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

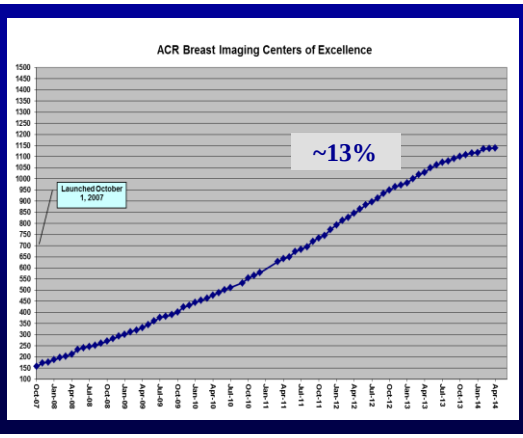
ACR Breast Imaging Centers of Excellence

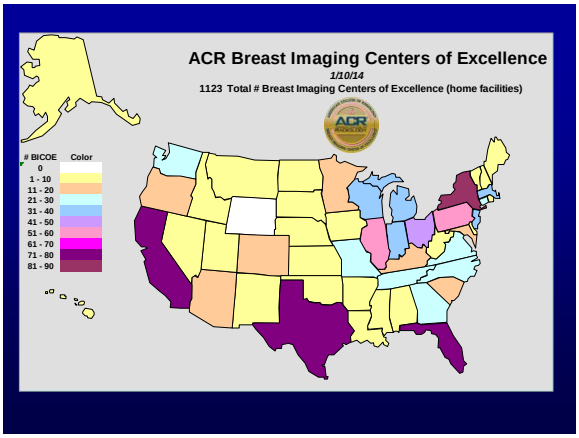
BICOE

- 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

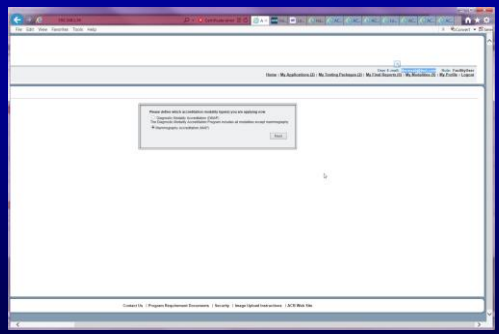




Online ACR MAP Submission

- 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

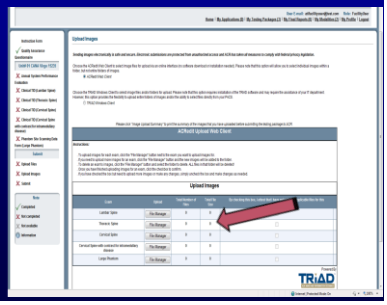
Online ACR MAP Submission



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

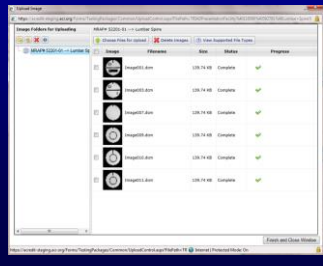
TRIAD

- 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

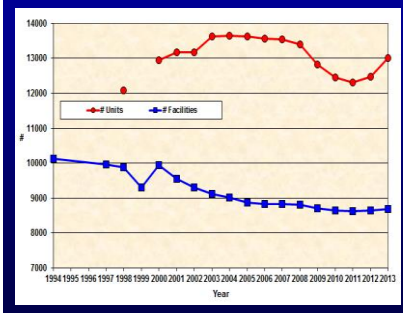
The Law:
Mammography Quality Standards Act (MQSA)

The Regulator:
US Food and Drug Administration (FDA)

The Accreditation Bodies:
(ACR, TX, IA, AR)

The Inspectors:
States

US Mammography Facilities and Units (October 1 each year)

