ACR Update on FFDM Accreditation

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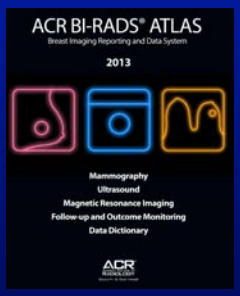
**No financial disclosures to report*

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.

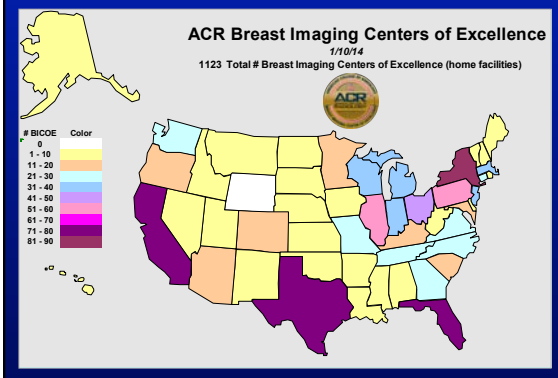
National Mammography Database

- 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

NATIONAL MAMMOGRAPHY DATABASE NMD

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)
  - 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

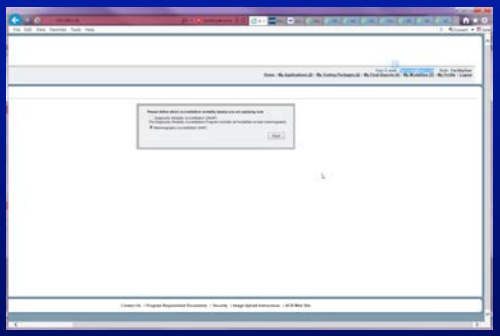
Online ACR MAP Submission

- Went Live January 20, 2014 for 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

Online ACR MAP Submission

Login Screen

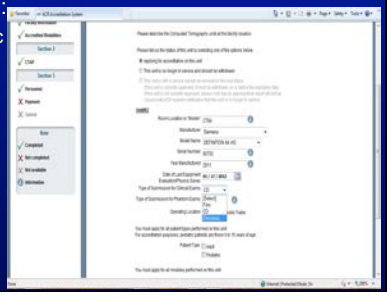
Online ACR MAP Submission



Login Screen - DMAP vs. MAP
Numbers will always stay separate but login will get you to see both.

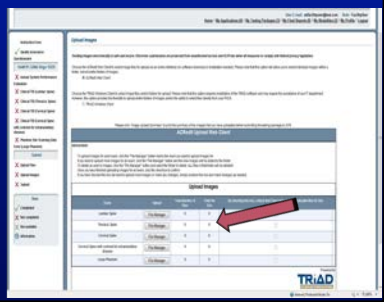
TRIAD

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



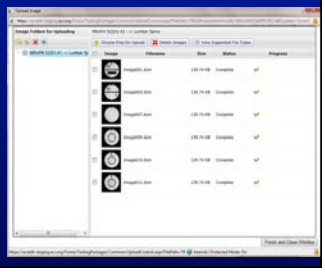
TRIAD

- Select how they want to upload the images

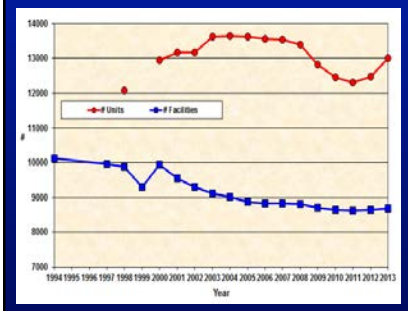


TRIAD - Web Client

- 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

Version	Manufacturer & Model	Comments
I	Gammex 156	Fiber 3 horz, fiber 4 vert
II	Gammex 156	No serial number
III	Gammex 156	Large 5th speck group
IV	Gammex 156	6 digit serial number
V	Nuc Associates 18-220 CIRS 015	Serial number has at least 1 letter

