ACR Update on FFDM Accreditation

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*No financial disclosures to report

Overview

• New ACR Activities
• QC Today
• QC Tomorrow

BI-RADS® 2013 – New !!

• The BI-RADS® Atlas provides standardized breast imaging findings terminology, report organization, assessment structure, and a classification system for mammography, ultrasound, and MRI of the breast.

National Mammography Database

• Launched July 2009
• Compare physician medical audit performance against peers
  – Recall Rates, Ca Detection Rates, Positive Predictive Value(s), Time from screening to Dx imaging, etc...
• Automatic data transmission (no manual entry)
• 11 vendors
• 100 active sites

ACR Breast Imaging Centers of Excellence

• A center must be fully accredited in:
  – Mammography by ACR (or FDA-approved state accrediting body)
  – Stereotactic Breast Biopsy by the ACR
  – Breast Ultrasound by the ACR (including the Ultrasound-Guided Breast Biopsy module)
  – Effective Jan 1, 2016: Breast MRI (can satisfy this requirement if refer to another accredited MR facility).
On-Line Application Process-ACRedit

- Many facilities already use ACRedit
  - CT
  - MRI
  - Breast MRI
  - PET
  - Nuclear Medicine
  - General Ultrasound
- All ACR accreditation modalities will eventually be included

ACRedit

- On-line Database for accreditation
  - Going from paper notification to email notification
    - Renewal
    - Testing Materials
    - Delinquent Letters
    - Reports
  - Able to manage all facilities from a single administrator account
  - Facility able to amend, add and track applications and testing material status outside of normal ACR business hours
    - Convenient
    - Efficient

Online ACR MAP Submission

- Went Live January 20, 2014 for Mammography
  - ACRedit: Main Database where MAP account (RIS)
  - TRIAD: Is a separate system that handles/stores uploaded images (PACS)
    - Images are kept 30-60 days in case they are appealed. Then deleted.
    - TRIAD is also software that reviewers have on their PCs for review.
  - Clear Canvas Software: (Image Viewer Software)
  - Future: Going to all web applications

Online ACR MAP Submission

- Facility selects submission type in ACRedit application:
  - Electronic
  - Film

TRIAD

Login Screen - DMAP vs. MAP
Numbers will always stay separate but login will get you to see both.
TRIAD
- Select how they want to upload the images

TRIAD - Web Client
- Accepts DICOM, JPEG, TIFF, BMP
- Select Images for ACR review by uploading from their PC
  - Fatty
  - Dense
  - Phantom
- Facility exports files into TRIAD

US Mammography Facilities and Units (October 1 each year)

- In 2000:
  - 12,956 units at 9933 facilities
  - 1.3 units/facility
- As of 3/1/14:
  - 13,322 units at 8710 facilities
  - 1% increase in units/12% drop in facilities since 2000
  - 93% are digital

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

Introduction
- As of 3-1-2014
- 4 Accrediting Bodies (AB’s)
- ~29 FDA approved units

Before You Begin
- Qualifications
  - Initial
    - Master’s or Bachelor’s Pathway’s
    - Board Certification
    - 8 hours of training in mammography (e.g. digital)
  - Continuing Experience
    - 2 Facilities & 6 Units over a 24-month Period
    - 15 CME’s in mammography in a 36-month period
### ACR Mammography Phantom

<table>
<thead>
<tr>
<th>Version</th>
<th>Manufacturer &amp; Model</th>
<th>Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td>I</td>
<td>Gammex 156</td>
<td>Fiber 3 horz, fiber 4 vert</td>
</tr>
<tr>
<td>II</td>
<td>Gammex 156</td>
<td>No serial number</td>
</tr>
<tr>
<td>III</td>
<td>Gammex 156</td>
<td>Large 5th speck group</td>
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<tr>
<td>IV</td>
<td>Gammex 156</td>
<td>6 digit serial number</td>
</tr>
<tr>
<td>V</td>
<td>Nuc Associates 18-220</td>
<td>Serial number has at least 1 letter</td>
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</table>

### ACR Stereo Phantom

#### Minimum Pass Criteria

<table>
<thead>
<tr>
<th></th>
<th>ACR Mammography Phantom</th>
<th>Mini Digital Phantom</th>
</tr>
</thead>
<tbody>
<tr>
<td>Fiber</td>
<td>4.0</td>
<td>5.0</td>
</tr>
<tr>
<td>Speck</td>
<td>3.0</td>
<td>4.0</td>
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<tr>
<td>Mass</td>
<td>3.0</td>
<td>3.5</td>
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</table>

