



## ACR Digital Mammography QC Manual

Eric Berns, Ph.D.

University of Colorado Hospital

Denver Health Medical Center

Member, NMQAAC

Chair, ACR Subcommittee on Quality Assurance in Mammography  
and lead author of the ACR Digital Mammography QC Manual

### Overview

- Welcome
- Introductions
- Phantom
- QC Program and Manual
- What's Next for the ACR

# ACR DM QC Manual – Status

- **February 17, 2016 - FDA approved ACR’s alternative standard allowing facilities to use new manual under MQSA**
  - Only applies to FFDM systems without advanced imaging capabilities (i.e., tomosynthesis, contrast enhancement, etc.)

American College of Radiology

The screenshot shows the FDA website interface. At the top, it displays the U.S. Department of Health and Human Services logo and the U.S. Food and Drug Administration logo with the tagline "Protecting and Promoting Your Health". A search bar is visible on the right. Below the navigation menu, the page is titled "Radiation-Emitting Products" and shows a breadcrumb trail: "Home > Radiation-Emitting Products > Mammography Quality Standards Act and Program > Regulations (MQSA)".

The main content area features a sidebar on the left with links for "Regulations (MQSA)", "Alternative Standards (MQSA)", "Federal Register Notices", and "Mammography Quality Standards Act (MQSA)". The main text area is titled "#24: Approval of an Alternative Standard for Using the Quality Assurance Program Recommended by the ACR Digital Mammography Quality Control Manual for Full-Field Digital Mammography Systems, for Systems without Advanced Imaging Capabilities".

The text of the regulation states: "This alternative standard was approved and became effective on February 17, 2016. It has no time limit. The alternative standard allows for the use by mammography facilities of the ACR Digital Mammography Quality Control Manual as an alternative to the quality assurance program recommended by the image receptor manufacturer. The FDA has determined that the ACR's quality control manual is, as required in § 900.18(a)(1): Alternative Requirements, 'at least as effective in assuring quality mammography' as following the manufacturers' QC manuals."

The original standard is 21 CFR 900.12(a)(5)(v), which states:

900.12(a)(5)(v) Quality control tests—other modalities. For systems with image receptor modalities other than screen-film, the quality assurance program shall be substantially the same as the quality assurance program recommended by the image receptor manufacturer, except that the maximum allowable dose shall not exceed the maximum allowable dose for screen-film systems in paragraph (e)(5)(v) of this section.

The approved alternative is:

900.12(a)(5)(v) Quality control tests—other modalities. For full-field digital mammography systems without advanced imaging capabilities, the quality assurance program shall be substantially the same as the quality assurance program recommended by the ACR Digital Mammography Quality Control Manual when used with the ACR Digital Mammography Phantom, except that the maximum allowable dose shall not exceed the maximum allowable dose for screen-film systems in paragraph (e)(5)(v) of this section.

Any facility may avail itself of the approved alternative standard for the described imaging systems.

Note: At this time, the new ACR Digital Mammography Quality Control Manual and accompanying phantom are not available for facility use. More information will be available in the near future. Please visit the ACR Mammography Accreditation website at <http://www.acraccreditation.org/Modalities/Mammography> for the latest information.

Page Last Updated: 03/07/2016  
 Note: If you need help accessing information in different file formats, see Instructions for Downloading Viewers and Players.

American College of Radiology

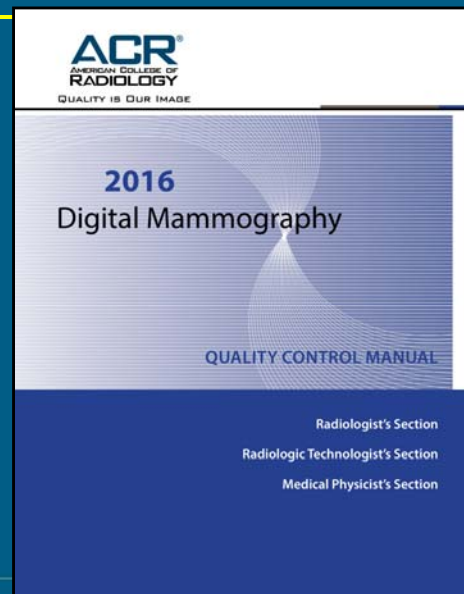
## Strengths & Take Home Points

- QC Manual is comprehensive
- Phantom is of major importance
  - Most failures are artifacts
- Includes most “legacy” tests
- Includes most “current” Mfr Tests
- Accommodates Mfr specific test (where app)
- Accommodates growth of QC program
- Manual can realistically be implemented

American College of Radiology

## ACR DM QC Manual

**Published  
July 29, 2016**



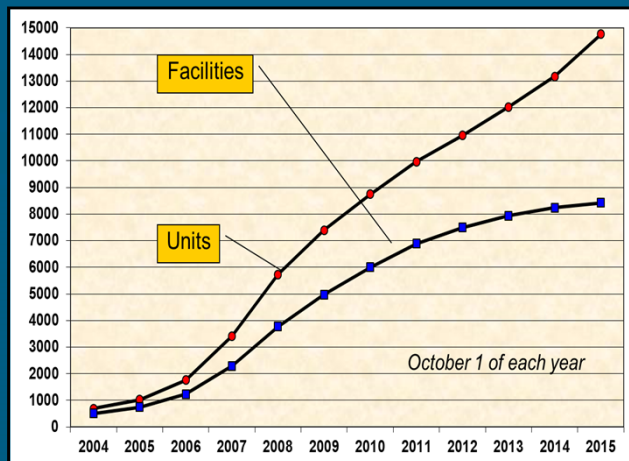
# ACR DM QC Manual Project

## Subcommittee on Quality Assurance in Mammography of the Committee on Mammography Accreditation

Eric Berns, PhD (chair)  
 Jay Baker, MD  
 Lora Barke, DO  
 Lawrence Bassett, MD, FACR  
 R. Edward Hendrick, PhD, FACR  
 Debra Monticciolo, MD, FACR  
 Doug Pfeiffer, MS, FACR  
 Margarita Zuley, MD  
 Christine Adent, RT(R)  
 Shelli Dixon, RT(R)  
 John Sandrick, PhD (MITA, retired)  
 Robert Uzenoff, BS (MITA)  
 Moustafa Zerhouni (MITA)  
 Priscilla Butler, MS, FACR (ACR Staff Member)  
 Marion Boston, RT(R) (ACR Staff Member)  
 Pamela Platt, BSRT(R) (ACR Staff Member)


American College of Radiology

# Digital Mammography in the US (as of 9/1/2016)



- 16,560 units at 8,748 facilities
- 12,601 FFDM units
- 3,703 DBT units

American College of Radiology



**ACR<sup>®</sup>**  
AMERICAN COLLEGE OF  
RADIOLOGY  
QUALITY IS OUR IMAGE

Full Field Digital Mammography (FFDM) or Digital Breast Tomosynthesis (DBT) Unit	Accreditation Body Approval Date Effective Date			
	ACR	SAR	SIA	STX
GE Senographe 2000D	12/18/02 02/15/03	08/15/06 08/15/06	08/28/03 10/01/03	05/21/04 05/21/04
Fischer Imaging SenoScan	07/24/03 08/15/03			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 09/15/04
Siemens Mammomat Novation DR	10/07/05 10/15/05	08/28/08 08/28/08	01/28/06 02/01/06	06/29/06 06/29/06
GE Senographe Essential	06/29/06 07/15/06	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 11/15/06	10/12/06 10/12/06	11/13/06 11/13/06	11/13/06 11/13/06
Hologic Selenia (Tungsten target)	02/01/08 02/01/08	02/01/08 02/01/08	02/01/08 02/01/08	02/01/08 02/01/08
Siemens Mammomat Novation S	02/11/09 02/11/09	02/11/09 02/11/09	02/11/09 02/11/09	02/11/09 02/11/09
Hologic Selenia S	02/11/09 02/11/09	02/11/09 02/11/09	02/11/09 02/11/09	02/11/09 02/11/09
Hologic Selenia Dimensions 2D	02/11/09 02/11/09	02/11/09 02/11/09	02/11/09 02/11/09	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	02/11/11 02/11/11	02/11/11 02/11/11	02/11/11 02/11/11	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 (Spectra) 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

- 4 accrediting bodies
- ~32 FDA approved models and manufacturers

Planned Nuance	12/13/11 12/27/11	12/20/11 12/20/11		01/20/12 01/20/12
Planned 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
Gotto Image 30i30L	11/02/12 11/02/12	7/24/12 7/24/12		03/09/12 03/09/12
Fuji Aspire HD	03/28/12 04/10/12	7/24/12 7/24/12	05/25/12 05/25/12	03/28/12 04/10/12
Konica Minolta Xpress Digital Mammography CR System	04/18/12 04/27/12	7/24/12 7/24/12		04/18/12 04/27/12
Agfa CR Mammography System	08/04/12 08/14/12	7/24/12 7/24/12		06/08/12 06/08/12
Fuji Aspire HD-s	06/25/13 06/25/13	06/25/13 06/25/13	06/25/13 06/25/13	06/25/13 06/25/13
Fuji Aspire HD Plus	06/25/13 06/25/13	06/25/13 06/25/13	06/25/13 06/25/13	06/25/13 06/25/13
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 L30	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
Fuji Aspire Cristalle	10/21/14 10/21/14	10/21/14 10/21/14	10/21/14 10/21/14	10/21/14 10/21/14
iRico 3600M Mammography CR System	01/20/15 02/03/15			
Siemens Mammomat Fusion	09/21/15 09/21/15	09/21/15 09/21/15		09/21/15 09/21/15

## Quality Control: What It and Why Is It Important?

### Primary Purpose

- Reduce exposure to patients and personnel
- Ensure adequate and consistent patient image quality
- Detect and correct for potential problems, before they impact patient image quality and care
- What it's not:
  - Not a detailed technical evaluation of a unit
  - Not a detailed measure of a limits of a unit
  - Not the optimization of a unit

American College of Radiology

## ACR DM QC Manual Project

- Subcommittee Goals:
  - Standardize all QC tests for all digital Mfr's
  - Standardize test frequencies
  - Standardize performance criteria

American College of Radiology

## ACR DM QC Manual Project

- QC Tests:
  - Tests come from a review of a variety of sources (MQSA, SFM, ACRIN DMIST, Manufacturer's QC programs, MITA, European and other Int'l QC programs, subcommittee clinical experience, etc.)
  - Clinically relevant
  - User/operator friendly
  - Eliminate non-productive testing
- *Just because you can test something, doesn't mean you should!*

