Everything You Need to Know About the New ACR FFDM Manual

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ACR Subcommittee on Quality Assurance

- Clinical Representatives
- MITA Representatives
- ACR Representatives

- Chaired by Eric Berns, PhD (Denver Health)

Clinical Representatives

- Chris Adent-Delaney, RT - Northwestern Memorial Hospital
- Jay Baker, MD – Duke University Medical Center
- Lawrence Bassett, MD – UCLA Medical Center
  - Chair, Joint Committee on Breast Imaging for Appropriateness Criteria and Guidelines
- Shelli Dixon, RT – The Women's Imaging Center of Denver
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  - Chair of ACR Accreditation Program Chairs
  - Chair of ACR Mammography Accreditation
- Douglas Pfeiffer, MS – Boulder Community Health
- Margarita Zuley, MD – University of Pittsburgh Medical Center

MITA Representatives

- Medical Imaging & Technology Alliance
  - [John Sandrik, PhD (Ret.) – GE Medical Systems]
  - Robert Uzenoff – FUJIFILM Medical Systems
  - [Stephen Vastagh – MITA (now in new position)]
  - Moustafa Zerhouni – Computerized Imaging References Systems

ACR Representatives

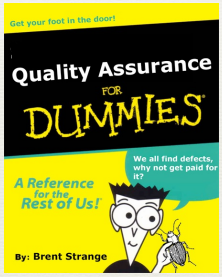
- Priscilla (Penny) Butler, MS – Senior Director and Medical Physicist
- Marion Boston, RT(R) – Assistant Director
- Pam Platt, BSRT(R) – ACR Liaison to FDA

▪

- Design ACR Accreditation Phantom for FFDM
- Write QC Manual for ACR FFDM Mammography Accreditation Program - STANDARDIZE
- Update the 1999 ACR Screen-Film QC Manual

QC Tests

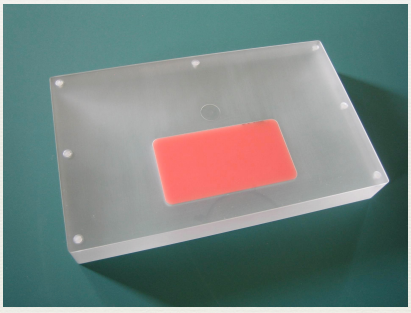
- Based on a variety of sources
  - MQSA
  - SFM
  - ACRIN DMIST
  - Manufacturer's QC programs
  - MITA
  - Subcommittee clinical experience
- Apply to all manufacturers
- Be clinically relevant
- Be user friendly



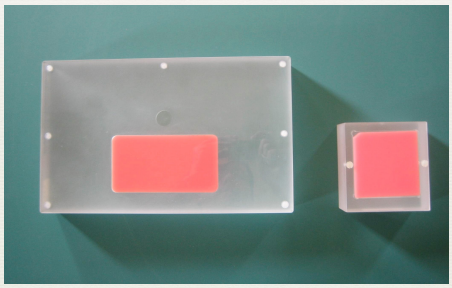
Phantom Design Goals

- More challenging targets
- More sensitive to changes
- Fewer digital processing artifacts
- Full field
- Same attenuation as current phantom
- Same Pass/Fail targets as current phantom

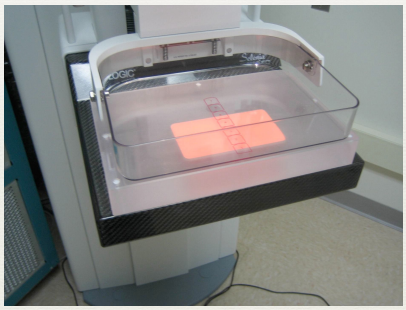
New Phantom



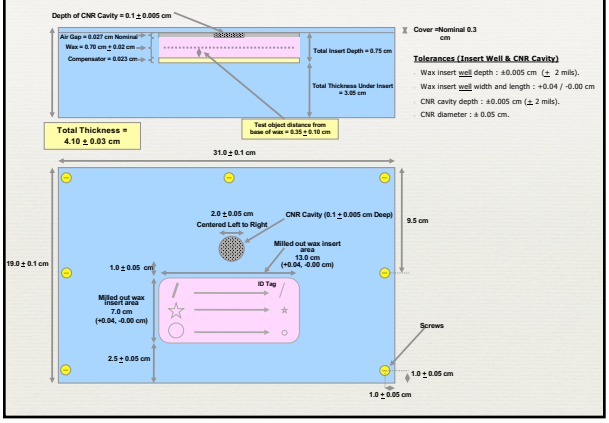
Cousins



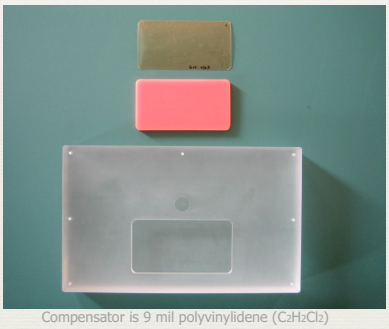
New Phantom in Clinical Environment



ACR Phantom Prototype

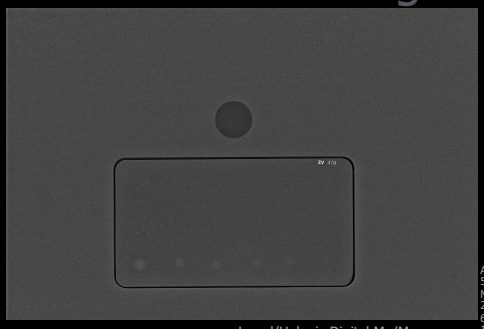


Attenuation Compensator



Compensator is 9 mil polyvinylidene ($C_2H_2Cl_2$)

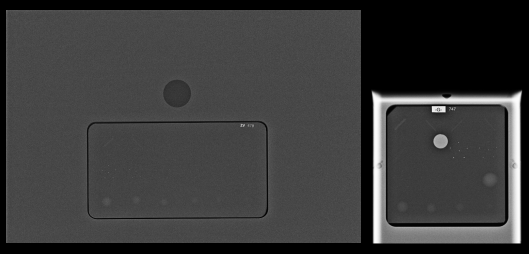
Clinical Unit Image



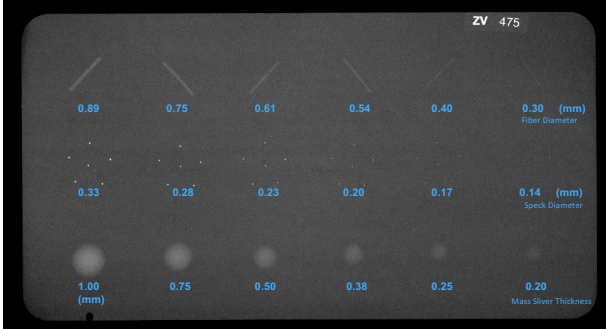
Auto-Filter
52 mm
Mo/Mo
29 kVp
66 mAs
1.64 mGy

