ACR Accreditation Update in Mammography

Eric Berns, PhD
University of Colorado Hospital
Denver Health Medical Center
Denver, CO

*No financial disclosures to report

Overview

• ACR Topics
• Requirements Today
• What’s Coming For Tomorrow

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

- 4 Accrediting Bodies (AB’s)
  - ACR
  - Arkansas
  - Iowa
  - Texas
- 12 approved Mfr’s
- ~31 FDA approved units

US Mammography Facilities and Units (October 1 each year)

In 2000
- 12,956 units
- 9933 facilities
As of 7/1/15
- 14,737 units at
- 8,741 facilities
- Increase in units by 1,781
- Drop in facilities by 1,192
- 97% are digital
- Only 446 SFM left

MAP REASONS FOR UNIT FAILURES - 1st ATTEMPT 2013
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)
Stereo Credits for MP’s

Q. In order to obtain continuing education credit for stereotactic breast biopsy, must the coursework be specifically designed for stereotactic breast biopsy?

DBT Credits for MP’s

U.S. Food and Drug Administration
Protecting and Promoting Your Health

Frequently Asked Questions about DBT and MQSA
Training Requirements

Stereo/ultrasound (DBT) or mammography reading under MQSA

6. Do the quality control requirements apply to newly purchased mammography equipment? New mammographic equipment that has been placed into service must have a mammographic quality control program in place. This program must include a quality assurance program that is designed to ensure the quality of the mammographic images. The program must include procedures for the calibration and maintenance of the equipment, as well as procedures for the evaluation of the images produced by the equipment. The program must also include procedures for the training of the personnel who use the equipment, as well as procedures for the quality control of the images produced by the equipment. The program must be documented in writing and be available for review by the appropriate regulatory agency. The program must be reviewed at least once every year, and any changes to the program must be reported to the appropriate regulatory agency within 30 days of the change. The program must be updated at least once every five years.
Supporting documentation for these requirements will be checked during annual MQSA inspections.

...
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

- Golden Rules
  - Still must use Manufacturer’s QC Manual
  - May refer to Monitor & Printer Manufacturers’ QC
  - Multimodality Workstations may have own separate QC
  - Printers may have their own QC
Introduction

• Tips from ACR……

  – Always get latest version of ACR Summary Forms from Web
  – Verify you’re using correct Mfr QC Manual version
  – Record the correct Mfr QC Manual version on your report
  – Make sure you perform all tests in the Mfr QC Manual!

The ACR FFDM Phantom Prototype

*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
**Summary**
- Permits testing of the MQSA 3.0 mGy dose limit (Single CC view) – Similar thickness and dose
- Eliminate subtraction for artifacts
- Add “Fail” for artifacts
- New pass/fail criteria from
  - 4,3,3 → 2,3,2
  - **But, objects are the same (effective) size as SFM Phantom**
- Can be used on both SFM & FFDM (.... Important b/c of CR)
- 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)