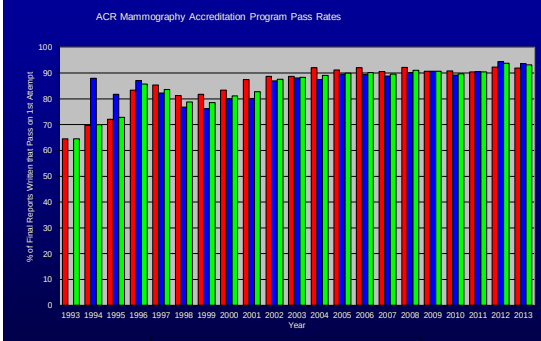


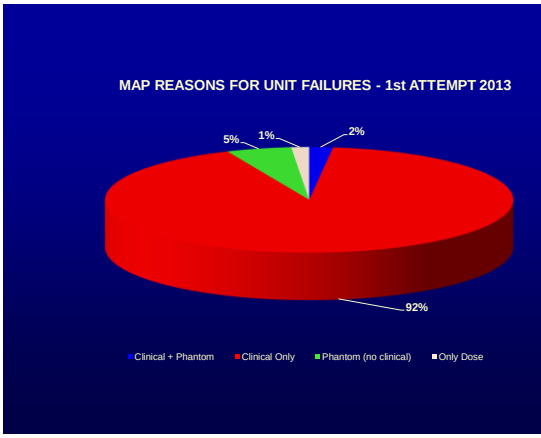
In 2000

- 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





Introduction

- 4 Accrediting Bodies (AB's)
- ~30 FDA approved units

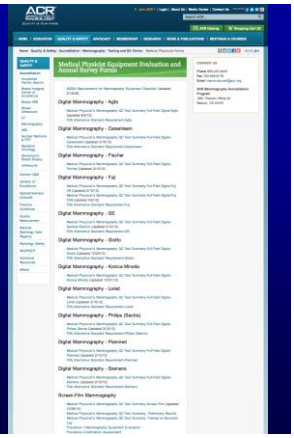
Full Field Digital Mammography (FFDM) or Digital Breast Tomosynthesis (DBT) Unit	Accreditation Body Approval Date Effective Date			
	ACR	BAS	BIA	STX
GE Senographe 2000D	12/18/02 03/18/03	08/15/06 08/15/06	08/28/03 10/01/03	05/21/04 05/21/04
Fischer Imaging SenoScan	07/24/03 09/15/03			05/21/04 05/21/04
Lorad/Hologic Selenia (Molybdenum target)	09/02/03 09/15/03	08/15/06 08/15/06	08/28/03 10/01/03	05/21/04 05/21/04
GE Senographe DS	08/12/04 09/15/04	08/15/06 08/15/06	01/12/06 01/17/06	08/12/04 05/15/04
Siemens Mammomat Novation DR	10/07/03 10/14/03	08/28/06 08/28/06	11/28/06 02/01/06	06/29/06 06/29/06
GE Senographe Essential	06/29/06 07/14/06	08/15/06 08/15/06	08/24/06 08/24/06	09/05/06 09/05/06
Fuji Computed Radiography for Mammography	11/13/06 11/13/06	10/12/06 10/12/06	11/13/06 11/13/06	11/13/06 11/13/06
Hologic Selenia (Tungsten target)	02/01/06 02/01/06	02/16/06 02/16/06	02/01/06 02/01/06	02/01/06 02/01/06
Siemens Mammomat Novation S	03/11/09 03/11/09	02/11/09 02/11/09	03/11/09 03/11/09	02/11/09 02/11/09
Hologic Selenia S	03/11/09 03/11/09	02/11/09 02/11/09	03/11/09 03/11/09	02/11/09 02/11/09
Hologic Selenia Dimensions 2D	03/11/09 03/11/09	02/11/09 02/11/09	03/11/09 03/11/09	02/11/09 02/11/09
Carestream Directview Computed Radiography (CR) Mammography	02/08/11 02/16/11	01/07/11 01/07/11	01/07/11 01/07/11	02/08/11 02/08/11
Siemens Mammomat Inspiration	03/11/11 03/11/11	02/11/11 02/11/11	03/11/11 03/11/11	02/11/11 02/11/11
Hologic Selenia Encore	06/15/11 06/15/11	06/15/11 06/15/11	06/15/11 06/15/11	06/15/11 06/15/11
Philips (Sectra) MicroDose L30	10/20/11 10/21/11	07/18/11 07/18/11		08/03/11 08/03/11
Siemens Mammomat Inspiration Pure	08/23/11 08/23/11	08/23/11 08/23/11	08/23/11 08/23/11	08/23/11 08/23/11
GE Senographe Care	10/07/11 10/07/11	10/07/11 10/07/11	10/07/11 10/07/11	10/07/11 10/07/11
Planmed Nuance	12/13/11 12/27/11	12/20/11 12/20/11		01/20/12 01/20/12
Planmed Nuance Excel	12/13/11 12/27/11	12/20/11 12/20/11		01/20/12 01/20/12
Fuji Aspire Computed Radiography for Mammography	01/20/12 01/20/12	01/20/12 01/20/12	01/20/12 01/20/12	01/20/12 01/20/12
Giotto Image 3D/3DL	11/02/12 11/02/12	07/24/12 07/24/12		03/08/12 03/08/12
Fuji Aspire HD	03/28/12 04/10/12	07/24/12 07/24/12	05/25/12 05/25/12	03/28/12 04/19/12
Konica Minolta Xpress Digital Mammography CR System	04/19/12 04/27/12	07/24/12 07/24/12		04/19/12 04/27/12
Agfa CR Mammography System	09/04/12 09/14/12	07/24/12 07/24/12		05/08/12 05/08/12
Fuji Aspire HD-s	05/25/13 05/25/13	06/25/13 06/25/13	06/25/13 06/25/13	05/25/13 05/25/13
Fuji Aspire HD Plus	05/25/13 05/25/13	06/25/13 06/25/13	06/25/13 06/25/13	05/25/13 05/25/13
Siemens Mammomat Inspiration Prime	07/11/13 07/11/13	07/11/13 07/11/13	07/11/13 07/11/13	07/11/13 07/11/13
Philips MicroDose SI L50	09/23/13 09/23/13	09/23/13 09/23/13	09/23/13 09/23/13	09/23/13 09/23/13
Siemens Mammomat Inspiration ECO	11/20/13 11/20/13	11/20/13 11/20/13	11/20/13 11/20/13	11/20/13 11/20/13

