MQSA and Accreditation for Full-Field Digital Mammography – Everything You Need to Know in ½ Hour

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What I’m Going to Talk About

• Changes in mammography
• So you decided to put in in a new digital system
  – What can you buy?
  – What regulations should you be aware of when buying?
  – What do you have to do before legally starting mammography?
  – What required tests does the medical physicist have to perform?
• How you can pass accreditation
  – Tips
  – Early results
• Where to go for help
• What’s new
The ACR’s Mammography Accreditation Program: Ten Years of Experience Since MQSA

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The ACR’s Mammography Accreditation Program has been helping facilities improve the quality of mammography through peer review and professional feedback since 1987. Initially conceived as a voluntary program, accreditation became mandatory when the Mammography Quality Standards Act (MQSA) of 1992 required all U.S. mammography facilities to become accredited and certified by October 1, 1994. Currently, the ACR is the largest of four accrediting bodies approved by the U.S. Food and Drug Administration, accrediting 12,729 units at 8,325 facilities by October 1, 2004. Between 1987 and 1991, 70% of the mammography units applying for accreditation with the ACR passed on their first attempts. In 2003, 88.3% of the units passed on their first attempts, indicating a marked improvement in the quality of mammography in the United States since MQSA went into effect 10 years ago.

Key Words: Breast radiography, quality assurance

US Mammography Facilities and Units

As of 11/1/07
- 13,590 units
- 8841 facilities
Full Field Digital Mammography in the US

As of 11/1/07

- 3644 FFDM units at
- 2434 facilities
- 27% of units are FFDM
- 6% growth/mo
FDA Office of Device Evaluation

- Clears FFDM for sale in US
- GE Senographe 2000D, DS, Essential
- Fischer SenoScan
- Lorad Selenia Amorphous Selenium
- Siemens Mammomat Novation DR
- Fuji FCRm
- Approves monitors and printers for sale in US

FDA Office of Communication, Education and Radiation Programs

- Writes and enforces MQSA regulations
- Issues MQSA certificates
FDA Regulations and Guidance You Should Know When Going Digital

- Digitizing analog images
- Transferring digital images
- Transmitting digital images for interpretation
- Image labeling
- Printers and monitors
- Archiving digital images

Guidance is available in writing on internet:
  - FDA Policy Guidance Help System
  - ACR FAQs (to help explain federalese)
May I Digitize Screen-Film Images?

- For comparison purposes
  - Yes, if interpreting physician deems it acceptable; FDA also suggest digitizers be cleared by FDA for mammography

- For retention purposes
  - No

- For final interpretation
  - No
How Must I Transfer Digital Images if Requested by Patient or MD?

- **Must be able to provide** hardcopy of final interpretation quality
  - Many complaints on poor hardcopies
- **Softcopy original or lossless compressed images**, *if acceptable by receiving party*
- **Charging for hardcopies**
  - May not charge for 1st hardcopy
  - May charge for additional copies (actual costs)
May I Transmit Digital Images for Final Interpretation?

- The original or lossless compressed FFDM data
  - *Yes, if acceptable by receiving party*
- Lossy compressed FFDM data
  - *No*
• 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 (view & laterality MUST be near axilla)
  – May be switched off
  – Applies to BOTH hardcopy and softcopy images
Printers and Monitors

• **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 *image receptor* manufacturer
  – Must pass (or be able to pass) accreditation clinical image review
May I Retain Digital Mammograms as:

- Original or lossless compressed FFDM data?
  - Yes

- Lossy compressed FFDM data?
  - No

- Hardcopy film of final interpretation quality?
  - Yes
FDA Approved ACR to Accred

- GE
  - 2000D, DS, Essential
- Fischer
  - Senoscan
- Lorad
  - Selenia
- Siemens
  - Novation
- Fuji
  - FCRm (computed radiography)
Facility Completes Entry Application

ACR Reviews Entry Application; Sends Facility Full Application

ACR Reviews Full Application

Facility Completes Full Application & Returns to ACR

ACR Reviews Full Application

Facility/Unit Deficiency (1st)

Facility/Unit Passes

Facility/Unit Repeats, Appeals or Withdraws

ACR Writes Final Report

Clinical Image Review

Phantom Image Review

ACR Notifies FDA

FDA Sends Facility 3-yr Certificate (facility may continue mammography)

FDA Sends Facility a 6-mo Provisional Certificate (facility may do mammography)

ACR Notifies FDA

Facility Renews Accreditation in 3 Years

The process is exactly the same as for screen-film

Accrediting FFDM
• Medical physicist must do all FDA-required Equipment Evaluation tests and they must pass

• Facility must send ACR the Entry Application, fees and Equipment Evaluation Pass/Fail results
  – ACR staff reviews and approves complete application and Equipment Evaluation and notifies FDA (or state certifier)

• Facility **must receive 6-month provisional MQSA certificate** (or interim notice)
  – Not more than 4 days from the time facility submits required documentation to ACR

• Recommend scheduling Equipment Evaluation **1 week before examining patients** (including “applications”)
Currently, you must send in hardcopy application; in the future, you will be able to submit applications on-line.