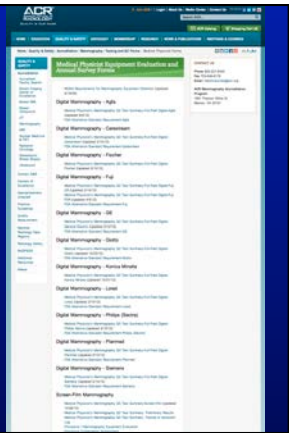
ACR Stereo Phantom

Minimum Pass Criteria

	ACR Mammography Phantom		Mini Digital Phantom	
	Film	Digital	Film	Digital
Fiber	4.0	5.0	2.0	3.0
Speck	3.0	4.0	2.0	3.0
Mass	3.0	3.5	2.0	2.5

Introduction

- ACR Accreditation Program



Introduction

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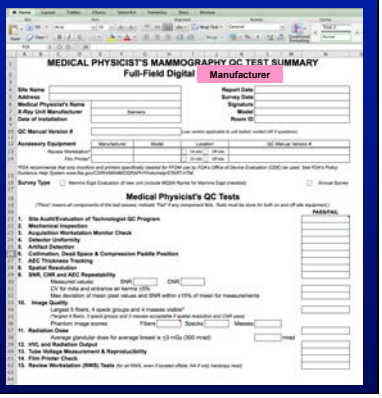
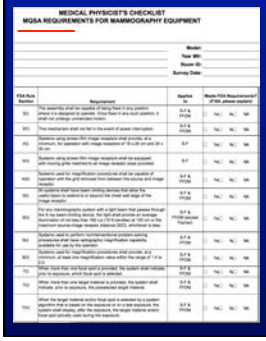


Introduction

- ACR Accreditation Program

Introduction



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
  - Most failures result in stopping 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

Technologist 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	**
	Management 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 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 Forms		
	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	Speck Diameter (Glass Spheres)	Mass Thickness
	mm	mm	mm
1	0.89 ± 0.05	0.33 ± 0.0100	1.00 ± 0.05
2	0.75 ± 0.03	0.28 ± 0.0083	0.75 ± 0.05
3	0.61 ± 0.03	0.23 ± 0.0069	0.50 ± 0.05
4	0.54 ± 0.03	0.20 ± 0.0059	0.38 ± 0.04
5	0.40 ± 0.03	0.17 ± 0.0084	0.25 ± 0.03
6	0.30 ± 0.03	0.14 ± 0.0070	0.20 ± 0.02

The ACR FFDM Phantom Prototype

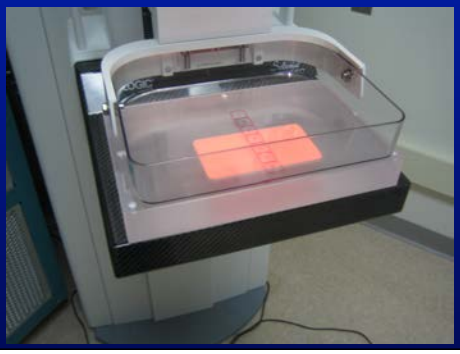


Image of Entire Phantom

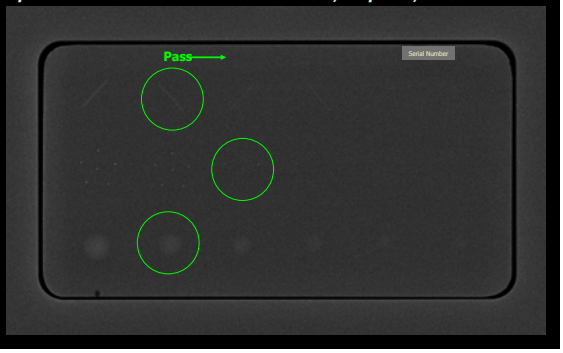
*Note: Gray dot in lower left corner of wax insert is an artifact due to a bubble in wax insert.

