologists, and a medical physicist. Several have also left our facility. (However, our Lead Interpreting Physician/Supervising Radiologist has not changed.) Do we need to report the change in personnel to the ACR?

A. No. The ACR needs only to be notified when your Lead Interpreting Physician/Supervising Radiologist changes. Other personnel changes (i.e. radiologists, technologists, medical physicists) should be reported when your facility renews its accreditation. However, you should be aware that the FDA or state MQSA inspector will verify the qualifications of your new personnel during your next inspection.

Q. Our current radiology group is leaving at the end of this month. We have a new group starting next month. What steps do I need to take for this transition?

A. It is important that accredited facilities notify us when they designate a new Lead Interpreting Physician/Supervising Radiologist.

You may update the Lead Interpreting physician in ACredit and print the necessary forms from the application. Once completed, please submit them to the ACR.

Q. I am a medical physicist who, by contract, is able to work at only one facility with a single mammography unit. Is it still possible to meet the FDA requirement for Medical Physicist Continuing Experience of surveying at least two mammography facilities and a total of 6 units during 24 months?

A. Yes. The FDA allows medical physicists to count surveys of the same facility and the same mammography unit more than once per year provided that the facility surveys are at least 10 months apart and the unit surveys are at least 60 days apart. See [FDA's Policy Guidance Help System](#) for specific guidance on this topic: FDA's Policy Guidance Help System. For example, you may meet the FDA requirement for continuing experience by surveying your unit three times a year (once every four months). You will then have 6 surveys in two years and meet the requirements. Keep in mind that each year at least one of the surveys must be a full **facility survey** (i.e., it must include an evaluation of the technologist's QC).

Q. Can a facility remain ACR accredited if any of the technologists performing mammography are not certified by the ARRT for passing the advanced registry in mammography (e.g., ARRT(M))?

A. The ACR follows MQSA's Final Regulations. MQSA does **not** require a registered technologist to hold the ARRT's Advanced Registry in Mammography. As long as a licensed or certified technologist becomes and remains **qualified** he/she may perform mammography independently. Please review the guidance regarding "Radiologic Technologist Overview" in the [FDA's Policy Guidance Help System](#).

Q. After submitting our application for renewal of our accreditation, we received notification from the ACR that one of our radiologists does not have enough continuing experience. We will not be able to pass accreditation without correcting this deficiency first. What does that mean, and how do we do that?

A. In order to be accredited by the ACR, **all** mammography personnel at your facility must meet FDA requirements for continuing education and continuing experience (as well as initial requirements). If personnel do not meet these requirements, they must **requalify**. See [FDA's Policy Guidance Help System](#) for their detailed instructions on **re-establishing** qualifications.

Q. May I count time spent presenting courses/lectures and/or reading/writing articles/papers towards the continuing education requirements?

A. Personnel may possibly receive continuing education credit for presenting courses/lectures and/or reading/writing articles/papers for journals. These credits must be from organizations who can assess and document the appropriate amount and type of continuing education awarded for the individual article/paper or course/lecture and are authorized to award such credit. Personnel should get a letter or other documentation from the authorized organization stating how many and what type of continuing education credits are awarded and the date the credit was given.

Faculty may claim credit for teaching in programs designated for AMA PRA Category 1 Credit by applying directly to the AMA. Two AMA PRA Category 1 Credits™ are awarded for every hour of interaction, up to 10 credits per year. The application is available at www.ama-assn.org/go/cme in the Physician Applications section. You will need to download, complete and submit the Direct Credit Application to the AMA for credit.

Additional information on obtaining continuing education credit for these activities is also available for medical physicists from CAMPEP at <http://www.campep.org/Criteria.asp> and for technologists from ASRT at <https://www.asrt.org/main/continuing-education>.

Testing – Clinical

Q. May I submit digital breast tomosynthesis (DBT) clinical images for FFDM or DBT accreditation?

A. No, and in fact we don't accept them. See the following table for the clinical image submission requirements for both FFDM and DBT accreditation.

ACR Accreditation Clinical Testing for Digital Breast Tomosynthesis (DBT)

Scenario 1. DBT - 2D Synthesized Images Available (whether or not 2D-Syn is used for interpretation)

Testing to be Submitted by Facility		
Type	2D FFDM Accreditation	DBT Accreditation
Clinical Testing (a clinical set = cc and mlo of 1 fatty and 1 dense case)	Whatever is primarily used clinically: 2D clinical set (cc and mlo), or 2D-Syn clinical set (cc and mlo), or 2D cc and 2D-Syn mlo clinical set, or 2D-Syn cc and 2D mlo clinical set	2D-Syn clinical set (cc and mlo), or 2D cc and 2D-Syn mlo clinical set, or 2D-Syn cc and 2D mlo clinical set

Scenario 2. DBT - 2D Synthesized Images Not Available on System

Testing to be Submitted by Facility		
Type	2D FFDM Accreditation	DBT Accreditation
Clinical Testing (a clinical set = cc and mlo of 1 fatty and 1 dense case)	2D clinical set	2D clinical set

Q. I am applying for accreditation for my FFDM unit that also has the capability to perform DBT. May I submit the same set of clinical images for the FFDM unit and the DBT unit?

A. Yes. The ACR recommends that you send different patients. However, you may submit the same fatty examination for both the FFDM and DBT testing, and the same dense examination for both the FFDM and DBT testing.

Q. The ACR testing instructions say we must submit clinical images for accreditation review that were interpreted as “negative” (BI-RADS® Assessment Category 1). May we submit “benign” images (BI-RADS® Assessment Category 2) or “incomplete” (BI-RADS® Assessment Category 0) cases?

A. Generally, no. The ACR requests **“negative”** images (**BI-RADS® Assessment Category 1**: “There is nothing to comment on. The breasts are symmetrical and no masses, architectural disturbances or suspicious calcifications are present.”) **Do not submit “benign” cases (BI-RADS® Assessment Category 2) or “incomplete” cases (BI-RADS® Assessment Category 0).** If an ACR reviewer finds an abnormality, this will delay the facility’s accreditation. FDA requires the accrediting body to return the images to the facility and the ACR requires the facility to follow up as appropriate before the ACR will issue a final report. Occasionally, low-workload facilities may not be able to find “negative” fatty and dense cases for submission during the given time. These facilities should call the ACR for assistance. **With prior permission**, these facilities may submit “benign” cases (BI-RADS® Assessment Category 2) along with the interpreting physician’s report for evaluation.

Q. Can my facility submit images that have benign calcifications or known benign lymph nodules? What about those patients who have had biopsies or known surgeries?

A. In general, no. Images submitted for accreditation review should be assessed as **“negative”** (BI-RADS® Category 1). The ACR clinical reviewers are radiologists who are currently working in mammography. They review these images as if they had no patient history. They do not have old images or patient history information for a complete assessment. If images are submitted and a possible abnormality is seen, the ACR must follow up with the facility. This could delay the facility’s accreditation. However, facilities may contact the ACR for assistance if they are unable to find BI-RADS® Category 1 images to submit for accreditation.

Q. Our facility performs only diagnostic mammography and does no screening mammography. We will not be able to submit “negative” cases (BI-RADS® Assessment Category 1) for accreditation review. What should we do?

A. Call the ACR for assistance. **With prior permission**, you may submit other cases along with the interpreting physician’s report for evaluation.

Q. Our facility provides mammography only to nursing home patients. Because our patients primarily have fatty breasts, it is impossible for us to find a case with dense breasts to submit for accreditation review. What should we do?

A. Call the ACR for assistance. **With prior permission**, you may submit other cases.

Q. May we use a model or a volunteer to obtain clinical images to submit for accreditation?

A. No. Any image submitted for accreditation review must be of a patient who needed a mammogram, typically for screening reasons. As with any mammogram, the interpreting physician must have sent a report to the patient's referring physician and a lay letter to the patient.