Lorad/Hologic Digital Mo/Mo

Attenuation Equalization



The New Insert



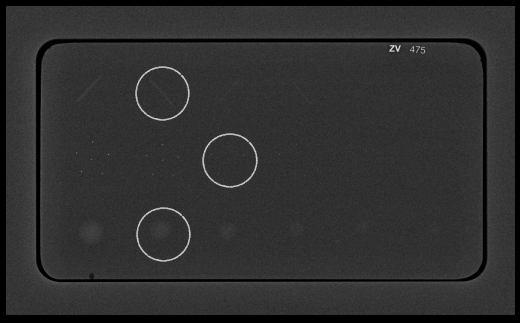
Specks are lime glass spheres

Test Object Comparison

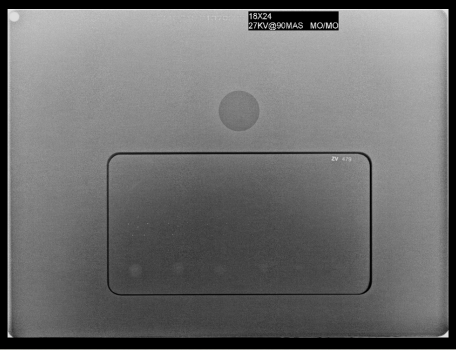
Visual

	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
Fail						
Pass	4 0.75	0.75 2	3 0.32	0.33	1 0.75	0.75 2
		0.61		0.28	0.50	0.50
	0.54	0.54	0.24	0.23 3		0.38
	0.40	0.40		0.20	0.25	0.25
		0.30	0.16	0.17		0.20
				0.14		

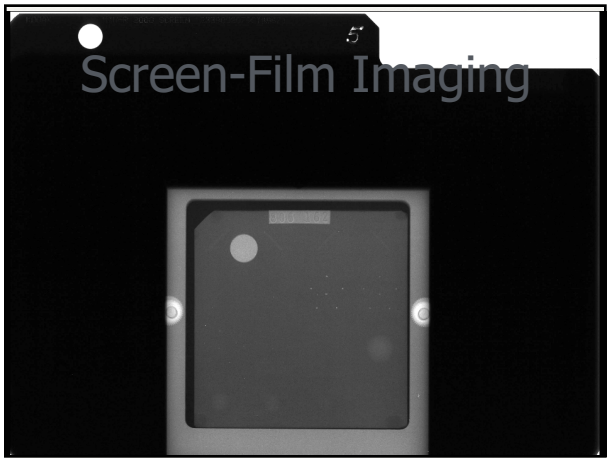
Phantom Scoring



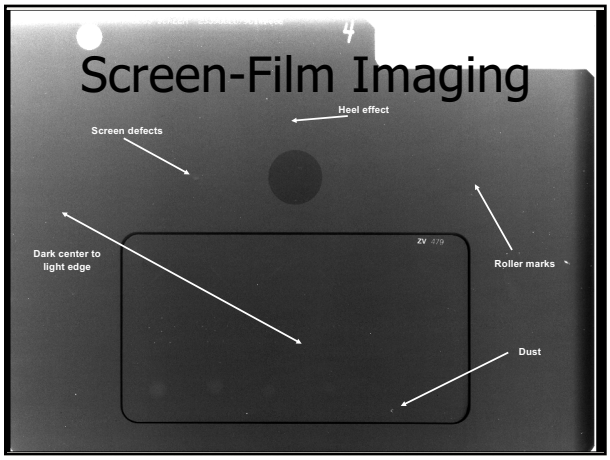
CR Imaging



Screen-Film Imaging



Screen-Film Imaging



AEC Technique Comparison

	Lorad – Mo		Lorad - W		Fuji CR 18 x 24 cm	
Mode	Auto-Filter		Auto-Filter		AA	
Phantom	FFDM	156	FFDM	156	FFDM	156
Compression Thickness (cm)	5.2	5.2	5.2	5.2	4.0	4.0
Target/Filter	Mo/Mo	Mo/Mo	W/Rh	W/Rh	Mo/Mo	Mo/Mo
kVp	29	29	28	28	27	27
mAs	66.4	65.4	92.5	97.6	90	89
Machine Reported Dose (mGy)	1.64	1.61	1.03	1.08	**	**

Manual Technique Signal Comparison

	Lorad/Hologic – Mo/Mo	
Mode	Manual	
Phantom	FFDM	SFM
Target/Filter	Mo/Mo	Mo/Mo
kVp	29	29
mAs	65	65
Signal in Wax	542.0	546.5
St. Dev. In Wax	9.7	9.7

Versatility!

50% of the required RT and MP tests incorporate the new phantom

QC Manual

- Focusses on FFDM
- Selective, high-yield tests
  - Challenge: Ensuring that all necessary tests are included, meaningful, and relevant
- Applicable to all units
  - Challenge: Accounting for, and incorporating, all the different FFDM technologies
  - Challenge: Predicting and accounting for future FFDM systems

QC Manual Structure

- Radiologist's Section
- Radiologic Technologist's Section
- Medical Physicist's Section
- Appendices
  - Revisions
  - ACR Digital Mammography Phantom Scoring Guide
  - Artifact Evaluation Guide

What Is New? Technologist Section

- Monitor QC for the interpretation workstations
- Management forms
  - ACR Technique and Procedure Summaries
  - Corrective Action Log
  - Facility Offsite Display Locations
  - QC Summary Checklists
    - Digital Mammography Unit QC Summary Checklist
    - Facility Display Device QC Summary Checklist
- Facility Equipment Inventory
- Improved QC Forms
- Instructions for Mobile Units
- Reduced calculations

What Is New? Medical Physicist Section

- Theme: provide better documentation and communication
  - MP Summary Form
    - For Facility, ACR, State and MQSA Inspectors
    - Action Item Summary included
  - Improved form for evaluating and documenting RT QC
  - MP letter to the Radiologist (optional)
  - MP to use same Corrective Action Log form as Techs
  - Provide QC forms in both PDF and Excel Worksheets

What Is New? Facility

- Guidance on how to handle multiple units at multiple locations
- Guidance on who/what/when tests need to be performed when "major" and "minor" Corrective actions are performed on unit
- Facility QC Review (Tech Test)

