HISTORY OF MQSA AND ACR
DEBORAH THAMES R.T. (R)(M)(QM)

WHY MQSA?
In the United States, there was a lack of standards in mammography imaging. Reporting, Imaging, Type of imaging screening/diagnostic, Equipment, Quality Control, Training.

HISTORY OF MQSA
• Why?
  • To establish national quality standards in mammography
• What is AB stand for?
  • Accreditation body approved by the FDA
• Who is the current AB for MQSA
• How many are there and name them...

REMEMBER TO DO MAMMOGRAPHY A FACILITY MUST....
  • Be accredited by an accreditation body
  • Be certified by FDA and/or State as Certifiers (SAC)
  • Be inspected by employee's of MQSA

WHAT IS SAC’S
• States as Certifiers (also known as SACs) are entities approved by the Food and Drug Administration (FDA) to carry out certification, inspection, and compliance activities, and have the same authority as the FDA to regulate mammography facilities located within their states. SACs ensure that facilities in their states adhere to the Mammography Quality Standards Act (MQSA) regulations as well as any state regulations related to mammography facilities, which can differ from FDA’s and be more stringent.

SAC ARE...
• Currently, the four FDA-approved SACs are:
  • Illinois (349 certified facilities – SAC since 2004)
  • Iowa (411 certified facilities – SAC since 2004)
  • South Carolina (111 certified facilities – SAC since 2005)
  • Texas (562 certified facilities – SAC since 2008)
WHAT'S DMQRP STAND FOR? WHAT'S CDRH STAND FOR?

- Division of Mammography Quality and Radiation Programs (DMQRP)
- Center for Devices and Radiological Health (CDRH)

MQSA DOSE LIMIT

- The average glandular dose delivered during a single view of FDA accepted phantom simulating a standard breast shall not exceed:
- 3 Rad or 3mg .003 gray

MQSA STATES ONLY THREE MANUFACTURES OF PHANTOM TO USE

- CIRS accreditation phantom Model 15 – 4.2 cm compressed breast of average glandular dose
- Gammex (RMI) Model 156 - 4.2 cm compressed breast of average glandular dose
- Nuclear Associates (Fluke) Model 18-220
UPCOMING CHANGES IN QC FOR FFDM

- New BI-RAD's and Lexicon Changes
- New ACR FFDM QC Control Manual
- New Digital Phantom for FFDM
- Possibly a new Phantom for DBT

NEW MANUAL

The new ACR manual will promote uniformity of testing since it will allow facilities with applicable systems to follow one manual instead of the dozens of different manuals that are mandated for the varying manufacturers and models of digital mammography equipment,” said Eric Berns, PhD, lead author and chair of the ACR Subcommittee on Mammography Quality Assurance. “The new manual focuses on tests that are clinically relevant for high-quality imaging and the structure for a thorough and complete quality control program,” he added.

UPDATE AS OF 8/2016

The Food and Drug Administration (FDA) approved the American College of Radiology’s (ACR) alternative standard request to allow mammography facilities to use the ACR’s new Digital Mammography Quality Control (QC) Manual and Digital Mammography QC Phantom in routine QC of digital equipment. The FDA requires digital mammography facilities to perform QC for approved imaging systems, according to their respective manufacturers’ quality control manuals. Approval of this alternative standard will enable mammography QC technologists and medical physicists to use the new ACR manual in lieu of manufacturers’ quality control manuals when it becomes available. The FDA alternative standard specifies that the new manual may be used only for full-field digital mammography systems without advanced imaging capabilities (e.g., tomosynthesis and contrast enhancement).

ACR Digital Mammography Quality Control Manual Now Available

August 02, 2016

The 2015 American College of Radiology (ACR) Digital Mammography Quality Control Manual is now available in electronic format. ACR Digital Mammography QC Manual, second edition. This is an important development for modern breast imaging practice, where the overwhelming majority of facilities work with digital equipment. The new ACR manual will enable facilities to consolidate their quality control responsibilities by working from a single resource.

A link was automatically sent to all mammography facilities accredited by the ACR to download the new manual at no charge. (Level technologists and online facility users should share this link with their colleagues at the facility.) Medical physicists associated with these facilities may also obtain the link from their facilities to download the new manual at no charge. Individuals not associated with ACR-accredited facilities may purchase the manual from the ACR catalog.
MORE QUESTIONS....

• Our facility has a mammography unit that performs 2D imaging using computed radiography (CR). Will we be allowed to use the new ACR Digital Mammography QC Manual instead of our CR manufacturer’s QC manual for QC on this unit?
• A. Yes.