Q. Is there any age limit for patients whose images are submitted for accreditation review?

A. No, but keep in mind that these images must be from patients who **need the mammogram** and generally must be interpreted as "negative" (i.e. BI-RADS[®] Assessment Category 1). These will most likely be from women undergoing screening. The [ACR Practice Guideline for the Performance of Screening and Diagnostic Mammography](#) states that screening mammography is indicated for asymptomatic women 40 years of age or older.

Q. May we send clinical images with a mole or nipple marker to the ACR for accreditation review?

A. Yes, as long as the mole or nipple is clearly marked in a conventional manner.

Q. May I submit clinical images of male patients for accreditation review?

A. No. The ACR needs to evaluate images from patients that are **typically** examined by your facility. The vast majority of mammography examinations are of women. Consequently, the ACR will only accept images of women for accreditation review.

Q. After submitting our accreditation testing material, our Lead Interpreting Physician/Supervising Radiologist was notified by the ACR that an abnormality was found on a set of images. Do we need to send another set of images to replace the ones that were returned to us?

A. No. When your Lead Interpreting Physician/Supervising Radiologist is notified of an abnormality the ACR reviewers have finished reviewing the images. Therefore, replacement images are not needed. Only the Abnormality Follow-Up Attestation must be returned once your Lead Interpreting Physician/Supervising Radiologist reads and signs it.

However, any decision on your facility's accreditation, including the final report, will be withheld pending receipt of the attestation that appropriate action will be taken. Failure to comply could result in a failure or deficiency for non-compliance. Furthermore, the ACR will randomly review facilities for compliance with this policy. We strongly suggest that all case review and any patient follow-up be documented.

Q. When submitting our clinical images for accreditation, may we remove the patient name and any identifying information for privacy purposes? I believe that the Health Insurance Portability and Accountability Act (HIPAA) prohibits sharing this information with outside entities.

A. No. Sections 164.512(b) and (d) of the HIPAA regulations issued by the Department of Health and Human Services (DHHS) (45CFR) allow a mammography facility to release patient information to an MQSA inspector without patient authorization because MQSA inspectors are performing health oversight activities required by law. Because the law requires that each mammography unit be accredited, releasing patient information to the accrediting body is considered part of the health oversight activity. Additional information regarding HIPAA requirements can be found on the DHHS Website at www.hhs.gov/ocr/hipaa/.

FDA requires the ACR to assess the following 8 clinical image attributes: **positioning, compression, exposure level, contrast, sharpness, noise, artifacts, and exam identification**. The mammogram must have a permanent ID label containing at least: **the facility name, city, state, zip code, the patient's first and last name, an additional patient identification number, and the date of the examination**. Consequently, the ACR requires facilities to include patient identifying information on images submitted for accreditation review.

Q. Are there any guidelines on an acceptable number of artifacts allowed on clinical images submitted for accreditation?

A. No. The ACR realizes that not all artifacts can be eliminated (for example, it is rare to see a screen-film image with no dust artifacts); however, artifacts should not be so numerous or severe that they significantly degrade image quality. The Lead Interpreting Physician/Supervising Radiologist should review and approve all images submitted for accreditation.

Testing – Phantom

Q. May I submit a 2D synthesized phantom image for the accreditation of my FFDM unit?

A. No. For FFDM accreditation the facility must submit **one** 2D phantom acquired image.

Q. May I submit the 2D acquired phantom image for the accreditation of my DBT system?

A. No. For DBT accreditation the facility must submit **one** image that best demonstrates all the test objects (“best-slice” image). See the following table for the phantom image submission requirements.

ACR Accreditation Phantom Testing for Digital Breast Tomosynthesis (DBT)

Scenario 1. DBT - 2D Synthesized Images Available (whether or not 2D-Syn is used for interpretation)

Testing to be Submitted by Facility		
Type	2D FFDM Accreditation	DBT Accreditation
Phantom Testing	2D phantom image	3D best-slice phantom image*

Scenario 2. DBT - 2D Synthesized Images Not Available on System

Testing to be Submitted by Facility		
Type	2D FFDM Accreditation	DBT Accreditation
Phantom Testing	2D phantom image	3D best-slice phantom image*

**The 3D best-slice phantom image allows for high-level evaluation of the impact of DBT-specific parameters (e.g., target, filter, etc) on image quality for accreditation. Best slice is defined as the slice that demonstrates all the test objects in the phantom better than any other slice in the tomosynthesis set. As with all accreditation, the medical physicist's annual survey (and/or MEE) provides the detailed evaluation of system performance.*

Q. How will the ACR phantom image reviewers score the ACR Digital Mammography Phantom when used in digital mammography?

A. ACR phantom image reviewers will follow the same process outlined in the ACR Digital Mammography Quality Control Manual in scoring the ACR Digital Mammography Phantom in digital mammography. Medical physicists and quality control technologists should follow the same procedures as part of their routine QC.

Q. How will the ACR phantom image reviewers score the Small ACR Mammography Phantom when used in digital mammography?

A. ACR phantom image reviewers will essentially follow the same process outlined in the 1999 ACR Mammography Quality Control Manual in scoring the Small ACR Mammography Phantom in both digital and screen-film mammography. Medical physicists and quality control technologists should follow the same procedures as part of their routine QC. Scoring clarifications are presented below.

Q. Occasionally, I see a linear artifactual structure in the image that looks like a partial fiber. How should I deduct from the fiber score?

A. Subtraction is a penalty against the phantom score to reflect the presence of disturbing artifacts that could interfere with detection or diagnosis on clinical films. This is why we deduct from the fiber score for artifactual structures larger than or equal to the last scored fiber, even though they would not be confused with the last scored fiber.

If the artifact is at least as apparent with a diameter at least as large as that of the last fiber scored and the artifact has a fiber-like, rather than a mass or speck-like shape, deduct the artifact from the raw score as follows:

- If the last fiber being scored is seen as a whole fiber and the artifact is seen as essentially a full fiber (at least 75%) then deduct 1.0.
- If the last fiber being scored is seen as one-half of a fiber and the artifact is seen as at least a half fiber then deduct 0.5 for a fiber-like artifact.
- Do this even if the artifact has a larger diameter than the last fiber scored. The normal rule that the deduction is only from the last fiber scored still applies. For example:

Fiber Scores	
Raw	Corrected
5	4
4.5	4
4	3

Q. In scoring the phantom image, the image of the smallest visible fiber does not appear to be intact; it appears to have a single, tiny break in the middle. However, the entire length of the fiber is visible. May I score this fiber as a whole fiber?

A. Maybe. The phantom image review instructions say to:

“Count each fiber as 1 point if the **full** length of the fiber is visible and the location and orientation are correct. Count the fiber as 0.5 point if not all, but more than half, of the fiber is visible, and its location and orientation are correct.”

In general, fiber images with breaks mean that the entire length is not visible and they should **not** be given the full point. However, if there is only 1 break in the fiber and the break is **smaller than the width of the fiber**, you may give it a full score as long as the full length of the fiber is visible.

Q. In scoring the fibers in the phantom image, 1 of the fibers is almost entirely visible but not quite. May I score this fiber as a whole fiber?

A. Maybe. The phantom image review instructions say to:

“Count each fiber as 1 point if the **full** length of the fiber is visible and the location and orientation are correct. Count the fiber as 0.5 point if not all, but more than half, of the fiber is visible, and its location and orientation are correct.”

Because of the small variability that may occur in the length of the fibers within any phantom, some leeway is allowed. You may score a fiber as a **full point** if its visible length is **within ± 2 mm of the length of the largest fiber**. If the fiber image is shorter than 2 mm of the length of the largest fiber (but is longer than 50%) you must score it as 0.5 point.