Phantom Scoring

Test Object	Full Point	Half Point
Fibers (6)	• Full length visible (≥8 mm long) • Correct location • Correct orientation • 1 break allowed (must be ≤ width of fiber)	• At least half of length visible (≥5 and <8 mm long) • Correct location • Correct orientation • 1 break allowed (must be ≤ width of fiber)
Speck Groups (6)	• 4 - 6 specks visible • Correct locations	• 2 - 3 specks visible • Correct locations
Masses (6)	• Density diference visible • Border is continuous and generally circular (≥ 3/4 border visible) • Correct location	• Density diference visible • Border is not continuous or generally circular (≥ 1/2 and < 3/4 border visible) • Correct location

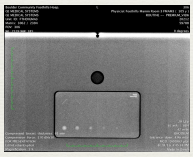
ACR Digital QC Manual - RT Tests

Test	Minimum Frequency	Corrective Action Timeframe
Technologist Tests		
1. ACR DM Phantom Image Quality	Weekly	Before clinical use
2. Computed Radiography (CR) Cassette Erasure *(if applicable)*	Weekly	Before clinical use
3. Compression Thickness Indicator	Monthly	Within 30 days
4. Visual Checklist	Monthly	Critical items: before clinical use; less critical items: within 30 days
5. Acquisition Workstation (AW) Monitor QC	Monthly	Within 30 days; before clinical use for severe defects
6. Radiologist Workstation (RW) Monitor QC	Monthly	Within 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	Within 30 days; before clinical use for severe artifacts
Optional - Radiologist Image Quality Feedback	As Needed	Not applicable

1. Phantom Image Quality

- For CR, erase plate first
- Create patient
  - use whatever ID system you want
- Align phantom
  - insert on top toward chest wall
- Compress to 5 daN (12 lb)
- Use CLINICAL technique
  - AEC cell under insert, if applicable
  - 4.2 cm compressed, 50%/50% breast
- Aquire image
- Record resulting technical factors

- Evaluate image
  - Count test objects
  - Artifacts
  - Use full resolution (1/1 pixel ratio)
  - Note no artifact deduction
    - Can fail image just for objectionable artifacts
  - **Must see 2 fibers, 3 speck groups, 2 masses**
  - **Artifacts must not interfere with interpretation**
- Corrective actions required prior to clinical use



2. CR Cassette Erasure (if applicable)

- Perform erasure procedure for all cassettes
- Document completion of the task

3. Compression Thickness Indicator

- Use any easily available object that's about 4-6 cm thick
  - Two tape rolls work well
  - Note actual dimension
- Use smallest, non-flex paddle available
- Compress to about 5 daN (12 lb)
  - Record value and be consistent
- Record indicated thickness
- **Must be accurate to ±5 mm**
- Corrective actions within 30 days

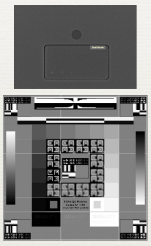
4. Visual Checklist

- Pretty much the same as it always is
- Make sure all bells and whistles are acting properly
- Be sure to rotate the C-arm the way you would for patient imaging
- When checking for cracks in paddles, face shields, and breast supports, only indicate issues that impact patient safety and image quality
- It may be necessary to add additional items to the checklist that are specific to your particular equipment or procedures
- Corrections required:
  - Prior to clinical use for critical tests
  - Within 30 days for non-critical tests

5. Acquisition Workstation Monitor QC

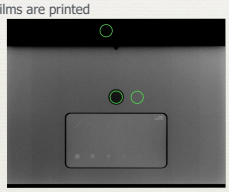
- Need TG18-QC test pattern or equivalent
  - If this is not possible, this part of the test cannot be performed
- Inspect monitor for fingerprints, etc.
  - Clean as needed
- View test pattern
  - **5%, 95% boxes visible**
  - **Line-pairs distinguishable center and corners**
- Corrective actions prior to clinical use
- Perform manufacturer automated QC if prescribed
  - Corrective actions within 30 days

6. Radiologist Workstation Monitor QC



- Need TG18-QC test pattern or equivalent
  - If this is not possible, this part of the test cannot be performed
- Inspect monitor for fingerprints, etc.
  - Clean as needed
- View ACR DM Phantom image
  - **Score and inspect for artifacts as in Test 1**
- View test pattern
  - **5%, 95% boxes visible**
  - **Line-pairs distinguishable center and corners**
- Corrective actions prior to clinical use
- Perform manufacturer automated QC if prescribed
  - Corrective actions within 30 days

7. Film Printer QC (if applicable)



- Required if images are printed for referring physicians and patients
- If printer used less than monthly, do before clinical films are printed
- Print ACR DM Phantom image
  - Do not adjust WW/WL
  - Print true size
  - Film size use for majority of clinical printing
- Score and inspect for artifacts as in Test 1
- Measure OD inside and outside of the cavity
- Calculate contrast = OD_{cavity} - $OD_{background}$
- Measure D_{max}
- **Same phantom score requirements**
- **Background OD must be ≥1.6, should be 1.7-2.2 (2.0 optimal)**
- **D_{max} must be ≥3.1, should be ≥3.5**
- Corrective actions prior to clinical use

8. Viewbox Cleanliness (if applicable)

- Required if prior or outside images are viewed on viewboxes
- Viewboxes must be clean and free of marks
- If viewboxes appear non-uniform, all lamps must be replaced
- Masks must be functioning
- Corrective actions prior to clinical use

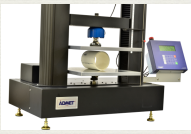
9. Facility QC Review

- Review of RT and MP QC efforts
- Must be done by
  - Lead interpreting physician
  - Facility manager
  - In person or by remote means
- Record MP test results on form
- Enter prior week of RT QC data
- Review most recent quarter of data with LIP and manager
- Review each QC test and results
- Note corrective action documentation present as needed
- Discuss reasons for failures
- Review MP results
- Document the review

Q

10. Compression Force

- Few changes from the 1999 ACR Mammography QC Manual
- **Must check that adequate force (≥25 lb) for length of average exposure**
- Corrective actions prior to clinical use



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11. Manufacturer Detector Calibration (if applicable)

- Required if a manufacturer specifies that a **calibration** must be performed
- Must follow manufacturer's procedure
- Must follow manufacturer's schedule
- Corrective actions prior to clinical use

Mfg

Optional Tests

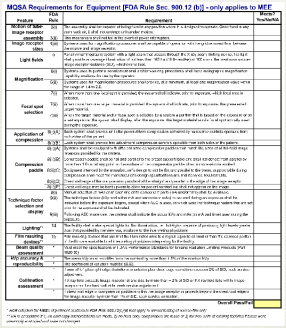
- Repeat analysis
- System QC for Radiologist
- Radiologist Image Quality Feedback