• Q. Our facility would like to begin using the new ACR Digital Mammography QC Manual. Can we do so as soon as we receive our new manual?
• A. Before the facility QC technologist may start using the new DMQC Manual on a particular unit, the medical physicist must first conduct an annual survey of the digital mammography unit and display devices using the new manual and phantom. This is important to provide testing techniques and procedures for the QC technologist to use during routine QC. After this is done, the QC technologist may start performing routine QC using the new manual.

• Q. May I use our old ACR phantom to perform the tests in the new ACR Digital Mammography QC Manual instead of obtaining the new ACR Digital Mammography Phantom?
• A. No. The new ACR Digital Mammography QC Manual procedures were designed around the new ACR Digital Mammography Phantom. The old ACR phantom cannot be used to conduct the tests in the new manual.

NEW PHANTOM

• For facilities that choose to use the new manual for quality control (QC), the manual and ACR Digital Mammography Phantom will go into effect next year. This means that facilities will not be able to submit images of the new phantom or QC testing results with the new manual for ACR accreditation until 2017. However, the ACR encourages mammography facilities to start using the new manual prior to that time alongside existing QC to become familiar with the changes.
Q. After July 2017, may our facility begin using the 2016 ACR Digital Mammography QC Manual and stop using our manufacturer’s manual?

A. Yes, but please note that before the facility QC technologist may start using the 2016 DMQC Manual on a unit, the medical physicist must first conduct an annual survey of the digital mammography unit and display devices using the 2016 manual and phantom. This is important to provide testing techniques and procedures for the QC technician to use during routine QC. After this is done, the QC technologist may start performing routine QC using the 2016 manual.

### THE ACR FFDM PHANTOM

**Improve Efficiencies for Physics Reviewers**
- Single image provides scores and artifacts for all relevant test results
- Decrease time at facilities with simplified testing and documentation

**Evaluate Image Quality and Detect Artifacts**
- Evaluate artifacts using the same window width (WW) and window level (WL)
- Equalize attenuation inside and outside the wax insert
- Permits evaluation of artifacts over the entire phantom area

**Specifications**
- Wax and acrylic equivalent to 4.2 cm thick compressed breast tissue. 50% adipose and 50%
- Mammography Phantom: FFDM
- Nylon Fibers (Fibrils): 6 Groups
- Micro-calculi (Specs): 6 Groups, Al₂O₃
- Masses: 6
- Dimensions (L/W/H): 31.0 ± 0.1 x 19 ± 0.1 x 4.1 ± 0.03 cm
- Dimensions: Wax Insert (L/W/H): 12.98 (+0.04) x 6.98 (+0.04) x 0.7 ± 0.02 cm
- CNR Cavity Depth: 0.1 ± 0.005 cm
- CNR Diameter: ± 0.05 cm
- Compensator: 9 ml Polyvinylidene

**Simplify Testing and Save Time**

The Mamm FFDM Phantom was evaluated and accredited by the ACR, and is also referred to as the ACR Digital Mammography Phantom. The Mamm FFDM Phantom simulates radiographic characteristics of compressed breast tissue, including micro-calculi, ductal fibrous structures and tumor-like masses. Identification of these small structures is essential to the early detection of breast cancer.
THE ACR FFDM PHANTOM

CERTIFICATION APPLICATION MINIMUM OF FOUR ITEMS

- Applicants must inform the DMQRP of its application for certification in writing.
- Following receipt of the requires, the FDA will provide additional information for completion.
- Furnish the FDA with three copies of an application with details of the facilities name, address, and phone number.
- Meet the strict standards with the facility according to the FDA and have a detailed description of the policies and procedures manual.

CERTIFYING AGENCIES MAY GRANT A FACILITY THREE TYPES OF CERTIFICATES

- 1. Provisional certificate allows a facility to perform mammography up to six months until the AB reviews all of the material and reviews the clinical images and phantom image that is required in the accreditation process.
- 2. Full certification allows the a three year certification while maintaining all the requirements.
- 3. 90 day extension certificate allows a certifying agent grant a one time 90 day extension to an existing provisional certificate for a facility who cannot complete the accreditation process within the allowed six month period.

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<tr>
<th>Test Object</th>
<th>Old ACR Mammography Phantom</th>
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<td>Masses</td>
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<td>2</td>
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<tr>
<td>Artifacts</td>
<td>Subtract scores for artifacts</td>
<td>Fail if clinically significant artifact present in a location that could impact clinical imaging</td>
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</table>
QC RECORDS HAVE TO BE MAINTAINED FOR HOW LONG?