Q. I see artifactual specks that are larger than the size of those in the last scored speck group. How should I deduct these from the speck group score?

A. Again, subtract these, one for one, from the specks in the last scored group to reduce the score. Subtract if the speck is at least as apparent (i.e., at least as bright as and of equal **or greater** diameter to the specks in the last scored group). Only subtract from the speck(s) seen in the last scored group (with either a full score or 0.5). **Do not subtract for artifacts that are obviously due to dust or emulsion pickoff and are much brighter than a speck would be.** The example in the table is given for 1 and for 2 artifactual specks.

Speck Group Scores			
Specks Seen	Raw	Corrected (deduct 1 speck)	Corrected (deduct 2 specks)
5 in 4 th group	4	4 in 4 th group = 4	3 in 4 th group = 3.5
4 in 4 th group	4	3 in 4 th group = 3.5	2 in 4 th group = 3.5
3 in 4 th group	3.5	2 in 4 th group = 3.5	1 in 4 th group = 3
2 in 4 th group	3.5	1 in 4 th group = 3	0 in 4 th group = 3

Q. I get a different answer depending on how I view the masses. What is the standard approach?

A. For scoring purposes, the masses should be viewed without a magnifier. A viewing distance of greater than 18 inches is suggested.

Q. When scoring the objects on the phantom image and looking for background artifacts that you would deduct from your total score of a group, do you look for artifacts for a group of objects over the entire wax insert or just in the area of that group of objects?

A. Artifacts should be deducted if they are seen anywhere in the area of the wax insert.

Testing – QC Documentation

Q. The ACR sent our facility a request for additional information stating that our medical physicist did not evaluate the technologist QC of our new mammography unit. When the medical physicist tested the unit, we had just installed it and were not yet performing the QC. Must the medical physicist still conduct this evaluation?

A. Yes, the FDA requires that the medical physicist evaluate the facility’s QC for all mammography units. Because an Equipment Evaluation is performed before a mammography unit is used clinically, the medical physicist is **not required to complete the “Evaluation of Site’s Technologist QC**

Program” section of the form during the Equipment Evaluation. However, your medical physicist must evaluate your facility’s QC program and complete the appropriate section of the QC Test Summary sometime within the 45 days you are provided to obtain the clinical and phantom images. This evaluation must be **submitted to the ACR along with the entire Equipment Evaluation report, the full application and/or testing materials.**

The medical physicist should check that all required QC tests are done by the QC technologist initially and then at the FDA-mandated frequencies. The ACR does not require the medical physicist to evaluate a certain number of days of QC. The ACR recognizes that, for this first survey, the medical physicist can only evaluate the number of tests that have been performed since the unit was installed. Note that the medical physicist need not evaluate the technologist’s QC program in person; review of the facility’s QC program may be done remotely (e.g., email, fax, etc.).

Q. What medical physicist QC documentation is required when a new facility submits the full application to the ACR?

A. Within 45 days of submitting the initial application, the facility must submit the full application to the ACR. In addition, the facility must submit the **entire**, most recent medical physicist’s Annual Survey report. Because this is a new unit, this Annual Survey report will generally include the Equipment Evaluation report. To summarize the results, the following ACR forms must be completed by the medical physicist and included with the **full report**:

1. [MQSA Requirements for Mammography Equipment](#), **and**
2. [Medical Physicist’s Mammography QC Test Summary](#) It is important to note that the medical physicist must now **complete the “Evaluation of Site’s Technologist QC Program” section** of this form.

The medical physicist should check that all required QC tests are done by the QC technologist initially and then at the FDA-mandated frequencies. The ACR does not require the medical physicist to evaluate a certain number of days of QC. The ACR recognizes that, for this first Annual Survey, the medical physicist can only evaluate the number of tests that have been performed since the unit was installed. Note that the medical physicist need not evaluate the technologist’s QC program in person; review of the facility’s QC program may be done remotely by mail or fax.

Q. I am a medical physicist responsible for evaluating two mammography units at a facility. I conduct the Annual Survey on two different dates during the year; however, I only review the entire facility’s technologist QC program once a year. On the “Medical Physicist’s Mammography QC Test Summary” form submitted for accreditation, may I complete only the “Evaluation of Site’s Technologist QC Program” section of the form on one unit?

A. Yes, as long as you indicate where and when you recorded the results of the technologist QC program evaluation. For example, if you evaluated the technologist’s QC for the entire facility during the January 15, 2018 Annual Survey of Unit #1, and you tested Unit #2 on April 15, 2018, indicate “see January 15, 2018 Annual Survey Report for Unit #1” on the “Evaluation of Site’s Technologist QC Program” page of Unit #2’s Annual Survey Report. Do **not** indicate “N/A” for these evaluations. Keep in mind, however, that during accreditation ACR staff looks for a complete Annual Survey Report for each unit that was performed no earlier than 14 months before the date on the full application. Your facility must be sure to send the ACR the reports **containing your evaluation of the technologist’s QC program with the pass/fail results** for each test of this evaluation. Unfortunately, **this does not always happen**. Consequently, it may be safer to record the pass/fail results for your evaluation of the technologist’s QC program on each unit’s Annual Survey Report so you can be sure the necessary information is sent to the ACR. If the evaluation was done on a different day from the main equipment tests, note the date of the evaluation on the form.

Accreditation and Certification

Q. From an MQSA standpoint, are there any differences between a computed radiography (CR) system and a FFDM system?

A. No, although the systems have significant physical differences, FDA treats them the same from an MQSA regulatory standpoint. CR systems are considered part of the FFDM mammographic modality. This means that facilities wishing to use a CR system must meet all applicable MQSA requirements, including those specific to FFDM units. (For example, all personnel using a CR system must have completed at least 8 hour of training specific to digital mammography prior to using the new CR system on patients. However, because CR systems are part of the FFDM mammographic modality, personnel who have already obtained 8 hours of training in FFDM do not have to obtain another 8 hours in CR prior to use on patients.)

Q. Even though my facility followed all the ACR-recommended guidelines for submitting the accreditation application on our first FFDM/DBT unit (including waiting three days and checking our My Applications page in ACRedit showing that the unit was accepted), the Centers for Medicare & Medicaid Services (CMS) is denying our facility payment for FFDM. They claim that we are not certified to perform FFDM and are requesting an MQSA certificate that states we are digitally certified.

A. A number of practices are experiencing payment problems with the CMS for FFDM services. The FDA does not provide MQSA certificates that specifically state that a facility is certified to perform FFDM. Instead, they send CMS a weekly file containing the most recent approval information. Your payer must look at the current MQSA file to see whether your facility is certified to perform digital mammography.

See [CMS Transmittal 913](#), on the handling of these files and provide a copy to your local payer. You may contact the appropriate CMS headquarter representatives:

- Medicare Carrier for non-payment of the professional component
- Medicare Fiscal Intermediary (FI) for non-payment of the technical component

Please provide them with your facility's 6-digit FDA ID number from your MQSA certificate and your MQSA expiration date.

	Contact Person	Phone	Email
Medicare Carrier	Teira Canty	(410) 786-1974	Teira.canty@cms.hhs.gov
Medicare FI	Bill Ruiz	(410) 786-9283	william.ruiz@cms.hhs.gov

If you continue to have problems after contacting the above individuals, please contact the ACR Economics Department for assistance at (800) 227-5463.

Q. We plan to add DBT to our existing accredited FFDM system. Do we need to accredit this new DBT system?

A. Yes.

Q. I heard that if I have FFDM system with DBT, my facility must accredit that unit as two separate units; FFDM and DBT. Is that true?