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

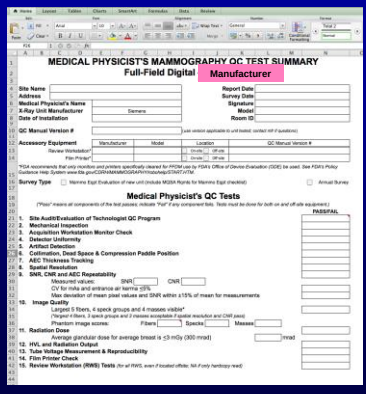
Introduction

- ACR Accreditation Program



Introduction

- ACR Accreditation Program



MEDICAL PHYSICIST'S MAMMOGRAPHY QC TEST SUMMARY

Full-Field Digital Manufacturer

Site Name
Address
Medical Physicist's Name
X-Ray Unit Manufacturer
Date of Installation
QC Manual Version #
Accessory Equipment
Survey Type

Report Date
Survey Date
Signature
Model
Room ID

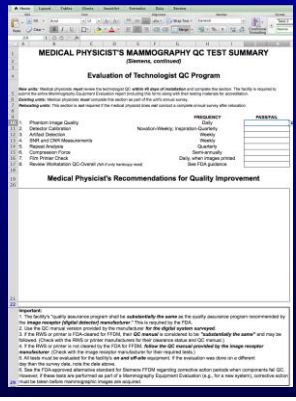
Medical Physicist's QC Tests

PASS/FAIL

1. Site Audit/Evaluation of Technologist QC Program
2. Mechanical Inspection
3. Acquisition Workstation Monitor Check
4. Detector Uniformity
5. Artifact Detection
6. Collimation, Dead Space & Compression Paddle Position
7. AEC Thickness Tracking
8. Spatial Resolution
9. SNR, CNR and AEC Repeatability
10. Image Quality
11. Radiation Dose
12. HVL and Radiation Output
13. Tube Voltage Measurement & Reproducibility
14. Film Printer Check
15. Review Workstation (RWS) Tests

Introduction

- ACR Accreditation Program



MEDICAL PHYSICIST'S MAMMOGRAPHY QC TEST SUMMARY

(Siemens, continued)

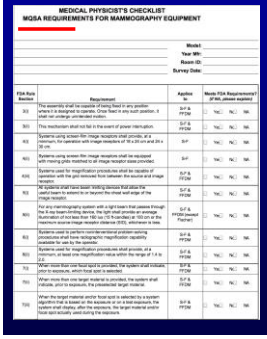
Evaluation of Technologist QC Program

PASS/FAIL

1. Phantom Image Quality
2. Detector Calibration
3. Artifact Detection
4. Shift and CNR Measurements
5. Repeat Analysis
6. Compression Force
7. Film Printer Check
8. Review Workstation QC-Overall

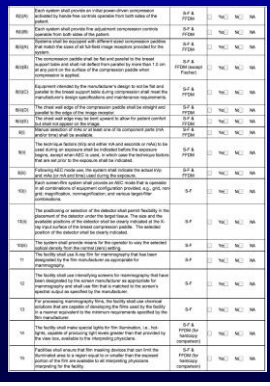
Medical Physicist's Recommendations for Quality Improvement

Introduction



MEDICAL PHYSICIST'S CHECKLIST
MQSA REQUIREMENTS FOR MAMMOGRAPHY EQUIPMENT

Model:
Year Mfr:
Room ID:
Survey Date:



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

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

ACR FFDM QC Manual Project

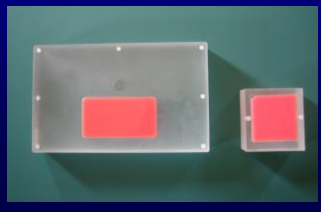
- Goals:
  - Keep in mind Mammo has MQSA Regulation
  - Account for all past, present, and future FFDM systems
  - Reasonable and appropriate for mass implementation (~13,000 units)

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

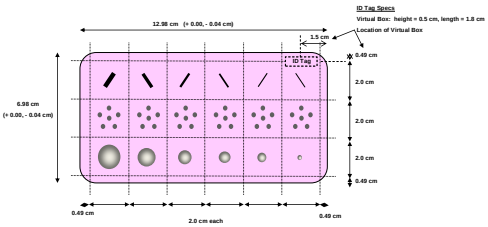
- Phantom Prototype Design Principles
  - Can be used on both SFM & FFDM
  - Total attenuation matched to current SFM phantom
    - Similar thickness
    - Similar total dose
  - Permits testing of the MQSA 3.0 mGy dose limit (Single CC view)



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".

