ACR Full-Field Digital Mammo QA Manual

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What I’m Going to Talk About

• Digital’s impact on mammography in the US
• Digital mammography QC – as it exists now
• Digital mammography QC – as we hope it will exist in the future
• Some general thoughts
In 2000
- 12,956 units at 9933 facilities
- 1.3 units/facility

As of 9/1/10
- 12,412 units at 8646 facilities
- 1.44 units per facility
- 4% drop in facilities/13% drop in units since 2000
Look at the Growth of FFDM in the US!

As of 9/1/10

- Significant increase since 2005 ACRIN result
- 8614 units at 5903 facilities
- Over 68% of all units in US are FFDM
FDA Approved ACR to Accredit

- **GE**
  - 2000D, DS, Essential
- **Fischer**
  - SenoScan
- **Lorad**
  - Selenia
- **Siemens**
  - Novation
- **Fuji**
  - FCRm (computed radiography)
## Accreditation Results

<table>
<thead>
<tr>
<th></th>
<th># Units*</th>
<th>Pass</th>
<th>Deficient</th>
</tr>
</thead>
<tbody>
<tr>
<td>Screen-Film</td>
<td>19,854</td>
<td>89.0%</td>
<td>11.0%</td>
</tr>
<tr>
<td>FFDM</td>
<td>5085</td>
<td>93.3%</td>
<td>6.7%</td>
</tr>
</tbody>
</table>

*1st attempt for both initials and renewals; 2/15/03 – 4/24/08*
Reasons Facilities Do Not Pass Accreditation

1st Attempt Screen-Film Deficiencies (2/15/03 - 4/24/08)
- Clinical: 72.6%
- Phantom: 27.4%

1st Attempt FFDM Deficiencies (2/15/03 - 4/24/08)
- Clinical: 81.2%
- Phantom: 18.8%
Clinical Images: Fatty vs. Dense Deficiencies

Screen-Film Clinical Deficiencies

- Dense: 56.3%
- Fatty: 43.7%

FFDM Clinical Deficiencies

- Dense: 47.3%
- Fatty: 52.7%
## Phantom Images and Dose

<table>
<thead>
<tr>
<th></th>
<th># Units</th>
<th>Fibers</th>
<th>Specks</th>
<th>Masses</th>
<th>Ave Dose* (mrads)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Screen-Film</strong></td>
<td>19,854</td>
<td>4.71</td>
<td>3.61</td>
<td>3.75</td>
<td>163.7</td>
</tr>
<tr>
<td>(SD)</td>
<td>(0.47)</td>
<td>(0.39)</td>
<td>(0.40)</td>
<td></td>
<td>(31.0)</td>
</tr>
<tr>
<td><strong>FFDM</strong></td>
<td>5085</td>
<td>5.01</td>
<td>3.90</td>
<td>4.12</td>
<td>129.7</td>
</tr>
<tr>
<td>(SD)</td>
<td>(0.55)</td>
<td>(0.31)</td>
<td>(0.40)</td>
<td></td>
<td>(42.2)</td>
</tr>
</tbody>
</table>

*as measured by TLD

Dose with FFDM is 20% lower than S-F
ACR’s Current FFDM QC Requirements

• Same as FDA’s
• Which are the same as the manufacturer’s
• ACR suggests using manufacturer’s data forms
• Tests vary for each manufacturer and model
  – Some tests same but names different
  – Some tests not required by some manufacturers
• Frequencies vary for each manufacturer and model
• Procedures vary for each manufacturer and model
• Pass/fail criteria vary for each manufacturer and model
• All of the above may vary with QC manual revisions of same manufacturer/model
Confusing for technologists with multiple manufacturers (or single manufacturer but multiple models or software versions) at same facility

Confusing for medical physicists surveying multiple facilities with different equipment for same reasons