A. Yes.

Q. My site has installed a unit that performs both FFDM and DBT. I know they need to be accredited as two units because they are considered separate modalities by the FDA, and are listed in the accreditation database as two separate units. Does it matter which one I apply for first?

A. Yes, the FFDM unit **must** be applied for before the DBT unit. If the FFDM unit is already accredited, you can add the DBT unit as a new unit. If this is a new unit to your facility, and neither FFDM or DBT have been accredited before, you must add them in the same application, but the FFDM unit **must** be entered into the application first.

Q. My mammography system has the capability to perform both FFDM and DBT, but my administration has decided that they do not want to use DBT. Do we still need to accredit as two separate units?

A. No, if the DBT portion is not being used clinically, it does not have to be accredited.

Q. My mammography system has the capability to perform both FFDM and DBT, but my administration has decided that we will only do DBT. Do we still need to accredit as two separate units?

A. Yes, the FFDM portion of the unit must be accredited, whether used clinically, as it is the basis for some of the QC testing for the DBT portion.

Q. We perform computed radiography (CR) mammography at our facility and will be replacing our single imaging plate reader with a multi-plate reader. Do we need to notify the ACR, and do we need to go through accreditation again?

A. No. You do not need to notify the ACR when you install a new reader, nor do you need to repeat accreditation. However, you must consult with your medical physicist to ensure that a Mammography Equipment Evaluation is performed and documented. MQSA inspectors will verify that the appropriate testing was performed during their annual inspection.

Q. When I expose the phantom to produce an image to send to the ACR for accreditation, should I use the exposure techniques specified in the FFDM manufacturer's QC manual?

A. Maybe. The ACR's accreditation testing instructions specify that the phantom be exposed under routine clinical conditions. The clinical techniques may differ significantly from the QC techniques specified by the FFDM manufacturer. Screen-film phantom images submitted for accreditation are produced with clinical techniques typically used for a 4.2 cm compressed breast of average density. The ACR's Committee on Mammography Accreditation has specified that FFDM/DBT images submitted for accreditation should also be produced under clinical conditions. Consequently, it is important that you carefully follow the [ACR's Testing Instructions](#) when producing images for accreditation review.

Q. May I submit FFDM/DBT phantom and clinical images to the ACR on a CD?

A. No. ACR reviewers only review uploaded images or hardcopies. If you submit hard copy films, you must print hardcopies of the test images using the film printer and processor (if applicable) normally used for digital mammograms.

Q. How should I window and level the FFDM/DBT phantom image for accreditation?

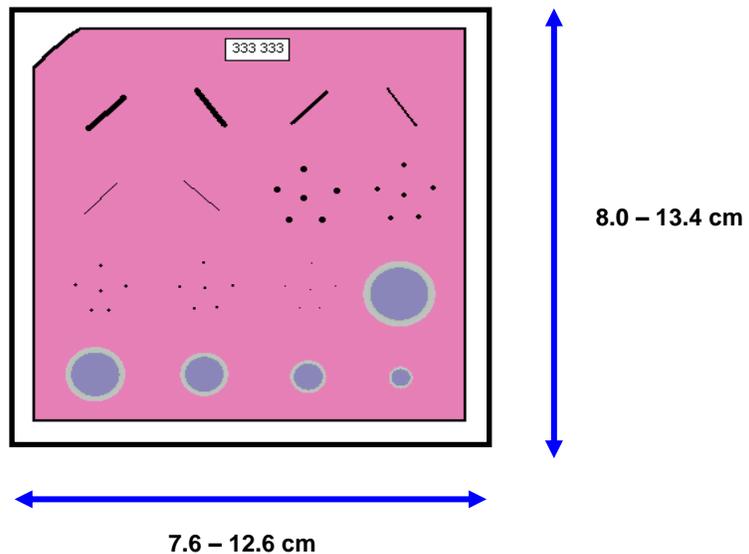
A. Process the image as typically done for digital mammography. You should window and level the display to best show the test objects without creating excessive noise. Do not zoom or rotate the image.

Q. When printing FFDM phantom images for accreditation, what size should they be? May I magnify or minify the phantom image?

A. Print the digital images without magnification or minification and as close to “true size” as possible. The ACR recommends:

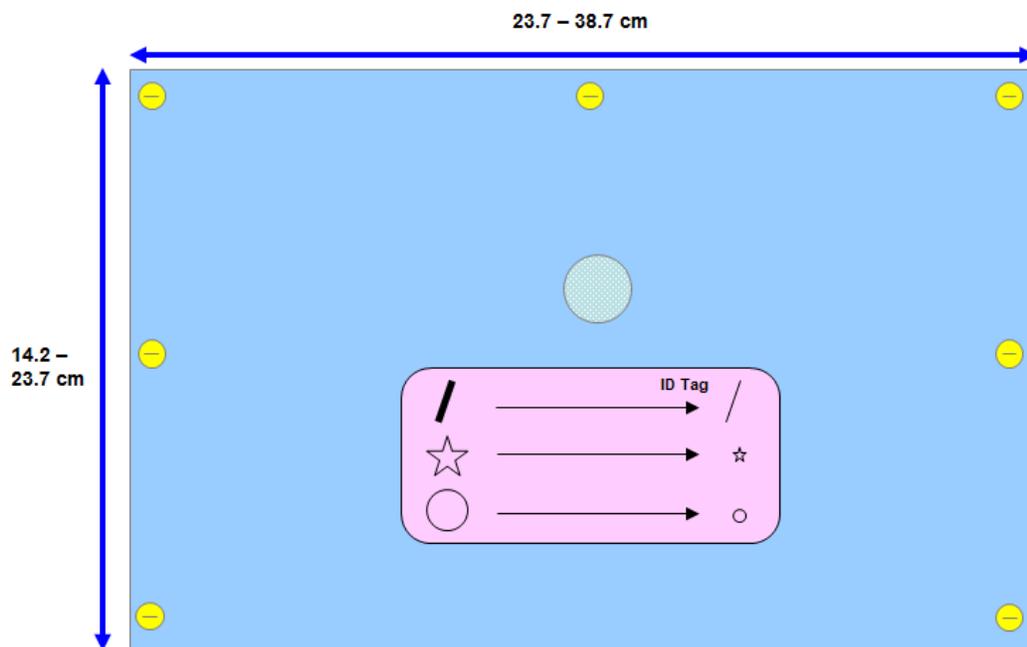
1. Printing the phantom images so that it is within 25% of the actual phantom size.
 - a. Small ACR Mammography Phantom - Since the accreditation phantom’s outside dimensions are 10.1 x 10.7 cm, the dimensions of the submitted image should be no smaller than 7.6 x 8.0 cm and no greater than 12.6 x 13.4 cm. (See figure.)

Small ACR Mammography Phantom - Recommended Size of Hard-Copy Image



- b. ACR Digital Mammography Phantom - Since the accreditation phantom's outside dimensions are 19.0 x 31.0 cm, the dimensions of the submitted image should be no smaller than 14.2 x 23.7 cm and no greater than 23.7 x 38.7 cm. (See figure.)

ACR Digital Mammography Phantom - Recommended Size of Hard-Copy Image



2. Printing the phantom images on the same size film as would normally be used to print clinical mammograms.
3. Not rotating the phantom during exposure or rotate the image when printing. ACR reviewers position digital films for scoring similar to screen-film images.

Q. What background density should be used when printing FFDM phantom images?

A. The ACR recommends that the background density of the hardcopy phantom images be between 1.7 and 2.2. (Approximately 2.0 is optimal.) Printed images from a digital mammography unit must be of sufficient quality for diagnostic interpretation when sent to another facility for review. This means that clinical mammograms should be of sufficient density and contrast when viewed by other physicians on appropriately bright mammography viewboxes.

