ACR Accreditation Update in Mammography

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*No financial disclosures to report*

Overview

• New ACR Activities
• Requirements Today
• What’s New For Tomorrow

ACR: Recognized by FDA and CMS

• 1987 – Mammography accreditation
• 1987 – Radiation oncology
• 1995 – Ultrasound
• 1996 – Stereotactic breast biopsy
• 1997 – MRI
• 1998 – Ultrasound guided breast biopsy
• 1999 – Nuclear medicine
• 2002 – CT and PET
• 2011 – Breast MRI
ACR Breast Imaging Centers of Excellence

BICOE

• 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)
  – Breast MRI (Effective Jan 1, 2016)

Adding Breast MR to BICOE Requirements

• Effective January 1, 2016 ..........
• Existing BICOE facilities have two years to become accredited in Breast MR, or have their associated locations become accredited
• Facilities applying for BICOE designation after January 1, 2016 must have Breast MR accreditation, or be associated with a facility this is accredited

~13%
Online ACR MAP Submission

- Went Live January 20, 2014 for Mammo
  - ACRedit: Main Database where MAP account
  - Triad: Is a separate system that handles/stores uploaded images
    - Images kept 30-60 days in case they are appealed. Then deleted.
  - Clear Canvas Software - Image Viewer Software
  - Future: Going to all web applications

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

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

As of 7/1/14
- 13,612 units at 8713 facilities
- 1% increase in units/12% drop in facilities since 2000
- 95% are digital

US Mammography Facilities and Units (October 1 each year)

ACR Mammography Accreditation Program Pass Rates

MAP REASONS FOR UNIT FAILURES - 1st ATTEMPT 2013
Introduction

• 4 Accrediting Bodies (AB’s)
• ~30 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

Introduction

• ACR Accreditation Program
Introduction

• ACR Accreditation Program

• MQSA
**Introduction**

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

- **Clinical Tips**
  - Always get latest version of ACR Summary Forms
  - Verify you’re using correct Mfr QC Manual
  - Record the correct Mfr QC Manual on your report
  - Read the Mfr QC Manual - make sure you perform all tests
    - Always seem to be updates or changed manuals

**ACR FFDM QC Manual Project**

- **Goals:**
  - Keep in mind Mammo has MQSA Regulation
  - Account for all past, present, and future FFDM systems
  - Reasonable and appropriate for mass implementation (~13,000 units)
**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 ~8,700 US facilities who already know how to use and score the existing phantom (~24,000 Techs)

**The ACR DM Phantom**

- Phantom Prototype Design Principles
  - Can be used on both SFM & FFDM
  - Total attenuation matched to current SFM phantom
    - Similar thickness
    - Similar total dose
  - Permits testing of the MQSA 3.0 mGy dose limit (Single CC view)

**Proposed Scoring Changes**

- Eliminate subtraction for artifacts
- Add “Fail” for artifacts
- New pass/fail criteria from
  - 4,3,3
  - To: 2,3,2
  - **But, objects are the same (effective) size as SFM Phantom**
Wax Insert Specifications with Virtual “Placement Grid”

Notes:
- Test objects to be centered on their respective "placement grid" locations.
- 0.49 cm perimeter around test object "placement grid".
- 0.635 cm (1/4 inch) radius on corners of wax insert.
- Fiber specifications:
  - Fiber Length = 1.0 cm ± 0.1 cm
  - Fiber Diameter = See Table
- Fiber Placement specs:
  - 1. Specks to be placed at points on star and middle of star
  - 2. Speck Size (spherical) = See Table
  - 3. Center speck placement to be within ± 0.1 cm of center of virtual grid
  - 4. Distance from center speck to center of speck on perimeter = 0.5 cm ± 0.1 cm

Mass Placement & Specs:
- Mass pre-cut sphere diameter = 5/8 inch ± 0.1 cm
- Mass placement to be within ± 0.1 cm of center of virtual grid