American College of Radiology

## ACR Digital QC Manual - Structure

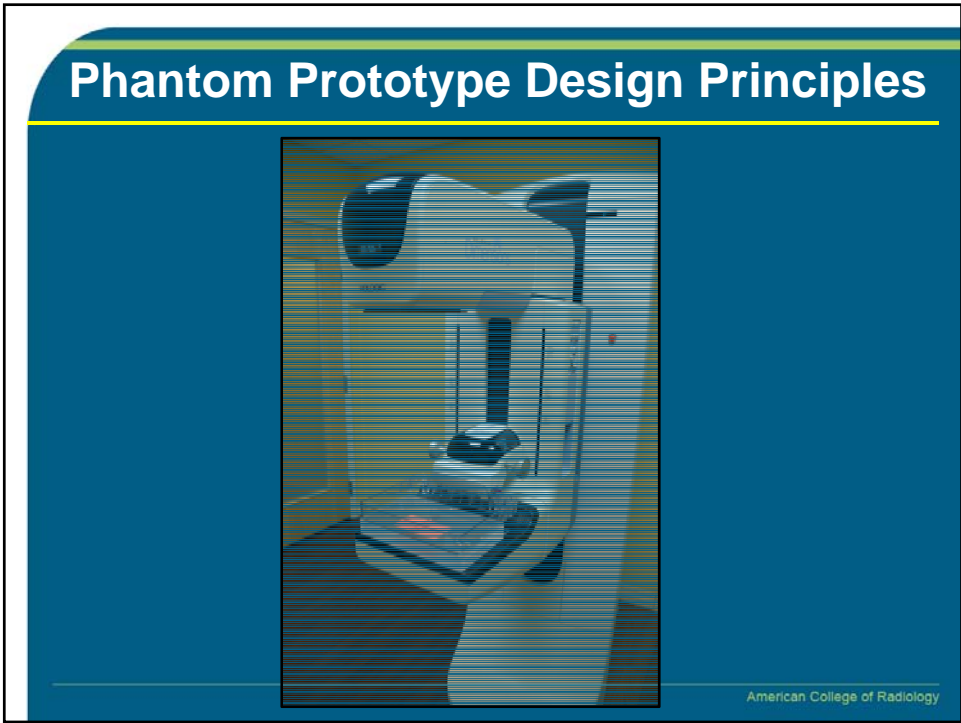
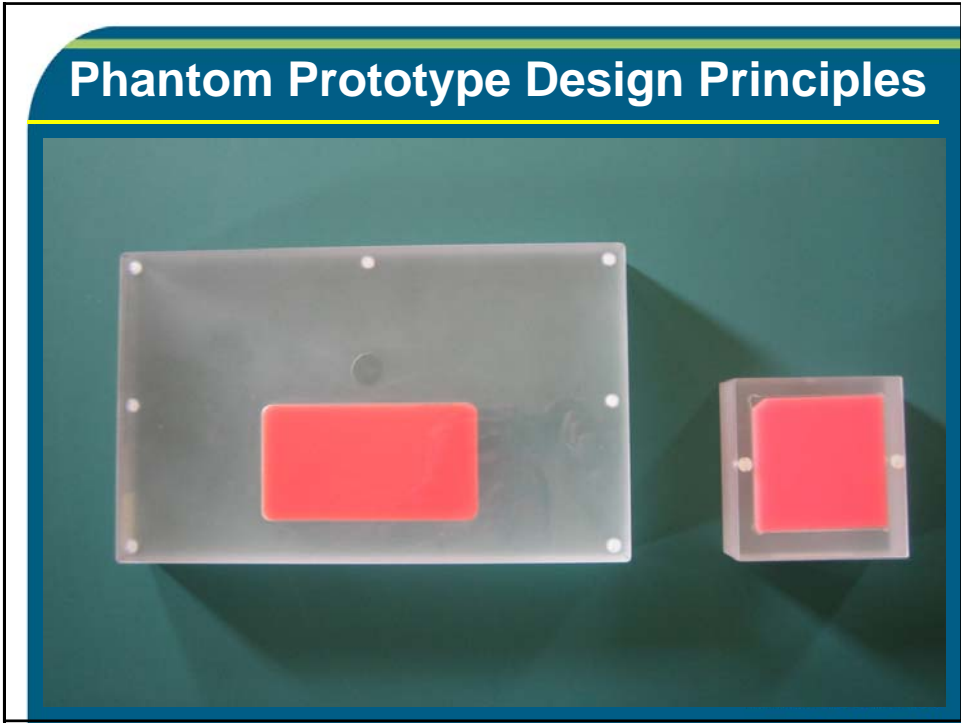
- Radiologist's Section
- Radiologic Technologist's Section
- Medical Physicist's Section
- Appendices
- **\*\*Clinical Image Quality Section (w/Patient Positioning and Compression and Clinical Image Quality Evaluation) will be revised at a later date and posted on ACR website**

American College of Radiology

## The ACR DM Phantom Prototype



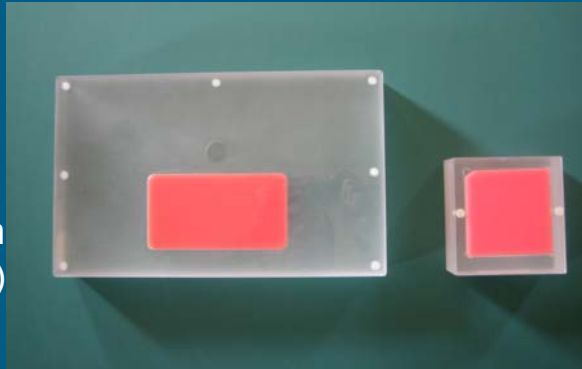
American College of Radiology





## Phantom Prototype Design Principles

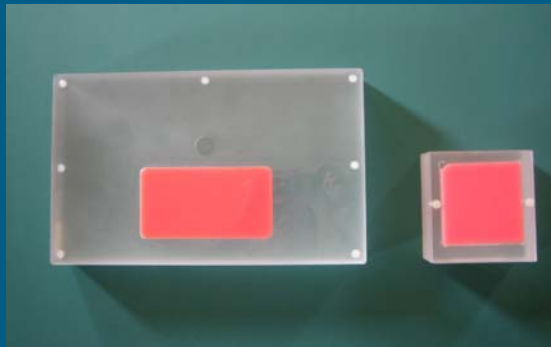
- Based on existing ACR Accreditation Phantom
- Similar imaging and scoring to current phantom
- Build on experience of QC techs and physicists at ~8,700 US facilities who already know how to use and score the existing phantom (~25,000+ techs)



American College of Radiology

## 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)



American College of Radiology

## Proposed Scoring Changes

- Eliminate subtraction for artifacts
- Added a “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

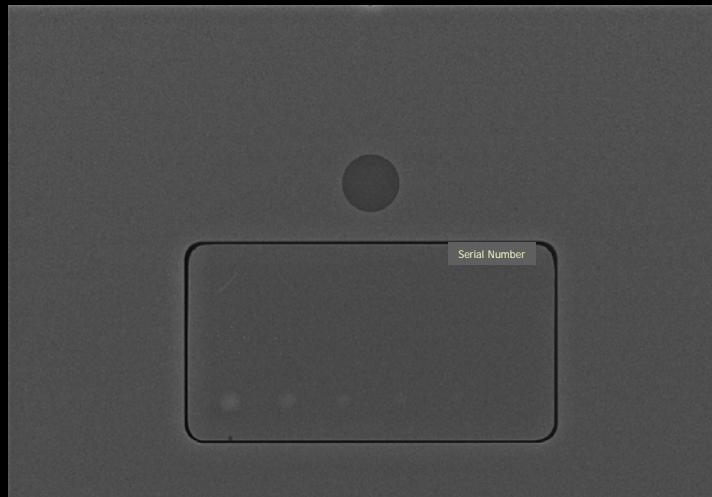
American College of Radiology

## The ACR DM Phantom Prototype



American College of Radiology

## 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:**

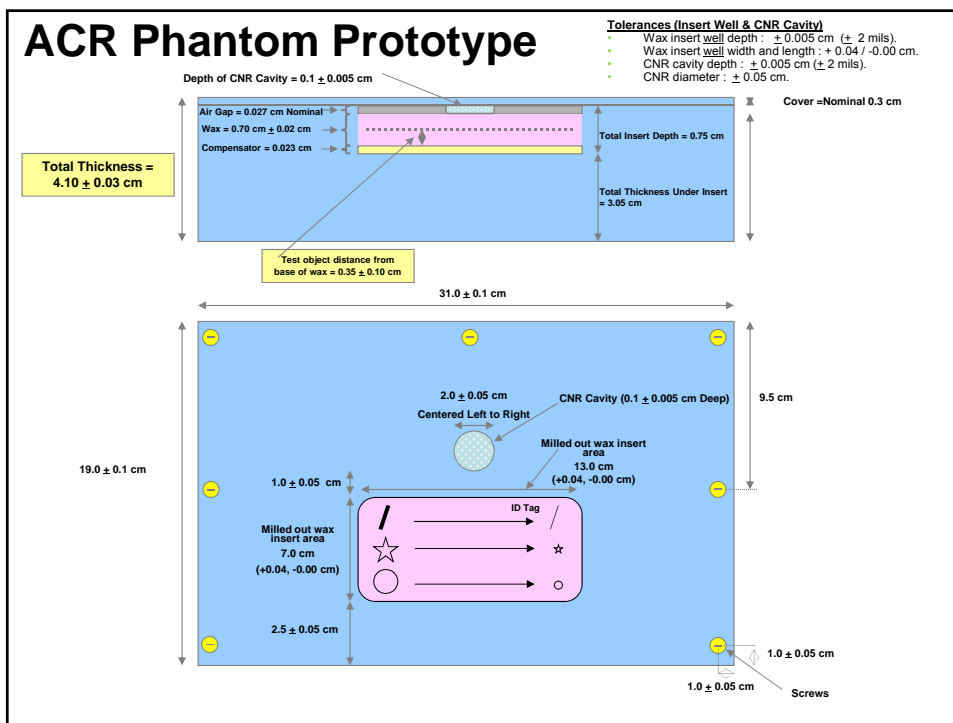
**4 Fibers, 3 Specks, 3 Masses**

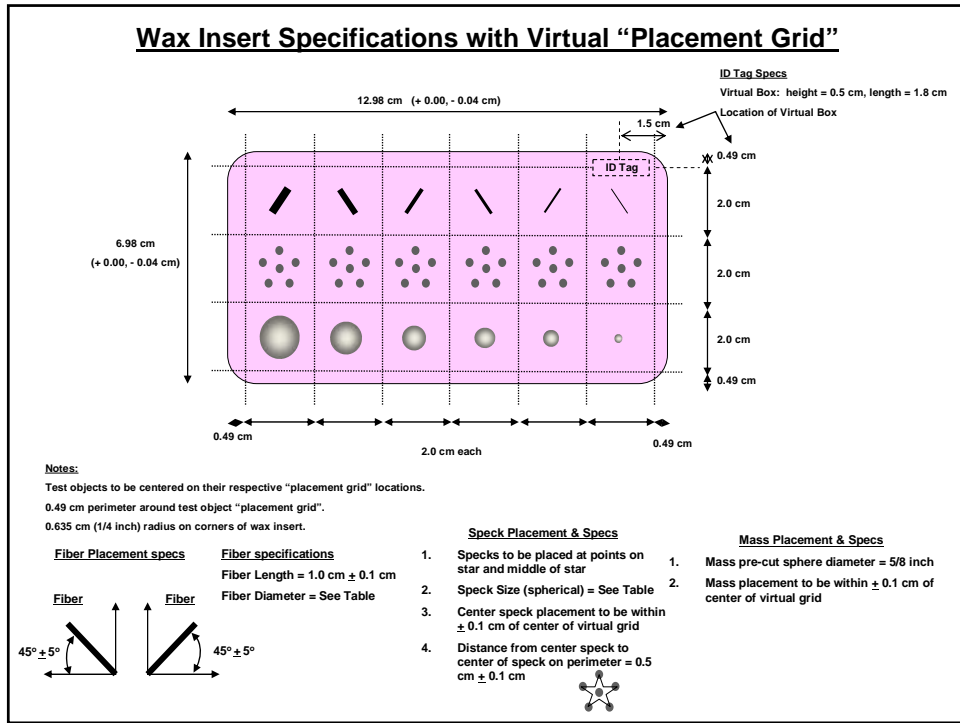


## Effects of Thickness Equalization



- 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.