As Needed

ACR Digital QC Manual - MP Tests

Test	Minimum Frequency	Corrective Action Timeframe
Medical Physicist Tests		
1. Mammography Equipment Evaluation (MEE) - 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 items: before clinical use; less critical items: within 30 days
7. Computed Radiography *(if applicable)*	MEE and Annual	Before clinical use
8. Acquisition Workstation (AW) Monitor QC	MEE and Annual	Within 30 days; before clinical use for severe defects
9. Radiologist Workstation (RW) Monitor QC	MEE and Annual	Within 30 days; before clinical use for severe defects
10. Film Printer QC *(if applicable)*	MEE and Annual	Before clinical use
11. Evaluation of Site's Technologist QC Program	Annual	Within 30 days
12. Evaluation of Display Device Technologist QC Program	Annual	Within 30 days
MEE or Troubleshooting - Beam Quality (Half-Value Layer) Assessment	MEE or Troubleshooting	Before clinical use
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

1. MEE - MQSA Requirements for Equipment

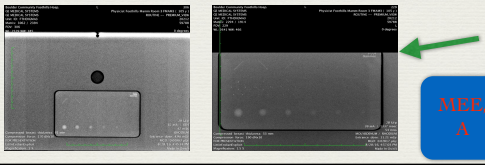

MQSA Requirements for Equipment [FDA Rule Sec. 900.12 (b)] - only applies to MEE

- Nothing really new
  - Reformatting
  - Alignment with approved changes
- "Lighting" and "Film masking" may be marked as "NA" if:
  - No hardcopy interpretations are made
  - No hardcopy comparisons are made
- Beam limiting device illumination
  - May be NA if systems such as slot scan
- Compression paddle deflection
  - Test according to manufacturer design

MEE

2. Phantom Image Quality

- For CR, erase plate first
- Create patient
  - use whatever ID system you want
- Align phantom
  - insert on top toward chest wall
- Compress to 5 daN (12 lb)
- Use CLINICAL technique
  - AEC cell under insert, if applicable
  - 4.2 cm compressed, 50%/50% breast
- Aquire image
- Record resulting technical factors
- **Repeat for magnification mode and commonly used T/F combinations**
- Evaluate image
  - Count test objects
  - Artifacts
  - Use full resolution (1/1 pixel ratio)
  - Note no artifact deduction
    - Can fail image just for objectionable artifacts
  - **Must see 2 fibers, 3 speck groups, 2 masses**
  - **Artifacts must not interfere with interpretation**



MEE, A

2. Phantom Image Quality

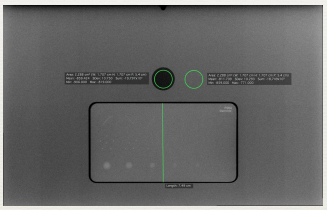
- Calculate SNR

$$SNR = \frac{signal_{background} - \text{DC offset}}{\text{std dev}_{background}}$$

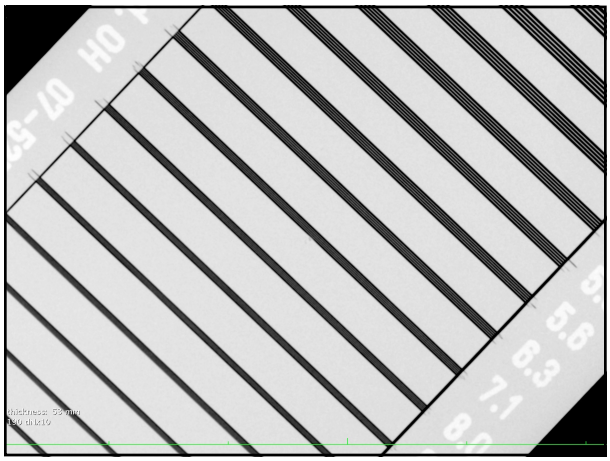
  - **Must be ≥40**
- Calculate CNR

$$CNR = \frac{abs\left(signal_{insert} - signal_{background}\right)}{\text{std dev}_{background}}$$

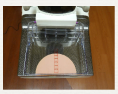
  - **Must be ≥2.0 and ≥85% of prior year (MEE if available)**
- Measure A-C insert dimension
  - **Must be 70.0 mm ±14.0 mm**
- All corrections prior to clinical use



MEE, A



4. Automatic Exposure Control Performance



- Attenuator
  - Acrylic, BR12, BR50, etc.
  - Approximately 2, 4, 6 cm
  - Large enough to simulate typical compressed breast
- Position phantom aligned to chest wall edge
- Compress to approximately 5 daN
- AEC setting used clinically (e.g., GE = AOP STD)
- Density control setting = 0
- AEC sensor in center of phantom
- Make exposure using 2, 4, 6 cm phantoms
- Record relevant technical information
  - Include indicated AGD
- Repeat for 4 cm using magnification stand
- Using 3 cm2 ROI, measure signal, standard deviation in the center of the phantom in each image
  - Can perform this step on any workstation with ROI capability
- Calculate SNR

$$SNR = \frac{signal_{background} - \text{DC offset}}{\text{std dev}_{background}}$$

- SNR must be
  - **≥40.0 for the 4 cm phantom**
  - **≥85% of the prior SNR for all phantoms (not applicable to MEE)**
- All corrections within 30 days

MEE, A

5. Average Glandular Dose

- Now using Dance method
  - Dance DR, Skinner CL, Young KC, et al. Additional factors for the estimation of mean glandular breast dose using the UK mammography dosimetry protocol. PhysMedBiol 2000;45:3225–3240.
- Protect the detector during dosimetry exposures
- Position dosimeter
  - 4.2 cm above breast support
  - Centered laterally
  - 4 cm in from chest wall edge
- Position compression paddle just in contact with dosimeter
- Set manual techniques as close as possible to those from the phantom image as possible
- Tables provided for calculating doses for other breast sizes

MEE, A

5. Average Glandular Dose

- Compute AGD
  - Only need to do it for the DM Phantom

$$D = K \cdot 8.76 \cdot g \cdot c \cdot s$$

where

D = AGD (mGy)

K = entrance exposure (R)

g = incident air kerma to mean glandular dose conversion factor for 50% glandularity

c = corrects for any composition difference from 50% glandularity

s = corrects for differences due to x-ray spectrum used

Table 3. *x*-factors for clinically used spectra and maximum errors that can be incurred when they are used.