ID Tag Specs:
- Virtual Box: height = 0.5 cm, length = 1.8 cm

The ACR FFDM Phantom Prototype

Image of Entire Phantom

*Note: Gray dot in lower left corner of wax insert is an artifact due to a bubble in wax insert.
**Wax Insert**

**Expanded view of Wax Insert**

**Pass Criteria:**
- 2 Fibers, 3 Specks, 2 Masses
- Equivalent to SFM Phantom: 4 Fibers, 3 Specks, 3 Masses

**Pass Criteria:**

**Serial Number:**
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.

## Technologist QC Tests

<table>
<thead>
<tr>
<th>Test Number</th>
<th>Name (If of Test Parameters)</th>
<th>Minimum Frequency</th>
<th>Required Corrective Action</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>ACR DM Phantom Image Quality (3-4)</td>
<td>Weekly</td>
<td>Before Clinical Use</td>
</tr>
<tr>
<td>2</td>
<td>Visual Checklist (1)</td>
<td>Monthly</td>
<td>As needed on Item</td>
</tr>
<tr>
<td>3</td>
<td>Acquisition Workstation (AW) Monitor QC (X)</td>
<td>Monthly</td>
<td>30 Days or Before Use for dense Artifacts</td>
</tr>
<tr>
<td>4</td>
<td>Radiologist Workstation (RW) Monitor QC (X)</td>
<td>Monthly</td>
<td>30 Days or Before Use for dense Artifacts</td>
</tr>
<tr>
<td>5</td>
<td>Film Printer QC (X)</td>
<td>Monthly</td>
<td>Before Clinical Use</td>
</tr>
<tr>
<td>6</td>
<td>Visual Quality Checklist (X)</td>
<td>Monthly</td>
<td>Before Clinical Use</td>
</tr>
<tr>
<td>7</td>
<td>Facility QC Review (X)</td>
<td>Quarterly</td>
<td>Not Applicable</td>
</tr>
<tr>
<td>8</td>
<td>Compression Force (X)</td>
<td>Semiannual</td>
<td>Before Clinical Use</td>
</tr>
</tbody>
</table>

- Management Forms:
  - ACR DM Phantom Technique Summary
  - AW & RW Monitor QC Summary
  - Film Printer Procedure Summary
  - Correction Action Log
  - Facility Equipment Inventory Form
  - Mammography System QC Summary Checklist
  - Display Device QC Summary Checklist

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Tech Tests
### Medical Physicists QC Tests

<table>
<thead>
<tr>
<th>Test Number</th>
<th>Test Description</th>
<th>Minimum Frequency</th>
<th>Required Corrective Action</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Mammography Equipment Evaluation and MQSA Req</td>
<td>MKS Only</td>
<td>Before Clinical Use</td>
</tr>
<tr>
<td>2</td>
<td>ACR DM Phantom Image Quality (1)</td>
<td>Annual</td>
<td>Before Clinical Use</td>
</tr>
<tr>
<td>3</td>
<td>Spatial Resolution (1)</td>
<td>Annual</td>
<td>Before Clinical Use</td>
</tr>
<tr>
<td>4</td>
<td>Automatic Exposure Control System Performance (1)</td>
<td>Annual</td>
<td>Before Clinical Use</td>
</tr>
<tr>
<td>5</td>
<td>Average Glandular Dose (1)</td>
<td>Annual</td>
<td>Before Clinical Use</td>
</tr>
<tr>
<td>6</td>
<td>Unit Checklist (1)</td>
<td>Annual</td>
<td>Before Clinical Use</td>
</tr>
<tr>
<td>7</td>
<td>Computed Radiography (If Applicable)</td>
<td>Annual</td>
<td>Before Clinical Use</td>
</tr>
<tr>
<td>8</td>
<td>Acquisition Workstation (AW) Monitor QC (3)</td>
<td>Annual</td>
<td>Before Clinical Use</td>
</tr>
<tr>
<td>9</td>
<td>Radiologist Workstation (RW) Monitor QC (9)</td>
<td>Annual</td>
<td>Before Clinical Use</td>
</tr>
<tr>
<td>10</td>
<td>Film Printer QC (5)</td>
<td>Annual</td>
<td>Before Clinical Use</td>
</tr>
<tr>
<td>11</td>
<td>Evaluation of Site’s Technologist QC Program (1)</td>
<td>Annual</td>
<td>Within 30 Days</td>
</tr>
<tr>
<td>12</td>
<td>Evaluation of Offsite Technologist QC Program (If App)</td>
<td>Annual</td>
<td>Within 30 Days</td>
</tr>
</tbody>
</table>