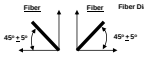
0.635 cm (1/4 inch) radius on corners of wax insert.

Fiber Placement specs

Fiber specifications

Fiber Length = 1.0 cm ± 0.1 cm

Fiber Diameter = See Table



Speck 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

1. Mass pre-cut sphere diameter = 5/8 inch
2. Mass placement to be within ± 0.1 cm of center of virtual grid

The ACR FFDM Phantom Prototype

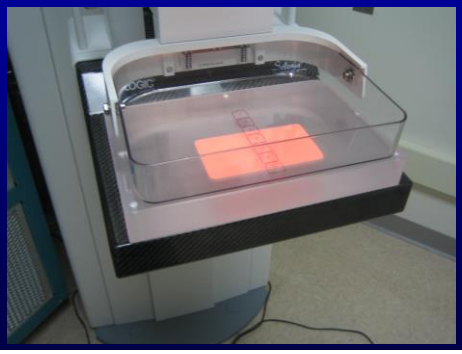


Image of Entire Phantom

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

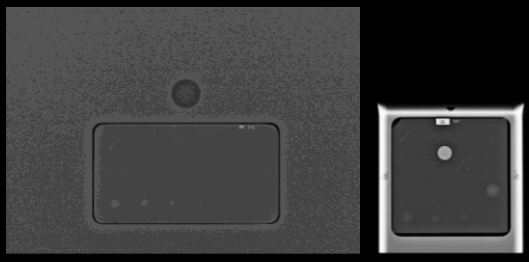
Wax Insert

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.

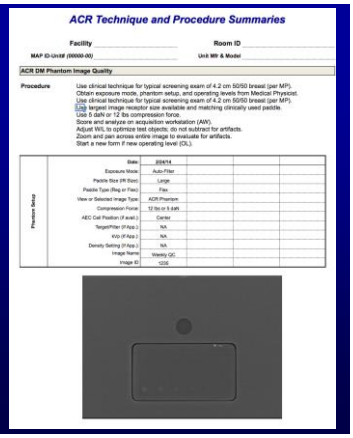
Technologist QC Tests

Test Number	Name (# of Test Elements)	Minimum Frequency	Required Corrective Action
1	ACR DM Phantom Image Quality (3-4)	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	Film Printer QC (4)	Monthly	Before Clinical Use
6	Viewbox Cleanliness (if app) (1)	Monthly	Before Clinical Use
7	Facility QC Review (1)	Quarterly	Not Applicable
8	Compression Force (1)	Semiannual	Before Clinical Use
9	Manufacturer Detector Calibration (If Applicable)	Per Mfr Recommendation	Before Clinical Use
	Optional - Repeat Analysis	As Needed	Within 30 days after analysis
	Optional – System QC for Radiologist	As Needed	30 Days or Before Use for Severe Artifacts
	Optional – Radiologist Image Quality Feedback	As Needed	Not applicable

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

Tech Tests



ACR Technique and Procedure Summaries

Facility _____ Room ID _____

MAP ID-Unit# (00000-00) _____ Unit Mfr & Model _____

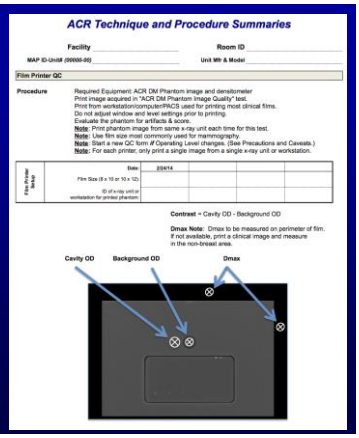
ACR DM Phantom Image Quality

Procedure

Use clinical technique for typical screening exam of 4.2 cm 50/50 breast (per MP).
Obtain exposure mode, phantom setup, and operating levels from Medical Physicist.
Use clinical technique for typical screening exam of 4.2 cm 50/50 breast (per MP).
Use largest image receptor size available and matching clinically used paddle.
Use 5 daN or 12 lbs compression force.
Score and analyze on acquisition workstation (AW).
Adjust W/L to optimize test objects; do not subtract for artifacts.
Zoom and pan across entire image to evaluate for artifacts.
Start a new form if new operating level (OL).