Wax Insert

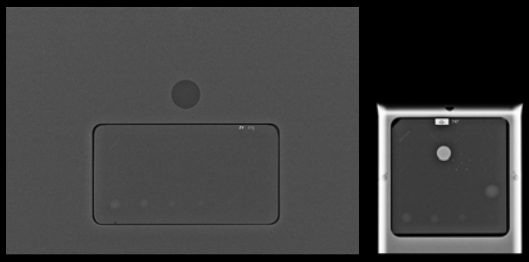
Expanded view of Wax Insert

Pass Criteria: ***2 Fibers, 3 Specks, 2 Masses***

Equivalent to SFM Phantom: ***4 Fibers, 3 Specks, 3 Masses***

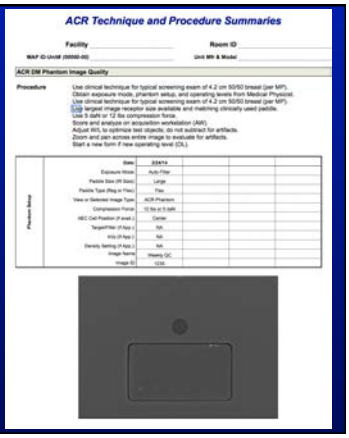


Effects of Thickness Equalization

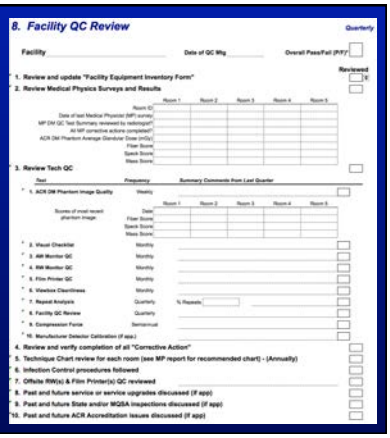


- New FFDM phantom equalizes attenuation inside and outside wax insert.
- This permits evaluation of artifacts over entire phantom area with same WW and WL used to score test objects.

Tech Tests



Tech Tests



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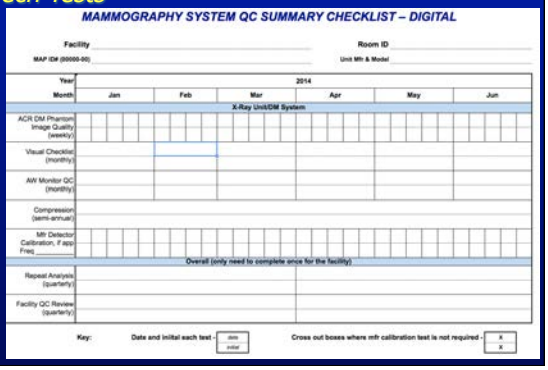
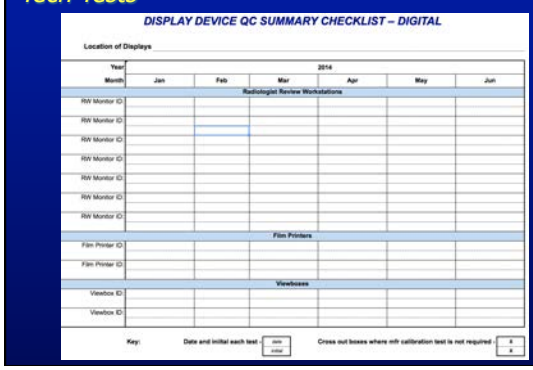
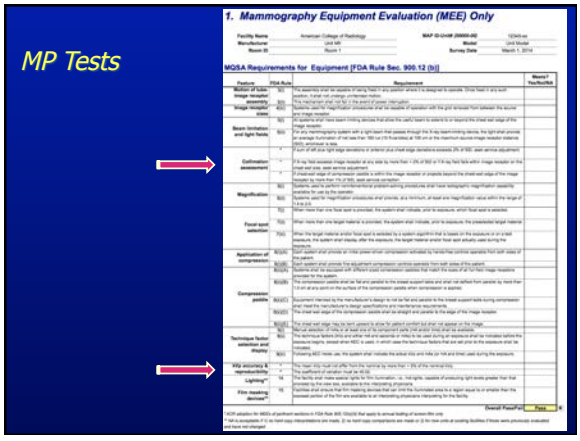
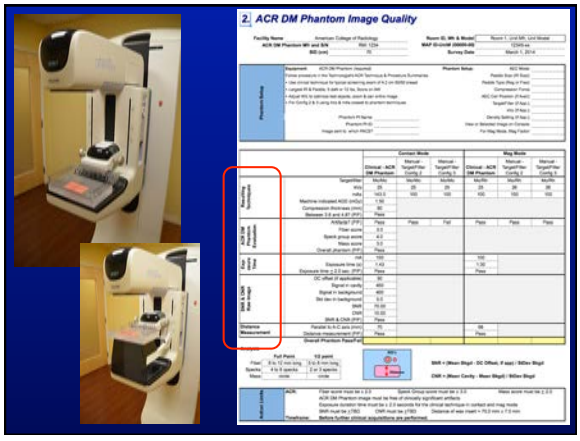