Spectrum	*x*-factor	Maximum error (%)
Mo/Mo	1.000	3.1
Mo/Rh	1.017	2.2
Rh/Rh	1.061	3.6
Rh/Al	1.044	2.4
W/Rh	1.042	2.1

Table 2. *g*-factors (mGy/mGy) for breast thicknesses of 2–11 cm and the HVL range 0.30–0.60 mm Al. The *g*-factors for breast thicknesses of 2–8 cm are taken from Dance (1990).

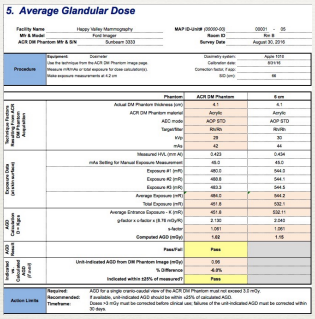
Breast thickness (cm)	HVL (mm Al)						
	0.30	0.35	0.40	0.45	0.50	0.55	0.60
2	0.390	0.433	0.473	0.509	0.543	0.573	0.587
3	0.274	0.309	0.342	0.374	0.406	0.437	0.466
4	0.207	0.235	0.261	0.289	0.318	0.346	0.374
4.5	0.183	0.208	0.232	0.258	0.285	0.311	0.339
5	0.164	0.187	0.209	0.232	0.258	0.287	0.310
6	0.135	0.154	0.172	0.192	0.214	0.236	0.261
7	0.114	0.130	0.145	0.163	0.177	0.202	0.224
8	0.098	0.112	0.126	0.140	0.154	0.175	0.195
9	0.0859	0.0981	0.1106	0.1233	0.1357	0.1543	0.1723
10	0.0763	0.0873	0.0986	0.1096	0.1207	0.1375	0.1540
11	0.0687	0.0786	0.0887	0.0988	0.1088	0.1240	0.1385

Table 6. *c*-factors for glandularities of 0.1–100% in the central region of the breast, breast thicknesses of 2–11 cm and HVLs of 0.30–0.60 mm Al. Surface layers of 100% adipose tissue 0.5 cm thick are assumed.

HVL (mm Al)	Thickness (cm)	Breast glandularity				
		0.1%	25%	50%	75%	100%
0.30	2	1.130	1.059	1.000	0.938	0.885
0.30	3	1.206	1.098	1.000	0.915	0.836
0.30	4	1.253	1.120	1.000	0.898	0.808
0.30	5	1.282	1.127	1.000	0.886	0.794
0.30	6	1.303	1.135	1.000	0.882	0.785
0.30	7	1.317	1.142	1.000	0.881	0.784
0.30	8	1.325	1.143	1.000	0.879	0.780
0.30	9	1.328	1.145	1.000	0.879	0.780
0.30	10	1.329	1.147	1.000	0.880	0.780
0.30	11	1.328	1.143	1.000	0.879	0.779

5. Average Glandular Dose

- Compute AGD
  - In spreadsheet
    - Enter measured HVL
    - Enter mAs used for exposure measurements
    - Enter exposure measurements in mR (it corrects mR to R)
    - Correction factor g·c·s·8.76 computed automatically
    - Dose computation automatic
- Limits
  - **AGD ≤ 3.0 mGy**
    - Corrected prior to use
  - **Displayed AGD within ±25% of measured**
    - Corrected within 30 days



5. Average Glandular Dose

Facility Name: Happy Valley Mammography
Mfr & Model: Fond Imager
ACR DM Phantom Mfr & S/N: Sunbeam 3333
MAP ID-Unit# (00000-00): 00001 - 05
Room ID: Rm 8
Survey Date: August 30, 2016

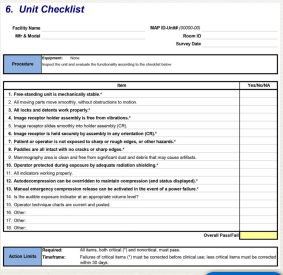
Procedure — Equipment: Dosimeter. Use the technique from the ACR DM Phantom image page. Measure mR/mAs or total exposure for close calculation(s). Make exposure measurements at 4.2 cm.
Dosimetry system: Agile 1015
Calibration date: 8/31/16
Correction factor, f-sp:
SID (cm): 66

	Phantom:	ACR DM Phantom	6 cm
Technique Factors (Recommended for ACR DM Phantom Acquisition)	Actual DM Phantom thickness (cm):	4.1	6.1
	ACR DM Phantom material:	Acrylic	Acrylic
	AEC mode:	AOP STD	AOP STD
	Target/filter:	Rh/Rh	Rh/Rh
	kVp:	29	30
	mAs:	42	44
Exposure Data (at least one method)	Measured HVL (mm Al):	0.422	0.434
	mAs Setting for Manual Exposure Measurement:	46.0	43.0
	Exposure #1 (mR):	480.0	544.0
	Exposure #2 (mR):	480.8	544.1
	Exposure #3 (mR):	483.3	544.5
	Average Exposure (mR):	484.7	544.2
	Total Exposure (mR):	481.8	532.1
AGD Calculation (3 + digits)	Average Entrance Exposure – K (mR):	451.8	532.11
	g-factor x c-factor x (8.76 mGy/R):	2.130	2.040
	s-factor:	1.081	1.081
	Computed AGD (mGy):	1.02	1.15
AGD Pass/Fail	Pass/Fail:	Pass	
Indicated AGD (Acceptance Check) (if unit)	Unit-indicated AGD from DM Phantom Image (mGy):	0.95	
	% Difference:	-6.9%	
	Indicated within ±25% of measured?:	Pass	

Action Limits — Required: AGD for a single cranio-caudal view of the ACR DM Phantom must not exceed 3.0 mGy.
Recommended: If available, unit-indicated AGD should be within ±25% of calculated AGD.
Timeframe: Doses >3 mGy must be corrected before clinical use; failures of the unit-indicated AGD must be corrected within 30 days.

6. Unit Checklist

- Have identified critical and non-critical items
- All must pass
- Correction time frame:
  - Prior to use for critical items
  - Within 30 days for non-critical items



6. Unit Checklist

Facility Name
Mfr & Model
MAP ID-Unit# (00000-00)
Room ID
Survey Data

Procedure — Equipment: None. Inspect the unit and evaluate the functionality according to the checklist below

Item	Yes/No/NA
1. Free-standing unit is mechanically stable.*	
2. All moving parts move smoothly, without obstructions to motion.	
3. All locks and detents work properly.*	
4. Image receptor holder assembly is free from vibrations.*	
5. Image receptor slides smoothly into holder assembly (CR).	
6. Image receptor is held securely by assembly in any orientation (CR).*	
7. Patient or operator is not exposed to sharp or rough edges, or other hazards.*	
8. Paddles are all intact with no cracks or sharp edges.*	
9. Mammography area is clean and free from significant dust and debris that may cause artifacts.	
10. Operator protected during exposure by adequate radiation shielding.*	
11. All indicators working properly.	
12. Auto-decompression can be overridden to maintain compression (and status displayed).*	
13. Manual emergency compression release can be activated in the event of a power failure.*	
14. Is the audible exposure indicator at an appropriate volume level?*	
15. Operator technique charts are current and posted.	
16. Other:	
17. Other:	
18. Other:	
	Overall Pass/Fail:

Action Limits — Required: All items, both critical (*) and noncritical, must pass.
Timeframe: Failures of critical items (*) must be corrected before clinical use; less critical items must be corrected within 30 days.