• For the last 12 months or since the last inspection, whichever is longer.

MQSA INSPECTOR – ONCE A YEAR

• Check six areas during inspection:
  1. Equipment performance for mammography
  2. Quality assurance records and policy and procedure manual
  3. Quality control test and records for QC technologist, medical physicist’s annual survey
  4. Personnel qualifications records, initial training, continuing education, continuing experience.
  5. Medical records including mammography reports and images and lay summaries
  6. Medical audit and outcome

FDA HAS CLASSIFIED ADVERSE INSPECTIONS INTO THREE LEVELS

• Level 1 – Observation indicates a failure to meet a key MQSA requirement that may compromise the quality of mammography performed at the facility.
• Level 2 – Observation indicates that facility meets all key MQSA requirements but fails to meet a significant mammography quality item.
• Level 3 – Observation indicates that facility meets all major MQSA requirements with only minor problems.
• If a repeat level 1 or 2 report is indicated during your inspection, you should correct all inspection observations as soon as possible.

SANCTIONS THAT CAN BE IMPOSED FOR INCOMPLIANCE TO MQSA & FDA

• Minor could be new plan of action
• Payment for the cost of onsite monitoring
• Civil money penalties not to exceed $10,000 dollars for failure of certificate, comply with standards, for severe violation.
• Suspension and revocation of mammography imaging
• Injunctions and possible judicial review with petition

NATIONAL ADVISORY COMMITTEE

• Between 12-19 members such as physicians, practitioners, other health professionals, and consumer and industrial representatives who have expertise in the practice of mammography
• Help to develop quality standards and regulations for mammography facilities
• Help to develop regulations with respect to sanctions
• Establish a mechanism to investigate consumer complaints
• Determine the cost and benefits of compliance with the requirements
• Develop procedures for monitoring compliance with standards

HISTORY OF ACR

• American College of Radiology for mammography
HISTORY

• 1987 – ACR’s voluntary Mammo Accreditation Program
• October 27, 1992 – President Bush signs the Mammography Quality Standards Act
• October 1, 1994 – FDA’s Interim Rules requires all mammo facilities in the US to be accredited, certified and inspected; QC regs mirror the ACR requirements
• April 28, 1999 – FDA’s Final Rules went into effect with new detailed requirements including direct patient notification
• Feb 6, 2002 tighter equipment act

WHY ACR ACCREDITATION?

• Validation of quality
• Peer process
  – Judy Destouet, M.D. – current chair, Committee on Mammography Accreditation
• Educational process
• MQSA requires accreditation for all mammo facilities (screening and diagnostic)
• Patient confidence
  – Facilities meet the highest standards of their profession

1. IT IS THE RESPONSIBILITY OF THE _____ TO ENSURE THAT THE FACILITY APPLIES FOR AND COMPLETES ACCREDITATION RENEWAL BEFORE MQSA CERTIFICATE EXPIRATION.

   A. Accrediting body
   B. Certifying body
   C. State inspectors
   D. Facility

When Do the MQSA Certificate and Accreditation Expire?

• ACR expiration dates on certificate and unit label
• Against the law to perform mammo without a current MQSA certificate
• Medicare will not reimburse under expired certificate

MEET ALL APPLICATION DEADLINES

• Renewal notices sent out 8 months prior to accreditation expiration
  – ACR must receive the complete entry application within 6 months prior to expiration
• You have 45 calendar days to return completed testing to ACR
  – This guarantees completion of the review process before accreditation expiration

1999 ACR QUALITY CONTROL MANUAL

• Aid for meeting FDA rules
• Consistent with MQSA requirements
• Additional recommendations for further quality improvement
• Meeting ACR recommendations not required for accreditation
• What year did ACR manual get published?
2. THE ACR STAFF EMPLOYEES 25 FULL-TIME CLINICAL IMAGE REVIEWERS, AND 15 PHANTOM IMAGE REVIEWERS AT THEIR RESTON, VA OFFICE TO ENSURE QUICK TURN AROUND OF YOUR ACCREDITATION IMAGES.

