Update on MQSA Regulations - Guidance Document # 9

ACMP – 2006 Annual Meeting

Mammography Update

for Physicists

June 3, 2006     Las Vegas, NV

Melissa C. Martin, M.S., FACR, FACMP, FAAPM

e-mail: Melissa@TherapyPhysics.com
Learning Objectives

- Become familiar with the latest updated requirements for MQSA compliance as outlined in Policy Guidance System # 9 - April 2006

- Be familiar with the Frequently Asked Questions of the ACR Accreditation Program for Mammography
Available on the web at:

http://www.fda.gov/cdrh/mammography
Citation:
900.12(e)(5)(i)(A)(B)(C): Annual quality control tests. Facilities with screen-film systems shall perform the following quality control tests at least annually:
(i) Automatic exposure control performance.
   (A) The AEC shall be capable of maintaining film optical density within ±0.30 of the mean optical density when thickness of a homogeneous material is varied over a range of 2 to 6 cm and the kVp is varied appropriately for such thicknesses over the kVp range used clinically in the facility. If this requirement cannot be met, a technique chart shall be developed showing appropriate techniques (kVp and density control settings) for different breast thicknesses and compositions that must be used so that optical densities within ±0.30 of the average under phototimed conditions can be produced.
   (B) After October 28, 2002, the AEC shall be capable of maintaining film optical density (OD) within ±0.15 of the mean optical density when thickness of a homogeneous material is varied over a range of 2 to 6 cm and the kVp is varied appropriately for such thicknesses over the kVp range used clinically in the facility.
   (C) The optical density of the film in the center of the phantom image shall not be less than 1.20.

(i) Each screen-film system shall provide an AEC mode that is operable in all combinations of equipment configuration provided, e.g., grid, nongrid, magnification, nomagnification, and various target-filter combinations.
(ii) The positioning or selection of the detector shall permit flexibility in the placement of the detector under the target tissue.
   (A) The size and available positions of the detector shall be clearly indicated at the X-ray input surface of the breast compression paddle.
   (B) The selected position of the detector shall be clearly indicated.
(iii) The system shall provide means for the operator to vary the selected optical density from the normal (zero) setting.

Discussion:

Question 1: What is meant by the terms “AEC”, “AEC mode”, “mean optical density”, and “configuration”?

Question 2: Can we continue to use technique charts after 10/28/2002?

Question 3: During the annual physics survey, how must the medical physicist test AEC performance and what action limits apply?

Question 4: During the mammography equipment evaluation, must the medical physicist test the AEC performance in all equipment configurations used clinically by the facility or can it be limited to the contact configuration? What action limits apply?
What is Small Field Digital Mammography (SFDM) and is it a mammographic modality?

Small Field Digital Mammography (SFDM) refers to the use of a small digital image receptor to produce mammographic images. Because this small receptor cannot image the entire breast, it cannot generally be used for screening examinations and is limited to use for either interventional or diagnostic purposes. When used for interventional purposes, SFDM is considered a subpart of the FFDM modality.
MQSA Final Regulations: Policy Guidance Help System # 9 - Small Field Digital Mammography

Which MQSA requirements must SFDM meet in order to use it clinically?

If the SFDM receptor is part of a mammography unit that is used solely for interventional procedures, the unit and the receptor are excluded from all MQSA requirements at this time.
Which MQSA requirements must SFDM meet in order to use it clinically for mammography?

1: The unit must be accredited and certified. The SFDM receptor does NOT have to undergo a separate accreditation or certification.

2: Personnel who already have 8 hours of training in FFDM do NOT have to obtain additional training to use the SFDM receptor.
Which MQSA requirements must SFDM meet in order to use it clinically for mammography?

3: Facilities must have the receptor pass a mammography equipment evaluation **prior** to initial use and must follow the SFDM manufacturer’s QC manual for periodic testing.

4: The receptor **MUST** also be checked as part of the annual physics survey.
FDA Policy Guidance Help System #9 – 4/19/06 - Image Transmission/Retention

- Transmitting images for final interpretation
  - Original or lossless compressed FFDM data – OK, if acceptable by receiving party
  - Lossy compressed FFDM data – Not OK

- Retention of digital mammograms
  - Original or lossless compressed FFDM data – OK
  - Lossy compressed FFDM data – Not OK
  - Hardcopy film of final interpretation quality – OK
Digitizing screen-film images
- For retention purposes – Not OK
- For final interpretation – Not OK
- For comparison purposes – OK, *if interpreting physician deems it acceptable*; FDA also suggest digitizers be cleared by FDA for mammograms