MEE, A

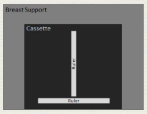
7. Computed Radiography

- Plate-to-plate uniformity
  - Erase all cassettes
  - Position DM Phantom on breast support and compress to 5 daN
  - Expose all plates using manual techniques as close as possible to AEC phantom technique
  - Process with as little image processing as possible
  - Measure signal and standard deviation with 5 cm^2 ROI in center of uniform area
  - Calculate SNR for all plates
- Review each image for artifacts
- Scanner performance
  - Place cassette on top of breast support
  - Place two steel rulers perpendicular on the cassette
  - Expose at approximately 25 kVp, 4 mAs
  - Process the cassette

MEE, A

7. Computed Radiography

- Performance requirements
  - Plate-to-plate uniformity
    - mAs of any one plate must not differ by more than ±10% from the mean mAs of that size
    - SNR of any one plate must not differ by more than ±15% from the mean SNR of that size
  - Artifacts
    - Must not obscure or mimic important structure or pathology
  - Scanner performance (recommended)
    - Edges of steel ruler crisp and linear
- Corrections required prior to clinical use



8. Acquisition Workstation Monitor QC

- Desired test patterns
  - TG18-QC test pattern or equivalent
    - If this is not possible, this part of the test cannot be performed
  - TG18-LN01 and TG18-LN18 test pattern or equivalent
    - If this is not possible, this part of the test cannot be performed
  - TG18-UNL80 test pattern or equivalent
    - If this is not possible, this part of the test cannot be performed
- Monitor condition
  - Inspect monitor for fingerprints, etc.
  - **Document findings**
  - Corrections prior to clinical use
- View TG18-QC test pattern
  - **Pattern properly centered**
  - **5%, 95% boxes visible**
  - **Line-pairs distinguishable center and corners**
  - **Alphanumerics sharp and legible**
  - **Grayscale ramps smooth and continuous**
  - Corrections within 30 days

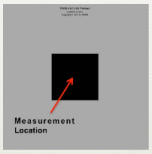
MEE, A

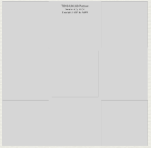
8. Acquisition Workstation Monitor QC

- Luminance measurements
  - Measure Lmin (TG18-LN01) and Lmax (TG18-LN18)
  - **Lmin within ±30% of manufacturer specification (or ≤ 1.5 cd/m²)**
  - **Lmax within ±10% of the manufacturer specification (or ≥ 150 cd/m²)**
  - Corrections within 30 days
- Luminance uniformity
  - Measure luminance at center and four corners of TG18-UNL80
  - Calculate %difference

$$\%difference = \frac{200 \times (L_{max} - L_{min})}{L_{max} + L_{min}}$$

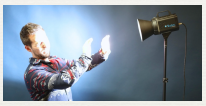
  - Lmax and Lmin are from the uniformity measurements on TG18-UNL80!
  - **%difference must be ≤30%**
  - Corrections within 30 days
- GSDF verification
  - Use manufacturer software to verify GSDF compliance
  - May make external measurements if felt necessary or if software not provided
  - **Measured contrast response must match targeted response to within ±10%**
  - Corrections within 30 days
- Manufacturer automated tests
  - Review settings for frequencies and actions limits to verify appropriate for mammography
  - **All manufacturer tests must pass**
  - Corrections within 30 days

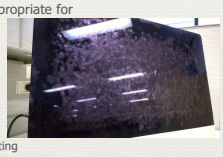




9. Radiologist Workstation Monitor QC

- Needed test patterns
  - TG18-QC test pattern or equivalent
  - TG18-LN01 and TG18-LN18 test pattern or equivalent
  - TG18-UNL80 test pattern or equivalent
- Ambient light
  - Verify that conditions in reading area are appropriate for mammographic interpretation
- Monitor condition
  - Inspect monitor for fingerprints, etc.
  - **Document findings**
  - Corrections prior to clinical use
- DM Phantom Image Quality
  - Display phantom acquired during annual or QC testing
  - Evaluate for artifacts and score the phantom test objects like in Test #2 DM Phantom Image Quality
  - **Same criteria as above for artifacts and object scores**
  - Corrections prior to clinical use





MEE, A

9. Radiologist Workstation Monitor QC

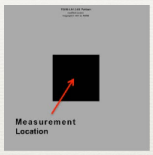
- Distance Measurement
  - Display phantom acquired during annual or QC testing
  - Measure A-C insert dimension
  - **Must be 70.0 mm ±14.0 mm**
  - Corrections prior to clinical use
- View TG18-QC test pattern
  - **Pattern properly centered**
  - **5%, 95% boxes visible**
  - **Line-pairs distinguishable center and corners**
  - **Alphanumerics sharp and legible**
  - **Grayscale ramps smooth and continuous**
  - Corrections within 30 days
- Luminance measurements
  - Measure Lmin (TG18-LN01) and Lmax (TG18-LN18)
  - **Lmin within ±30% of manufacturer specification (or ≤ 1.5 cd/m²)**
  - **Lmax within ±10% of the manufacturer specification (or ≥ 420 cd/m²)**
  - Corrections within 30 days

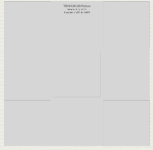
9. Radiologist Workstation Monitor QC

- Luminance uniformity
  - Measure luminance at center and four corners of TG18-UNL80
  - Calculate %difference

$$\%difference = \frac{200 \times (L_{max} - L_{min})}{L_{max} + L_{min}}$$

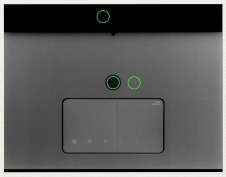
  - Lmax and Lmin are from the uniformity measurements on the TG18-UNL80 pattern!
  - **%difference must be ≤30%**
  - Corrections within 30 days
- GSDF verification
  - Use manufacturer software to verify GSDF compliance
  - May make independent measurements if felt necessary or if software not provided
  - **Measured contrast response must match targeted response to within ±10%**
  - Corrections within 30 days
- Manufacturer automated tests
  - Review settings for frequencies and actions limits to verify appropriate for mammography
  - **All manufacturer tests must pass**
  - Corrections within 30 days