**Technologist QC Tests**

<table>
<thead>
<tr>
<th>Test Number</th>
<th>Name</th>
<th>Minimum Frequency</th>
<th>Required Correction Action</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>ACR DM Phantom Image Quality</td>
<td>Weekly</td>
<td>Before Clinical Use</td>
</tr>
<tr>
<td>2</td>
<td>US Geometry QC (If Applicable)</td>
<td>Weekly</td>
<td>Before Clinical Use</td>
</tr>
<tr>
<td>3</td>
<td>Visual Checklist</td>
<td>Monthly</td>
<td>As stated on form</td>
</tr>
<tr>
<td>4</td>
<td>Acquisition Workstation (IRM Monitor QC)</td>
<td>Monthly</td>
<td>30 Days or Before Use for Sensors Artifacts</td>
</tr>
<tr>
<td>5</td>
<td>Radiologist Workstation (IRM Monitor QC)</td>
<td>Monthly</td>
<td>30 Days or Before Use for Sensors Artifacts</td>
</tr>
<tr>
<td>6</td>
<td>Film Printer QC</td>
<td>Monthly</td>
<td>Before Clinical Use</td>
</tr>
<tr>
<td>7</td>
<td>Wireless Densities (FFDM)</td>
<td>Monthly</td>
<td>Before Clinical Use</td>
</tr>
<tr>
<td>8</td>
<td>Facility QC Review</td>
<td>Quarterly</td>
<td>Not Applicable</td>
</tr>
<tr>
<td>9</td>
<td>Compression Force</td>
<td>Biennial</td>
<td>Before Clinical Use</td>
</tr>
<tr>
<td>10</td>
<td>Manufacturer Detector Calibration (If Applicable)</td>
<td>Per IRM Recommendation</td>
<td>Before Clinical Use</td>
</tr>
<tr>
<td></td>
<td>Optional – Repeat Analysis</td>
<td>As Needed</td>
<td>Within 70 days after analysis</td>
</tr>
<tr>
<td></td>
<td>Optional – System QC for Radiologist</td>
<td>As Needed</td>
<td>30 Days or Before Use for Sensors Artifacts</td>
</tr>
<tr>
<td></td>
<td>Optional – Radiologic Image Quality Feedback</td>
<td>As Needed</td>
<td>Not Applicable</td>
</tr>
</tbody>
</table>

**Management Forms**

- ACR Technique and Procedures Sustainer
- Correction Action Log
- Facility With Display Locations
- Digital Mammography Unit QC Summary Checklist
- Facility Display Device QC Summary Checklist

**Tech Tests**

- **Facility QC Review**
  - Name of Facility
  - Name of Tech
  - Date
  - Mammography System Name
  - Mammography System Type
  - Mammography System Make
  - Mammography System Model
  - Mammography System Serial No.
  - Mammography System Camera
  - Mammography System Detector
  - Mammography System Image Processing
  - Mammography System Digital Imaging System
  - Mammography System Quality Assurance Program
  - Mammography System QA Program Participation
  - Mammography System QA Program Certification
  - Mammography System QA Program Accreditation

- **Repeat Analysis**
  - Name of Facility
  - Name of Tech
  - Date
  - Mammography System Name
  - Mammography System Type
  - Mammography System Make
  - Mammography System Model
  - Mammography System Serial No.
  - Mammography System Camera
  - Mammography System Detector
  - Mammography System Image Processing
  - Mammography System Digital Imaging System
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- **Add “Fail” for artifacts**
  - Name of Facility
  - Name of Tech
  - Date
  - Mammography System Name
  - Mammography System Type
  - Mammography System Make
  - Mammography System Model
  - Mammography System Serial No.
  - Mammography System Camera
  - Mammography System Detector
  - Mammography System Image Processing
  - Mammography System Digital Imaging System
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  - Mammography System QA Program Certification
  - Mammography System QA Program Accreditation

- **New pass/fail criteria from**
  - Name of Facility
  - Name of Tech
  - Date
  - Mammography System Name
  - Mammography System Type
  - Mammography System Make
  - Mammography System Model
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### MP Tests

#### 4. Automatic Exposure Control System Performance

<table>
<thead>
<tr>
<th>Distance</th>
<th>Mfr 1</th>
<th>Mfr 2</th>
<th>Mfr 3</th>
</tr>
</thead>
<tbody>
<tr>
<td>1234</td>
<td>567</td>
<td>890</td>
<td>234</td>
</tr>
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</table>

#### ACR DM Phantom Image Quality

<table>
<thead>
<tr>
<th>Facility</th>
<th>Contact Mode</th>
<th>Target/Filter Config 2</th>
<th>Target/Filter Config 3</th>
<th>Distance</th>
</tr>
</thead>
</table>

#### Radiologist Workstation (PW) Monitor QC

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<th>Contact Mode</th>
<th>Target/Filter Config 2</th>
<th>Target/Filter Config 3</th>
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What’s Next

Status

• Final draft is in the submission process to the FDA for an alternative standard under current regulations
  – Alternative standard application must include a statement from MITA that use of the ACR Manual results in substantially the same clinical image quality as use of the manufacturer’s manuals.
  – 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

End of Presentation

Questions?