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The 2018 ACR Digital Mammography Quality Control Manual

What the Medical Physicist's Needs to Know

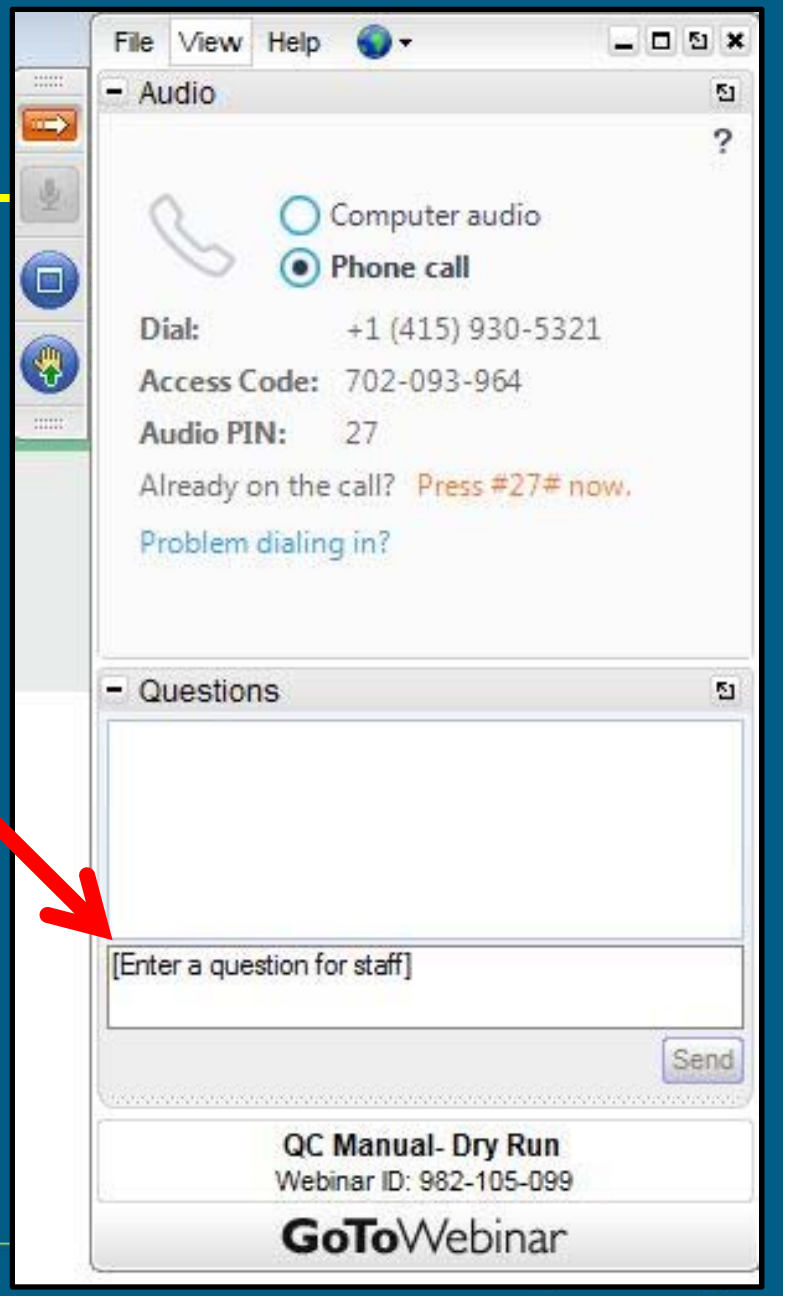
By Eric Berns, PhD, FACR

Chair, Subcommittee on Breast X-ray Imaging Physics

American College of Radiology

Questions

- Submit questions at any time during the webinar
- If we don't get to your question, send them via email to dmqc@acr.org and we'll respond ASAP
- Fodder for future FAQs



Overview

- ***Why:***
  - The benefits of the ACR QC Digital Mammography Program
- ***Resources:***
  - Where to go for help
- ***Overview of Tests & Phantom:***
  - Tech and MP Test Summary
- ***When:***
  - Strategy and Steps to transition to the new QC Manual
- ***How:***
  - How to perform the QC tests

Definition

Definition

- An Alternative Standard was issued by the FDA for the ACR DM QC Manual.
  - This means it *can* replace any other Manufacturer QC Manual.
  - Therefore, you have the option to stop using Mfr QC Manuals when you switch to the ACR DM Manual.
  - *Facilities are not required to switch. This is an option, and a choice, to switch to the ACR DM QC Program.*

Definition

Definition

- **Note:** Some Mfr's have "calibrations" that are different than QC Tests. These calibrations are Mfr specific and may need to continue if the Mfr requires them.
- It is important to differentiate "calibrations" and "QC Tests" to Technologists and help them understand the difference.