Phantom Setup					
	Date	2/24/14			
	Exposure Mode	Auto-Filter			
	Paddle Size (Mfr Size)	Large			
	Paddle Type (Reg or Flex)	Flex			
	View or Selected Image Type	ACR Phantom			
	Compression Force	12 lbs or 5 daN			
	AEC Cell Position (if avail.)	Center			
	Target/Filter (if App.)	NA			
	KVp (if App.)	NA			
	Density Setting (if App.)	NA			
	Image Name	Weekly QC			
	Image ID	1256			

Tech Tests



ACR Technique and Procedure Summaries

Facility _____ Room ID _____

MAP ID-Unit# (00000-00) _____ Unit Mfr & Model _____

Film Printer QC

Procedure

Required Equipment: ACR DM Phantom image and densitometer
Print image acquired in "ACR DM Phantom Image Quality" test.
Print from workstation/computer/PACS used for printing most clinical films.
Do not adjust window and level settings prior to printing.
Evaluate the phantom for artifacts & score.
Note: Print phantom image from same x-ray unit each time for this test.
Note: Use film size most commonly used for mammography.
Note: Start a new QC form if Operating Level changes. (See Precautions and Caveats.)
Note: For each printer, only print a single image from a single x-ray unit or workstation.

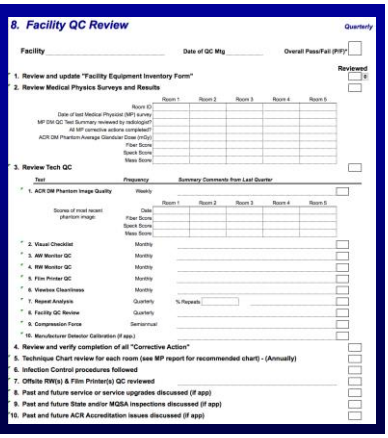
Film Printer Set-up	Date	2/24/14			
	Film Size (8 x 10 or 10 x 12)				
	ID of x-ray unit or workstation for printed phantom				

Contrast = Cavity OD - Background OD

Dmax Note: Dmax to be measured on perimeter of film. If not available, print a clinical image and measure in the non-breast area.

Cavity OD Background OD Dmax

Tech Tests



8. Facility QC Review Quarterly

Facility _____ Date of QC Mtg _____ Overall Pass/Fail (P/F)

1. Review and update "Facility Equipment Inventory Form" Reviewed
2. Review Medical Physics Surveys and Results

	Room 1	Room 2	Room 3	Room 4	Room 5
Room ID					
Date of last Medical Physicist (MP) survey					
MP DM QC Test Summary reviewed by radiologist?					
All MP corrective actions completed?					
ACR DM Phantom Average Glandular Dose (mGy)					
Fiber Score					
Speck Score					
Mass Score					

3. Review Tech QC

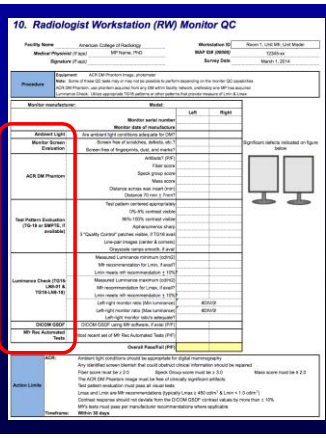
Test	Frequency	Summary Comments from Last Quarter
1. ACR DM Phantom Image Quality	Weekly	
Scores of most recent phantom image: Date / Fiber Score / Speck Score / Mass Score		Room 1 / Room 2 / Room 3 / Room 4 / Room 5
2. Visual Checklist	Monthly	
3. AW Monitor QC	Monthly	
4. RW Monitor QC	Monthly	
5. Film Printer QC	Monthly	
6. Viewbox Cleanliness	Monthly	
7. Repeat Analysis	Quarterly	% Repeats:
8. Facility QC Review	Quarterly	
9. Compression Force	Semiannual	
10. Manufacturer Detector Calibration (if app.)		

4. Review and verify completion of all "Corrective Action"
5. Technique Chart review for each room (see MP report for recommended chart) - (Annually)
6. Infection Control procedures followed
7. Offsite RW(s) & Film Printer(s) QC reviewed
8. Past and future service or service upgrades discussed (if app)
9. Past and future State and/or MQSA inspections discussed (if app)
10. Past and future ACR Accreditation issues discussed (if app)

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	Average Glandular Dose (1)	Annual	Before Clinical Use
6	Unit Checklist (1)	Annual	Before Clinical Use
7	Computed Radiography (If Applicable) (3)	Annual	Before Clinical Use
8	Acquisition Workstation (AW) Monitor QC (5)	Annual	Before Clinical Use
9	Radiologist Workstation (RW) Monitor QC (9)	Annual	Before Clinical Use
10	Film Printer QC (5)	Annual	Before Clinical Use
11	Evaluation of Site's Technologist QC Program (1)	Annual	Within 30 Days
12	Evaluation of Off-Site Technologist QC Program (If App) (1)	Annual	Within 30 Days
	MEE or Troubleshooting Test Forms		
	Beam Quality (Half-Value Layer) Assessment	MEE or Troubleshooting	Before Clin or 30 D
	kVp Accuracy and Reproducibility	MEE or Troubleshooting	Before Clin or 30 D
	Collimation Assessment	MEE or Troubleshooting	Before Clin or 30 D
	Ghost Image Evaluation (Troubleshooting only)	Troubleshooting	Before Clinical
	Viewbox Luminance (Troubleshooting only)	Troubleshooting	**
	Summary Report Forms		
	Medical Physicist DM QC Summary		
	Technique Chart (Clinical & Phantom)		
	Medical Physicist Summary Letter for the Radiologist		