Q. The manufacturer of our FFDM unit requires that at least 5 fibers, 4 speck groups, and 4 masses are visible for phantom QC. Does the ACR use the same criteria for accreditation?

A. No. The ACR uses one phantom image criteria (4 fibers, 3 speck groups, and 3 masses) when reviewing images submitted for accreditation from all manufacturers' FFDM units as well as those with screen-film. However, the ACR will check the facility's QC to ensure that they meet their FFDM manufacturer's QC criteria (as required by FDA).

Q. When submitting clinical images to accredit my FFDM unit, may I minify them in order to fit multiple images on one sheet of film?

A. No. You must print all clinical images as close to "true size" as possible. Do not magnify or minify them.

Q. May I submit my digital accreditation images on 14 X 17 inch film?

A. Yes, if this is the same format that you use to provide hardcopies to your patients. Although the ACR prefers smaller format film, we will accept digital mammography clinical and phantom images submitted on 14 x 17 inch film. However, the clinical and phantom images themselves must be as close to “true size” as possible (i.e. without magnification or minification). Furthermore, hardcopy images provided to patients and physicians must also be printed as close to “true size” as possible.

Q. Should facilities use lead laterality (L/R) markers on each image during the exposure, or is it acceptable to place computer generated markers on the image after the exposure using computer annotation?

A. Either is acceptable. The College considers them equivalent. The same potential for error exists whether the computer or lead markers are used. It is the technologist’s responsibility to ensure that the annotation is correct.

Q. On the accreditation final report, the ACR clinical image reviewer suggested that we may not be using the correct algorithm. What is an algorithm?

A. An algorithm is a step-by-step mathematical procedure (i.e. the program) performed by the computer on the workstation. In digital mammography, image processing algorithms allow for manipulation of fine differences in image contrast and/or detail. Different manufacturers will use different algorithms to process the clinical image for display on the workstation. You should contact your FFDM unit’s and/or workstation’s manufacturer for further information on their system’s algorithm.

FFDM Quality Control – General

Q. The manufacturer of our FFDM unit has a number of different revisions of their QC manual available. Which one should we follow for the medical physicist and technologist QC tests?

A. In general, you should use the most current version of the QC manual for the ***unit installed at the facility***. Note that the correct manual version may depend not only on the FFDM unit but also the software version of the unit.

For ***Lorad/Hologic FFDM systems***, you may use any of the Lorad/Hologic QC manuals that are applicable to your model; not necessarily the latest.

If there are any questions, check with the manufacturer of your FFDM unit.

Q. What tests must the medical physicist perform after a facility installs a new full-field digital mammography (FFDM) or Digital Breast Tomosynthesis (DBT) unit? What documentation must the medical physicist provide to the facility to send in for ACR accreditation?

A. FDA requires a medical physicist to perform a Mammography Equipment Evaluation whenever a new unit is installed. This evaluation must determine if the new unit meets the ***applicable*** equipment requirements listed in [900.12\(b\)](#) of the regulations ***and*** the quality assurance requirements listed in [900.12\(e\)](#).

Section (b) of the FDA regulations is more specific and the ACR has developed a simple checklist entitled “MQSA Requirements for Mammography” to help medical physicists document this section of the evaluation.

Section (e) of the FDA regulations requires the medical physicist to follow a quality assurance program that is “substantially the same as the quality assurance program recommended by the ***image receptor manufacturer***.” This complicates the testing since the tests, frequencies, and

pass/fail criteria vary across manufacturers, models, and QC manual versions. The ACR developed a short form entitled "[Medical Physicist's Mammography QC Test Summary](#)" for each manufacturer of FFDM equipment to simplify this documentation. These ACR forms are routinely updated as the manufacturers update their QC manuals and are available on the ACR website on the [Mammography Forms Page](#). The FDA requires the ACR to collect and review this information as part of accreditation.

To summarize – the medical physicist **must** perform the FDA-required evaluation and tests and submit the following completed ACR forms to the facility:

- MQSA Requirements for Mammography Equipment
- Medical Physicist's Mammography QC Test Summary – *Unit Manufacturer-Specific*

The facility must submit these forms to the ACR with documentation showing that all failures have been corrected before they may use the new unit to perform exams on patients.

Q. Every time one of the FFDM/DBT manufacturers updates its QC manual, the ACR changes its Medical Physicist's Mammography QC Test Summary form. Is this necessary? How can medical physicists keep informed of the most current summary form to use?

A. Yes, it is necessary. The FDA requires accrediting bodies to evaluate the medical physicist's Mammography Equipment Evaluation and Annual Survey results based on the most current version of the QC manual for the unit tested at the facility. Consequently, each time an FFDM/DBT QC manual is revised by the manufacturer, the ACR has to revise its Medical Physicist's Mammography QC Test Summary form to ensure that the appropriate results are collected and evaluated. The most current ACR forms are available on the ACR website on the [Mammography Forms Page](#). Note that the QC form names on the website include the revision date so you may easily determine if you have the latest version.

You are required to submit the ACR summary form that was appropriate to the unit you tested at the time of your survey. If you are testing a new installation, you should use the newest ACR summary form for the manufacturer of that system. In those cases, please check the ACR website. If you are doing an annual survey on an older piece of equipment, the ACR will accept an older ACR summary form.

Q. We recently had a software upgrade to our digital unit and now have some new or different QC that needs to be done. Does the ACR provide updated, detailed quality control data forms for each manufacturer and model?

A. No. The equipment manufacturers provide the QC data forms in their manuals.

Film Printers

Q. Does the ACR Mammography Accreditation Program or the FDA require mammography facilities with digital mammography units to have the ability to print hard-copy images?

A. No. Having access to a hard copy printer for printing of digital images is no longer required for the ACR Mammography Accreditation Program or by the FDA. On November 18, 2015, the FDA clarified their requirements on their website, saying "in today's world, the option to maintain a printer and/or the ability to print hard-copy images is a decision left to each individual facility." They further outlined that, "If a facility chooses to maintain a printer, it must follow all the quality control requirements that are prescribed by the manufacturer of the printer and mammographic unit. The manufacturer's quality control program benefits the facility that wants to provide the best possible quality in any hard copy mammography images it prints. Although the FDA's MQSA inspection program has removed printer QC questions from its inspection procedures, if a facility decides to maintain a printer, medical physicists must continue to include that printer QC in the Mammography Equipment Evaluation upon

installation, after a major repair, and annually, if required by the printer's or image receptor's manufacture quality control program." The FDA also changed their requirements for Certification Extension review to allow for either hard copy or soft copy submission of digital breast tomosynthesis phantom images. For more information, visit: <http://www.fda.gov/Radiation-EmittingProducts/MammographyQualityStandardsActandProgram/FacilityScorecard/ucm473469.htm>

Q. May the facility use the printer of a third party to print hardcopies?

The FDA no longer requires an FFDM facility to have access to an **on-site** or **off-site** third party printer. However, if the facility chooses to maintain a printer, the printer must **be tested** by a qualified medical physicist according to the FFDM unit manufacturer's recommendations **before the facility performs mammography on patients**. The facility must also include information and QC data for the film printer in its accreditation application as it does for film processors.

Q. How must FFDM hardcopy images be labeled?

A. Exactly the same way as screen-film images. This includes:

- Name of patient and additional patient identifier
- Date of examination
- View and laterality place on the image near the axilla
- Facility name and location
- Technological identification
- Cassette identification (CR only)
- Mammography unit identification (if more than one unit at facility)

Q. The FFDM unit manufacturer's QC manual specifies that the film printer QC must be performed weekly. However, my facility only prints hard-copy mammograms to give to patients once or twice a month. Do we need to perform QC on the printer during weeks no printing occurs?