TRUE or FALSE

ACR IMAGE REVIEWERS

- 85 radiologists and 35 medical physicists qualified under MQSA
- In clinical (or physics) practice across the US
- Board certified
- 5+ years of experience in accreditation modality
- Participate in formal training program
- May not review images from the same state

Phantom Image Quality Evaluation

- Phantom Image Reviewers use same criteria in ACR QC Manual
- Subtract artifacts if they appear
  - Fiber-like
  - Spack-like
  - Mass-like

3. ACR RADIOLOGIST REVIEWERS ASSUME THAT CLINICAL IMAGES SUBMITTED FOR ACCREDITATION ARE

A. Examples of your facility’s best work
B. Examples of your facility’s typical work
C. Benign cases
D. Reviewed by your facility’s mammography QC technologist
E. A and C

FOLLOW INSTRUCTIONS SUBMITTING CLINICAL IMAGES

- Examples of facility’s best work
- Supervising radiologist should review & approve images
- Submit “negative” images
  - BI-RADS assessment category 1 (“nothing to comment on...breasts are symmetrical...no masses, architectural disturbances or suspicious calcifications”)
  - ACR will accept BI-RADS assessment category 2 (“benign”) with prior approval & report
- Do NOT use models or volunteers

4. THE RADIOLOGIST REVIEWERS WILL NOT REVIEW CLINICAL IMAGES SUBMITTED FOR ACCREDITATION THAT ARE NOT ADEQUATELY FATTY OR DENSE.

TRUE or FALSE
DIFFERENT BREAST DENSITIES (BI-RADS) PRESENT DIFFERENT IMAGING CHALLENGES OLD VERSION AND NOT RECOMMENDED

- Comp Cat 1: <25% glandular (Fatty)
- Comp Cat 2: 25-50% glandular
- Comp Cat 3: 51-75% glandular (Dense)
- Comp Cat 4: >75% glandular

BI-RADS

- In the BI-RADS edition 2003 the assignment of the breast composition was based on the overall density resulting in ACR category 1 (<25% fibroglandular tissue), category 2 (25-50%), category 3 (50-75%) and category 4 (>75%).
- In BI-RADS 2013 the use of percentages is discouraged, because in individual cases it is more important to take into account the chance that a mass can be obscured by fibroglandular tissue than the percentage of breast density as an indicator for breast cancer risk.

TWO CATEGORIES

- A/B CATEGORY = ONE
- C/D CATEGORY = TWO

Breast composition

A. entirely fatty
B. scattered areas of fibroglandular density
C. heterogeneously dense, which may obscure masses
D. extremely dense, which lowers sensitivity

5. THE MAJOR REASON FOR FAILURE OF ACR ACCREDITATION IS

- Excessive patient dose
- Poor phantom image quality
- Poor clinical image quality (Positioning)
- Processor QC (more than 3 data points outside of control limits without corrective action)

CLINICAL IMAGE QUALITY EVALUATED IN EIGHT CATEGORIES

- Positioning
- Compression
- Exposure level
- Contrast
- Sharpness
- Noise
- Artifacts
- Exam ID

- Review evaluation criteria in “Clinical Image Evaluation” section of 1999 QC Manual before submitting images

- (*Primary reason for accreditation failure)
**Clinical Image Quality Evaluted in Eight Categories**

- Positioning*
- Compression
- Exposure level
- Contrast
- Sharpness
- Noise
- Artifacts
- Exam ID

- Review evaluation criteria in “Clinical Image Evaluation” section of 1999 QC Manual before submitting images

- (*Primary reason for accreditation failure)

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**6. Your facility does not pass accreditation after the initial application. (The clinical images were not acceptable.) You must immediately cease performing mammography.**

TRUE or FALSE

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**CLINICAL IMAGE QUALITY EVALUATION WILL NOT DIFFER**

- Hard copy images only/changed now to both are acceptable Electronic/hard copy
- Evaluate the same 8 attributes as screen-film
  - Positioning
  - Compression
  - Exposure
  - Contrast
  - Sharpness
  - Noise
  - Artifacts
- Labeling
- ACR radiologists reviewing FFDM images are digital-qualified under MQSA

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**PHANTOM IMAGE QUALITY EVALUATION WILL NOT DIFFER**

- Hard copy images/Electronic Submission
- Scoring is the same as screen-film
  - Fibers
  - Specks
  - Masses
  - Subtraction for artifacts
- ACR medical physicists reviewing FFDM images are digital-qualified under MQSA

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**PERSONNEL REQUIREMENTS ARE DIFFERENT FOR FFDM**

- Interpreting physician
- Medical physicist
- Radiologic technologist
INTERPRETING PHYSICIAN (FFDM)

- Initial training
  - 8 hours (doesn't need to be Cat I)
  - Special training courses
  - Mfr applications training
  - Residency training
  - Hands on training (e.g., soft copy interpretation)
  - Exemptions
    - If began interpreting before 4/28/99
    - Either document or attest
- Continuing education
  - 15 ceus in mammography categories every 36 months
  - Continuing experience read 960 mammography exams within 24 months.