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# (99000): 12345-xx
Survey Date: March 1, 2014

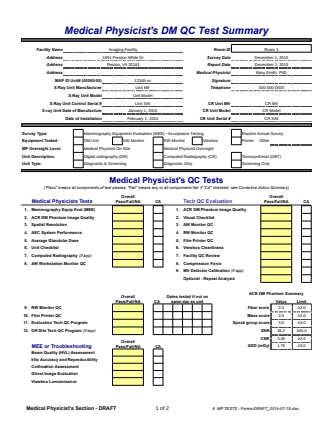
Procedure
Equipment: ACR DM Phantom Image, photometer
Note: Some of these QC tests may or may not be possible to perform depending on the monitor QC capabilities
ACR DM Phantom: use phantom acquired from any DM within facility network, preferably one MP has acquired
Luminance Check: Utilize appropriate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

Monitor manufacturer:		Model:	Left	Right
		Monitor serial number:		
		Monitor date of manufacture:		
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?			
ACR DM Phantom		Artifacts? (Y/F)		
		Fiber score		
		Speck group score		
		Mass score		
		Distance across eye mark (mm)		
		Distance 70 mm ± 1mm?		
Test Pattern Evaluation (TG-18 or SMPTE, if available)	Test pattern centered appropriately			
	0% 4% contrast visible			
	96% 100% contrast visible			
	Appropriately sharp			
	5 "Quality Control" patches visible, if TG18 avail			
	Line-pair images (center & corners)			
	Grayscale ramps smooth, if avail			
Luminance Check (TG18-LUM-01 & TG18-LUM-16)	Measured Luminance minimum (cd/m2)			
	MR recommendation for Lmin, if avail?			
	Lmin meets MR recommendation ± 10%?			
	Measured Luminance maximum (cd/m2)			
	MR recommendation for Lmax, if avail?			
	Lmin meets MR recommendation ± 10%			
	Left-right monitor ratio (Min luminance)	#DIV/0!		
	Left-right monitor ratio (Max luminance)	#DIV/0!		
	Left-right monitor ratio's adequate?			
DICOM GSDF	DICOM GSDF using MR software, if avail (FP)?			
MR Rec Automated Tests	Most recent set of MR Rec Automated Tests (FP)?			
	Overall Pass/Fail (FP)?			

Significant defects indicated on figure below

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



Medical Physicist's DM QC Test Summary

Facility Name: Imaging Facility
Address: 1891 Preston White Dr
Address: Reston, VA 20191
Address:
MAP ID (until 20000-00): 12345-xx
X-Ray Unit Manufacturer: Unit MR
X-Ray Unit Model: Unit Model
X-Ray Unit Control Serial #: Unit SN
X-ray Unit Date of Manufacture: January 1, 2015
Date of Installation: February 1, 2015
Room ID: Room 1
Survey Date: December 1, 2015
Report Date: December 2, 2015
Medical Physicist: Mary Smith, PhD
Signature:
Telephone: 202-000-0000
CR Unit Mfr: CR Mfr
CR Unit Model: CR Model
CR Unit Serial #: CR S/N

Survey Type: Mammography Equipment Evaluation (MEE) Acceptance Testing; Routine Annual Survey
Equipment Tested: DM Unit; RW Monitor; Printer; Other
MP Oversight Level: Medical Physicist On-Site; Medical Physicist Oversight
Unit Description: Digital radiography (DR); Computed Radiography (CR); Tomosynthesis (DBT)
Unit Type: Diagnostic & Screening; Diagnostic Only; Screening Only

Medical Physicist's QC Tests
("Pass" means all components of test passed, "Fail" means any or all components fail, if "CA" checked, see Corrective Action Summary)

Medical Physicists Tests	Overall Pass/Fail/NA	CA
1. Mammography Equip Eval (MEE)		
2. ACR DM Phantom Image Quality		
3. Spatial Resolution		
4. AEC System Performance		
5. Average Glandular Dose		
6. Unit Checklist		
7. Computed Radiography (if App)		
8. AW Workstation Monitor QC		
9. RW Monitor QC		
10. Film Printer QC		
11. Evaluation Tech QC Program		
12. Off-Site Tech QC Program (if app)		
MEE or Troubleshooting		
Beam Quality (HVL) Assessment		
KVp Accuracy and Reproducibility		
Collimation Assessment		
Chest Image Evaluation		
Viewbox Luminance		

Tech QC Evaluation	Overall Pass/Fail/NA	CA
1. ACR DM Phantom Image Quality		
2. Visual Checklist		
3. AW Monitor QC		
4. RW Monitor QC		
5. Film Printer QC		
6. Viewbox Cleanliness		
7. Facility QC Review		
8. Compression Force		
9. Mfr Detector Calibration (if app)		
Optional - Repeat Analysis		