A. No. The following serves to clarify FDA's position on film printer testing, as of January 4, 2012:

Facilities are required to follow the testing requirements for film printers as outlined in the FFDM manufacturer's QC manual (or the film printer manufacturer's QC manual if more appropriate) but **only on those days or weeks** when they are actually printing out images. In the case of a facility that performs its final interpretations using softcopy, the facility would only have to test the printer on those days or weeks when producing clinical hardcopy images for patients or healthcare providers or for retention purposes.

Q. We have a digital mammography unit on a mobile van and want to put a film printer on it. Does my printer need to be approved by FDA for mobile mammography?

A. No. See the MQSA regulations and guidance on [Other Modality Quality Control](#).

Q. My facility can print hardcopy images for our FFDM unit from three separate workstations. Which one should I use to print images to submit for accreditation?

A. The ACR suggests that you print from the workstation you typically use to print hardcopy images to give to patients. Per FDA guidance, hardcopy images should be of "final interpretation quality", therefore it is important for your radiologist to review and approve these hardcopy images before you submit them for accreditation.

Because your submission contains HIPPA data, you must send your images via a traceable method with a signature required for delivery.

Q. When patients request the release of their mammogram and we print a hardcopy for them may we charge for the hardcopy?

A. You may not charge them for the first hardcopy version of the mammogram; however, if the patient requests additional hardcopies of the mammogram, the facility may pass the costs of the additional hardcopies on to the patient. Appropriate charges for transfer of mammographic records could include items such as: administrative time costs incurred in logging in the request, retrieving the mammography films and reports, having the patient sign a release, packaging and mailing charges for the materials, and photocopying costs incurred in making copies of reports. See the [FDA's Policy Guidance Help System](#).

Monitors and Workstations

Q. Do I have to use an FDA-approved review workstation to interpret digital mammograms?

A. No. However, the FDA **recommends** that only monitors specifically cleared for FFDM use by FDA's Office of Device Evaluation (ODE) be used. (See [FDA's Policy Guidance Help System](#).)

Q. We just installed our first FFDM unit. Does our medical physicist also have to test the review workstation along with the new FFDM unit as part of the Mammography Equipment Evaluation? Do we have to submit the review workstation test results for accreditation?

A. Yes and yes.

Q. We have just added a second FFDM unit. Images from this unit are interpreted on our current review workstation. This review workstation was evaluated during the medical physicist's Annual Survey of our old FFDM unit. Does our medical physicist have to retest that review workstation along with the new FFDM unit as part of the Mammography Equipment Evaluation? Do we have to submit the review workstation test results for accreditation?

A. No and yes. If the review workstation was tested previously with another FFDM unit at that site during its Mammography Equipment Evaluation or Annual Survey, the medical physicist does not have to retest the workstation. However, the **medical physicist should indicate on the Mammography Equipment Evaluation summary forms sent with the accreditation application when the workstation was tested and the results.**

Q. The physician's review workstation is not at the same physical location as the FFDM unit. (It is off site). Is the medical physicist still required to test it during Mammography Equipment Evaluations and Annual Surveys of our facility's unit? Does the facility still need to submit QC results on that workstation to the ACR during accreditation?

A. Possibly and yes. There are at least two possible situations to consider if the review workstation is **not** located at the same facility as the FFDM unit:

- If the workstation **was** tested previously with another FFDM unit (either at the location of the workstation or a sister site), the medical physicist does not have to retest the workstation. However, the medical physicist should indicate on the Mammography Equipment Evaluation summary forms **the MAP ID # of the facility where the workstation is located, when the workstation was tested and the results.**
- If the workstation is located off-site e.g., in an office with no FFDM units or in a residence and **was not** tested previously, the medical physicist **must include the review workstation in the FFDM unit's Mammography Equipment Evaluation.**

In either case, the review workstation testing results must be included in the accreditation application to the ACR.

Q. Our facility uses a third-party review workstation for interpreting our FFDM images (it was not provided by the FFDM unit manufacturer). May I follow the review workstation's QC manual when performing the Mammography Equipment Evaluation tests or QC on the workstation?

A. Possibly. The FDA requires that facilities with **FFDM** systems comply with a QC program that is substantially the **same as that recommended by the image receptor manufacturer (i.e., GE, Fischer, Fuji, Lorad/Hologic, Siemens)**. This requirement also applies to **review workstations (monitors)**. However, the FDA allows some flexibility for workstation QC depending on the device's clearance from the FDA's Office of Device Evaluation (ODE) for FFDM use. You should **check with the workstation manufacturer** for their device's FDA clearance status.

- **Workstations approved by the FDA's ODE for FFDM** - FDA considers the workstation's QC manual to be "substantially the same" as that of the image receptor manufacturer and the facility may follow it for QC
- **Workstations not approved by the FDA's ODE for FFDM** - the facility **must** follow the QC manual provided by the **image receptor manufacturer** (check with the image receptor manufacturer for their required tests)

Q. All clinical images at our new FFDM facility will be printed and interpreted on hardcopy. There is no review workstation for the physician. Do we need to have access to a review workstation and submit the results of its Mammography Equipment Evaluation and QC testing for accreditation?

A. No. However, since this is an unusual situation (most facilities interpret from the softcopy), you **must provide a letter signed by your lead interpreting physician** stating that all interpretations will be done from hardcopy. Also, please note that any testing required by the manufacturer for the FFDM unit's display is still required since the technologist clinically uses this display when performing the examination.

Q. We just installed a new review workstation. (We have had our FFDM unit for several years.) Does our medical physicist have to conduct a Mammography Equipment Evaluation of this workstation? Do we have to submit the results of this test to the ACR?

A. Yes and no. It is important that your medical physicist conduct a Mammography Equipment Evaluation of your new workstation (and document the results in a report) to ensure that it is operating properly for image interpretation. However, you do not need to send this to the ACR at this time. We will request the results of the entire system's Annual Survey (which must include the review workstation tests) during accreditation renewal.

Data Compression

Q. What is data "compression" and what is the difference between lossless and lossy compression for FFDM images?

A. In digital mammography, data "compression" is a mathematical method used to reduce the size (i.e., number of "bits") of a digital image file so that less computer storage is necessary and images can be more efficiently transmitted. There are various techniques of accomplishing this, with varying results.

- "**Lossless**" compression refers to methods of data compression in which all the original data is preserved and can be completely restored.

- “**Lossy**” compression refers to methods in which the original data cannot be completely reconstituted.

The FDA requires a facility to use lossless compressed images for final interpretation and storage.

See the [FDA's Policy Guidance Help System](#) for more information.

Q. May I burn a case on a CD and walk it to the main facility for interpretation?

A. Yes. However, it must be saved as an original or **lossless compressed file**. Check with the FFDM manufacturer to verify the files are being saved accordingly.

Digitizing Film Mammograms

Q. My facility has a large archive of film images. Can we legally digitize them and discard the old film images to help reduce our storage problem?

A. No. The FDA regulations do not allow this because a digitized film image is not produced through radiography of the breast; under MQSA it is not considered a mammogram and cannot be used for retention or final interpretation. See the [FDA's Policy Guidance Help System](#).

Q. My facility just purchased a FFDM unit and wants to digitize all of our previous film images so they may be more efficiently used for comparison purposes. Is this allowed under MQSA?

A. Yes. The FDA allows digitized or copied images of previously obtained film mammograms to be used for comparison purposes, **if the interpreting physician deems that acceptable**. However, because such images are not considered mammograms under MQSA, they cannot be counted towards initial or continuing experience requirements for the interpreting physician. See the [FDA's Policy Guidance Help System](#).