Tech Tests



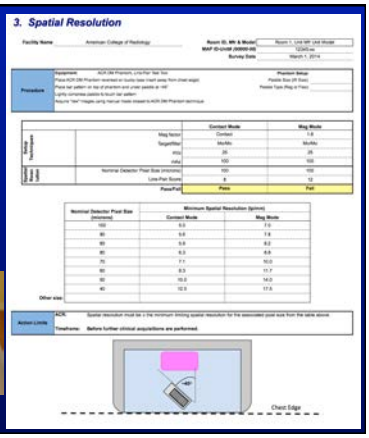
MP Tests

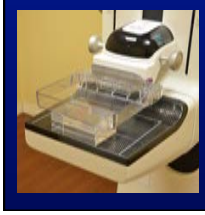




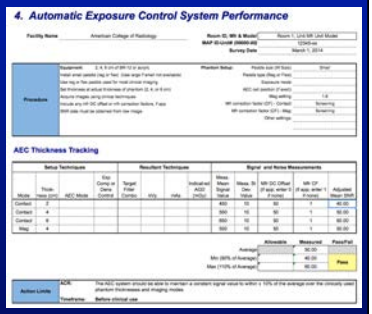
MP Tests

3. Spatial Resolution



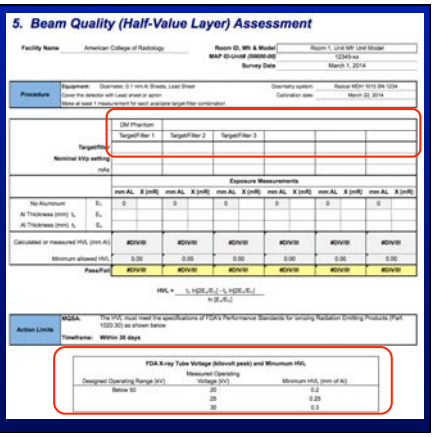


4. Automatic Exposure Control System Performance



MP Tests

5. Beam Quality (Half-Value Layer) Assessment



D = Kgcs

D = Mean Glandular Dose

K = Entrance surface air kerma

g = glandularity of 50%

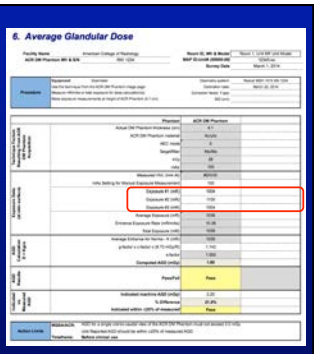
c = corrects for difference in composition (age dependent)

s = X-ray spectrum correction (Target/Filter)

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

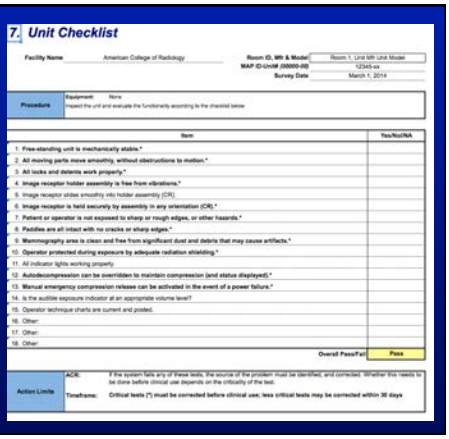
Primary Ref: D.R. Dance, et al. Additional for the Estimation of Mean Glandular Breast Dose Using the UK Mammography Dosimetry Protocol. Physics in Medicine and Biology 45, 3225-3240, 2000.