Why should we switch?

Non-obvious reasons and benefits of switching

- Resets and re-establishes the relationship of the MP with the Tech, Rad, and Facility - *Demonstrates MP Value*
- Establishes the MP as the QC leader and the go-to resource - *Demonstrates MP Value*
- Establishes communication directly with the Lead Interpreting Radiologist - *Demonstrates MP Value*
- Establishes communication directly with the Facility (including the Quarterly QC Meetings) - *Demonstrates MP Value*

Why should we switch?

Performing the QC Tests are more efficienct:

- Fewer QC tests than mfr QC
- Less total time spent on QC tests
- 2D *and* Tomo are both included
- Both paper (PDF) and electronic (Excel) forms are provided by the ACR and can downloaded for free.
- ….Yet, QC tests provide a better quality evaluation of the system.

Why should we switch?

Highlights for Medical Physicist tests:

- ACR Phantom
  - Can now fail for artifacts
  - Phantom covers majority of detector area
  - Evaluate CNR at MEE, compare annual CNR to MEE CNR for consistency
- DBT Z-Resolution & DBT Volume
  - Excellent, streamlined, tests for verifying DBT slice performance

Why should we switch?

Highlights for Medical Physicist tests:

- AEC Testing
  - Evaluates 4 cm SNR at MEE
    - But measures 2, 4, 6, 8, and 4 cm mag at MEE
  - Annual is comparing SNR's to MEE SNR's for consistency
- Average Glandular Dose
  - Utilizes a calculation (Dance method) for both 2D and DBT which covers all target-filter combinations
  - Formula can expand to different thicknesses and densities

Why should we switch?

Highlights for Medical Physicist tests:

- AW & RW Testing (Display Devices)
  - Display devices (monitors) are now considered stand alone devices
  - Tests and forms are singular for each device
  - System in place to keep track of display devices throughout multiple MAP facilities and locations
- Tech QC Review
  - Improved method for documentation QC Review
  - Evaluating Tech QC for units and displays are now separate tests

Why should we switch?

Highlights for Medical Physicist tests:

- MEE
  - HVL, kVP, and Collimation are now MEE only
  - However, for DBT system, collimation is annual

Why else should we switch?

Improved quality

- Much better (new) phantom
- Better artifact detection
- QC program is structured for modern facilities (with multiple **units**, multiple **RW's**, and at multiple **facilities**)
- Team approach emphasized with QA Committee
  - To include: Tech, Rad, Management, Medical Physicist
- Radiologist involvement and feedback incorporated in QC program

Why *else* should we switch?