Adverse Accreditation Decisions

Reapplying for Accreditation

Q. What happens if the facility does not pass accreditation during the first attempt?

A. If the facility has adequate time remaining on its MQSA certificate, it will be given the opportunity to **repeat** the test that was deficient. If there is not enough time to repeat the tests before the MQSA certificate expires, the facility will have to submit a corrective action plan and **reinstate** by completing and returning the full application, all testing materials and a reinstatement fee.

If the site repeats (or reinstates) and receives a second deficiency, it **fails** accreditation. The ACR will notify the FDA (or the state certifying body) of this failure. In order to resume the accreditation process, the facility must reinstate. The following table summarizes these steps:

Accreditation Attempt	Accreditation Result	Facility Options
1 st	NOT GRANTED 1 st Deficiency Facility may continue performing mammography with the unit as long as they have a valid certificate.	REPEAT not acceptable area(s) <i>(only if more than 60 days on MQSA certificate),</i> REINSTATE by retesting all areas <i>(if 60 days or less on MQSA certificate),</i> APPEAL decision on original images or WITHDRAW
2 nd	NOT GRANTED 2 nd Deficiency = 1 st Failure ACR strongly recommends that facility cease performing mammography with the unit	REINSTATE by retesting all areas <i>(with corrective action),</i> APPEAL decision on original images or WITHDRAW
3 rd	NOT GRANTED 3 rd Deficiency = 2 nd Failure ACR strongly recommends that facility cease performing mammography with the unit	REINSTATE after participating in Scheduled On-Site Survey, APPEAL decision on original images <i>(may not operate until the appeal is complete)</i> or WITHDRAW

Q. We received a deficiency for clinical images and must repeat with new clinical images. Only our dense breast images failed. May we submit just the dense images?

A. No. The entire deficient area must be repeated in order for the reviewers to assess the overall improvement in clinical image quality since the previous deficiency. Consequently, both fatty and dense images must be reacquired and submitted.

Q. May we go back and select mammograms from a previous date to submit during the repeat process?

A. No. You must select images from a time period after the date you received the final report specifying that you were deficient in the clinical area. This allows the reviewers to assess the overall improvement in clinical image quality since the previous deficiency and to determine if the facility took all their comments into consideration.

Q. What is required for reinstatement?

A. **Reinstating** requires the facility to fully document its history and to address all deficiencies noted in previous reports. An appropriate corrective action plan should be designed, approved by the ACR, and implemented. Once all corrective actions are completed and supporting documentation has been forwarded to the ACR, the facility may receive a 6-month provisional reinstatement certificate from the FDA (or state certifying body) and go through the accreditation process again. If the facility fails again, it will have to participate in a **Scheduled On-Site Survey**. The Scheduled On-Site Survey is conducted so that an ACR review team (consisting of a radiologist, a medical physicist and an ACR staff mammography technologist) can review the facility's progress and provide on-site training in areas where help may be needed. This process takes time, and the facility is responsible for payment of a base site-visit fee in addition to all travel expenses incurred by the ACR team.

Q. My facility submitted a plan of corrective action for reinstatement, but this is what we plan on doing to start the reinstatement process, and the actions have not yet been carried out. Is this enough to start the process and get the provisional certificate from the FDA?

A. No. Although the corrective action plan may discuss the problems the facility had in obtaining accreditation and what they plan to do to correct these deficiencies, these plans must be **fully** carried out and specifically documented to show proof of correction. That is the primary reason for reinstatement. If facilities were to be reinstated based on what they plan to do and without fully implementing the plan, their past problems might remain uncorrected. This could hinder their next testing cycle for accreditation and ultimately prevent them from obtaining accreditation.

Q. My facility failed accreditation due to positioning. Our corrective action plan stated that the technologist who performed the submitted exam will have additional training. Today we received an incomplete memo indicating that all technologists at our facility have to receive additional training as part of the corrective action. Why is this necessary?

A. The ACR specifies that you send an example of your best quality work during accreditation. If the clinical images do not pass accreditation, the ACR must assume that all mammography performed at your facility (by all technologists) is of equal or lower quality. Consequently, all technologists must receive training in order to address this. Proper patient positioning, is crucial to obtaining consistently high quality mammograms so that your patients receive the best medical care possible.

Q. My facility failed accreditation due to positioning and we have scheduled hands-on training to be performed at another accredited site, with a technologist that is not on our personnel list. How many hours of training are required?

A. Typically, the ACR recommends 8 hours of hands-on training to be completed for corrective action. The positioning documentation must be signed by the MQSA-qualified technologist providing the training, if at another site, include their MAP#, address all the deficiencies noted in the previous reports, and include a statement that resultant images were critiqued and acceptable.

Appealing an Adverse Accreditation Decision

Q. My facility failed accreditation. May we appeal the decision? If so, what's involved?

A. Yes. Facilities that receive a deficiency or a failure may **appeal** the determination in writing within 30 days of the date of the final report. The **original images** or data must be submitted with a letter describing your reason for appealing. Only those images reviewed for the original determination will be considered during the appeal evaluation. Both fatty and dense cases must be submitted for clinical appeals in order to allow the reviewer to assess the overall clinical performance of the facility. Images will be forwarded to an arbitrator (a reviewer who did not participate in the initial review) with a copy of the previous reviews and the appeal letter written by the facility. **No other images or data will be sent to the reviewer for consideration in the evaluation.** The arbitrator's determination will be final.

If a unit is denied accreditation after an appeal of a **failure** (second deficiency), the facility may appeal directly to the FDA. However, such an appeal will stop the ACR application process until the FDA renders a decision. Further, the facility making the appeal may not perform mammography during the FDA appeal process. Facilities are not permitted to appeal **to the FDA after** a first deficiency **appeal is denied by the ACR.**

Interim Accreditation and MQSA Certificate Extensions

Q. What's the difference between "interims" and "extensions"?

A. Certain **fully accredited** facilities with **full MQSA certificates** may be eligible for a 45-day **Interim Accreditation** (one time only) from the ACR if additional time is needed to complete the review and/or renewal process. The ACR will render the decision in these cases based on the facility's accreditation history. Certain facilities with **provisional MQSA certificates** or **provisional MQSA reinstatement certificates** who are not currently accredited may be eligible for a 90-day **Extension** to their MQSA certificate (one time only) from their certifying body (either the FDA or the state) if additional time is needed to complete the review and/or reinstatement process. Although the ACR makes a recommendation to the facility's certifying body based on the facility's accreditation history, the certifying body makes the final decision to grant or deny the Extension.

Q. My facility has a full 3-year accreditation and a full MQSA certificate that expires soon. Can I get an Interim Accreditation to allow me to legally continue performing mammography?

A. Possibly. The ACR understands that, at times, a facility may not be able to complete renewal accreditation testing within the allotted 6-month time frame before their full MQSA certificate expires. Under certain conditions, a facility may apply to their accrediting body for a 45-day Interim Accreditation. **In order to be eligible for Interim Accreditation, your facility must be fully accredited and you must have already submitted testing materials to the ACR. In addition, you must have adhered to ACR's time frames for submitting the necessary paperwork and images.** Facilities failing to meet the ACR's time frames may have their Interim Accreditation request denied.

Contact the ACR to obtain a Request for Interim Accreditation form. Complete all requested items on the form including providing the reason why Interim Accreditation is being requested and the steps you have taken to achieve accreditation. Fax the form to the ACR as instructed. (The final decision regarding approval or denial will be made when the facility has 14 days or less on their MQSA certificate.) The ACR will review your Interim Accreditation request and will contact you regarding its approval or denial. If the ACR **approves** your request, we will fax you an Interim Accreditation Approval Letter with an expiration date of 45 days from your current MQSA certificate expiration so you may continue to perform mammography. The FDA or state certifying body will also send you an Interim Notice with the same expiration date. If the request is **denied**, the ACR will fax and mail you a denied Interim Accreditation Letter. If your request is denied, contact the ACR at (800) 227-6440 for instructions on how to resume the accreditation process in order to continue providing mammography services. Finally, the ACR will only accept Interim Accreditation requests if there are 30 days or less on the facility's MQSA certificate.