MEDICAL PHYSICIST (FFDM)

- Initial training
  - 8 hours
  - Special training courses
  - Mfr applications training
  - Graduate training
  - Hands-on training (e.g., soft copy QC testing)
  - Exemptions
    - If began surveying units before 4/28/99
    - Either document or attest
- Continuing education
  - Include 15 CEUs in mammography every 36 months

RADIOLOGIC TECHNOLOGIST (FFDM)

- Initial training of 40 hours
  - 8 hours
  - Special training courses
  - Mfr applications training
  - RT training
  - Include hands on training (e.g., QC testing)
  - Exemptions
    - If began using FFDM before 4/28/99
    - Either document or attest
- Continuing education
  - 15 CEUs every 36 months in mammography specific

KNOW WHEN YOUR ACCREDITATION AND MQSA CERTIFICATION EXPIRE

- Make every effort to stay within our timeframe
- If you don't submit your accreditation materials to us in a timely manner, we may have to fail your facility for non-compliance
- Our expiration date is on your ACR certificate and unit decal
- FDA and ACR are synchronizing dates

RADIOLOGISTS:

- Don’t assume everything is OK
- Radiologist is responsible for everything that impacts the interpretation of the patients’ films
- Lead interpreting physician has responsibility to ensure that the QA program meets all requirements
  - ACR recommends that you review your facility’s QC at least quarterly
- Review and approve all accreditation materials (including clinical images)
- ACR sends all accreditation materials to the lead interpreting physician (he/she signs all survey agreements)

MEDICAL PHYSICISTS:

- The medical physicist has responsibility over QC
- Talk with the technologists and radiologists; ask them about problems and concerns; have them show you
- Verbally explain your report to the facility staff
- Be aware of the new ACR Equipment Evaluation requirements for accreditation
MAMMOGRAPHY TECHNOLOGISTS:

- Keep your radiologist(s) informed and involved
- The lead interpreting physician has the responsibility of ensuring that the quality assurance program meets all MQSA requirements
- Be sure he/she reviews all accreditation materials (including clinical images) before sending them to the ACR

FEW NEW CHANGES

- Is the 2016 QC manual available in hard copy?
  - A. No. The 2016 manual is only available as an electronic file (PDF). If you would like a hard copy you may print the PDF file. You may wish to use a commercial office printing company to print the manual double-sided and in color.

FEW NEW CHANGES

- In the 2016 manual, why is the Repeat Analysis an optional test and not required as before?
  - A. The ACR Subcommittee on Quality Assurance in Mammography believed that the Repeat Analysis better serves the mammography community as an optional, rather than a mandated, test and that each facility should decide if the time and effort it takes to correctly perform the test generates useful information. (Even though the system is digital, collecting accurate, relevant data is difficult and time-consuming.) The Subcommittee also believed that there were more effective ways to promote clinical improvement such as the use of the Radiologist Image Quality Feedback form.

FEW NEW CHANGES

- Will the ACR update the Digital Mammography QC Manual to include tests for tomosynthesis?
  - A. Yes. The ACR Subcommittee on Quality Assurance is currently working on an appendix for technologist and medical physicist tests of tomosynthesis features. Once completed, the appendix will be reviewed by tomosynthesis equipment manufacturers for applicability. The ACR draft must be reviewed and approved by the FDA before it becomes final. We hope the approved appendix will be available in 2017.

FEW NEW CHANGES

- Q. I understand that there is no Clinical Image Quality Section in the new ACR Digital Mammography QC Manual. May I still access the Clinical Image Quality Section that was in the 1999 ACR Mammography QC Manual?
  - A. Yes. The Clinical Image Quality Section of the 1999 ACR Mammography QC Manual is located on the ACR Mammography Accreditation web page.

TRANSFER OF IMAGES

- If the facility continues to refuse to transfer the images, it is cause for a “Serious Complaint” according to the FDA’s criterion. i.e. a serious adverse event is one “for which a facility fails to take appropriate corrective action in a timely manner.” The ACR will initiate an investigation of the facility.
## SERIOUS ADVERSE EVENTS

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<th>Serious Adverse Events - Examples</th>
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<tbody>
<tr>
<td>Poor image quality</td>
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<tr>
<td>Missed cancers</td>
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<tr>
<td>The use of personnel that do not meet FDA qualifications</td>
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<td>Failures to send the mammography reports or lay summaries within 30 days</td>
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