6. Average Glandular Dose



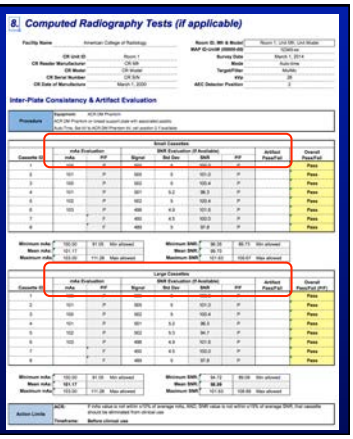
MP Tests

7. Unit Checklist



MP Tests

8. Computed Radiography Tests (if applicable)



MP Tests

8. Computed Radiography Tests (if applicable) Cont'd

Facility Name: American College of Radiology

Room ID, MR & Model: 10/00

MAP ID-Unit# (00000-00): 12345-xx

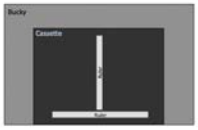
Survey Date: March 1, 2014

CR Reader Scanner Performance

Procedure	Equipment: 2 thin metal rulers Place rulers in the shape of a 'T' on a cassette which is placed on top of the bucky. Expose at relatively low manual technique (~25 kVp, 4 mAs).

	Pass/Fail
Parallel to Chest Wall	Pass
Perpendicular to Chest Wall	Pass

Action Limits	ACR: The edges of the "T" should appear smooth and sharp. If they are not, and appear jagged or non-smooth, then this could indicate a problem with the CR reader performance. Timeframe: Before clinical use



MP Tests

9. Acquisition Workstation (AW) Monitor QC

Facility Name: American College of Radiology

Medical Physicist (if app): MP Name, PhD

Signature (if app):

Workstation ID: Room 1, Unit MR, Unit Model

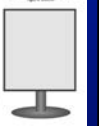
MAP ID# (99999): 12345-xx

Survey Date: March 1, 2014

Procedure	Equipment: Photometer Note: Some of these QC tests may or may not be possible to perform depending on the monitor QC capabilities Test Pattern Check: Can use either SMPTE or TG18-QC (if available) Luminance Check: Utilize appropriate TG18 patterns or other patterns that provide measure of Lmin & Lmax

Monitor manufacturer:	Model:
	Monitor serial number:
	Monitor date of manufacture:
Monitor Screen Evaluation	Screen free of scratches, defects, etc.?
	Screen free of fingerprints, dust, and marks?
Test Pattern Evaluation (TG18 or SMPTE, if available)	Test pattern centered appropriately
	0%-5% contrast visible
	95%-100% contrast visible
	Alphanumerics sharp
	3 "Quality Control" patches visible, if TG18 avail
	Line-pair images (center & corners)
	Grayscale ramps smooth (if avail)
Luminance Check (if relevant test pattern is available for measurement - TG18-LN8-01 & TG18-LN8-18)	Measured Luminance minimum (cd/m2)
	MR recommendation for Lmin, if avail*
	Lmin meets mfr recommendation ± 10%?
	Measured Luminance maximum (cd/m2)
	MR recommendation for Lmax, if avail*
	Lmin meets mfr recommendation ± 10%?
DICOM GSDF	DICOM GSDF using MR software, if avail (Y/F): Pass
MR Rec Automated Tests	Most recent set of MR Rec Automated Tests (P/F): Pass
	Overall Pass/Fail (P/F): Pass