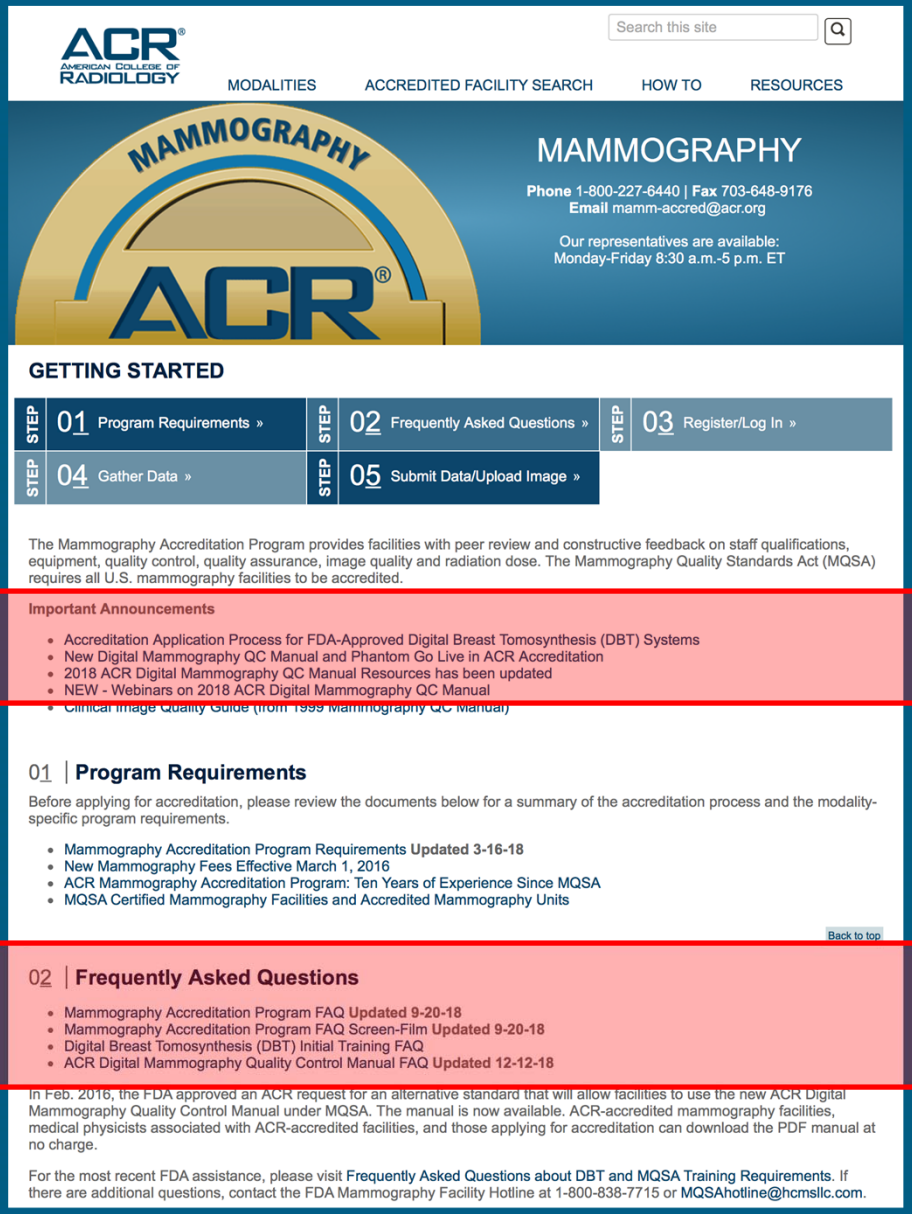
Life is easier with standardization

- Expect cleaner MQSA inspections
- Standardization reduces errors
- No more chasing mfr QC manual versions
- Current edition & future revisions will provided by ACR
- Current & future QC forms will be provided by the ACR for free

… Remember the days when we had a single QC program? Now were re-joining CT and MRI. ***1 QC Program, 1 Phantom, that applies to all units.***