See www.acr.org for New Facility Application
New Unit at Accredited Facility - Before You May Examine Patients

• **Call ACR** for appropriate application materials
• **Medical physicist** must do all FDA-required Equipment Evaluation tests and they must pass
• **Facility must send ACR** the application, fees **and** Equipment Evaluation Pass/Fail results
• **Facility does not have to wait for a response from ACR** to use the new unit for mammography
  – Facility already has a current MQSA certificate
• **Beware if you have digital**, CMS will not reimburse if they don’t have notification from FDA that you are approved for digital
  – Call ACR to be sure we have received your FFDM application and transmitted it to the FDA before using
FFDM Equipment Evaluations, Annual Surveys and QC

*FDA regulations require facilities to follow FFDM manufacturer’s QC – this makes life interesting for everyone*
FDA’s Current FFDM QC Requirements

- Follow latest version of mfr’s QC manual procedures for unit tested
- Meet mfr’s performance standards
- Failures must be fixed before use on patients (no more 30 days)
  - GE, Lorad and Fuji applied for alternative standards to allow 30 days for some QC tests
900.12(e)(6) QC Tests-Other Modalities:

“the quality assurance program shall be substantially the same as the quality assurance program recommended by the image receptor manufacturer, except that the maximum allowable dose shall not exceed the maximum allowable dose for screen-film systems in this section”

• The “image receptor manufacturer” would be GE, Fischer, Lorad, Siemens or Fuji
ACR’s Current FFDM QC Requirements

- Same as FDA’s
- ACR suggests using mfr’s data forms
- Medical physicist **must** complete ACR’s summary forms
  - MQSA Requirements for Mammography Equipment (checklist)
  - Medical Physicist’s Mammography QC Test Summary form
  - Available on ACR website in Excel
- Forms provides ACR with essential pass/fail information
  - If medical physicist passes test, ACR accepts it
  - If he/she fails test, ACR requests corrective action
  - If he/she writes “N/A,” “see comments” (or anything other than pass or fail), ACR will follow-up; accreditation will be delayed
- Different formats (even if they contain all the necessary information) will delay review
Medical Physicist’s Mammography
QC Test Summary Forms

• Use for both Equipment Evaluations and Annual Surveys
• Addresses 900.12(e) of the FDA regulations
• All have been revised to further streamline
• Excel format
  – Built-in P/F drop-down boxes
• Use the one for your digital unit manufacturer
  – General Electric Fischer
  – Lorad Siemens
  – Fuji
• Check version of manufacturer's QC manual used
• Single overall review workstation assessment
### MEDICAL PHYSICIST'S CHECKLIST

**MQSA REQUIREMENTS FOR MAMMOGRAPHY EQUIPMENT**

<table>
<thead>
<tr>
<th>Feature</th>
<th>FDA Rule Section</th>
<th>Requirement</th>
<th>Applies to</th>
<th>Meets FDA Requirements? (if NA, please explain)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Motion of tube-image receptor assembly</td>
<td>3(i)</td>
<td>The assembly shall be capable of being fixed in any position where it is designed to operate. Once fixed in any such position, it shall not undergo unintended motion.</td>
<td>S-F &amp; FFDM</td>
<td>☑ Yes ☐ No ☐ NA</td>
</tr>
<tr>
<td></td>
<td>3(ii)</td>
<td>This mechanism shall not fail in the event of power interruption.</td>
<td>S-F &amp; FFDM</td>
<td>☑ Yes ☐ No ☐ NA</td>
</tr>
<tr>
<td>Image receptor sizes</td>
<td>4(i)</td>
<td>Systems using screen-film image receptors shall provide, at a minimum, for operation with image receptors of 18 x 24 cm and 24 x 30 cm.</td>
<td>S-F</td>
<td>☑ Yes ☐ No ☐ NA</td>
</tr>
<tr>
<td></td>
<td>4(ii)</td>
<td>Systems using screen-film image receptors shall be equipped with moving grids matched to all image receptor sizes provided.</td>
<td>S-F</td>
<td>☐ Yes ☑ No ☐ NA</td>
</tr>
<tr>
<td></td>
<td>4(iii)</td>
<td>Systems used for magnification procedures shall be capable of operation with the grid removed from between the source and image receptor.</td>
<td>S-F &amp; FFDM</td>
<td>☐ Yes ☑ No ☐ NA</td>
</tr>
</tbody>
</table>
**MEDICAL PHYSICIST'S MAMMOGRAPHY QC TEST SUMMARY**