### 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

## Summary of Test Object "Visual Equivalency"

Test Object	Fibers (mm)		Specks (mm)		Masses (mm)	
	ACR 156	FFDM	ACR 156	FFDM	ACR 156	FFDM
	1.56					
	1.12		0.54		2.00	
	0.89	0.89	0.40		1.00	1.00
	0.75	0.75	0.32	0.33	0.75	0.75
		0.61		0.28	0.50	0.50
	0.54	0.54	0.24	0.23		0.38
	0.40	0.40		0.20	0.25	0.25
		0.30	0.16	0.17		0.20
				0.14		

## Pass/Fail Criteria

Test Object	Fibers (mm)		Specks (mm)		Masses (mm)	
	ACR 156	FFDM	ACR 156	FFDM	ACR 156	FFDM
	1.56					
	1.12		0.54		2.00	
Fail	0.89	0.89	0.40		1.00	1.00
Pass	0.75	0.75	0.32	0.33	0.75	0.75
		0.61		0.28	0.50	0.50
	0.54	0.54	0.24	0.23		0.38
	0.40	0.40		0.20	0.25	0.25
		0.30	0.16	0.17		0.20
				0.14		

## Benefits of Prototype Phantom Design

- Provides view of entire detector – artifact evaluation
- W/L optimized for test objects optimizes for artifact evaluation
- Finer gradations and smaller sizes of test objects
- AGD measurement & limit same as SFM – Meets MQSA
- Provides single image/exposure for evaluation(s)
- Minimal training
- Provides basis for monitor and printer QC
- ACR Physics Reviewers
  - Can see scores and artifacts on single submitted film (or image)
  - Do not need different WW/WL settings

American College of Radiology

## ACR Digital Mammography Phantom Approval

- Open to all manufacturers – specifications, tolerances and performance criteria provided
- Approval process
  - Ensures uniformity of construction and performance
  - Mfr submits 2 samples to ACR
  - ACR medical physicist tests against tolerances and performance criteria
  - Approval or feedback for improvement
- Two manufacturers approved to date
  - CIRS
  - Gammex (Sun Nuclear)

American College of Radiology



### Digital Mammography Quality Control Tests

#### Radiologic Technologist's Tests

Test*	Minimum Frequency**	Corrective Action Timeframe
1. ACR Digital Mammography Phantom Image Quality	Weekly	Before clinical use
2. CR Cassette Erasure (if applicable)	Weekly	Before clinical use
3. Compression Thickness Indicator	Monthly	Within 30 days
4. Visual Checklist	Monthly	Critical- before clinical use; less critical- w/in 30 days
5. Acquisition Workstation (AW) Monitor QC	Monthly	W/in 30 days; before clinical use for severe defects
6. Radiologist Workstation (RW) Monitor QC	Monthly	W/in 30 days; before clinical use for severe defects
7. Film Printer QC (if applicable)	Monthly	Before clinical use
8. Viewbox Cleanliness (if applicable)	Monthly	Before clinical use
9. Facility QC Review	Quarterly	Not applicable
10. Compression Force	Semiannual	Before clinical use
11. Manufacturer Detector Calibration (if applicable)	Mfr. Recommendation	Before clinical use
Optional - Repeat Analysis	As Needed	Within 30 days after analysis
Optional - System QC for Radiologist	As Needed	W/in 30 days; before clinical use for severe artifacts
Optional - Radiologist Image Quality Feedback	As Needed	Not applicable

*\* All required tests (except Facility QC Review) must be performed upon installation of new equipment and before clinical use.*  
*\*\* This is a minimum frequency; tests may be performed more often if problems are noted. Also, weekly tests do not need to be performed if mammography is not performed during that week. However, the test must be performed prior to examining patients once mammography resumes. In these cases, be sure to note in the QC charts that mammography was not performed during this time period.*

#### Management Forms

- ACR Technique and Procedure Summaries
- Corrective Action Log
- Facility Offline Display Locations
- Digital Mammography Unit QC Summary Checklist
- Facility Display Device QC Summary Checklist

#### Mobile Systems

In addition to meeting the minimum frequencies outlined in the table above, the following tests must be performed, evaluated, and pass after each move of the mobile system to a new location:

- ACR Digital Mammography Phantom Image Quality - after each move and prior to examining patients
- Radiologist Workstation (RW) Monitor QC (mobile RW only) - after each move and prior to interpretation
- Film Printer QC (mobile film printers only) - after each move and prior to printing patient images

#### QC Equipment List - Technologist

- ACR Digital Mammography Phantom
- Densitometer
- Scale
- Tweezers
- Appropriate monitor cleaning materials

College of Radiology

### Digital Mammography Quality Control Tests

#### Radiologic Technologist's Tests

Test*	Minimum Frequency**	Corrective Action Timeframe
1. ACR Digital Mammography Phantom Image Quality	Weekly	Before clinical use
2. CR Cassette Erasure (if applicable)	Weekly	Before clinical use
3. Compression Thickness Indicator	Monthly	Within 30 days
4. Visual Checklist	Monthly	Critical- before clinical use; less critical- w/in 30 days
5. Acquisition Workstation (AW) Monitor QC	Monthly	W/in 30 days; before clinical use for severe defects
6. Radiologist Workstation (RW) Monitor QC	Monthly	W/in 30 days; before clinical use for severe defects
7. Film Printer QC (if applicable)	Monthly	Before clinical use
8. Viewbox Cleanliness (if applicable)	Monthly	Before clinical use
9. Facility QC Review	Quarterly	Not applicable
10. Compression Force	Semiannual	Before clinical use
11. Manufacturer Detector Calibration (if applicable)	Mfr. Recommendation	Before clinical use
Optional - Repeat Analysis	As Needed	Within 30 days after analysis
Optional - System QC for Radiologist	As Needed	W/in 30 days; before clinical use for severe artifacts
Optional - Radiologist Image Quality Feedback	As Needed	Not applicable

*\* All required tests (except Facility QC Review) must be performed upon installation of new equipment and before clinical use.*  
*\*\* This is a minimum frequency; tests may be performed more often if problems are noted. Also, weekly tests do not need to be performed if mammography is not performed during that week. However, the test must be performed prior to examining patients once mammography resumes. In these cases, be sure to note in the QC charts that mammography was not performed during this time period.*

American College of Radiology

**Management Forms**

ACR Technique and Procedure Summaries  
 Corrective Action Log  
 Facility Offsite Display Locations  
 Digital Mammography Unit QC Summary Checklist  
 Facility Display Device QC Summary Checklist

**Mobile Systems**

In addition to meeting the minimum frequencies outlined in the table above, the following tests must be performed, evaluated, and pass after each move of the mobile system to a new location:

- ACR Digital Mammography Phantom Image Quality - after each move and prior to examining patients
- Radiologist Workstation (RW) Monitor QC (mobile RW only) - after each move and prior to interpretation
- Film Printer QC (mobile film printers only) - after each move and prior to printing patient images

**QC Equipment List - Technologist**

ACR Digital Mammography Phantom  
 Densitometer  
 Scale  
 Towels  
 Appropriate monitor cleaning materials

American College of Radiology

**1.#ACRDM#Phantom#Image#Quality** Weekly

Facility \_\_\_\_\_ Room ID \_\_\_\_\_  
 MAP ID-Unit# (00000-00) Unit Mfr & Model \_\_\_\_\_

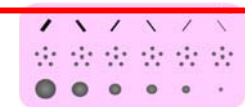
Reporting Technician	Date (month/day)	Year				
		1	2	3	4	5
ACR Phantom	Image/Resistor/Tag	largest	largest	largest	largest	largest
	Target/Tag					
	WV					
	mAs					
	Artifacts/WF					
Fiber/Score						
Speed/Group/Score						
Mass/Score						
<b>Overall Pass/Fail</b>						

P = Pass
F = Fail

Frequency	Full Point		Half Point	
	Fibers	10 Fibers/Tag	10 Fibers/Tag	10 Fibers/Tag
Specks	4/100 Specks	2/100 Specks	2/100 Specks	2/100 Specks
Masses	2/100 Resistor	2/100 Resistor	2/100 Resistor	2/100 Resistor

**Action Limits**

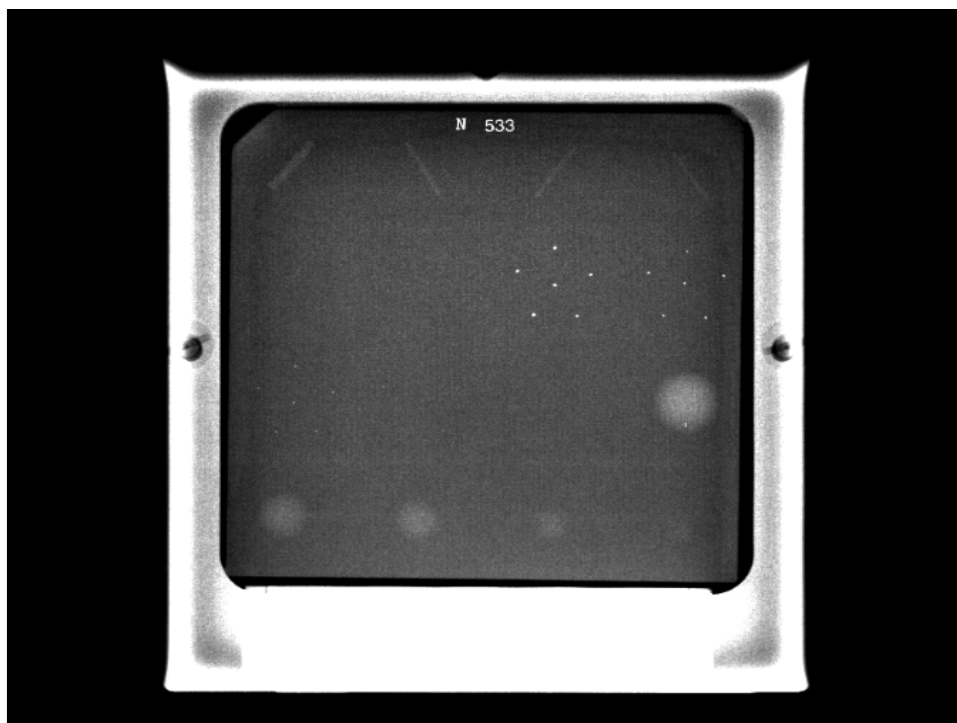
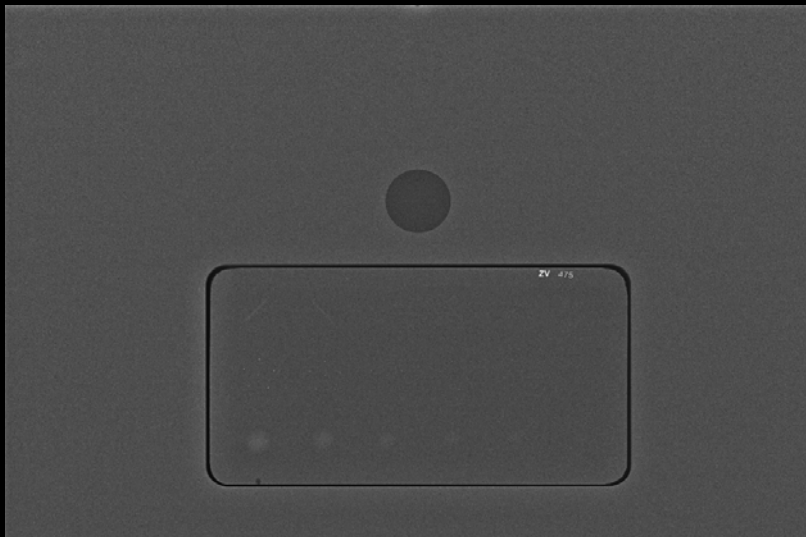
Required: ACR DM Phantom Image/Resistor/Tag/Speed/Group/Score/Artifacts/Fiber/Score/Resistor/Tag/2.0/100 Specks/Resistor/Tag/10.0/100 Specks/Resistor/Tag/10.0  
 Threshold: Required/Resistor/Tag/Resistor/Tag/Resistor/Tag/Resistor/Tag