Resources

ACR Mammography Accreditation Website



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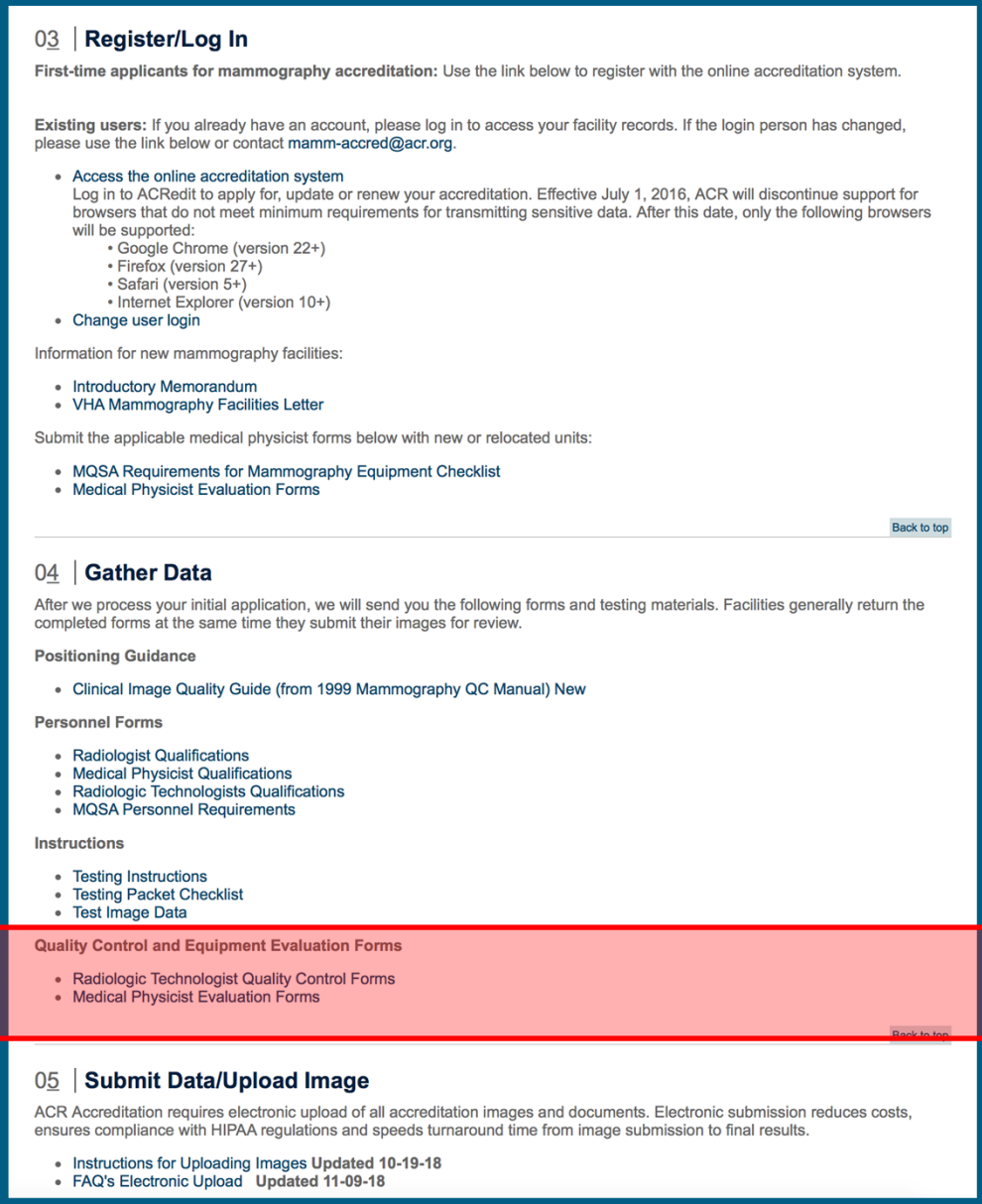


03 | Register/Log In

First-time applicants for mammography accreditation: Use the link below to register with the online accreditation system.

Existing users: If you already have an account, please log in to access your facility records. If the login person has changed, please use the link below or contact mamm-accred@acr.org.

- Access the online accreditation system
  Log in to ACRedit to apply for, update or renew your accreditation. Effective July 1, 2016, ACR will discontinue support for browsers that do not meet minimum requirements for transmitting sensitive data. After this date, only the following browsers will be supported:
  - Google Chrome (version 22+)
  - Firefox (version 27+)
  - Safari (version 5+)
  - Internet Explorer (version 10+)
- Change user login

Information for new mammography facilities:

- Introductory Memorandum
- VHA Mammography Facilities Letter

Submit the applicable medical physicist forms below with new or relocated units:

- MQSA Requirements for Mammography Equipment Checklist
- Medical Physicist Evaluation Forms

Back to top

04 | Gather Data

After we process your initial application, we will send you the following forms and testing materials. Facilities generally return the completed forms at the same time they submit their images for review.