Q. My facility is not yet accredited with the ACR, and my 6-month provisional MQSA certificate expires soon. Can I get an Extension to my MQSA provisional certificate to allow me to legally continue performing mammography?

A. Possibly. Under MQSA's Final Rules, facilities that are provisionally certified may receive a 90-day Extension to their MQSA certificate from their certifying body (either the FDA or the state) if they meet certain conditions. **In order to be eligible for an Extension, your facility must be provisionally certified, and you must have already submitted testing materials to the ACR. In addition, you must have adhered to the ACR's time frames for submitting the necessary paperwork and images. You must also provide written evidence that there would be a significant adverse impact on access to mammography in the geographic area served if you did not obtain an extension.**

Contact the ACR to obtain an Extension Request form. Complete all requested items on the form including providing the reason why an Extension to your MQSA certificate is being requested, the steps you have taken to achieve accreditation, and the evidence that there would be a significant

adverse impact on access to mammography in the geographic area served if you did not obtain an extension. (If testing materials have not been submitted, your facility must provide reasons why you could not submit testing materials.) Fax the form to the ACR as instructed. (The final decision regarding approval or denial will be made when the facility has 14 days or less on their MQSA certificate.) After the Extension Request form is received at the ACR, we will forward your request with our recommendation to your certifying body. Once the decision to approve or deny the Extension request is made by your certifying body, they will typically fax, and then mail, a letter of the approval or denial to the facility. If approved, your certifying body will send you a 90-day MQSA certificate shortly after the approval has been granted. If your request is denied, contact the ACR at (800) 227-6440 for instructions on how to resume the accreditation process in order to continue providing mammography services.

Annual Updates

Q. What is an Annual Update?

A. The FDA requires the ACR to request updated information annually from each accredited facility. The ACR will email your facility an Annual Update on your accreditation anniversary. When you receive it, please note any changes to information pertinent to your facility's accreditation (e.g., address, lead interpreting physician/supervising radiologist, etc.).

Validation Image Checks

Q. My facility received a Validation Image Check but no mammography examinations were performed on the assigned date. Can we disregard this?

A. No. Under the Food and Drug Administration's Quality Mammography Standards; Final Rule that went into effect April 28, 1999, the ACR Mammography Accreditation Program is required to conduct "random clinical image reviews of a sample of facilities to monitor and assess their compliance with standards established by the body for accreditation." Facilities are required to participate if requested. You should contact the ACR Mammography Accreditation Program Information Line at (800) 227-6440 for further instructions if your facility cannot comply with the terms of the Validation Image Check.

Q. Will a facility lose its accreditation as a result of a failed Validation Image Check?

A. In most situations, no. If a facility receives a deficiency report for a Validation Image Check, they must submit a corrective action plan to the ACR within 14 calendar days of the report. All documentation showing completion of the corrective action plan is due to the ACR within 60 days of the deficiency report. Following this, the facility must participate in a repeat Validation Image Check (or undergo early accreditation renewal if there is less than 13 months left on the facility's accreditation) to demonstrate that they have adequately corrected the identified problems.

Loaner and Demo Units

Q. What is the difference between "loaner" and "demonstration" mammography units?

A. For purposes of MQSA certification and ACR accreditation,

- A **loaner unit** is one that a facility has in use while the facility's unit is undergoing in-house or off-site repair.
- A **demonstration unit** is any unit a facility obtains from the manufacturer for use on a temporary basis either to determine whether the unit meets their needs before deciding to make a purchase or to use while awaiting delivery of a new unit.

Q. Our mammography unit is being sent out for a major repair. We are temporarily installing a loaner unit. Are there any accreditation requirements for a loaner mammography unit?

A. The facility must submit a letter to the ACR signed by the lead interpreting physician or president/CEO documenting that:

1. They have a loaner unit
2. The reason for the loaner
3. The estimated date when it will be replaced by the permanent unit
4. The loaner unit manufacturer, model, and serial number

A qualified medical physicist must perform an Equipment Evaluation (as required by MQSA) after the loaner unit is installed and before it is put into service. The facility must submit the Medical Physicist's Mammography QC Test Summary and the Medical Physicist's Checklist - MQSA Requirements for Mammography Equipment to the ACR. Once received and reviewed, the ACR will send the facility a response letter acknowledging receipt of notification and compliance.

A loaner unit may not be used for more than **30 days** without applying for ACR accreditation. (This period may be extended for up to 90 days upon written verification from a repair service that there is legitimate cause for repairs to exceed 30 days.)

When the **repaired unit is returned and reinstalled**, a qualified medical physicist must perform an Equipment Evaluation (as required by MQSA) before the old unit is returned to service.

Q. Our mammography facility is using a demo unit for several weeks before deciding whether to purchase it. Are there any accreditation requirements for a demo mammography unit?

A. The facility must submit a letter to the ACR signed by the lead interpreting physician or president/CEO documenting that:

1. They have a demonstration unit in place.
2. The loaner unit manufacturer, model and serial number of the demonstration unit.

A qualified medical physicist must perform an Equipment Evaluation (as required by MQSA) after the demonstration unit is installed and before it is put into service. The facility must submit the Medical Physicist's Mammography QC Test Summary and the Medical Physicist's Checklist - MQSA Requirements for Mammography Equipment to the ACR. Once received and reviewed, the ACR will send the facility a response letter acknowledging receipt of notification and compliance.

The facility is required to maintain compliance with all routine quality control tests and frequencies as defined under MQSA. A facility may use a demonstration unit for **no more than 90 days** without applying for ACR accreditation.

If the facility purchases the demonstration unit after evaluation or finds that it needs to continue to use the demonstration unit for more than 90 days, it must proceed with accreditation. The required accreditation process will be determined by the amount of time left on the facility's MQSA certificate. Call the ACR for assistance specific to your situation.

Q. Must I accredit my loaner or demonstration unit if it is in place more than 90 days?

A. Yes. If the loaner or demonstration unit is going to be in place **more than 90 days**, and the facility has **more than 13 months** left on its MQSA certificate, the temporary unit must either undergo full testing following the instructions in the New Unit Addendum or give up its current MQSA certificate and accredit the temporary unit (and any other active units) with the New Unit Reinstatement process. If the facility that has **less than 13 months** left on its MQSA certificate, the facility must renew its

accreditation early with the temporary unit in addition to any of the other mammography units in use at the facility. In all cases, the temporary unit must undergo clinical and phantom image quality testing as part of this accreditation. Call the ACR for assistance specific to your situation.

Q. My loaner/demonstration system is digital. We are currently only accredited for screen-film at my site. Will CMS reimburse us at the higher digital rate for exams performed with the digital system?

A. If a facility chooses to use the FFDM unit as a demonstration unit without starting the accreditation process, reimbursement may become an issue. ***The Center for Medicare and Medicaid Services (CMS) will not reimburse for FFDM examinations until the FDA has received notification that a facility has applied for accreditation of a FFDM unit.*** In these cases, the ACR recommends that facilities start accreditation on the temporary FFDM unit so that they may be reimbursed at the higher digital rate.

The 1999 ACR Mammography QC Manual

See the 1999 ACR Mammography QC Manual section of [the American College of Radiology Mammography Accreditation Program – Screen-Film: Frequently Asked Questions](#).

The ACR Digital Mammography Quality Control Manual

See the [American College of Radiology Digital Mammography QC Manual: Frequently Asked Questions](#).