### Introduction

- ACR Accreditation Program
**Introduction**

- **Golden Rules**
  - Must use manufacturer’s QC procedures
  - Mandate action limits
  - Manufacturers’ QC may refer to Monitor & Printer
  - Multimodality Workstations may have own separate QC
  - Printers may have their own QC
  - Most failures result in stopping clinical imaging until failure can be corrected

**Tomorrow’s Quality Control…..**

- “The more elaborate our means of communications, the less we communicate.” (Priestly)
- “The single biggest problem in communication is the illusion that it has taken place.” (GB Shaw)
- “Complexity is the enemy of reliability”.
  (Documentary on Nuclear Weapons)

**ACR FFDM QC Manual Project**

- **Subcommittee Goals:**
  - Standardize all QC tests for all digital manufacturers
  - Standardize test frequencies
  - Standardize performance criteria

**ACR FFDM QC Manual Project**

- **Subcommittee Goals:**
  - Keep in mind Mammo has MQSA Regulation
  - Account for all past, present, and future FFDM systems
  - Reasonable and appropriate for mass implementation
  - Eliminate unnecessary complicated procedures & analysis
  - Maximize user experience:
    - Especially for Techs, Rads, & Facilities
  - Philosophy
    - Measurements be made with external equipment
    - Dosimeters, photometers, etc.
    - Minimal software requirements
    - CNR & SNR

**ACR Digital QC Draft Manual**

- **Structure of Manual:**
  - Radiologist’s Section
  - Clinical Image Quality Section
  - Radiologic Technologist’s Section
  - Medical Physicist’s Section
  - Educational, Guidance, and Troubleshooting Section
  - Glossary
  - References
  - Index
Technologist QC Tests

<table>
<thead>
<tr>
<th>Test Number</th>
<th>Name (# of Test Elements)</th>
<th>Minimum Frequency</th>
<th>Corrective Action</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>ACR DM Phantom Image Quality (3)</td>
<td>Weekly</td>
<td>Before Clinical Use</td>
</tr>
<tr>
<td>2</td>
<td>Visual Checklist (1)</td>
<td>Monthly</td>
<td>As noted on form</td>
</tr>
<tr>
<td>3</td>
<td>Acquisition Workstation (AW) Monitor QC (3)</td>
<td>Monthly</td>
<td>30 Days or Before Use for Severe Artifacts</td>
</tr>
<tr>
<td>4</td>
<td>Radiologist Workstation (RW) Monitor QC (4)</td>
<td>Monthly</td>
<td>30 Days or Before Use for Severe Artifacts</td>
</tr>
<tr>
<td>5</td>
<td>Printer QC (4)</td>
<td>Monthly</td>
<td>Before Clinical Use</td>
</tr>
<tr>
<td>6</td>
<td>Viewbox Cleanliness (1)</td>
<td>Monthly</td>
<td>Before Clinical Use</td>
</tr>
<tr>
<td>7</td>
<td>Repeat Analysis (1)</td>
<td>Quarterly</td>
<td>Within 30 Days of Analysis</td>
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<tr>
<td>8</td>
<td>Facility QC Review (1)</td>
<td>Quarterly</td>
<td>Not Applicable</td>
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<tr>
<td>9</td>
<td>Compression Force (1)</td>
<td>Descriptive</td>
<td>Before Clinical Use</td>
</tr>
<tr>
<td>10</td>
<td>Manufacturer Detector Calibration (If Applicable)</td>
<td>As Required</td>
<td>Before Clinical Use</td>
</tr>
<tr>
<td>11</td>
<td>Optional - System QC for Radiologist</td>
<td>As Needed</td>
<td>—</td>
</tr>
<tr>
<td>12</td>
<td>Optional - Radiologist Image Quality Protocol</td>
<td>As Needed</td>
<td>—</td>
</tr>
</tbody>
</table>

Management Forms

- ACR DM Phantom Technique Summary
- SFM & AW/Monitor QC Summary
- Mammography System QC Summary
- Film Printer Procedure Summary
- Corrective Action Log
- Facility Equipment Inventory Form
- Mammography System QC Summary Checklist
- Display Device QC Summary Checklist