Transferring digital mammograms
- Must be able to provide hardcopy of *final interpretation quality*
- Softcopy original or lossless compressed images, *if acceptable by receiving party*

Charging for hardcopies
- 1st – no
- Subsequent – yes (actual costs)
FDA Policy Guidance Help System #9 – Printers and Monitors

- FDA-required image annotation
  (view & laterality, pt name and ID, etc)
  - All must be visible on each displayed image in the standard or default display
  - May be switched off
  - Must be on each hardcopy image
Printers & monitors

– FDA *recommends* facilities only use printers & monitors that were approved by FDA for FFDM

– It is legal to use those not approved

– All must comply with a QA program substantially the *same as recommended by the FFDM manufacturer*

– Must pass (or be able to pass accreditation clinical image review)
Can a manufacturer hook up a printer or monitor to its FFDM unit if the printer or monitor were not part of its original PMA?

Manufacturers will need to check the exact wording of their PMA to see if this is allowed.

HOWEVER, facilities are not restricted by the PMA and may hook up and use printers and monitors other than those approved by the FDA for use with the manufacturer’s FFDM unit as long as they meet the requirements for acceptable clinical image review.
<table>
<thead>
<tr>
<th>FFDM Mfr</th>
<th>Model</th>
<th>Laser Printer QC</th>
</tr>
</thead>
<tbody>
<tr>
<td>GE</td>
<td>2000D</td>
<td>Follow the laser printer mfr’s QC</td>
</tr>
<tr>
<td>GE</td>
<td>Senographe DS</td>
<td>Follow the laser printer mfr’s QC</td>
</tr>
<tr>
<td>Fischer</td>
<td>SenoScan</td>
<td>Follow the laser printer mfr’s QC</td>
</tr>
<tr>
<td>Lorad</td>
<td>Selenia</td>
<td>Follow the Lorad Selenia QC Manual</td>
</tr>
<tr>
<td>Siemens</td>
<td>Mammomat Novation DR</td>
<td>Follow the laser printer mfr’s QC (but conduct QC every day you print)</td>
</tr>
</tbody>
</table>
Monitor (i.e., Workstation) QC

- All must comply with a QA program substantially the same as recommended by the FFDM manufacturer (e.g., GE, Fischer, Lorad, Siemens)

- FDA has informed the ACR that following the FDA FFDM-approved monitor QC manual is "substantially the same"

- If monitor mfr has no QC manual, must follow one by FFDM mfr
# Equipment Evaluations on FFDM Components

<table>
<thead>
<tr>
<th>Item/Repair</th>
<th>MP Involvement</th>
</tr>
</thead>
<tbody>
<tr>
<td>Bucky &amp; detector replacement</td>
<td>MP must evaluate in person</td>
</tr>
<tr>
<td>Bucky (but not detector) replacement</td>
<td>MP must oversee</td>
</tr>
<tr>
<td>Any detector replacement or repair</td>
<td>MP must evaluate in person</td>
</tr>
<tr>
<td>Software modifications</td>
<td>MP must evaluate in person (some alternative standards otherwise)</td>
</tr>
<tr>
<td>Monitor (display) or printer replacement</td>
<td>Must follow FFDM mfr’s QC manual</td>
</tr>
</tbody>
</table>
Unanimous recommendation of panel to reclassify FFDM units from Class III (PMA) devices to Class II (510(k)) devices. Class II devices require only that the manufacturer to establish that their devices is safe and effective and “substantially equivalent” to a device already marketed.

Fuji CR system for Mammography received marketing approval in the US on 5/26/06.
FDA released a new version of the procedures to be used to inspect mammography facilities as of 5/15/06.

Most significant change is the elimination of all x-ray unit tests by MQSA inspectors as part of their site inspections.

Medical Physicists must still make these measurements as part of their annual evaluations.
MQSA inspectors will NO LONGER make the following equipment tests:

- Collimation: X-ray field/image receptor and compression paddle alignment
- Exposure measurements for dose determinations
- Exposure reproducibility
- Beam Quality (HVL)
FDA will allow FFDM QC Test Images to be retained according to the following schedule:

- Images produced from daily QC tests - previous 30 days
- Images produced from weekly QC tests - previous 12 weeks
- Images produced from monthly & quarterly QC tests - until the next annual inspection has been completed and FDA has determined that the facility is in compliance with the quality assurance requirements.
- Images produced from semi-annual QC tests - until the next annual inspection has been completed and FDA has determined that the facility is in compliance with the quality assurance requirements or until the test has been performed two additional times at the required frequency, whichever is longer.
FDA will allow FFDM QC Test Images to be retained according to the following schedule:

Images produced from semi-annual QC tests - until the next annual inspection has been completed and FDA has determined that the facility is in compliance with the quality assurance requirements or until the test has been performed two additional times at the required frequency, whichever is longer.
Can a facility digitize (scan) its paper QC records, MEE and annual physics survey reports, and personnel documentation, keep the digital data in a retrievable format, and then discard the original paper records?

