Update on MQSA and Mammography Accreditation

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MQSA - Who’s Who

The Law: Mammography Quality Standards Act (MQSA)
The Regulator: US Food and Drug Administration (FDA)
The Accreditation Bodies: (ACR, TX, IA, AR)
The Inspectors: States

US Mammography Facilities and Units (October 1 each year)

In 2000
- 12,956 units at 9933 facilities
- 1.3 units/facility

As of 4/1/11
- 12,313 units at 8641 facilities
- 1.42 units per facility
- 5% drop in units/15% drop in facilities since 2000

MQSA and New Units

- What you must do before examining patients on a new unit depends on
  - If you are a brand new facility
  - If you installed a new unit at an already accredited facility
If You Are a Brand New Facility - Before You May Examine Patients

• Your medical physicist must
  – Do all FDA-required Equipment Evaluation tests
  – All tests must pass
• You must send ACR
  – A complete Entry Application
  – Equipment Evaluation Pass/Fail results
  – Fees
• Then...

If You Are a Brand New Facility - Before You May Examine Patients

• ACR staff must
  – Review and approve complete application and Equipment Evaluation
  – Notify FDA (or state certifier) OK to send MQSA certificate (or interim notice)
• There’s more...

If You Are a Brand New Facility - Before You May Examine Patients

• You must physically have a
  – 6-month provisional MQSA certificate (or interim notice)
• Timing
  – Getting the MQSA certificate takes approximately 4 days from the time facility submits complete documentation to ACR
  – Recommend scheduling Equipment Evaluation 1 week before examining patients (including “applications”)

See www.acr.org for New Facility Application
If Your Facility Is Already Accredited - Before You May Examine Patients

• You must call ACR for appropriate application materials
• Your medical physicist must
  – Do all FDA-required Equipment Evaluation tests
  – All tests must pass
• You must send ACR
  – A complete Entry Application
  – Equipment Evaluation Pass/Fail results
  – Fees
• Then...

If Your Facility Is Already Accredited - Before You May Examine Patients

• ACR staff must
  – Review and approve complete application and Equipment Evaluation
  – Notify FDA (or state certifier)
• However...

If Your Facility Is Already Accredited - Before You May Examine Patients

• You do not have to wait for a response from ACR to use the new unit for mammography
  – Your facility already has a current MQSA certificate
• Beware of the catch if installing facility’s 1st digital unit:
  – 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 and reviewed your complete application and transmitted it to the FDA before using the new digital unit

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)
Medical Physicist’s QC

- 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

Download Medical Physicist 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

Tips for Passing Accreditation
Accreditation Testing

- Clinical image (fatty and dense breast)
  - Phantom image
  - Dose (<300 mrad)
- Hard copy QC
  - Film processor
  - Laser printer (see mfr QC manual)
- Criteria the same for digital as with screen-film

Clinical Image Quality Evaluation - FFDM

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

Breast Imaging

Reasons for Failure of a Mammography Unit at Clinical Image Review in the American College of Radiology Mammography Accreditation Program

Purpose: To identify the most common deficiencies in the quality of mammograms submitted for clinical image evaluation of image from screen-film mammography.

Methods and Results: In 1991, the American College of Radiology (ACR) developed the mammography accreditation program. In a 1993 survey, mammography facilities were still reporting clinical image deficiencies. A follow-up study was conducted in 1995 to survey mammography facilities that failed the accreditation process. X-ray images were obtained with a Philips MDM unit, processed with a Kodak 1000 processor, and read with a Mammorad 1100 reader. Images were scored according to the ACR criteria for image quality. The 1993 survey revealed that 23% of mammograms failed the accreditation process. The 1995 survey showed that 15% of mammograms failed the accreditation process.

Results: The following deficiencies were noted:

1. POSITIONING: 20% of images failed for positioning, particularly for the craniocaudal view. The positioning of the breast was often incorrect, with the breast not fully depressed or the skinfold not accurately aligned.
2. EXPOSURE: 15% of images failed due to exposure, with underexposure being the most common issue.
3. COMPRESSION: 14% of images failed due to compression, with insufficient compression leading to inadequate visualization of the breast tissue.
4. SHARPNESS: 13% of images failed due to sharpness, with images appearing blurry or out of focus.
5. CONTRAST: 13% of images failed due to contrast, with images appearing too dark or too light.
6. ARTIFACTS: 11% of images failed due to artifacts, with厂家 being the most common issue.
7. LABELING: 8% of images failed due to labeling, with issues such as missing or inaccurate labels.
8. NOISE: 5% of images failed due to noise, with images appearing grainy or noisy.

Reasons for Clinical Failure – still the major reason for failure with FFDM

<table>
<thead>
<tr>
<th>Imaging Category</th>
<th>Failure Rate (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Positioning</td>
<td>20</td>
</tr>
<tr>
<td>Exposure</td>
<td>15</td>
</tr>
<tr>
<td>Compression</td>
<td>14</td>
</tr>
<tr>
<td>Sharpness</td>
<td>13</td>
</tr>
<tr>
<td>Contrast</td>
<td>13</td>
</tr>
<tr>
<td>Artifacts</td>
<td>11</td>
</tr>
<tr>
<td>Labeling</td>
<td>8</td>
</tr>
<tr>
<td>Noise</td>
<td>5</td>
</tr>
</tbody>
</table>
Why Did This Digital Case Fail Accreditation?