10. Film Printer QC (if applicable)

- Required if images are printed for referring physicians and patients
- If printer used less than monthly, do before clinical films are printed
- Print ACR DM Phantom image
  - Do not adjust WW/WL
  - Print true size
  - Film size use for majority of clinical printing
- Score and inspect for artifacts as in Test 1
- Measure OD inside and outside of the cavity
- Calculate contrast = OD_{cavity} - $OD_{background}$
- Measure D_{max}
- Measure A-C insert dimension
- **Same phantom score requirements**
- **Background OD must be ≥1.6, should be 1.7-2.2 (2.0 optimal)**
- **D_{max} must be ≥3.1, should be ≥3.5**
- **Insert dimension must be 70.0 mm ±14.0 mm**
- Corrective actions prior to clinical use



MEE, A

11. Evaluation of Site RT QC Program

- Evaluate if each technologist QC test
  - Is being performed correctly, at the appropriate frequency, and that QC data appear to be correct
  - Is analyzed correctly, that calculations are performed according to the Technologist Section procedures, and that results are compared to the procedures' action limits
  - Needed corrective actions being performed and documented
  - Record any deficiencies or give positive feedback
- Performance requirements
  - **No significant missing data**
  - **Analyzed without gross errors**
  - **Corrective action performed and documented**
- The following FDA Level 2 non-compliance items can be used as guidance to determine whether the Overall Technologist QC Program fails:
  - Not conducting a phantom image test for 2-3 weeks in a consecutive 12-week working period
  - Failure to conduct a phantom image test at clinical settings
  - Not taking timely corrective action for failed items
- Corrective actions within 30 days

MEE, A

12. Evaluation Display Device RT QC Program

- Display devices include
  - RW monitors
  - Film printers
  - Viewboxes
- Verify that QC is properly performed for each device used by that facility
- Review corrective action log for appropriate documentation
- Perform for all local devices
- For off-site devices
  - QC evaluation may be performed by another medical physicist
  - Annual documentation must be provided to the local site
    - Completed Evaluation of Display Device Technologist QC Program form
- Performance criteria
  - **QC must be performed correctly**
  - **Needed corrective actions must be performed and documented**
- Corrective actions within 30 days

MEE, A

Beam Quality / HVL

- Only required at MEE or for troubleshooting
- Typical protocol
  - No C- factors
- Automatic determination by solid state detectors is acceptable
- Check phantom kVp, low kVp, high kVp
- At least one measurement for each target-filter combination
- Performance criteria

X-ray Tube Voltage (kilovolt peak) and Minimum HVL		
Designed Operating Range (kV)	*Measured Operating Voltage (kV)*	*Minimum HVL (millimeters of aluminum)*
Below 50	*20*	*0.20*
	25	*0.25*
	30	*0.30*

- Corrective actions prior to clinical use

MEE

kVp Accuracy and Reproducibility

- Only required at MEE or for troubleshooting
- Typical protocol
- Check
  - Lowest measurable kVp
  - Most commonly used kVp
  - Highest clinically used kVp
- Make three exposures at most commonly used kVp for reproducibility
- Ensure that measuring device properly calibrated for the T-F combination used
  - Do not need to measure for different T-F combinations
- Performance criteria
  - **Accurate to within ±5% of the nominal value**
  - **Coefficient of variation ≤0.02**
- Corrective actions
  - MEE - prior to clinical use
  - Troubleshooting - within 30 days

MEE

Collimation Assessment and Paddle Alignment

- Only required at MEE or for troubleshooting
- Typical protocol
  - For paddle alignment, tape coin to the underside of the compression paddle and within the paddle so that the outer edge of the coin is aligned with the inner chest-wall edge of the paddle
  - Must measure
    - large and small field sizes
    - all paddle positions (if paddle shifts)
    - all anode tracks for field sizes and paddle positions
- Performance criteria
  - **Light field coincidence within 2% SID each direction**
  - **Radiation field does not extend beyond any side by more than 2% SID**
  - **Radiation field extends at least to the chest wall edge of the receptor**
  - **Compression paddle**
    - **extends just beyond chest wall edge of image receptor**
    - **does not extend by more than 1% SID**
- Corrective actions
  - MEE - prior to clinical use
  - Troubleshooting - within 30 days

MEE

Ghost Image Evaluation

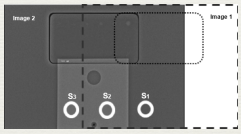
- Only required for troubleshooting
- Turn off all image processing
- Large compression paddle
- Position DM phantom
  - Wax insert away from chest wall
  - Extending about 2.5 cm beyond the lateral center line
  - Ensure that AEC cells, if present, are covered
- Compress to 5 daN
- Expose using clinical AEC technique
- Reposition phantom
  - Centered laterally
  - 0.1 mm Al centered laterally at chest wall edge
- Wait 1 minute
- Expose using the same techniques as the first image

TS

Ghost Image Evaluation

- Analyze the image
  - Three ROIS as in image
- Calculate the Ghosting Index

$$\text{Ghosting Index} = \frac{S_3 - S_2}{S_1 - S_2}$$



- Performance criteria
  - **-0.03 ≤ Ghosting Index ≤ +0.03**
- Corrective actions prior to clinical use

Viewbox Luminance

- Only required for troubleshooting
- Typical protocol
  - Measure ambient illuminance on the viewbox
  - Measure luminance of each viewbox
  - Visually evaluate brightness uniformity between panels
- Performance criteria
  - **Ambient illuminance should be ≤ 45 lux**
  - **Luminance should be ≥ 3000 cd/m2**
- Corrective actions
  - No time limit specified

TS

Testing Scenarios

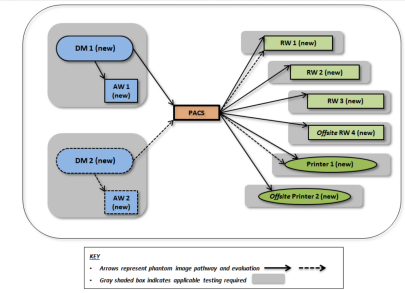


Figure x – MEE – All New Digital Mammography Units and Display Devices.