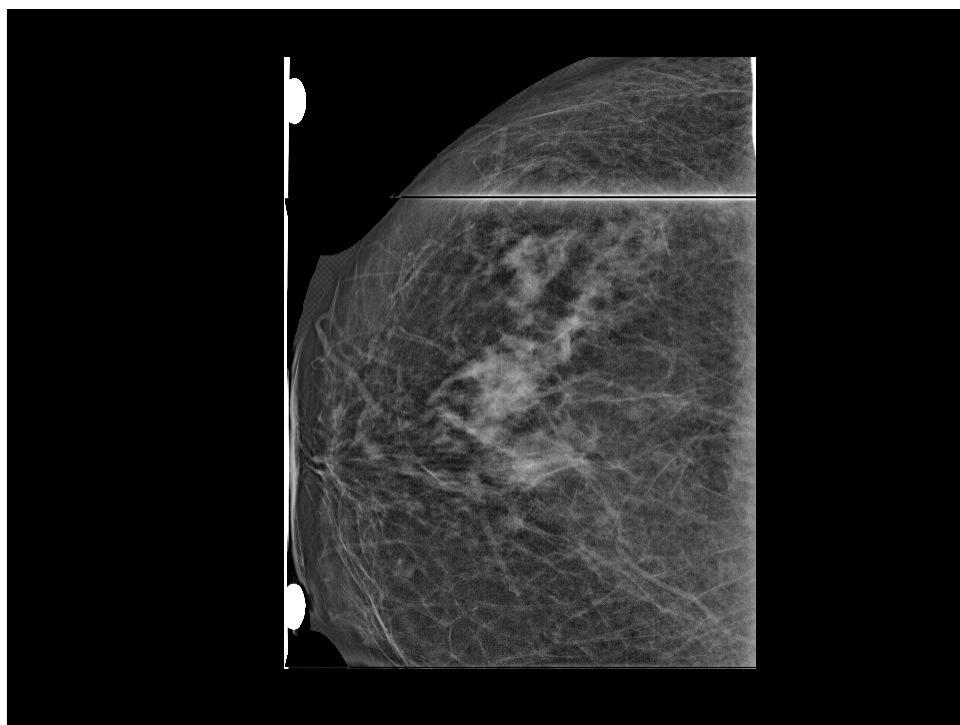
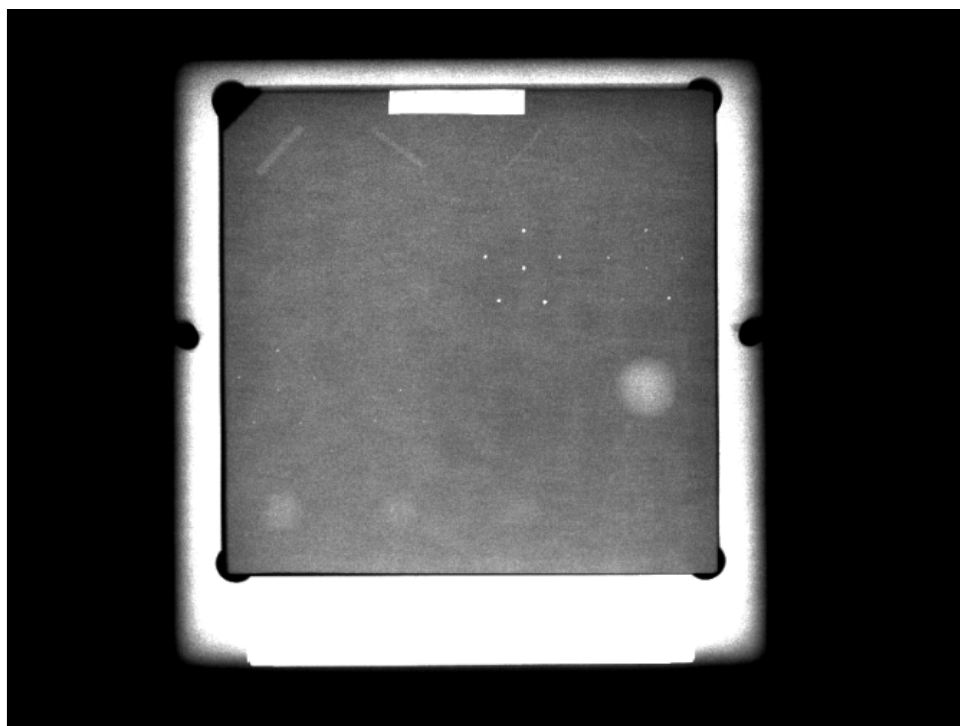


Radiologic Technologist's Section
Page 7/9/16
4#ECHO#FORUS#Final#v01\_2015-12-16.xlsx

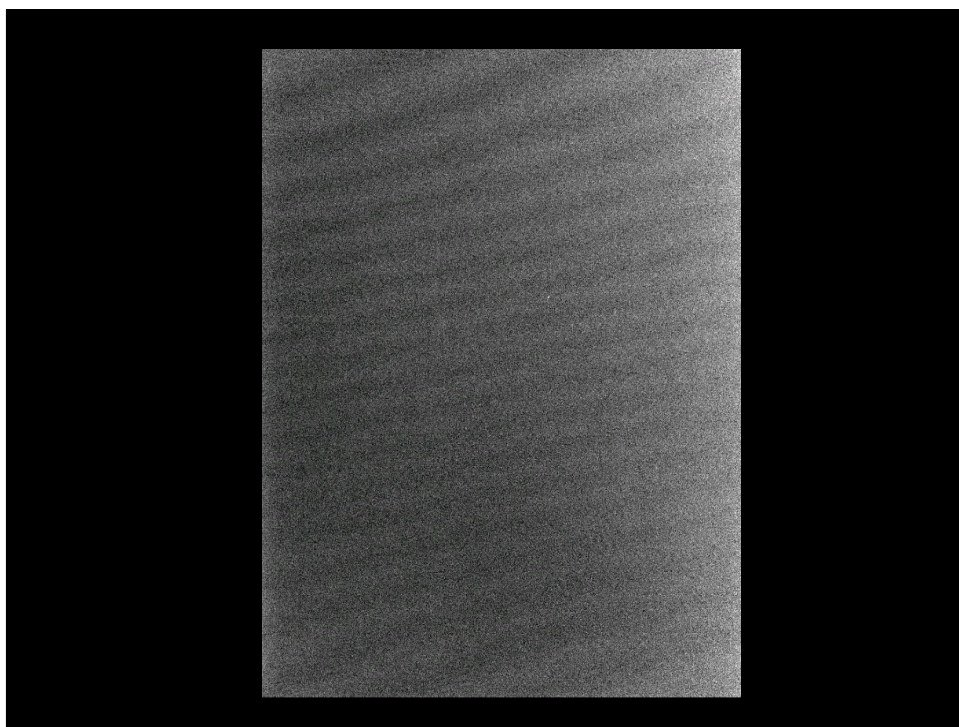
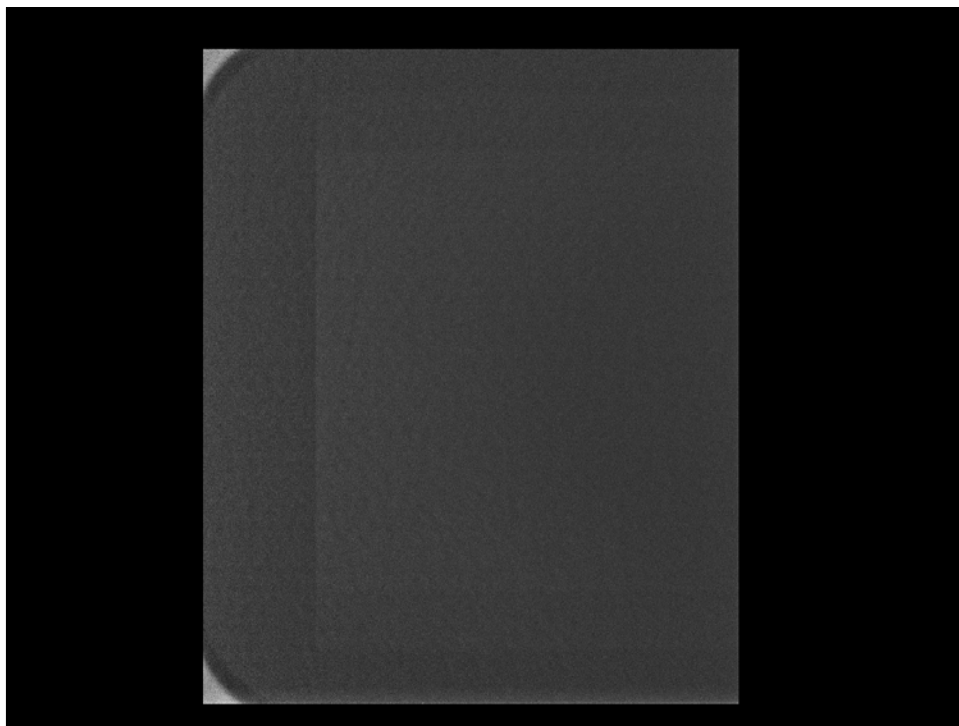
American College of Radiology