**MEE or Troubleshooting Test Forms**

- Basic Quality (Half Value Layer) Assessment: MEE or Troubleshooting
- kVp Accuracy and Reproducibility: MEE or Troubleshooting
- Calibration Assessment: MEE or Troubleshooting
- Ghost Image Evaluation (Troubleshooting only): Troubleshooting
- Viewbox Luminance (Troubleshooting only): Troubleshooting

**Summary Report Forms**

- Medical Physical DM QC Summary
- Technique Chart (Clinical & Phantom)
- Medical Physicist Summary Letter for the Radiologist
### Medical Physicist's OM QC Test Summary

<table>
<thead>
<tr>
<th>Test Title</th>
<th>Pass/Fail</th>
<th>Notes</th>
</tr>
</thead>
<tbody>
<tr>
<td>Test 1</td>
<td>Pass</td>
<td></td>
</tr>
<tr>
<td>Test 2</td>
<td>Fail</td>
<td></td>
</tr>
<tr>
<td>Test 3</td>
<td>Pass</td>
<td></td>
</tr>
<tr>
<td>Test 4</td>
<td>Pass</td>
<td></td>
</tr>
<tr>
<td>Test 5</td>
<td>Fail</td>
<td></td>
</tr>
<tr>
<td>Test 6</td>
<td>Pass</td>
<td></td>
</tr>
<tr>
<td>Test 7</td>
<td>Pass</td>
<td></td>
</tr>
<tr>
<td>Test 8</td>
<td>Fail</td>
<td></td>
</tr>
<tr>
<td>Test 9</td>
<td>Pass</td>
<td></td>
</tr>
<tr>
<td>Test 10</td>
<td>Fail</td>
<td></td>
</tr>
<tr>
<td>Test 11</td>
<td>Pass</td>
<td></td>
</tr>
<tr>
<td>Test 12</td>
<td>Pass</td>
<td></td>
</tr>
<tr>
<td>Test 13</td>
<td>Fail</td>
<td></td>
</tr>
<tr>
<td>Test 14</td>
<td>Pass</td>
<td></td>
</tr>
<tr>
<td>Test 15</td>
<td>Pass</td>
<td></td>
</tr>
<tr>
<td>Test 16</td>
<td>Fail</td>
<td></td>
</tr>
<tr>
<td>Test 17</td>
<td>Pass</td>
<td></td>
</tr>
<tr>
<td>Test 18</td>
<td>Pass</td>
<td></td>
</tr>
<tr>
<td>Test 19</td>
<td>Fail</td>
<td></td>
</tr>
<tr>
<td>Test 20</td>
<td>Pass</td>
<td></td>
</tr>
<tr>
<td>Test 21</td>
<td>Pass</td>
<td></td>
</tr>
<tr>
<td>Test 22</td>
<td>Fail</td>
<td></td>
</tr>
<tr>
<td>Test 23</td>
<td>Pass</td>
<td></td>
</tr>
<tr>
<td>Test 24</td>
<td>Pass</td>
<td></td>
</tr>
<tr>
<td>Test 25</td>
<td>Fail</td>
<td></td>
</tr>
<tr>
<td>Test 26</td>
<td>Pass</td>
<td></td>
</tr>
<tr>
<td>Test 27</td>
<td>Pass</td>
<td></td>
</tr>
<tr>
<td>Test 28</td>
<td>Fail</td>
<td></td>
</tr>
<tr>
<td>Test 29</td>
<td>Pass</td>
<td></td>
</tr>
<tr>
<td>Test 30</td>
<td>Pass</td>
<td></td>
</tr>
<tr>
<td>Test 31</td>
<td>Fail</td>
<td></td>
</tr>
<tr>
<td>Test 32</td>
<td>Pass</td>
<td></td>
</tr>
<tr>
<td>Test 33</td>
<td>Pass</td>
<td></td>
</tr>
<tr>
<td>Test 34</td>
<td>Fail</td>
<td></td>
</tr>
<tr>
<td>Test 35</td>
<td>Pass</td>
<td></td>
</tr>
<tr>
<td>Test 36</td>
<td>Pass</td>
<td></td>
</tr>
<tr>
<td>Test 37</td>
<td>Fail</td>
<td></td>
</tr>
<tr>
<td>Test 38</td>
<td>Pass</td>
<td></td>
</tr>
<tr>
<td>Test 39</td>
<td>Pass</td>
<td></td>
</tr>
<tr>
<td>Test 40</td>
<td>Fail</td>
<td></td>
</tr>
<tr>
<td>Test 41</td>
<td>Pass</td>
<td></td>
</tr>
<tr>
<td>Test 42</td>
<td>Pass</td>
<td></td>
</tr>
<tr>
<td>Test 43</td>
<td>Fail</td>
<td></td>
</tr>
<tr>
<td>Test 44</td>
<td>Pass</td>
<td></td>
</tr>
<tr>
<td>Test 45</td>
<td>Pass</td>
<td></td>
</tr>
<tr>
<td>Test 46</td>
<td>Fail</td>
<td></td>
</tr>
<tr>
<td>Test 47</td>
<td>Pass</td>
<td></td>
</tr>
</tbody>
</table>