Medical Physicists QC Tests

<table>
<thead>
<tr>
<th>Test Number</th>
<th>Name (# of Test Elements)</th>
<th>Minimum Frequency</th>
<th>Corrective Action</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Mammography Equipment Evaluation and MQSA Req</td>
<td>Annual</td>
<td>Before Clinical Use</td>
</tr>
<tr>
<td>2</td>
<td>ACR DM Phantom Image Quality (5)</td>
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<td>Before Clinical Use</td>
</tr>
<tr>
<td>3</td>
<td>Spatial Resolution (1)</td>
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<td>4</td>
<td>Automatic Exposure Control System Performance (1)</td>
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<td>5</td>
<td>Beam Quality (Half-Value Layer) Assessment (1)</td>
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<tr>
<td>6</td>
<td>Average Transmission Bone (1)</td>
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<td>Before Clinical Use</td>
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<tr>
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<td>Unit Checklist (1)</td>
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<td>8</td>
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<td>Before Clinical Use</td>
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<td>9</td>
<td>Acquisition Workstation (AW) Monitor QC (3)</td>
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<tr>
<td>10</td>
<td>Radiologist Workstation (RW) Monitor QC (7)</td>
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<td>11</td>
<td>Film Printer QC (5)</td>
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<td>12</td>
<td>Viewbox Luminance and Room Illuminance (2)</td>
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<tr>
<td>13</td>
<td>Evaluation of Site's Technologist QC Program (If App)</td>
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<td>Within 30 Days</td>
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</table>

** MEE or Troubleshooting Test Forms

- kVp Accuracy and Reproducibility
- Contrast Evaluation
- Dose Image Evaluation (Troubleshooting only)

Summary Report Forms

- Medical Physicist MEE QC Summary
- Technique Chart (Clinical & Phantom)
- Medical Physicist Summary Letter for the Radiologist

The ACR DM Phantom

- Phantom Prototype Design Principles
  - Based on existing ACR Accreditation Phantom
  - Similar imaging and scoring to current SFM phantom
  - Build on experience of QC techs and physicists at 8000+ US facilities who already know how to use and score the existing phantom

Proposed Scoring Changes

- Eliminate subtraction for artifacts
- Add “Fail” for artifacts
- Improve specific rules for scoring
- New pass/fail criteria from
  - 4,3,3
  - To: 2,3,2
  - **But, objects are the same (effective) size as SFM Phantom

Wax Insert Test Object Specifications

<table>
<thead>
<tr>
<th>Test Object</th>
<th>Fiber Diameter(mm)</th>
<th>Speck Diameter (Glass Spheres)</th>
<th>Mass Thickness(mm)</th>
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<td>0.14士0.0070</td>
<td>0.20士0.02</td>
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</tbody>
</table>
The ACR FFDM Phantom Prototype

Image of Entire Phantom

Wax Insert

Expanded view of Wax Insert

Pass Criteria:

Equivalent to SFM Phantom:

- 2 Fibers, 3 Specks, 2 Masses
- 4 Fibers, 3 Specks, 3 Masses

Effects of Thickness Equalization

- New FFDM phantom equalizes attenuation inside and outside wax insert.
- This permits evaluation of artifacts over entire phantom area with same WW and WL used to score test objects.

*Note: Gray dot in lower left corner of wax insert is an artifact due to a bubble in wax insert.*/
**D = Kgcs**

- **D** = Mean Glandular Dose
- **K** = Entrance surface air kerma
- **g** = glandularity of 50%
- **c** = corrects for difference in composition (age dependent)
- **s** = X-ray spectrum correction (Target/Filter)

**Note:** g and c depend on thickness, glandularity, and HVL.

Challenges

- Accounting for, and incorporating, all the different current & future FFDM technologies
- Handling offsite equipment
- Ensuring all necessary tests are included, meaningful, and relevant for an accreditation program

What’s Next

3 Steps

- Draft being sent to manufacturers for preliminary feedback
- Final draft to be sent to FDA from ACR to apply for alternative standard under current regulations
  - Alternative standard will allow facilities to use this instead of the manufacturer’s manuals
  - Potential for ACR QC Manual to be basis for new MQSA Regulations
**Preemptive Questions**

- Cost of phantom?
  - Don’t know. Reason to believe it will be affordable.
- Implementation and roll-out?
  - ACR to develop a plan to include some form of training.
- When?
  - 2014.

**End of Presentation**

*Questions?*