Action Limits	ACR: Any identified screen blemish that could obstruct clinical information should be repaired Test pattern evaluation must pass all visual tests Lmax and Lmin are MR recommendations (typically Lmax ≥ 450 cd/m² & Lmin < 1.0 cd/m²) Contrast response should not deviate from the DICOM GSDF contrast values by more than ± 10% MR's tests must pass per manufacturer recommendations where applicable Timeframe: Within 30 days



MP Tests

10. Radiologist Workstation (RW) Monitor QC

Facility Name: American College of Radiology

Medical Physicist (if app): MP Name, PhD

Signature (if app):

Workstation ID: Room 1, Unit MR, Unit Model

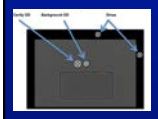
MAP ID# (99999): 12345-xx

Survey Date: March 1, 2014

Procedure	Equipment: ACR DM Phantom Image, photometer Note: Some of these QC tests may or may not be possible to perform depending on the monitor QC capabilities ACR DM Phantom: use phantom acquired from any DM unit within facility network, preferably one MP has just acquired Luminance Check: utilize appropriate TG18 patterns or other patterns that provide measure of Lmin & Lmax

Monitor manufacturer:	Model:	Left	Right
Ambient Light:	Are ambient light conditions adequate for DM?		
Monitor Screen Evaluation:	Screen free of scratches, defects, etc.?		
	Screen free of fingerprints, dust, and marks?		
		Monitor serial number	
		Monitor date of manufacture	
ACR DM Phantom:	Artifacts? (P/F)		
	Fiber score		
	Speck group score		
	Mass score		
	Distance across wax insert (mm)		
	Distance TO mm ± 7mm?		
Test Pattern Evaluation (TG18 or SMPTE, if available):	Test pattern centered appropriately		
	0%-5% contrast visible		
	95%-100% contrast visible		
	Alphanumerics sharp		
	3 "Quality Control" patches visible, if TG18 avail		
	Line-pair images (center & corners)		
	Grayscale ramps smooth, if avail		
Luminance Check (TG18-LN8-01 & TG18-LN8-18):	Measured Luminance minimum (cd/m2)		
	MR recommendation for Lmin, if avail*		
	Lmin meets mfr recommendation ± 10%?		
	Measured Luminance maximum (cd/m2)		
	MR recommendation for Lmax, if avail*		
	Lmin meets mfr recommendation ± 10%?		
	Left-right monitor ratio (Max luminance)	≤[1.2]	
	Left-right monitor ratio (Max luminance)	≤[1.2]	
	Left-right monitor ratio's adequate?		
DICOM GSDF	DICOM GSDF using MR software, if avail (P/F)		
MR Rec Automated Tests:	Most recent set of MR Rec Automated Tests (P/F)		
	Overall Pass/Fail (P/F)		

Action Limits	ACR: Ambient light conditions should be appropriate for digital mammography Any identified screen blemish that could obstruct clinical information should be repaired Fiber score must be ≥ 2.0 — Speck Group score must be ≥ 3.0 — Mass score must be ≥ 2.0 The ACR DM Phantom image must be free of clinically significant artifacts Test pattern evaluation must pass all visual tests Lmax and Lmin are MR recommendations (typically Lmax ≥ 450 cd/m² & Lmin < 1.0 cd/m²) Contrast response should not deviate from the DICOM GSDF contrast values by more than ± 10% MR's tests must pass per manufacturer recommendations where applicable Timeframe: Within 30 days



MP Tests

11. Film Printer QC

Facility Name: American College of Radiology

Medical Physicist (if app):

Signature (if app):

Printer ID: Printer #1

MAP ID# (99999): 12345-xx

Survey Date: March 1, 2014

Procedure	Equipment: Densitometer Print an ACR DM Phantom image acquired from any DM unit within facility network, preferably one MP has just acquired. Do not change enhancement settings from acquired image prior to printing. Print the phantom image from the workstation/computer typically used to print clinical films. Films should be measured either at patients left or right edge of film or at extreme non-chest wall edge.