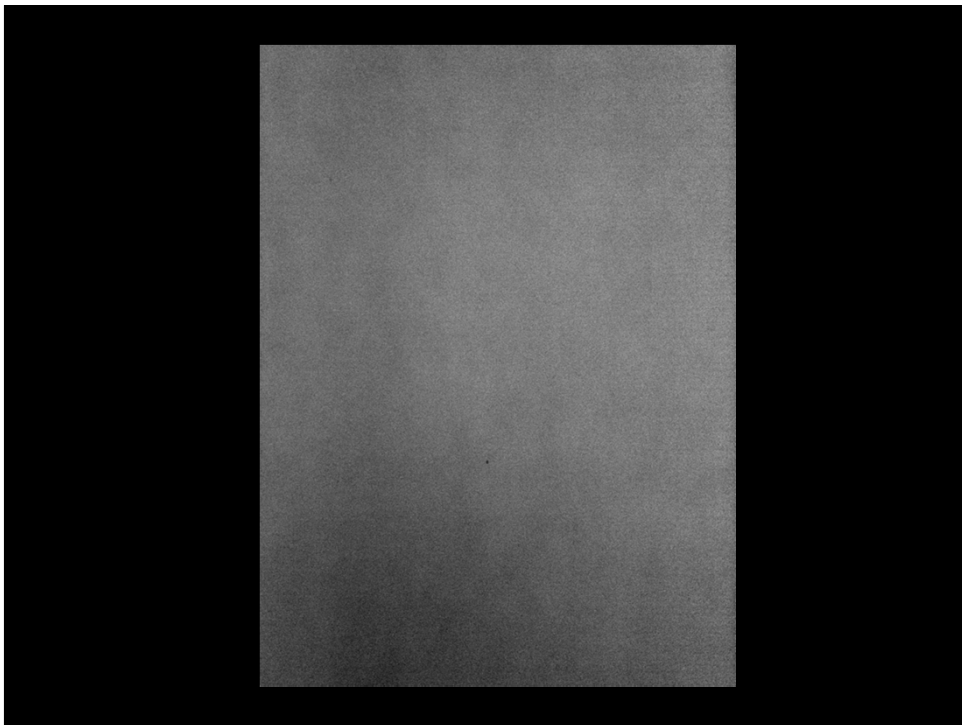
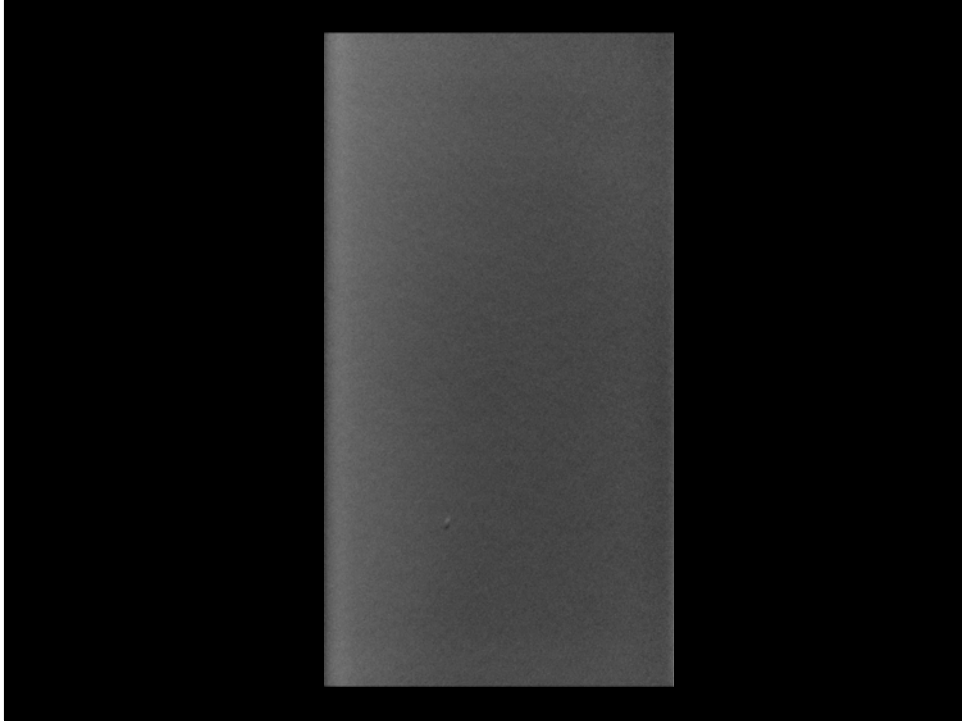
# Example

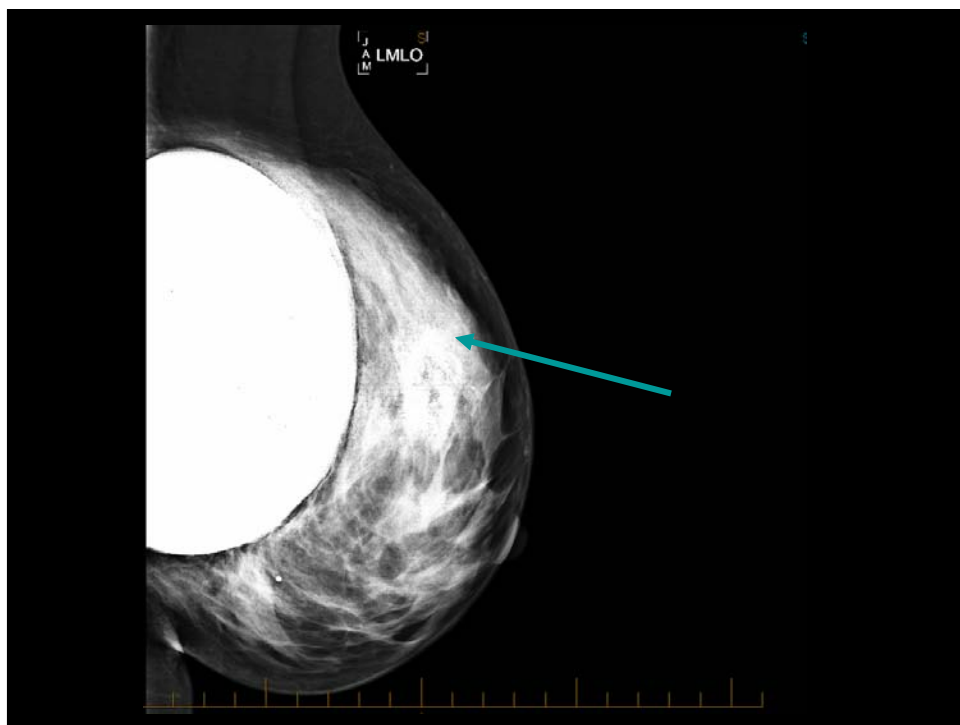
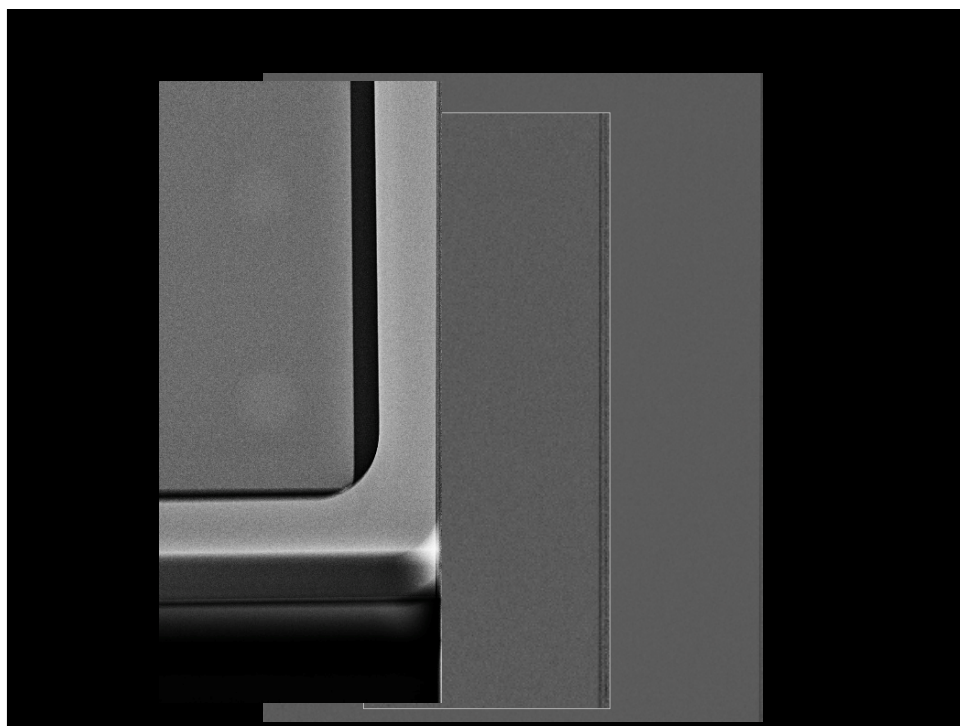