Testing Scenarios

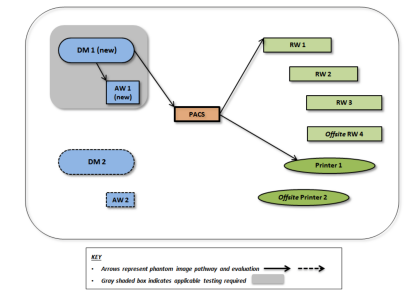


Figure x – MEE – New Digital Mammography Units (with Existing Display Devices).

Testing Scenarios

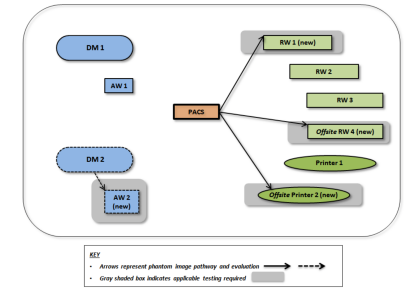


Figure x – MEE – New Display Devices (with Existing Digital Mammography Units).

Testing Scenarios

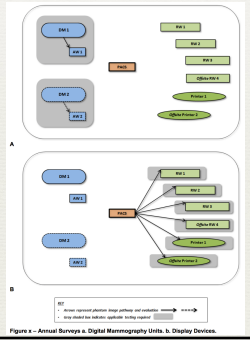


Figure x – Annual Surveys a. Digital Mammography Units. b. Display Devices.

Testing Scenarios

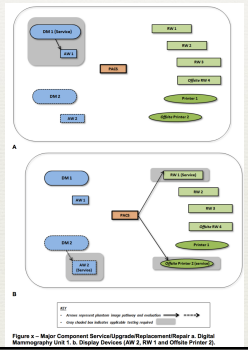


Figure x – Major Component Service/Upgrade/Replacement/Repair a. Digital Mammography Unit 1. b. Display Devices (AW 2, RW 1 and Offsite Printer 2).

FAQs

- FAQ available at http://www.acraccreditation.org/~/media/ACRAccreditation/Documents/Mammography/DMQCFAQs.pdf?la=en
- Don't have a copy of the manual? Contact one of your facilities; they're supposed to share the link with you.
- Electronic forms? RT and MP forms are available in Excel format. Equations are embedded.
- Keep using old phantom with new manual? No! They are too different and the manual was designed around the new phantom
- Transition to new manual? MP must first conduct an annual survey and display devices using new manual to establish techniques and QC procedures.
- Pick and choose? No! It's all or nothing. Must fully transition to the new manual for a unit or fully stick with the manufacturer's manual.
  - It is, however, ok to continue to perform some of the manufacturer tests if the facility desires, but the entire ACR manual must be followed.
- Switch back? Yes, after an annual survey is completed by the MP using the manufacturer's manual
- When can we start? Manual goes into effect July 2017, so that's when ACR will start accepting QC testing results for accreditation. Encouraged to start using it prior to that along side current QC to become familiar with it.

DBT?

- DBT is not included in the manual at this time
  - Appendix in progress
- Will need to follow manufacturer QC until DBT included by FDA
- OK to use new manual for another unit that only does 2D imaging

Status

- FDA has approved the manual as an alternative standard under current regulations
- Allows facilities to use this instead of the manufacturer's manuals
- ACR is determining manufacturer interest in adopting the new manual as their own after DBT appendix is available

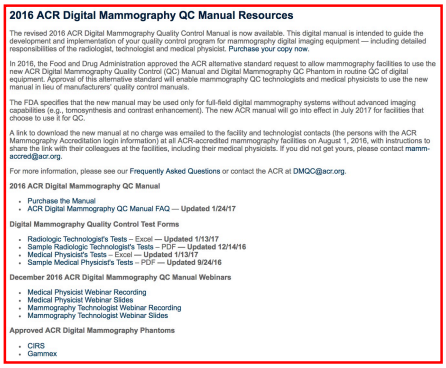
Be Physicists!

- Nothing in the ACR DM QC Manual precludes performing tests from the manufacturer's QC manuals
- You may determine that additional testing is appropriate
- If something seems awry, dive deeper into the system with an appropriate manufacturer test

Other Questions

- Implementation and roll-out?
  - ACR is developing a plan to provide training - various modes and methods
- NB: Yes, there are some typographical and other errors still extant, despite extermination efforts!
  - Tell the ACR (Penny Butler or Pam Platt), but be nice!
- Phantom availability?
  - CIRS and Gammex are currently approved to produce phantom
  - List price from one: $1290

New Webpage:
www.acraccreditation.org/ Resources/Digital-Mammography-QC-Manual-Resources



2016 ACR Digital Mammography QC Manual Resources

The revised 2016 ACR Digital Mammography Quality Control Manual is now available. This digital manual is intended to guide the development and implementation of your quality control program for mammography digital imaging equipment — including detailed responsibilities of the radiologist, technologist and medical physicist. Purchase your copy now.

In 2016, the Food and Drug Administration approved the ACR alternative standard request to allow mammography facilities to use the new ACR Digital Mammography Quality Control (QC) Manual and Digital Mammography QC Phantom in routine QC of digital equipment. Approval of this alternative standard will enable mammography QC technologists and medical physicists to use the new manual in lieu of manufacturers' quality control manuals.

The FDA specifies that the new manual may be used only for full-field digital mammography systems without advanced imaging capabilities (e.g., tomosynthesis and contrast enhancement). The new ACR manual will go into effect in July 2017 for facilities that choose to use it for QC.

A link to download the new manual at no charge was emailed to the facility and technologist contacts (the persons with the ACR Mammography Accreditation login information) at all ACR-accredited mammography facilities on August 1, 2016, with instructions to share the link with their colleagues at the facilities, including their medical physicists. If you did not get yours, please contact mammaccred@acr.org.

For more information, please see our Frequently Asked Questions or contact the ACR at DMQC@acr.org.

2016 ACR Digital Mammography QC Manual

- Purchase the Manual
- ACR Digital Mammography QC Manual FAQ — **Updated 1/24/17**

Digital Mammography Quality Control Test Forms

- Radiologic Technologist's Tests – Excel — **Updated 1/13/17**
- Sample Radiologic Technologist's Tests – PDF — **Updated 12/14/16**
- Medical Physicist's Tests – Excel — **Updated 1/13/17**
- Sample Medical Physicist's Tests – PDF — **Updated 9/24/16**

December 2016 ACR Digital Mammography QC Manual Webinars

- Medical Physicist Webinar Recording
- Medical Physicist Webinar Slides
- Mammography Technologist Webinar Recording
- Mammography Technologist Webinar Slides

Approved ACR Digital Mammography Phantoms

- CIRS
- Gammex

Many Thanks...

- Eric Berns, PhD
- Penny Butler, MS


Questions?