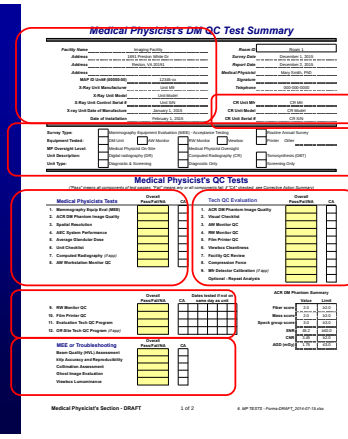
Dates tested if not on same day as unit

ACR DM Phantom Summary

	Value	Limit
Fiber score	4.0	≥ 3.0
Mass score	5.0	≥ 4.0
Speck group score	4.0	≥ 3.0
SNR	45.2	≥40.0
CNR	5.26	≥4.0
ASD (cm/kg)	1.76	≤2.0

Medical Physicist's Section - DRAFT 1 of 2 4. MP TESTS - Forms-DRAFT_2014-07-15.xlsx

MP Tests



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CR Unit Model: CR Model
CR Unit Serial #: CR S/N

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2. ACR DM Phantom Image Quality		
3. Spatial Resolution		
4. AEC System Performance		
5. Average Glandular Dose		
6. Unit Checklist		
7. Computed Radiography (if App)		
8. AW Workstation Monitor QC		
9. RW Monitor QC		
10. Film Printer QC		
11. Evaluation Tech QC Program		
12. Off-Site Tech QC Program (if app)		
MEE or Troubleshooting		
Beam Quality (HVL) Assessment		
KVp Accuracy and Reproducibility		
Collimation Assessment		
Chest Image Evaluation		
Viewbox Luminance		

Tech QC Evaluation	Overall Pass/Fail/NA	CA
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3. AW Monitor QC		
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5. Film Printer QC		
6. Viewbox Cleanliness		
7. Facility QC Review		
8. Compression Force		
9. Mfr Detector Calibration (if app)		
Optional - Repeat Analysis		

Dates tested if not on same day as unit

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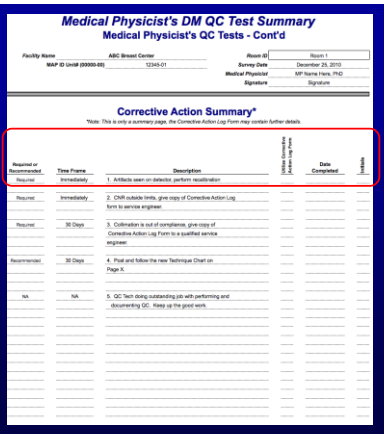
Medical Physicist's Section - DRAFT 1 of 2 4. MP TESTS - Forms-DRAFT_2014-07-15.xlsx

MP Tests



Medical Physicist's DM QC Test Summary

Medical Physicist's QC Tests - Cont'd

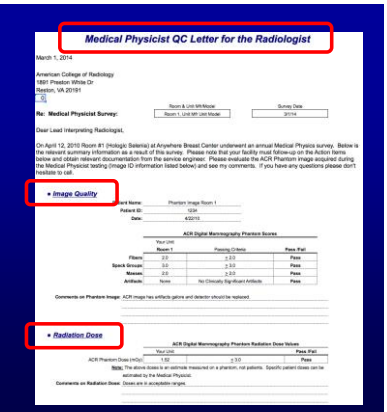
Facility Name	ABC Breast Center	*Room ID*	Room 1
MAP ID Unit# (00000-00)	12345-01	*Survey Date*	December 25, 2010
		Medical Physicist	MP Name Here, PhD
		Signature	Signature

Corrective Action Summary*

*Note: This is only a summary page, the Corrective Action Log Form may contain further details.

Required or Recommended	Time Frame	Description	Write Down the Action Log Page #	Date Completed	Initials
Required	Immediately	1. Artifacts seen on detector, perform recalibration			
Required	Immediately	2. CNR outside limits, give copy of Corrective Action Log form to service engineer.			
Required	30 Days	3. Collimation is out of compliance, give copy of Corrective Action Log Form to a qualified service engineer.			
Recommended	30 Days	4. Post and follow the new Technique Chart on Page X.			
NA	NA	5. QC Tech doing outstanding job with performing and documenting QC. Keep up the good work.			

MP Tests



Medical Physicist QC Letter for the Radiologist

March 1, 2014

American College of Radiology
1891 Preston White Dr
Reston, VA 20191

Re: Medical Physicist Survey:	Room & Unit M/Model	Survey Date
	Room 1, Unit M/ Unit Model	3/1/14

Dear Lead Interpreting Radiologist,

On April 12, 2010 Room #1 (Hologic Selenia) at Anywhere Breast Center underwent an annual Medical Physics survey. Below is the relevant summary information as a result of this survey. Please note that your facility must follow-up on the Action Items below and obtain relevant documentation from the service engineer. Please evaluate the ACR Phantom Image acquired during the Medical Physicist testing (Image ID information listed below) and see my comments. If you have any questions please don't hesitate to call.