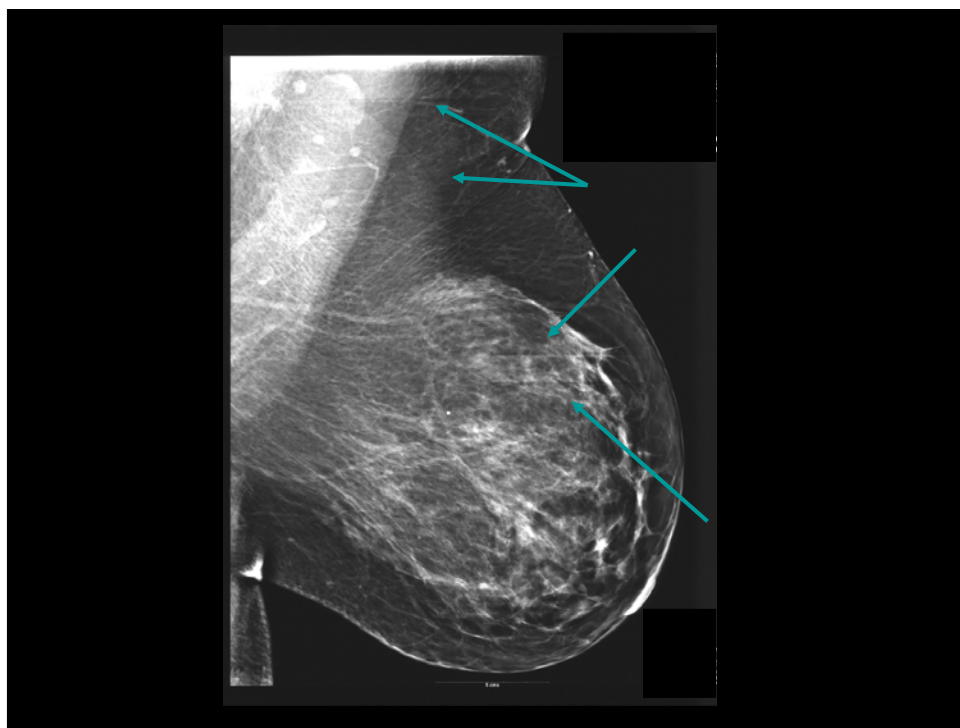


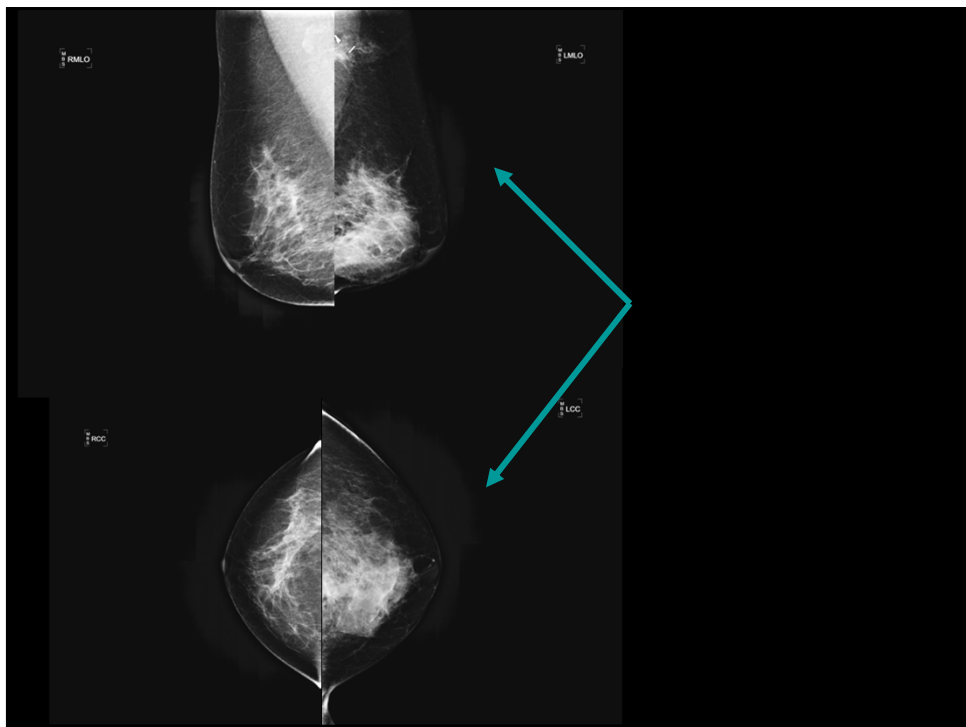
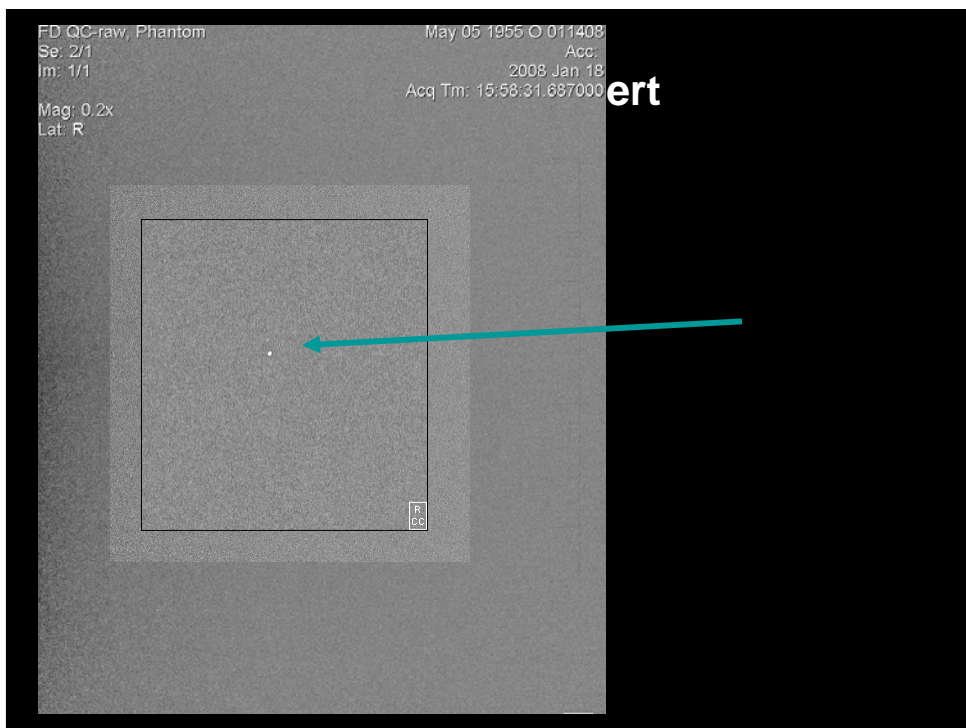


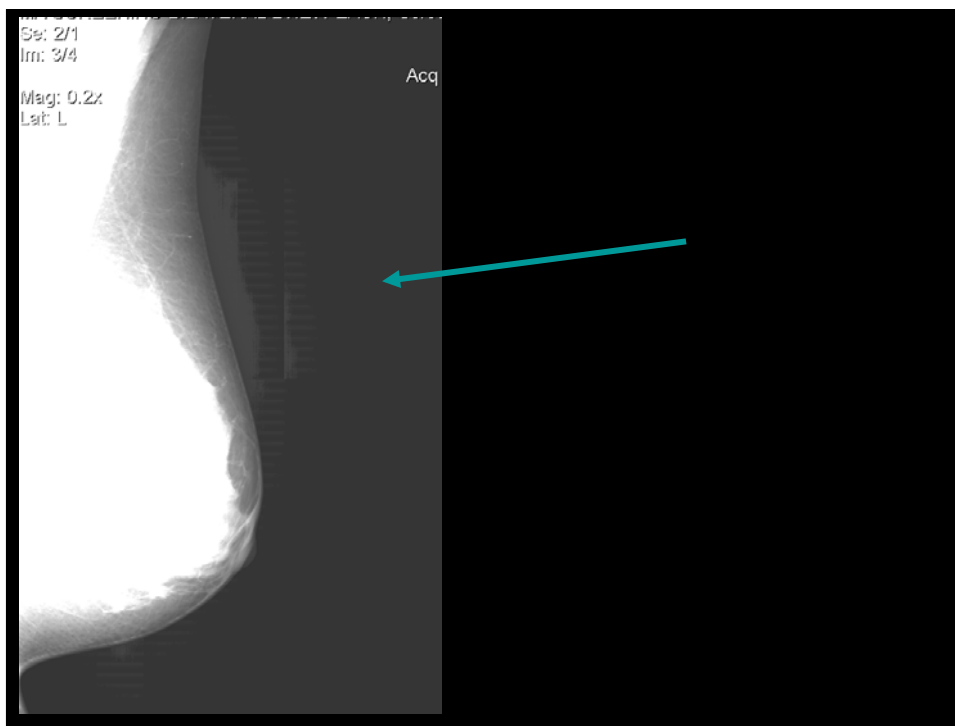












**9. Facility QC Review** Quarterly

Facility \_\_\_\_\_ Date of QC Mtg \_\_\_\_\_ Overall Pass/Fail

**1. Review Medical Physics Surveys and Results** Reviewed

Room 1	Room 2	Room 3	Room 4	Room 5
Room 1	Room 2	Room 3	Room 4	Room 5
Date of last Medical Physics (MP) Survey				
MP DM QC Test Summary reviewed by radiologist				
All MP corrective actions completed				
ACR DM Phantom Average Standard Deviation (SD)				
Fiber Score				
Speech Score				
Mask Score				

**2. Review Tech QC** Summary Comments from Last Quarter \_\_\_\_\_

**2a. ACR DM Phantom Image Quality** Frequency \_\_\_\_\_

Room 1	Room 2	Room 3	Room 4	Room 5
Room 1	Room 2	Room 3	Room 4	Room 5
Score of most recent phantom image				
Fiber score				
Speech group score				
Mask score				

**2b. CR Cassette Exposure (if app)** Visual \_\_\_\_\_

**3. Compression Thickness Indicator** Monthly \_\_\_\_\_

**4. Visual Checklist** Monthly \_\_\_\_\_

**5. AWR Monitor QC** Monthly \_\_\_\_\_

**6. IRW Monitor QC** Monthly \_\_\_\_\_

**7. Film Printer QC** Monthly \_\_\_\_\_

**8. Wireless Checklines (if app)** Monthly \_\_\_\_\_

**9. Facility QC Review** Quarterly \_\_\_\_\_

**10. Compression Force Calibration (if app)** Semiannual \_\_\_\_\_

**11. Manufacturer Detector Calibration (if app)** As Needed \_\_\_\_\_

Optional - Repeat Analysis % Repeat

**3. Review and verify completion of all "Corrective Action"** \_\_\_\_\_

**4. Technician Chart review for each room (see MP report for recommendations) - (Annually)** \_\_\_\_\_

**5. Infection Control procedures followed** \_\_\_\_\_

**6. Offsite RW(s) & Film Printer(s) QC reviewed** \_\_\_\_\_

**7. Past and future service or service upgrades discussed (if app)** \_\_\_\_\_

**8. Past and future State and/or MQSA Inspections discussed (if app)** \_\_\_\_\_

**9. Past and future ACR Accreditation issues discussed (if app)** \_\_\_\_\_

Lead Interpreting Radiologist \_\_\_\_\_ Facility Manager (if App) \_\_\_\_\_ QC Technologist \_\_\_\_\_

**9. Facility QC Review (continued)** Quarterly

Page 1 of 2

4 TECH FORMS - Final Draft, 2015-12-18.xlsx

American College of Radiology



### Facility Display Device QC Summary Checklist

Facility \_\_\_\_\_ MAP ID# (0000) \_\_\_\_\_  
 Address \_\_\_\_\_  
 Address \_\_\_\_\_

**QC Summary Information for display devices at this MAP ID**

Physical Location of Facility		ID Designation	Device	Model	Manufacturer																
Jan	Diag																				
	Tech IntLab																				
Feb	Diag																				
	Tech IntLab																				
Mar	Diag																				
	Tech IntLab																				
Apr	Diag																				
	Tech IntLab																				
May	Diag																				
	Tech IntLab																				
Jun	Diag																				
	Tech IntLab																				
Jul	Diag																				
	Tech IntLab																				
Aug	Diag																				
	Tech IntLab																				
Sep	Diag																				
	Tech IntLab																				
Oct	Diag																				
	Tech IntLab																				
Nov	Diag																				
	Tech IntLab																				
Dec	Diag																				
	Tech IntLab																				
Medical Physicist Survey Data																					
Medical Physicist Name(s)																					

Radiologic Technologist's Section - DRAFT Page 25 of 25 4. TECH TESTS - Forms FDA Rev. 2016-02-19