**Note:** All tests are conducted on the specified date.
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

2 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.
In digital mammography, who mandates the pass/fail criteria for site QC?

- 6% 1. The American College of Radiology
- 24% 2. The FDA
- 24% 3. The FFDM unit manufacturer
- 39% 4. MITA
- 18% 5. MQSA
To meet the FDA requirement for continuing experience, how many mammography facilities and mammography unit surveys must be performed within the previous 24 months?

1. 6 Facilities and 2 Mammography Units
2. 4 Facilities and 6 Mammography Units
3. 2 Facilities and 6 Mammography Units
4. 1 Facilities and 6 Mammography Units
5. 2 Facilities and 12 Mammography Units

Answer: 3 - The FFDM unit manufacturer

References

- MQSA Regulations 900.12(e)(6)
- http://www.fda.gov/CDRH/MAMMOGRAPHY/frmamcom2.html#s90012
For FFDM, the exposure for a single CC view of the ACR phantom shall not exceed:

<table>
<thead>
<tr>
<th>Option</th>
<th>Exposure (mGy/exposure)</th>
</tr>
</thead>
<tbody>
<tr>
<td>12%</td>
<td>0.75</td>
</tr>
<tr>
<td>8%</td>
<td>1.25</td>
</tr>
<tr>
<td>12%</td>
<td>2.00</td>
</tr>
<tr>
<td>15%</td>
<td>3.00</td>
</tr>
<tr>
<td>15%</td>
<td>4.00</td>
</tr>
</tbody>
</table>

Answer: 4 – 3.00 mGy/exposure

References

- 900.12(e)(5)(v): Dosimetry. The average glandular dose delivered during a single craniocaudal view of an FDA-accepted phantom simulating a standard breast shall not exceed 3.6 miligray (mGy) (0.3 rad) per exposure. The dose shall be determined with technique factors and conditions used clinically for a standard breast.
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