Digitization and storage of paper QC records, MEE and Annual Physics Survey Reports and Personnel Documentation is acceptable under the following conditions:

1. The digitized data is easily accessible for review by the inspector during MQSA inspections. Failure to have records available at the time of inspection may result in a citation.
2. The digitized record needs to look like the original paper record, including any handwritten signatures or annotations that may be on the original record.

3. The facility has the capability of printing a hardcopy from the digitized records.

4. The facility maintains the original paper charts and records of QC tests performed by the radiologic technologist. These original paper QC records must be maintained for the time frame required by the regulations.

5. For all other digitized records, the digitized data must be maintained for the time frame required by the regulations.
1. Records that require, but lack, adequate identification of who performed the test, survey, etc. are not acceptable.

2. Some mammomammo units and QC test measurement devices are automated and electronically store the QC test data. In addition, some facilities may record their QC data on a computer, rather than using handwritten charts or tables. In these cases, the facility may maintain either the electronic data or a hardcopy printout of the data.

3. State laws may impose more stringent requirements for the retention of these records. A facility must check with the State regarding its requirements.
Continuing Education Units for Medical Physicists

Are there specific subject areas that are acceptable for continuing education units in mammography and others that are not acceptable?

All CEUs related to the diagnosis or treatment of breast disease or other areas that will aid facility personnel in improving the quality of mammography will be acceptable toward meeting the CEU requirement. However, CEU’s not in mammography should not constitute a majority of the 15 hour requirement.
How Many MQSA-Certified FFDM Facilities and Units are there in the US?

As of April 1, 2006

- 1331 FFDM units/13,606 Total Units
  - 9.8% of all mammography units
- 942 facilities had FFDM units/8860 Total Facilities
  - 10.6% of all US facilities
How many Mammography Facilities and units are Accredited by the ACR?

- As of November 1, 2005, 8864 mammography facilities with 13,615 units were accredited by the ACR.
Mammography Accreditation Program

Accreditation Portal

The FDA has designated the American College of Radiology (ACR) as an accrediting body for both screen-film and full-field digital mammography units. This is the country’s oldest and largest accrediting body for mammography. Click here for more information on the history of this program.

Program Overview

- Click here for Mammography Program Overview

Frequently Asked Questions

- MQSA and FDA Regulations
- ACR Mammography Accreditation
- The 1999 ACR Mammography Quality Control Manual

New Mammography facility application package

- New mammography facilities may click here to apply for accreditation.

Personnel, Testing and QC Forms

The ACR sends the following documents with testing materials to the facility after the initial application has been processed.

- Click here to view all Personnel Testing and QC Forms.
Mammography Frequently Asked Questions

Accreditation Portal

ACR Homepage
Accreditation Index
Accredited Facility Search

Accreditation Programs

Mammography
History
Mammography Overview
Facility Application Package
Sample Lay Report Letters
Apply for Accreditation
FAQs
Testing and QC Forms

Radiation Oncology
Breast Ultrasound
Computed Tomography
MRI
Nuclear Medicine and PET
Stereotactic Breast Biopsy
Ultrasound

Useful Links

Why Get Accredited?
Apply for Accreditation

General FAQ

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

1.2. How many MQSA-certified full-field digital mammography facilities and units are there in the United States?

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

1.4. I have questions about my facility’s accreditation. Where can I go for help?

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

Current data on the number of MQSA-certified facilities and units may be obtained from:

https://www.acr.org/Quality-Safety/Resources/Mammography-Accreditation...
2.2. 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 the facility a 6-month provisional MQSA certificate within two business days of receiving the ACR notification. Hence, a total of four business days may elapse from the time a facility submits all required documentation to the ACR and when they 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.
8.2. 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 sent the complete new unit application (with the Equipment Evaluation results) to the ACR.

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.** However, the ACR has become aware that the **Center for Medicare and Medicaid Services (CMS) will not reimburse for examinations performed on an FFDM 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 unit to examine patients:

- **Fax** the application materials with the Equipment Evaluation results to the ACR at (703) 648 9176, and
- After three business days, **call** the ACR at (800) 227 6440 to confirm that the new unit information was sent to the FDA.

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

- MQSA Requirements for Mammography Equipment form and

- the Medical Physicist’s Mammography QC Test Summary for screen-film or full-field digital mammography, as applicable.
How Should the Medical Physicist Summarize the Results of the Equip't. Eval?