		Contact	Magnification Mode
Laser Printer Manufacturer		Laser Printer Serial Number	
Laser Printer Model		Laser Printer Date of Manufacture	
Device where most images printed (DM or Workstation):		DM ID or workstation ID	
	Film size		
ACR DM Phantom:	Artifacts? (P/F)		
	Fiber score		
	Speck group score		
	Mass score		
	Background OD (Outside cavity)		
	OD - Inside cavity		
	Contrast ($OD_{Outside}$ - OD_{Inside})		
	Dmax OD		
Distance Measurement	Parallel to A-C axis (mm)		
	Distance measurement (P/F)		
	Size of printed image appears to be correctly sized (P/F):		
	Phantom appears to be correctly positioned on the film (P/F):		
	Overall Pass/Fail	Pass	Pass / Fail

Action Limits	ACR: Fiber score must be ≥ 2.0 — Speck Group score must be ≥ 3.0 — Mass score must be ≥ 2.0 Background OD must be = 1.40 (ACR recommends the background OD be 1.80 ± 0.30) Contrast should be ≥ 0.15 OD The image of the wax insert should be 75 mm ± 7.0 mm Timeframe: Before clinical use

MP Tests

12. Viewbox Luminance and Room Illuminance

Facility Name: American College of Radiology

Medical Physicist (if app):

Signature (if app):

Printer ID: Room 1, Unit MR, Unit Model

MAP ID# (99999): 12345-xx

Survey Date: March 1, 2014

Procedure	Equipment: Photometer Measure luminance for all viewboxes, record the luminance value for the viewbox with the lowest luminance. Note: Only check a deficiency if it is significant and could impact interpretation. If the observation is not significant, just make a note in comments.

	Measurements		Significant Deficiencies					
Viewbox Designation	Viewbox Luminance (cd/m²)	Illuminance on Viewbox Surface (lux)	Dirt and Marks	Color Difference	Luminance Difference	Non-Uniformity	Conspicuous Marks Missing	Pass/Fail
1.								
2.								
3.								
4.								
5.								
6.								
7.								
8.								
9.								
10.								
							Overall Pass/Fail	

Comments:

Action Limits	ACR: The luminance on the viewbox surface should be ≥ 50 lux Mammography viewboxes should be capable of a luminance of 3,000 cd/m², if these levels are not met, corrective action should be taken Timeframe: Before clinical use

MP Tests

13. Evaluation of Site's Technologist QC Program

Facility Name: American College of Radiology

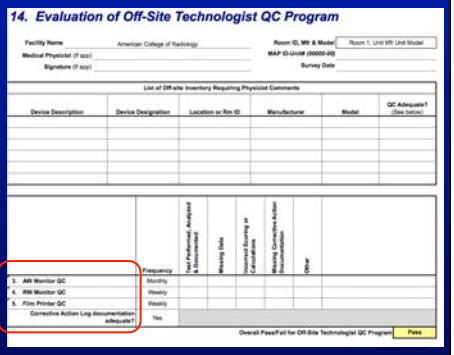
Room ID, MR & Model: Room 1, Unit MR Unit Model

MAP ID-Unit# (00000-00): 12345-xx

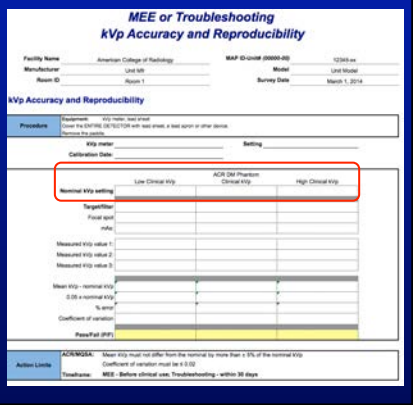
Survey Date: March 1, 2014

	Frequency	Test Performed, Analyzed & Documented	Missing Data	Corrective Steps Documented	Missing Corrective Action Documentation	Other	Comments
1. ACR DM Phantom Image Quality	Weekly						
Scores of latest phantom image: Latest QC Tech Score / Med Phys Score							
Fiber							
Speck group							
Mass							
2. Visual Checklist	Monthly						
3. AW Monitor QC	Monthly						
4. RW Monitor QC	Weekly						
5. Film Printer QC	Weekly						
6. Viewbox Cleanliness	Monthly						
7. Repeat Analysis	Quarterly						
8. Facility QC Review	Quarterly						
9. Compression Force	Semiannual						
10. MR Detector Calibration (if app)							
Corrective Action Log documentation adequate?	Yes						
					Overall Pass/Fail for Technologist QC Program		Pass

