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.

CR

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 <u>BICOE</u>

• 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)
- <u>Effective Jan 1, 2016</u>: Breast MRI (can satisfy this requirement if refer to another accredited MR facility).



On-Line Application Process-ACRedit

- · Many facilities already use ACRedit

 - 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 Mammo

- > 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 PC's for review.
 - > Clear Canvas Software: (Image Viewer Software)
- > Future: Going to all web applications



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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





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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

Д	NCR <u>Mammogra</u>	aphy Phantom
Version	Manufacturer & Model	Comments
- I	Gammex 156	Fiber 3 horz, fiber 4 vert
Ш	Gammex 156	No serial number
III	Gammex 156	Large 5 th speck group
IV	Gammex 156	6 digit serial number
V	Nuc Associates 18-220 CIRS 015	Serial number has at least 1 letter

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Introduction

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

Introduction

- Golden Rules 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

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

	Technologis	t QC Tests	
Test Number	Name (# of Test Elements)	Minimum Frequency	Required Corrective Action
1	ACR DM Phantom Image Quality (3)	Weekly	Before Clinical Use
2	Visual Checklist (1)	Monthly	As noted on form
3	Acquisition Workstation (AW) Monitor QC (3)	Monthly	30 Days or Before Use for Severe Artifacts
4	Radiologist Workstation (RW) Monitor QC (4)	Monthly	30 Days or Before Use for Severe Artifacts
5	Printer QC (4)	Monthly	Before Clinical Use
6	Viewbox Cleanliness (1)	Monthly	Before Clinical Use
7	Repeat Analysis (1)	Quarterly	Within 30 Days of Analysis
8	Facility QC Review (1)	Quarterly	Not Applicable
9	Compression Force (1)	Semiannual	Before Clinical Use
10	Manufacturer Detector Calibration (If Applicable)	Per Mfr Recommendation	Before Clinical Use
	Optional – System QC for Radiologist	As Needed	
	Optional – Radiologist Image Quality Feedback	As Needed	
	Managemer	nt Forms	
	ACR DM Phantom Technique Summary		
	AW & RW Monitor 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	s QC Tests	
Test Number	Name (# of Test Elements)	Minimum Frequency	Required Corrective Action
1	Mammography Equipment Evaluation and MQSA Req	MEE Only	Before Clinical Use
2	ACR DM Phantom Image Quality (5)	Annual	Before Clinical Use
3	Spatial Resolution (1)	Annual	Before Clinical Use
4	Automatic Exposure Control System Performance (1)	Annual	Before Clinical Use
5	Beam Quality (Half-Value Layer) Assessment (1)	Annual	Within 30 Days
6	Average Glandular Dose (1)	Annual	Before Clinical Use
7	Unit Checklist (1)	Annual	Before Clinical Use
8	Computed Radiography (If Applicable) (3)	Annual	Before Clinical Use
9	Acquisition Workstation (AW) Monitor QC (5)	Annual	Before Clinical Use
10	Radiologist Workstation (RW) Monitor QC (7)	Annual	Before Clinical Use
11	Film Printer QC (5)	Annual	Before Clinical Use
12	Viewbox Luminance and Room Illuminance (2)	Annual	Before Clinical Use
13	Evaluation of Site's Technologist QC Program (1)	Annual	Within 30 Days
14	Evaluation of Off-Site Technologist QC Program (If App)	Annual	Within 30 Days
	MEE or Troubleshooting	Test Forms	
	kVp Accuracy and Reproducibility		
	Collimation Assessment		
	Ghost Image Evaluation (Troubleshooting only)		
	Summary Report F	orms	
	Medical Physicist DM 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



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 3.0 mGy dose limit (Single CC view)



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

Test Object	Fiber Diameter	Mass Thickness	
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2	0.75 <u>+</u> 0.03	0.28 <u>+</u> 0.0083	0.75 <u>+</u> 0.05
3	0.61 <u>+</u> 0.03	0.23 <u>+</u> 0.0069	0.50 <u>+</u> 0.05
4	0.54 <u>+</u> 0.03	0.20 <u>+</u> 0.0059	0.38 <u>+</u> 0.04
5	0.40 <u>+</u> 0.03	0.17 <u>+</u> 0.0084	0.25 <u>+</u> 0.03
6	0.30 <u>+</u> 0.03	0.14 <u>+</u> 0.0070	0.20 <u>+</u> 0.02















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	6. Facility GC Review	Quartery					
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	5. Technique Chart review for each ro	iom (see MP rep	ort for recomme	inded chart)	- (Annuality)		-
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facility QC Review (quarterly)															

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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?