- ***Image Quality***

Exam Name: Phantom Image Room 1
Patient ID: 1234
Date: 4/22/10

ACR Digital Mammography Phantom Scores

	Your Unit: Room 1	Passing Criteria	Pass /Fail
Fibers:	2.0	≥ 2.0	Pass
Speck Groups:	3.0	≥ 3.0	Pass
Masses:	2.0	≥ 2.0	Pass
Artifacts:	None	No Clinically Significant Artifacts	Pass

Comments on Phantom Image: ACR image has artifacts galore and detector should be replaced.

- ***Radiation Dose***

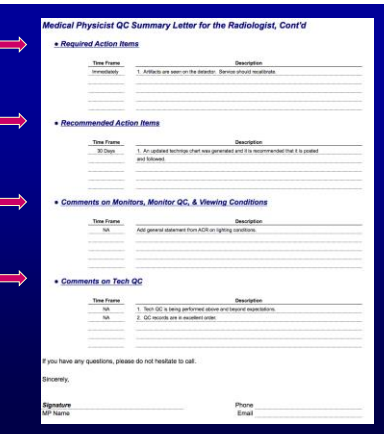
ACR Digital Mammography Phantom Radiation Dose Values

	Your Unit		Pass /Fail
ACR Phantom Dose (mGy):	1.52	≥ 3.0	Pass

Note: The above dose is an estimate measured on a phantom, not patients. Specific patient doses can be estimated by the Medical Physicist.

Comments on Radiation Dose: Doses are in acceptable ranges.

MP Tests



Medical Physicist QC Summary Letter for the Radiologist, Cont'd

- ***Required Action Items***

Time Frame	Description
Immediately	1. Artifacts are seen on the detector. Service should recalibrate.

- ***Recommended Action Items***

Time Frame	Description
30 Days	1. An updated technique chart was generated and it is recommended that it is posted and followed.

- ***Comments on Monitors, Monitor QC, & Viewing Conditions***

Time Frame	Description
NA	Add general statement from ACR on lighting conditions.

- ***Comments on Tech QC***

Time Frame	Description
NA	1. Tech QC is being performed above and beyond expectations.
NA	2. QC records are in excellent order.

If you have any questions, please do not hesitate to call.

Sincerely,

Signature
MP Name

Phone
Email

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.

End of Presentation

Questions?

AAPM 2014

Berns

SAM's Questions

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

29% 4. MITA

18% 5. MQSA

Answer: 3 - The FFDM unit manufacturer

References

- MQSA Regulations 900.12(e)(6)
- http://www.fda.gov/CDRH/MAMMOGRAPHY/frmamcom2.html#s90012

To meet the FDA requirement for continuing experience, how many mammography facilities and mammography unit surveys must be performed within the previous 24 months?

5% 1. 6 Facilities and 2 Mammography Units
15% 2. 4 Facilities and 6 Mammography Units
0% 3. 2 Facilities and 6 Mammography Units
25% 4. 1 Facilities and 6 Mammography Units
10% 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

Answer 3: 2 Facilities and 6 Mammography Units

References

- http://www.fda.gov/CDRH/MAMMOGRAPHY/robohelp/START.HTM
- 900.12(a)(3)(iii)(B): Continuing experience. Following the second anniversary date of the end of the calendar quarter in which the requirements of paragraphs (a)(3)(i) and (a)(3)(ii) of this section were completed or of April 28, 1999, whichever is later, the medical physicist shall have surveyed at least two mammography facilities and a total of at least six mammography units during the 24 months immediately preceding the date of the facility's annual MQSA inspection or the last day of the calendar quarter preceding the inspection or any date in between the two. The facility shall choose one of these dates to determine the 24-month period. No more than one survey of a specific facility within a 10-month period or a specific unit within a period of 60 days can be counted towards this requirement.

For FFDM, the exposure for a single CC view of the ACR phantom shall not exceed:

12% 1. 0.75 mGy/exposure

8% 2. 1.25 mGy/exposure

12% 3. 2.00 mGy/exposure

15% 4. 3.00 mGy/exposure

15% 5. 4.00 mGy/exposure

Answer: 4 – 3.00 mGy/exposure

References

- http://www.fda.gov/Radiation-EmittingProducts/MammographyQualityStandardsActandProgram/Guidance/PolicyGuidanceHelpSystem/ucm052690.htm
- *900.12(e)(5)(vi): Dosimetry. The average glandular dose delivered during a single craniocaudal view of an FDA-accepted phantom simulating a standard breast shall not exceed 3.0 milligray (mGy) (0.3 rad) per exposure. The dose shall be determined with technique factors and conditions used clinically for a standard breast.*

ACR Accreditation Update in Mammography

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*No financial disclosures to report