- These forms are provided with each new facility or new unit application.
- They can also be downloaded from the ACR website: www.acr.org
- *It is important to note that summaries submitted in different formats will delay the ACR’s review even if they contain all of the required information.*
- Be sure that all requirements *pass* before submitting the application.
Laser Printer Requirements for FFDM units

Does the ACR or FDA require an FFDM facility to have a laser film printer at the facility? May the facility use the laser printer of a third party to print hard copies?

Neither the ACR nor the FDA requires an FFDM facility to have an on-site laser film printer. However, for purposes of transferring films, the FDA does require a facility to be able to “provide the medical institution, physician, health provider, patient or patient’s representative, with hard copy films of primary interpretation quality. Consequently, the ACR and FDA require FFDM facilities to have access to a compatible laser printer.
Laser Printer Requirements for FFDM units

Does the ACR or FDA require an FFDM facility to have a laser film printer at the facility? May the facility use the laser printer of a third party to print hard copies?

The printer must exist and 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 include information and QC data for the laser film printer in its accreditation application.

MQSA inspectors will review the laser film printer QC when he/she inspects each FFDM unit.
During accreditation of a FFDM unit, does the facility have to send the ACR a laser printer QC chart if hard copy printing is done by a third party?

YES. Even though a third party may produce the hard copy image, the facility is responsible for ensuring that the quality of the hard copy is of primary interpretation quality. Evaluating laser printer quality control is part of the facility’s QC program.

Each facility must follow their FFDM unit’s manufacturer’s recommendations for laser printer QC.
Does a facility with an FFDM unit need to submit QC data for their laser film printer even if the physicians interpret only from the soft copy?

YES. The ACR reviews a copy of the laser camera QC as part of accreditation. FDA requires that each facility be able to print diagnostic quality hard copy for purposes of transferring images.

For accreditation, clinical and phantom images must be taken within the same 30 day time frame and must be within the time frame period shown on the laser film printer QC chart.
The manufacturer of the FFDM unit has a number of different revisions of their QC manual available. Which one should the medical physicist and technologists follow for their QC tests?

The most current version of the QC manual for the unit installed at the facility must be followed.

Note: The correct manual version may not only depend on the FFDM unit but also on the software version of the unit.
Should the facility follow the review work station manufacturer’s QC manual when performing QC on the work station to comply with FDA regulations?

FDA regulations require the QA program at FFDM facilities to be substantially the same as the QA program recommended by the image receptor manufacturer. Some FFDM QC manuals provide specific instructions on performing QC of the review workstations used with their systems. Other manufacturers instruct the user to follow the QC manual of the review work station manufacturer.
Phantom Exposure Techniques for Accreditation

Should the exposure techniques specified in the manufacturer’s QC manual be used to expose the phantom to produce an image for ACR accreditation?

No. Although several manufacturers specify fixed, manual radiographic techniques to expose the phantom for routine QC, 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 manufacturer.
Is it acceptable for facilities to submit their phantom and clinical images to the ACR for accreditation on a CD?

No. ACR reviewers only review hard copy images at this time. Furthermore, the FDA has only approved the ACR to review hard copy images. The facility should print hard copies of the test images using the laser film printer and film processor (if applicable) normally used for digital mammograms.
When submitting phantom and clinical images to accredit a FFDM unit, is it acceptable to minify the image to fit multiple images on one sheet of film?

No. All accreditation images must be printed as close to “true size” as possible. Images should not be magnified or minified.
Demo Mammography Units

Are there any accreditation requirements for a facility to use a demo mammography unit?

A demonstration unit may be used for a limited time period before a facility is required to apply to have the unit included under its accreditation.

A facility may use a demo unit for 90 days without applying for ACR accreditation.

The facility is required to notify the ACR that they have a demo unit in place and to have a Qualified Medical Physicist perform an Equipment Evaluation after the demo unit is installed and before it is put into service.
Relocating Mammography Units

An accredited mammography unit is being relocated to another room in the same building. Are there any ACR/FDA requirements regarding post-move accreditation or QC?

If the address and facility are not changing, the ACR does not require any additional paperwork or accreditation testing.

If the unit is being disassembled and reassembled as part of the relocation, the FDA requires a QMP to conduct an Equipment Evaluation to ensure that the unit works properly. If the move consists of rolling the unit into a different room, no Equipment Evaluation is required. A phantom image test is required before use on patients.
Conclusion

All Qualified Medical Physicists performing mammography equipment evaluations and annual QC testing MUST become familiar with both the FDA and the ACR websites for the latest information and forms.

No excuses are accepted by either body for not being aware of a required test or updated form.