**Full-Field Digital – General Electric**

<table>
<thead>
<tr>
<th>Site Name</th>
<th>Report Date</th>
</tr>
</thead>
<tbody>
<tr>
<td>Address</td>
<td>Survey Date</td>
</tr>
<tr>
<td>Medical Physicist's Name</td>
<td>Signature</td>
</tr>
<tr>
<td>X-Ray Unit Manufacturer</td>
<td>Model</td>
</tr>
<tr>
<td>Date of Installation</td>
<td>Room ID</td>
</tr>
</tbody>
</table>

**QC Manual Version:** (check one; **must** use version applicable to unit tested; contact mfr if questions)  
- DS 5133453-2-100 Rev 1, 2006  
- ESSENTIAL 5141465-2-100 Rev 1, 2006  
- OTHER (write in):  

**Accessory Equipment:**

<table>
<thead>
<tr>
<th>Manufacturer</th>
<th>Model</th>
<th>Location</th>
<th>QC Manual Version</th>
</tr>
</thead>
<tbody>
<tr>
<td>Review Workstation*</td>
<td></td>
<td>On-site</td>
<td></td>
</tr>
<tr>
<td>Laser Film Printer*</td>
<td></td>
<td>Off-site</td>
<td></td>
</tr>
</tbody>
</table>

* **FDA recommends** that only monitors and printers specifically cleared for FFDM use by FDA’s Office of Device Evaluation (ODE) be used, but the use of others is also legal. See FDA’s Policy Guidance Help System Modification Document #9 (page 27).

**Survey Type:**  
- Mammo Eqpt Evaluation of new unit (include MQSA Rqmts for Mammo Eqpt checklist)  
- Annual Survey

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**Medical Physicist's QC Tests**

1. **Flat Field**
2. **Phantom Image Quality**
   - Phantom IQ Test on AWS  
   - Phantom IQ Test on Printer

15. **Review Workstation (RWS) Tests*** (for all RWS, even if located offsite)

**Overall Results** (*Pass* means all tests pass; indicate "Fail" if any test fails)

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* **FDA requires** that all RWS comply with a QC program that is **substantially the same** as that recommended by the image receptor manufacturer. If the RWS has been approved by the FDA’s ODE for FFDM, the FDA considers the RWS’s QC manual to be "substantially the same" and you may follow it for QC. (Check with the RWS manufacturer for their system’s FDA clearance status and their QC manual.) If the RWS has not been approved by the FDA’s ODE for FFDM, you must follow the QC manual provided by the image receptor manufacturer. (In this case, check with the image receptor manufacturer for their required tests.)

*** YOUR MEDICAL PHYSICIST MUST SUMMARIZE HIS/HER RESULTS ON THIS FORM ***

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3rd Party Components used with the FFDM Unit

*Life gets even more interesting*
FDA *recommends* only using printers cleared by FDA’s Office of Device Evaluation for FFDM (but may legally use others)

- Facility must have access to a laser printer (either on-site or someplace else)
- Printer *must exist and be tested* by MP before the facility performs mammography
- Laser film printer QC

<table>
<thead>
<tr>
<th>FFDM Mfr</th>
<th>Model</th>
<th>FFDM Mfr’s Printer QC Instructions</th>
</tr>
</thead>
<tbody>
<tr>
<td>GE</td>
<td>2000D, DS, Essential</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>
Monitors and Workstations

- FDA MQSA regs state facilities must comply with a QA program *substantially the same as recommended by the FFDM manufacturer* (i.e., GE, Fischer, Lorad, Siemens, Fuji)
  - Impractical; sometimes impossible since some is software-based

- FDA has informed the ACR that
  - If the monitor/workstation has been approved by FDA’s ODE for FFDM, the monitor’s QC manual is “substantially the same” and facilities may follow
  - If monitor was not approved by FDA ODE for FFDM facilities must follow one by FFDM mfr

- FDA ODE approved monitors/workstations
  - Over 500 approved total
  - ??? have been approved for FFDM
<table>
<thead>
<tr>
<th>Test</th>
<th>Flat Field</th>
</tr>
</thead>
<tbody>
<tr>
<td>GE</td>
<td>“Flat Field”</td>
</tr>
<tr>
<td>Fischer</td>
<td>“Flat Field”</td>
</tr>
<tr>
<td>Lorad</td>
<td>“Artifact Evaluation”</td>
</tr>
<tr>
<td>Siemens</td>
<td>“Detector Calibration”</td>
</tr>
</tbody>
</table>
Mfr QC Manuals Are All Very Different
Example: Technologist Tests