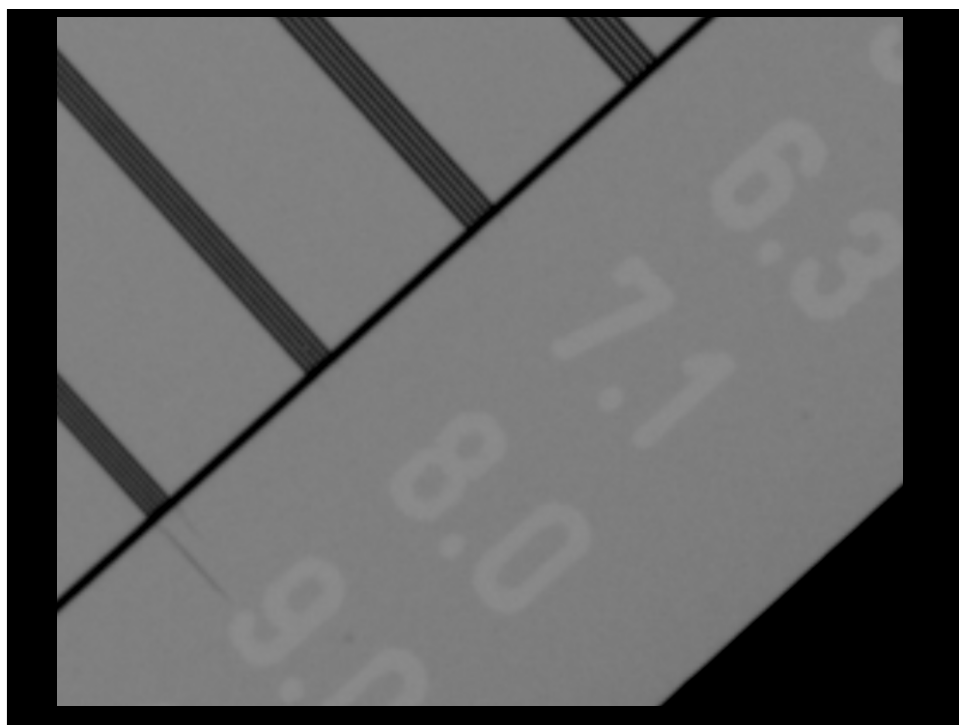
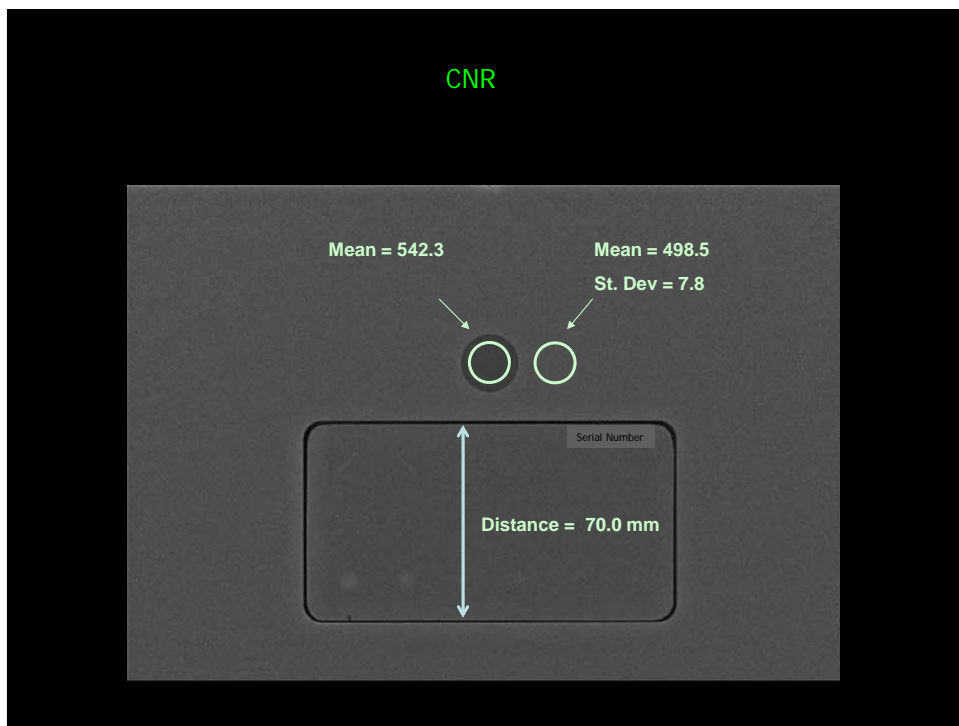
American College of Radiology

### Digital Mammography Quality Control Tests Medical Physicist's Tests

Test	Minimum Frequency	Corrective Action Timeframe
1. Mammography Equipment Evaluation - MQSA Requirements	MEE	Before clinical use
2. ACR DM Phantom Image Quality	MEE and Annual	Before clinical use
3. Spatial Resolution	MEE and Annual	Within 30 days
4. Automatic Exposure Control System Performance	MEE and Annual	Within 30 days
5. Average Glandular Dose	MEE and Annual	Before clinical use
6. Unit Checklist	MEE and Annual	Critical: before clinical use; less critical: w/in 30 days
7. Computed Radiography (if applicable)	MEE and Annual	Before clinical use
8. Acquisition Workstation (AW) Monitor QC	MEE and Annual	W/in 30 days; before clinical use for severe defects
9. Radiologist Workstation (RW) Monitor QC	MEE and Annual	W/in 30 days; before clinical use for severe defects
10. Film Printer QC	MEE and Annual	Before clinical use
11. Evaluation of Site's Technologist QC Program	MEE and Annual	Within 30 days
12. Evaluation of Display Device Technologist QC Program	MEE and Annual	Within 30 days
MEE or Troubleshooting - Beam Quality (Half-Value Layer) Assessment	MEE or Troubleshooting	MEE - before clinical use; troubleshooting - w/in 30 days
MEE or Troubleshooting - kVp Accuracy and Reproducibility	MEE or Troubleshooting	MEE - before clinical use; troubleshooting - w/in 30 days
MEE or Troubleshooting - Collimation Assessment	MEE or Troubleshooting	MEE - before clinical use; troubleshooting - w/in 30 days
Troubleshooting - Ghost Image Evaluation	Troubleshooting	Before clinical use
Troubleshooting - Viewbox Luminance	Troubleshooting	NA

**Summary Report Forms**

Medical Physicist's DM QC Test Summary  
 Mammography Technique Chart  
 Medical Physicist QC Letter for the Radiologist



$$D = Kgcs$$

**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.



### 9. Radiologist Workstation (RW) Monitor QC

Facility Name: Imaging Facility		Workstation ID: Room 1, Unit MR, Unit Model		
Medical Physicist (if app):		MAP ID: 00000		
Signature (if app):		Survey Date: December 1, 2015		
<b>Equipment:</b> ACB DM Phantom Image, Luminance meter <b>Note:</b> Some of these QC tests may or may not be possible to perform depending on the monitor QC capabilities. <b>ACB DM Phantom:</b> use phantom acquired from any DM vendor facility network, preferably one MP has acquired. <b>Test Pattern Image Quality:</b> Use TQ18-GC, SMPTE or other relevant pattern. <b>Luminance:</b> TG 18-UMC10, UMC18 & 12, 16, UMCL10 test patterns or other relevant test patterns				
Monitor manufacturer:	Model:	Left:	Right:	
	Monitor serial number:			
Ambient Light: Any ambient light conditions adequate for DM?		Significant findings indicated on figures below		
Monitor Condition:	Significant findings PPI			
	Artifacts PPI			
Distance Measurement:	Fiber score			
	Speck group scores			
Test Pattern Image Quality:	Mass score			
	Character PPI			
Luminance Check:	Measured Luminance minimum (cd/m <sup>2</sup> )			
	MR recommendation for L <sub>min</sub> (if avail)			
DICOM GSDF (if avail):	Measured Luminance maximum (cd/m <sup>2</sup> )			
	MR recommendation for L <sub>max</sub> (if avail)			
MTR Automated Test:	L <sub>min</sub> meets mfr recommendation (50%)?			
	L <sub>max</sub> meets mfr recommendation (10%)?			
Luminance Uniformity		Monitor	Left	Right
DICOM GSDF (if avail):		Center	125	120
MTR Automated Test:		Upper L	140	140
MTR Automated Test:		Upper R	120	120
MTR Automated Test:		Lower L	100	100
MTR Automated Test:		Lower R	100	100
MTR Automated Test:		Max	140	140
MTR Automated Test:		Min	100	100
MTR Automated Test:		% DM	33.3	33.3
MTR Automated Test:		PPI		
MTR Automated Test:		Luminance Matching		
MTR Automated Test:		PPI		
<b>Action Limits:</b> Any identified monitor element that could interfere with clinical information must be removed. ACB DM Phantom image must be free of clinically significant artifacts. Fiber score must be ≥ 2.0, speck group score must be ≥ 3.0, mass score must be ≥ 2.0. Measured distance of wax insert must be 70.0 ± 1.0 mm. Test pattern image quality must pass all visual tests. L <sub>min</sub> must be within ±30% of mfr specifications (or, if not available ±1.5 cd/m <sup>2</sup> ). L <sub>max</sub> must be within ±10% of mfr specifications (or, if not available ±20 cd/m <sup>2</sup> ). Luminance uniformity must be ≤20%, luminance matching must be ≥20%. GSDF measured contrast response must be within ±10% of targeted contrast response. MTR's automated tests must pass mfr specifications (if 1 test fails, indicate "N"). <b>Recommended:</b> Ambient light conditions should be appropriate for mammography, max of 45 lux is recommended. <b>Timeframe:</b> Phantom must pass and significant monitor cleanliness defects must be corrected before clinical use, all other required tests must be corrected within 30 days.				

### 11. Evaluation of Site's Technologist QC Program

Facility Name \_\_\_\_\_ Imaging Facility \_\_\_\_\_ Room ID, MR & Modality \_\_\_\_\_ Room 1, Unit MR-Unit Mask  
 MAP ID-Unit# (0000-00) \_\_\_\_\_ 12345-xx  
 Survey Date \_\_\_\_\_ December 3, 2015

Radiologist Technologist's Quality Control Tests	Frequency	Test Performed, Analyzed & Documented	Missing Data	Incorrect Scoring or Calculations	Missing Corrective Action Documentation	Mfr Automated Tests (if Applicable)	Other	Comments
<b>1. ACR DM Phantom Image Quality</b>								
Scores of latest phantom image:								
Lateral QC Tech Score _____	Med Phys Score _____							
File# _____								
Spot group _____								
Head _____								
<b>2. CR Cassette Exposure (if app)</b>	Weekly							
<b>3. Comp Thickness Indicator</b>	Monthly							
<b>4. Visual Checklist</b>	Monthly							
<b>5. AW Monitor QC</b>	Monthly							
<b>6. Facility QC Review</b>	Quarterly							
<b>7a. Compression Force</b>	Determined							
<b>7b. MR Detector Calibration (if app)</b>	As Needed							
Optional - Repeat Analysis	Yes							
Optional - Radiologist QC on Radiologist	No							
Optional - Radiologist QC Feedback	NA							
Corrective Action Log documentation adequate?								
<b>Overall Pass/Fail for Performance of Technologist QC Program</b>								

**Additional Comments:** \_\_\_\_\_

**Required:** MQSA regulations (FDA Rule 900.120(f)(1)) specify that "each facility shall have the services of a medical physicist available to survey mammography equipment and oversee the equipment-related quality assurance practices of the facility." Completion of this "Evaluation of Site's Technologist QC Program" form documents that this oversight has been conducted. In order for the overall evaluation to pass, there must be no significant missing data. If the tests must be analyzed without gross errors, and if appropriate corrective action for failures must be taken (and documented). See test procedures for more information.