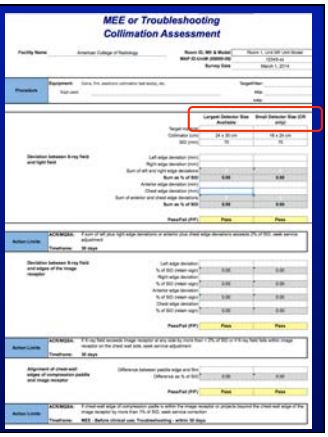
MP Tests


14. Evaluation of Off-Site Technologist QC Program

MP Tests


MEE or Troubleshooting
kVp Accuracy and Reproducibility

MP Tests


MEE or Troubleshooting
Collimation Assessment

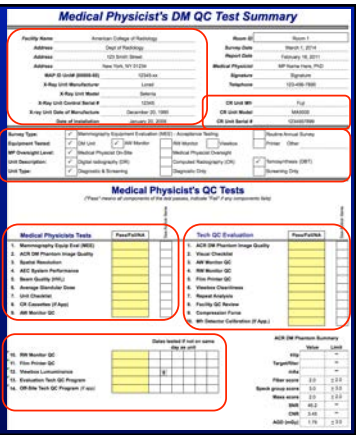
MP Tests


Troubleshooting
Ghost Image Evaluation

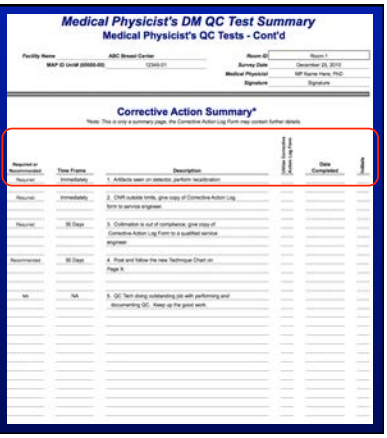
MP Tests


Medical Physicist's DM QC Test Summary

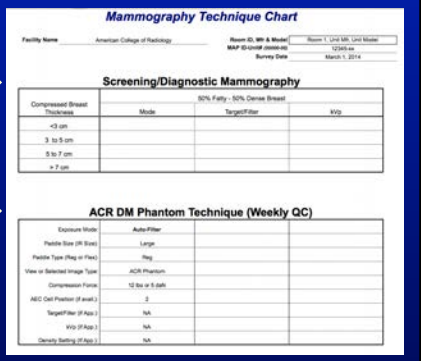
MP Tests


Medical Physicist's DM QC Test Summary

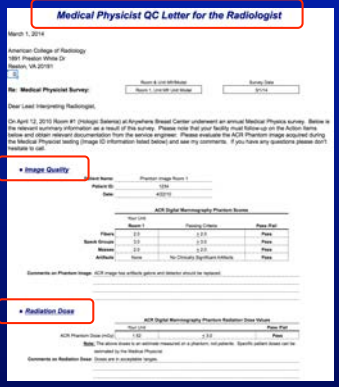
MP Tests


Medical Physicist's DM QC Test Summary
Medical Physicist's QC Tests - Cont'd
Corrective Action Summary*

MP Tests


Mammography Technique Chart
Screening/Diagnostic Mammography
ACR DM Phantom Technique (Weekly QC)

MP Tests


Medical Physicist QC Letter for the Radiologist
• Image Quality
• Radiation Dose

MP Tests


Medical Physicist QC Summary Letter for the Radiologist, Cont'd
• Required Action Items
• Recommended Action Items
• Comments on Monitors, Monitor QC, & Viewing Conditions
• Comments on Tech QC

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?