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
    - Be sure to 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 (w/in +/- 25%)
  - Do not send in 14X17 images
- 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

Look at the Growth of FFDM in the US!

As of 4/1/11
- 9387 units at 6523 facilities
- Over 76% of all units in US are FFDM

US Full-Field Digital Mammography (FFDM) Units and Facilities

October 1 of each year
**FDA Approved ACR to Accredit**

- GE
  - 2000D, DS, Essential
- Fischer
  - SenoScan
- Lorad
  - Selenia
- Siemens
  - Novation
- Fuji
  - FCRm (computed radiography)
- Carestream
  - DirectView

**Digital Breast Tomosynthesis (DBT) System Accreditation**

- Accreditation Bodies (ABs) cannot accredit the DBT modality portion of the unit because they do not have the capability to review DBT images
- Facilities with DBT must apply for accreditation of Selenia Dimensions 2D aspect of AND
- Apply to FDA to extend its certification to include DBT
  - Submit additional DBT testing results and other documentation directly to FDA for review and approval

**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

**Manufacturer’s FFDM QC Requirements – They Vary…A Lot**

- By manufacturer and model
  - Some tests same but names different
  - Some tests not required by some manufacturers
  - Frequencies vary
  - Procedures vary
  - Pass/fail criteria
- All of the above may vary with QC manual revisions of same manufacturer/model
QC, Equipment Evaluation, and Annual Survey Conduct and Review

• 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>
</tbody>
</table>

Mfr QC Manuals Are All Very Different

Example: Medical Physicist Tests-Names

<table>
<thead>
<tr>
<th>Test</th>
<th>Flat Field</th>
<th>SNR and/or CNR</th>
<th>MTF/ Sys Res</th>
</tr>
</thead>
<tbody>
<tr>
<td>GE</td>
<td>Flat Field</td>
<td>AOP Mode and SNR; CNR</td>
<td>MTF or Sub-System MTF</td>
</tr>
<tr>
<td>Fischer</td>
<td>Flat Field</td>
<td>Phantom Image Acquisition</td>
<td>System Resolution/Scan Speed Uniformity</td>
</tr>
<tr>
<td>Fuji</td>
<td>System Artifact Evaluation</td>
<td>AEC System Performance; Interplate Consistency</td>
<td>System Resolution</td>
</tr>
<tr>
<td>Lorad</td>
<td>Artifact Evaluation</td>
<td>SNR; CNR</td>
<td>Evaluation of System Resolution</td>
</tr>
<tr>
<td>Siemens</td>
<td>Detector Uniformity and Artifact Detection</td>
<td>SNR; CNR</td>
<td>Spatial Resolution</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
Laser Film Printers

- 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

<table>
<thead>
<tr>
<th>Laser Film Printer QC</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>FFDM Mfr</strong></td>
</tr>
<tr>
<td>Fischer</td>
</tr>
<tr>
<td>Fuji</td>
</tr>
<tr>
<td>GE</td>
</tr>
<tr>
<td>Lorad</td>
</tr>
<tr>
<td>Siemens</td>
</tr>
</tbody>
</table>

Monitors and Workstations

- FDA MQSA regs: 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

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)**
- 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 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”
  - Still undergoing field testing by committee and manufacturers
- 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

New Manual Technologist QC Tests-III (draft)

• 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

New Manual Medical Physicist Tests (draft)

• 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)
New Manual Medical Physicist Tests-I (draft)
- ACR Phantom Image Quality (Acquisition Workstation)
  - Phantom scoring
  - Artifacts
  - SNR
  - CNR
  - Geometric accuracy
- Ghost Image Evaluation
- Automatic Exposure Control System Performance

New Manual Medical Physicist Tests-II (draft)
- 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)

New Manual Medical Physicist Tests-III (draft)
- Beam Quality (Half-Value Layer) Assessment
- Average Glandular Dose
  - Phantom
  - 2 cm attenuator
  - 6 cm attenuator
- Unit Checklist

New Manual Medical Physicist Tests-IV (draft)
- 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
ACR FFDM QC Manual – Approval Process

• 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

We Tell Facilities that Their Medical Physicist Is Their 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)

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>
The ACR Website Has Lots of Info...If you Know Where to Find It

Mammography HAS Improved, Thanks to Your Efforts

The ACR’s Accreditation Portal
www.acr.org

FDA Policy Guidance Help System
(ww.fda.gov/cdrh/mammography)
Radiation!

The ACR and Society of Breast Imaging Statement on Radiation Received to the Thyroid from Mammography

April 4, 2011

Some Americans have expressed concern that the small amount of radiation received during a mammogram may significantly increase the likelihood of developing thyroid cancer. This concern simply is not supported by scientific evidence. Studies of radiation exposure from X-ray mammograms show that the amount of radiation delivered to the thyroid is low and not of sufficient magnitude to be associated with an increased risk of thyroid cancer. The American Cancer Society makes no exception to this statement and encourages both patients and providers to get mammograms as early and as often as recommended by their physician. For more information, please visit www.imagewisely.org.