Confusing for accreditation staff and inspectors to review for same reasons

Examples…
# Mfr QC Manuals Are All Very Different

## Example: Technologist Tests-Frequencies

<table>
<thead>
<tr>
<th>Test</th>
<th>Monitor Cleaning</th>
<th>SNR and/or CNR</th>
<th>Flat Field</th>
<th>MTF/ Sys Res</th>
</tr>
</thead>
<tbody>
<tr>
<td>Fischer</td>
<td>Not in QC</td>
<td>Weekly</td>
<td>Weekly</td>
<td>Monthly</td>
</tr>
<tr>
<td>Fuji</td>
<td>Not req’d</td>
<td>Weekly</td>
<td>Not req’d</td>
<td>Not req’d</td>
</tr>
<tr>
<td>Lorad</td>
<td>Not req’d</td>
<td>Weekly</td>
<td>Weekly</td>
<td>Not req’d</td>
</tr>
<tr>
<td>Siemens</td>
<td>Daily (Syngo)</td>
<td>Weekly</td>
<td>Weekly</td>
<td>Not req’d</td>
</tr>
<tr>
<td>Test</td>
<td>Flat Field</td>
<td>SNR and/or CNR</td>
<td>MTF/Sys Res</td>
<td></td>
</tr>
<tr>
<td>-------</td>
<td>---------------------</td>
<td>-------------------------------</td>
<td>---------------------------------</td>
<td></td>
</tr>
<tr>
<td>GE</td>
<td>Flat Field</td>
<td>AOP Mode and SNR; CNR</td>
<td>MTF or Sub-System MTF</td>
<td></td>
</tr>
<tr>
<td>Fischer</td>
<td>Flat Field</td>
<td>Phantom Image Acquisition</td>
<td>System Resolution/Scan Speed Uniformity</td>
<td></td>
</tr>
<tr>
<td>Fuji</td>
<td>System Artifact Evaluation</td>
<td>AEC System Performance; Interplate Consistency</td>
<td>System Resolution</td>
<td></td>
</tr>
<tr>
<td>Lorad</td>
<td>Artifact Evaluation</td>
<td>SNR; CNR</td>
<td>Evaluation of System Resolution</td>
<td></td>
</tr>
<tr>
<td>Siemens</td>
<td>Detector Uniformity and Artifact Detection</td>
<td>SNR; CNR</td>
<td>Spatial Resolution</td>
<td></td>
</tr>
</tbody>
</table>
FDA’s Current FFDM QC Requirements

• Follow latest version of mfr’s QC manual procedures for unit tested
  – Lorad (Hologic) allows facility to follow any of their manuals

• Meet mfr’s performance standards

• Failures must be fixed before use on patients
  – GE, Lorad and Fuji applied for alternative standards to allow 30 days for some QC tests
• 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

*(current as of 4/10)*

<table>
<thead>
<tr>
<th>FFDM Mfr</th>
<th>Model</th>
<th>FFDM Mfr’s Printer QC Instructions</th>
</tr>
</thead>
<tbody>
<tr>
<td>Fischer</td>
<td>SenoScan</td>
<td>Follow the laser printer mfr’s QC</td>
</tr>
<tr>
<td>Fuji</td>
<td>FCRm</td>
<td>Follow the laser printer mfr’s QC</td>
</tr>
<tr>
<td>GE</td>
<td>2000D, DS, Essential</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>
• 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 says
  – 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
Medical Physicist's QC

• Medical physicist must complete ACR’s summary forms
  – MQSA Requirements for Mammography Equipment (checklist)
  – Medical Physicist’s Mammography QC Test Summary (FFDM mfr-specific)
• Forms provides ACR with needed pass/fail information
  – If medical physicist passes test, ACR accepts it
  – If she fails test, ACR requests corrective action
  – If she writes “NA,” “see comments” (or anything other than pass or fail), ACR will follow-up; accreditation will be delayed
• Significantly different formats (even if they contain all the necessary information) will delay review
Have Your Medical Physicist Download Summary Forms

- www.acr.org
- In Excel format
- Required for Equipment Evaluation report
- Addresses 900.12(b) of the FDA regulations
- Same for S-F and FFDM

**MEDICAL PHYSICIST'S CHECKLIST**
**MQSA REQUIREMENTS FOR MAMMOGRAPHY EQUIPMENT**

<table>
<thead>
<tr>
<th>Facility Name:</th>
<th>Model:</th>
</tr>
</thead>
<tbody>
<tr>
<td>Unit Manufacturer:</td>
<td>Year Mfr:</td>
</tr>
<tr>
<td>Serial number:</td>
<td>Room ID:</td>
</tr>
<tr>
<td>Medical Physician:</td>
<td>Survey Date:</td>
</tr>
</tbody>
</table>

<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</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 interrupt</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 16 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</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 QC Tests

*“Pass” means all components of the test pass; indicate “Fail” if any component fails*

<table>
<thead>
<tr>
<th>Test Description</th>
<th>Manufacturer</th>
<th>Model</th>
<th>Location</th>
<th>QC Manual Version</th>
</tr>
</thead>
<tbody>
<tr>
<td>Flat Field</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Phantom Image Quality</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Phantom IQ Test on AWS</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Phantom IQ Test on Printer</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>CNR Measurement (NA for DS or Essential if Sub-System MTF test done)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>CNR</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Change in CNR ≤ 0.2 (NA for Mammography Equipment Evaluations)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

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

<table>
<thead>
<tr>
<th>RWS Tests Description</th>
<th>Overall Results</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td><strong>Fail</strong></td>
</tr>
</tbody>
</table>
ACR FFDM QC Manual Project

• Eric Berns, Ph.D., chair, Subcommittee on QA
• Subcommittee includes medical physicists, radiologists, MITA representatives and technologists
• Standardize QC tests, performance criteria and frequencies across all systems
  – Will apply to all manufacturers and models
  – New phantom to be more applicable to digital (but usable with screen-film)
New ACR FFDM Phantom (prototype)

- Same scoring
- Smaller fibers, specks and masses
- But P/F criteria (size) will be same
- Larger to cover entire detector
- AEC response better
- Permits artifact evaluation
- To be used with most tests
New ACR FFDM Phantom (prototype)
ACR FFDM QC Phantom