Frequencies

<table>
<thead>
<tr>
<th>Test</th>
<th>Soft Copy Display</th>
</tr>
</thead>
<tbody>
<tr>
<td>GE</td>
<td>Monthly</td>
</tr>
<tr>
<td>Fischer</td>
<td>Daily</td>
</tr>
<tr>
<td>Lorad</td>
<td>Weekly</td>
</tr>
<tr>
<td>Siemens</td>
<td>Daily</td>
</tr>
</tbody>
</table>
Time for QC

- QC takes longer with digital
- Techs need adequate time for routine QC
  - Includes actual testing and documentation
  - More time needed for corrective action if problems
- Don’t be stingy
  - High-profile cases of fraudulent QC
  - MQSA certifications revoked
  - Fines levied
  - License and/or tech certificate revoked
  - Some cases went to court
  - Tech blamed insufficient time
Accreditation Testing Must Pass

• Clinical image review (fatty and dense breast)
• Phantom image review
• Dose (<300 mrads)
• Processor QC or
• Laser QC for FFDM
  – Follow your mfr QC manual
• Criteria the same for digital as with screen-film
Clinical Image Quality Evaluation

- Positioning
  - Major reason for failure
- Compression
- Exposure level
- Contrast
- Sharpness
- Noise
- Artifacts
- Exam ID
  - Must be present
  - OK under HIPAA

Failure due to positioning and missing tissue
Phantom Image Quality Evaluation

- Follow ACR testing instructions
  - Expose at technique for 4.2 cm breast
- Process image as done for clinical images
- Window and level to best show test objects
- Scoring criteria
  - 4 largest fibers
  - 3 largest speck groups
  - 3 largest masses
  - Subtract for artifacts
For Digital, ACR Only Accepts Hardcopy for Accreditation

• **Phantom**
  - Do not zoom or rotate
  - Print as close to “true size” as possible (within +/- 25%)

• **Clinical**
  - Must be of “final interpretation quality”
  - Entire breast must fit on image; no “tiling”
  - Print as close to “true size” as possible
  - Must contain patient ID information

• **Lead interpreting physician must review and approve all hardcopy images**
Where to Go for Help on Digital QC, MQSA Certification and ACR Accreditation
Your Medical Physicist Is Your Friend

• Talk with her before the annual survey
  – Let her know if you have equipment or QC problems/questions

• Talk with her after you receive the report
  – Make sure you understand all results, recommendations and timeframes

• Talk with her during the year any time you have questions or concerns about equipment performance
  – Show clinical images illustrating the problem (physicists like pictures too)
<table>
<thead>
<tr>
<th>FFDM Mfr</th>
<th>Phone #</th>
<th>Website</th>
</tr>
</thead>
<tbody>
<tr>
<td>GE</td>
<td>(800) 643-6439</td>
<td><a href="http://www.gemedicalsystems.com">www.gemedicalsystems.com</a></td>
</tr>
<tr>
<td>Fischer (Kodak)</td>
<td>(800) 825-8434</td>
<td><a href="http://www.fischerimaging.com">www.fischerimaging.com</a></td>
</tr>
<tr>
<td>Fuji</td>
<td>(800) 272-8465</td>
<td><a href="http://www.fujimed.com">www.fujimed.com</a></td>
</tr>
<tr>
<td>Lorad</td>
<td>(781) 999-7300</td>
<td><a href="http://www.hologic.com">www.hologic.com</a></td>
</tr>
<tr>
<td>Siemens</td>
<td>(888) 826-9702</td>
<td><a href="http://www.medical.siemens.com">www.medical.siemens.com</a></td>
</tr>
</tbody>
</table>
Citation:
900.12(e)(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 photometric 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, nonmagnification; and various target-film 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 applies?

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 applies?
Mammography

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.

Contact Us
For additional information, contact us by:
- Email: mamm-accred@acr.org
- Phone: (800) 227-6440

Program Overview
- Click here for Mammography Program Overview
- The ACR Mammography Accreditation Program and MQSA
- MQSA Certified Mammography Facilities and Accredited Mammography Units
- Update on Accreditation of Screen-Film and Digital Mammography: RC221

Frequently Asked Questions
- MQSA and FDA Regulations
- ACR Mammography Accreditation
NEW!
ACR Breast Imaging Centers of Excellence
Breast Imaging Center of Excellence
Designation Criteria

• A center must be fully accredited in:
  – Mammography by the ACR (or an FDA-approved state accrediting body)
  – Stereotactic Breast Biopsy by the ACR
  – Breast Ultrasound by the ACR (including the Ultrasound-Guided Breast Biopsy module)

• 164 Breast Imaging Centers of Excellence (10/18/07)
  – 173 accredited mammography facilities
  – 170 accredited breast ultrasound facilities
  – 166 accredited stereotactic breast biopsy facilities

• For more information, go to