**Action Limits:** \_\_\_\_\_

**Timeframe:** Failures must be corrected within 30 days.

Medical Physicist's Section      1 of 1      © MP FORMS - Final Draft\_2015-12-18.xlsx

American College of Radiology

### 12. Evaluation of Display Device Technologist QC Program

Facility Name \_\_\_\_\_ Imaging Facility \_\_\_\_\_ MAP ID-Unit# (0000-00) \_\_\_\_\_ 12345-xx  
 Medical Physicist (if app) \_\_\_\_\_ Location of Display Devices \_\_\_\_\_ Frederick, MD office  
 Signature (if app) \_\_\_\_\_ Survey Date \_\_\_\_\_

Display Device ID & Room	Display Device Description (RW, Printer, Viewbox)	Test Performed, Analyzed & Documented Inconcrely	Missing Data	Incorrect Scoring or Calculations	Missing Corrective Action Documentation	Mfr Automated Tests (if Applicable)	Other	Comments
Example: Mammography reading room	RW	✓	✓	✓	✓			Discussed with manager
<b>Corrective Action Log documentation adequate?</b>								
<b>Overall Pass/Fail for Performance of Display Device Technologist QC Program</b>								

**Additional Comments:** \_\_\_\_\_

American College of Radiology



### Medical Physicist QC Letter for the Radiologist

December 2, 2015

John Doe, MD  
Imaging Facility  
1891 Preston White Dr  
Reston, VA 20191

**Re: Medical Physicist Survey:** Room & Unit M/Model: Room 1, Unit M/ Unit Model Survey Date: 12/1/2015

Dear Lead Interpreting Radiologist,

The above mammography unit at your facility recently 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 Digital Mammography 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**

Patient Name (Phantom): \_\_\_\_\_  
Patient ID (Phantom): \_\_\_\_\_  
Date: 12/1/2015

ACR Digital Mammography Phantom Scores			
Your Unit	Room 1	Passing Criteria	Pass /Fail
Fiber score		≥2.0	
Speck group score		≥3.0	
Mass score		≥2.0	
Artifacts		No Clinically Significant Artifacts	

Comments on phantom image: \_\_\_\_\_  
\_\_\_\_\_

**Radiation Dose**

ACR Digital Mammography Phantom Radiation Dose Values			
Your Unit	Room 1	Passing Criteria	Pass /Fail
ACR Phantom Dose (mGy)		≤3.0	

Note: The above dose is an estimate determined with a phantom representing the FDA-defined 4.2 cm thick, 50% glandular/50% adipose standard breast. Doses will vary with patient size and density. Specific patient doses can be estimated by your medical physicist.

Comments on radiation dose: \_\_\_\_\_  
\_\_\_\_\_

American College of Radiology

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

**Required Action Items**

Time Frame	Description

**Recommended Action Items**

Time Frame	Description

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

Time Frame	Description

**Comments on Tech QC**

Time Frame	Description

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

Sincerely,

\_\_\_\_\_  
Mary Smith, PhD

Phone: 000-000-0000  
Email: physicist@xxx.com

American College of Radiology

The following combination of testing must be performed:

**KEY**

- Arrows represent phantom image pathway and evaluation
- Gray shaded box indicates applicable testing required

**Figure x – MEE – All New Digital Mammography Units and Display Devices.**

**2. Mammography Equipment Evaluation (MEE) – New Digital Mammography Units (with Existing Display Devices)**

In this scenario, only the digital mammography unit 1 is new (including the acquisition workstation). The display devices (review workstations and film printers) are pre-existing as is digital mammography unit 2. The new digital mammography unit may be new, previously owned or relocated from another facility under the same ownership.

American College of Radiology

The following combination of testing must be performed:

**KEY**

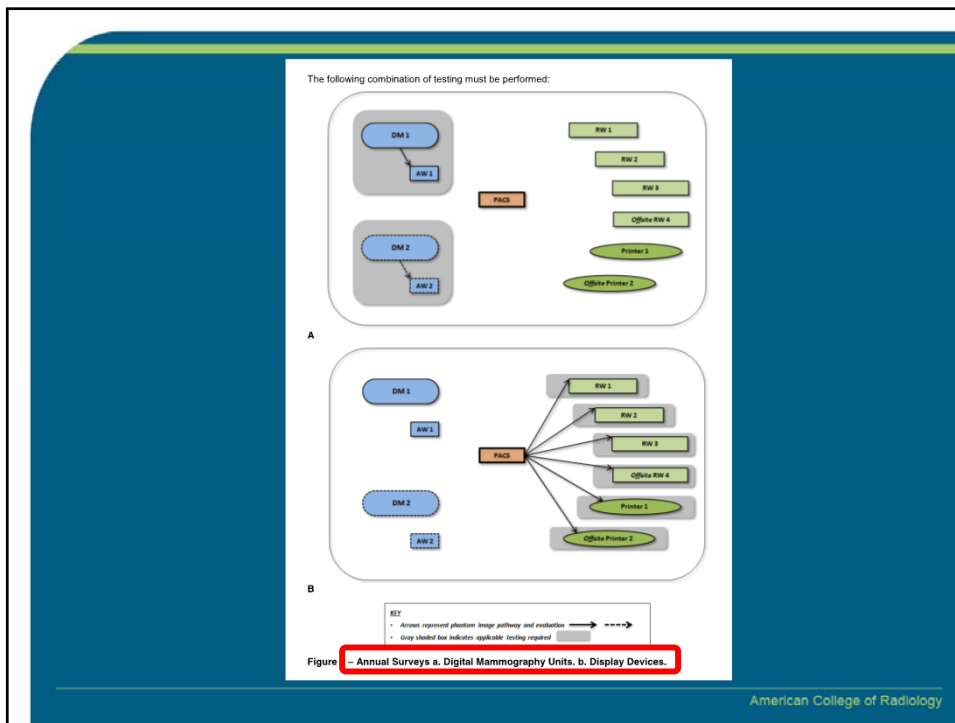
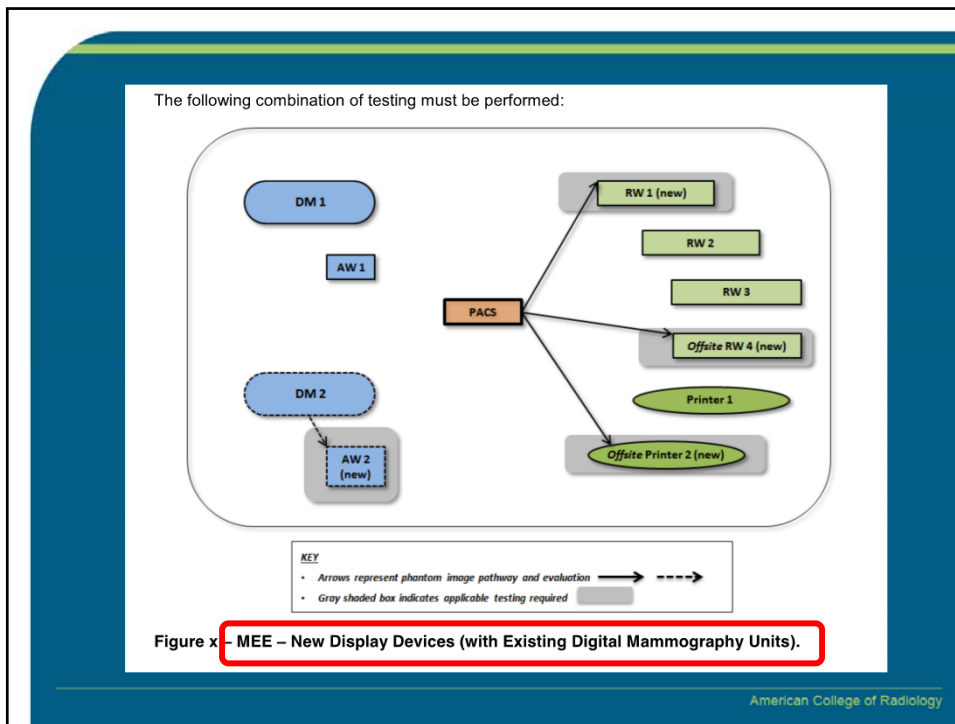
- Arrows represent phantom image pathway and evaluation
- Gray shaded box indicates applicable testing required

**Figure 3 – MEE – New Digital Mammography Units (with Existing Display Devices).**

**3. Mammography Equipment Evaluation (MEE) – New Display Devices (with Existing Digital Mammography Units)**

In this scenario, only display devices (an acquisition workstation 2, review workstation 1 and 4 and film printer 2) are new. The digital mammography unit 2 is pre-existing. Digital mammography unit 1 and also AW 1 are also pre-existing. The display devices may be new, previously owned or relocated from another facility under the same ownership. The phantom images used for evaluation should have been acquired from any of the facility's digital mammography units within the past month.

American College of Radiology



## ACR DM QC Manual – What's Next

- ACR developing training for techs, physicists, reviewers, inspectors and manufacturers
  - Webinars
  - In-person
- ACR revising accreditation process and software to incorporate new manual and phantom

American College of Radiology

## ACR Website & FAQs – Updated 8/22/16

([www.acraccreditation.org/Modalities/Mammography](http://www.acraccreditation.org/Modalities/Mammography))

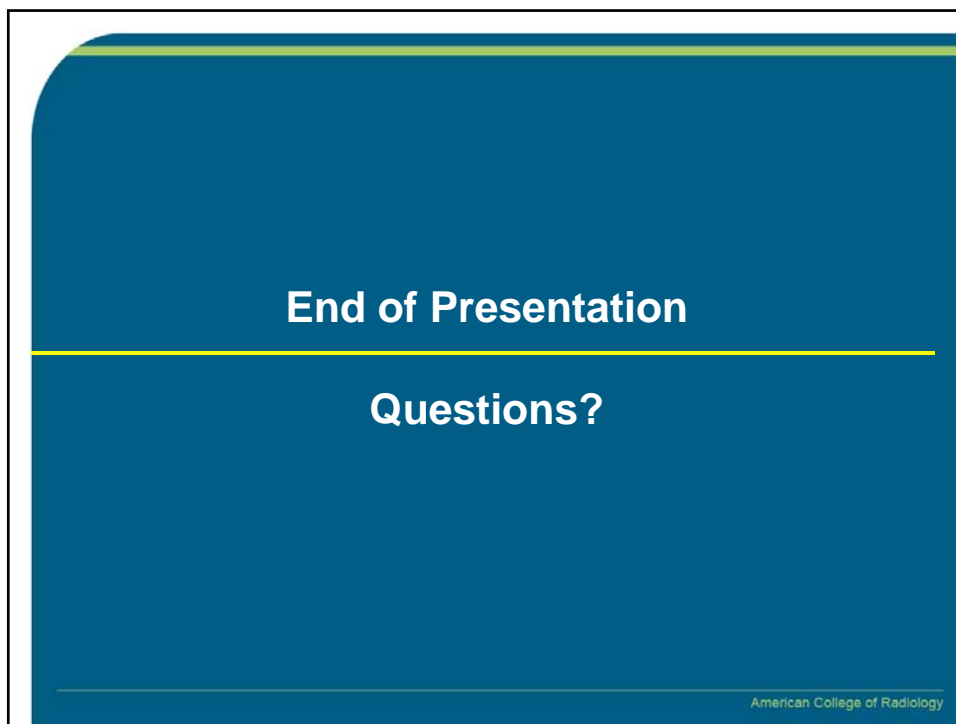
**Our facility would like to begin using the new ACR Digital Mammography QC Manual. Can we do so as soon as we receive our new manual?**

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.

**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?**

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.

American College of Radiology



**End of Presentation**

---

**Questions?**

American College of Radiology