- Developed with assistance and input from several MITA phantom and equipment manufacturers
- Still a prototype
- Will not be commercially available for use in accreditation until the FDA reviews and approves it along with the manual
New Manual Technologist QC Tests (draft)

• Fewer tests and written to be “tech friendly”
  – Field tested in December 2009

• More pictures

• Excel forms downloadable from website – may be completed on paper or via computer
New Manual Technologist QC Tests-I (draft)

- Monitor Cleanliness (weekly)
- ACR Phantom Image Quality – multipurpose (weekly)
  - Technique evaluation
  - Compression thickness
  - Dose display
  - Contrast-to-noise
  - Artifacts
  - Scoring
- Laser Printer QC – done with phantom (weekly)
  - Scoring
  - Artifacts
  - Optical density
  - No graphing (record data on chart)
New Manual Technologist QC Tests-II (draft)

- Monitor QC - AWS and RWS (weekly)
  - Phantom evaluation (scoring and artifacts)
  - AAPM TG-18 test pattern
  - Built in automatic tests (if available from manufacturer)
- Viewbox Cleanliness Check – same (weekly)
- Visual Checklist (monthly)
- Repeat Analysis (quarterly)
- Compression Force (semi-annual)
- Detector Calibration (optional)
- Quarterly QC Review
• QC Review – new (quarterly)
  – To enhance communication among key mammography personnel
  – Reviewers
    • QC technologist
    • Facility manager
    • Supervising radiologist
  – Review
    • Technique chart
    • QC in the last quarter
    • Corrective action
• Excel forms downloadable from website – designed to be completed via computer (with calculations built in)
• New summary form designed for radiologist (in addition to main summary form)
• ACR Phantom Image Quality (Acquisition Workstation)
  – Phantom scoring
  – Artifacts
  – SNR
  – CNR
  – Geometric accuracy
• Ghost Image Evaluation
• Automatic Exposure Control System Performance
• Spatial Resolution
  – Bar pattern

• Collimation Assessment
  – Traditional method,
  – Ready pack film/paper, or
  – Electronic device

• kVp Accuracy and Reproducibility
  – For Mammography Equipment Evaluations only (not annually)
• Beam Quality (Half-Value Layer) Assessment

• Average Glandular Dose
  – Phantom
  – 2 cm attenuator
  – 6 cm attenuator

• Unit Checklist
• Monitor QC
  – Acquisition station monitor
  – Radiologist work station monitors
  – Use phantom image and AAPM TG-18
  – Must consider diverse practice patterns

• Laser Printer QC
  – Use phantom image and AAPM TG-18
  – Must consider diverse practice patterns

• Evaluation of Site’s Technologist QC Program
  – MPs need to play a stronger role

• Computed Radiography Tests
• When ready, draft will be sent to manufacturers for their input before it is sent to FDA
  – We hope manufacturers will adopt this manual

• Draft should be completed in 2010 for review by FDA
  – When final, ACR will apply for FDA alternative standard
  – Alternative standard will allow facilities to use this instead of the manufacturer’s manuals
Where to Go for Help on Digital QC, MQSA Certification and ACR Accreditation
• 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)
Contact FFDM Manufacturer for QC Assistance

<table>
<thead>
<tr>
<th>FFDM Mfr</th>
<th>Website</th>
</tr>
</thead>
<tbody>
<tr>
<td>GE</td>
<td><a href="http://www.gehealthcare.com">www.gehealthcare.com</a></td>
</tr>
<tr>
<td>Fuji</td>
<td><a href="http://www.fujimed.com">www.fujimed.com</a></td>
</tr>
<tr>
<td>Lorad</td>
<td><a href="http://www.hologic.com">www.hologic.com</a></td>
</tr>
<tr>
<td>Siemens</td>
<td><a href="http://www.medical.siemens.com">www.medical.siemens.com</a></td>
</tr>
</tbody>
</table>
Other Modalities Quality Control Tests

Citation:

900.12(e)(6): Quality Control tests — other modalities. For systems with image receptor modalities other than screen-film, 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 paragraph (e)(5)(vi) of this section.

Questions:

1. What are the required quality control tests for new mammographic modalities?

2. Can a facility use printers and monitors that were not specifically approved as part of its FFDM unit?

3. Can a manufacturer hook up a printer or monitor to its FFDM unit if the printer or monitor were not part of its original Pre-Market Approval (PMA)?

4. Must a facility perform all the required QC testing on a laser printer even if the facility is using only soft copy for final interpretation and is using the printer only to provide final interpretation quality hard copy images to patients, their representatives, and health-care providers or for retention purposes? If not, is the facility subject to citation during an MQSA inspection?
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) 227-5440

Program Requirements

- Click here for Mammography Accreditation Program Requirements
- The ACR Mammography Accreditation Program: Ten Years of Experience Since MOSA
- MOSA Certified Mammography Facilities and Accredited Mammography Units
- MOSA and Accreditation for Full-Field Digital Mammography

Frequently Asked Questions

- The ACR Mammography Accreditation Program: Frequently Asked Questions (PDF, updated 8/5/09)

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.
“Toto, I don’t think we are in Texas anymore.”