Positioning Guidance

- Clinical Image Quality Guide (from 1999 Mammography QC Manual) New

Personnel Forms

- Radiologist Qualifications
- Medical Physicist Qualifications
- Radiologic Technologists Qualifications
- MQSA Personnel Requirements

Instructions

- Testing Instructions
- Testing Packet Checklist
- Test Image Data

Quality Control and Equipment Evaluation Forms

- Radiologic Technologist Quality Control Forms
- Medical Physicist Evaluation Forms

Back to top

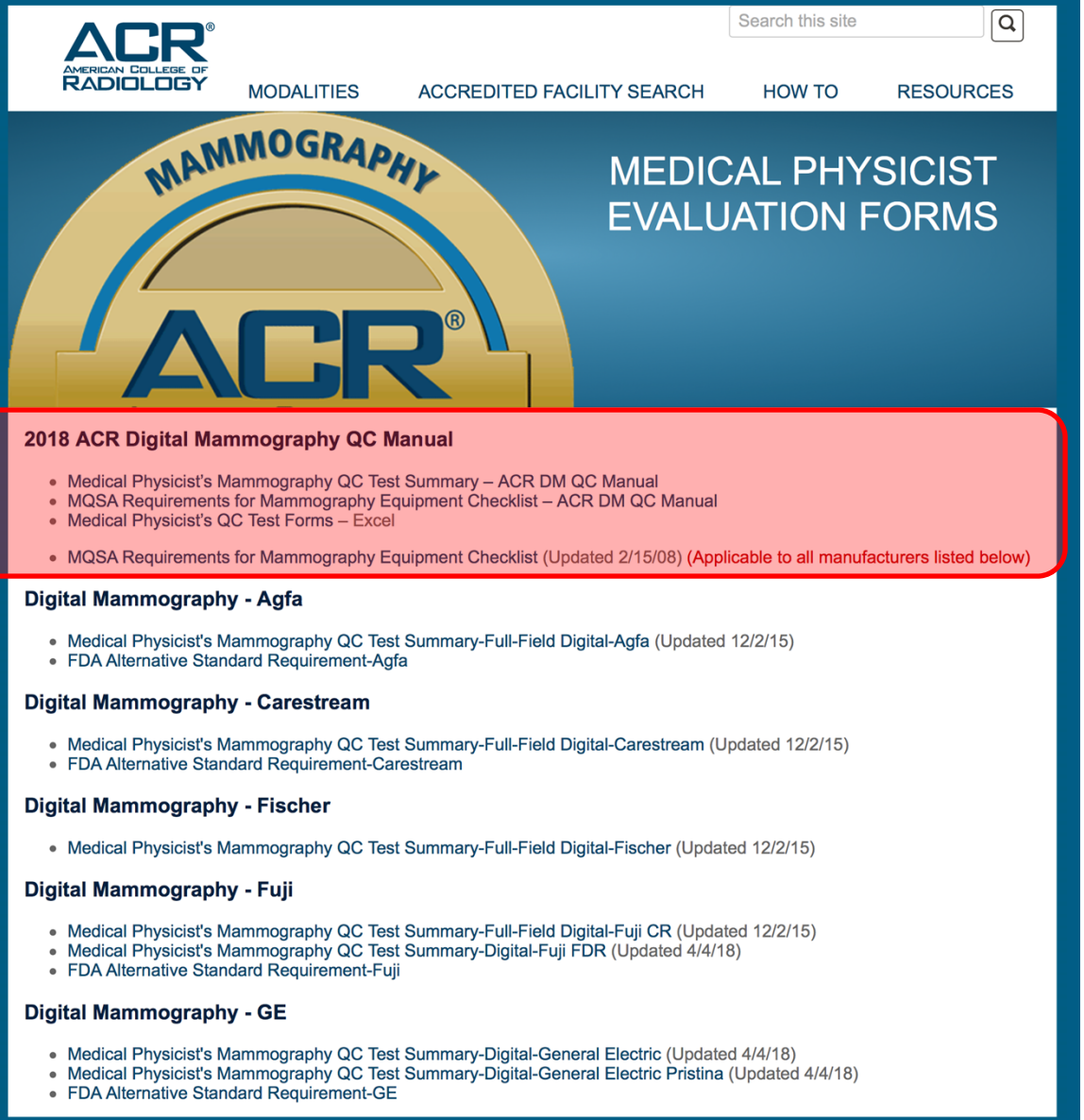
05 | Submit Data/Upload Image

ACR Accreditation requires electronic upload of all accreditation images and documents. Electronic submission reduces costs, ensures compliance with HIPAA regulations and speeds turnaround time from image submission to final results.

- Instructions for Uploading Images **Updated 10-19-18**
- FAQ's Electronic Upload **Updated 11-09-18**

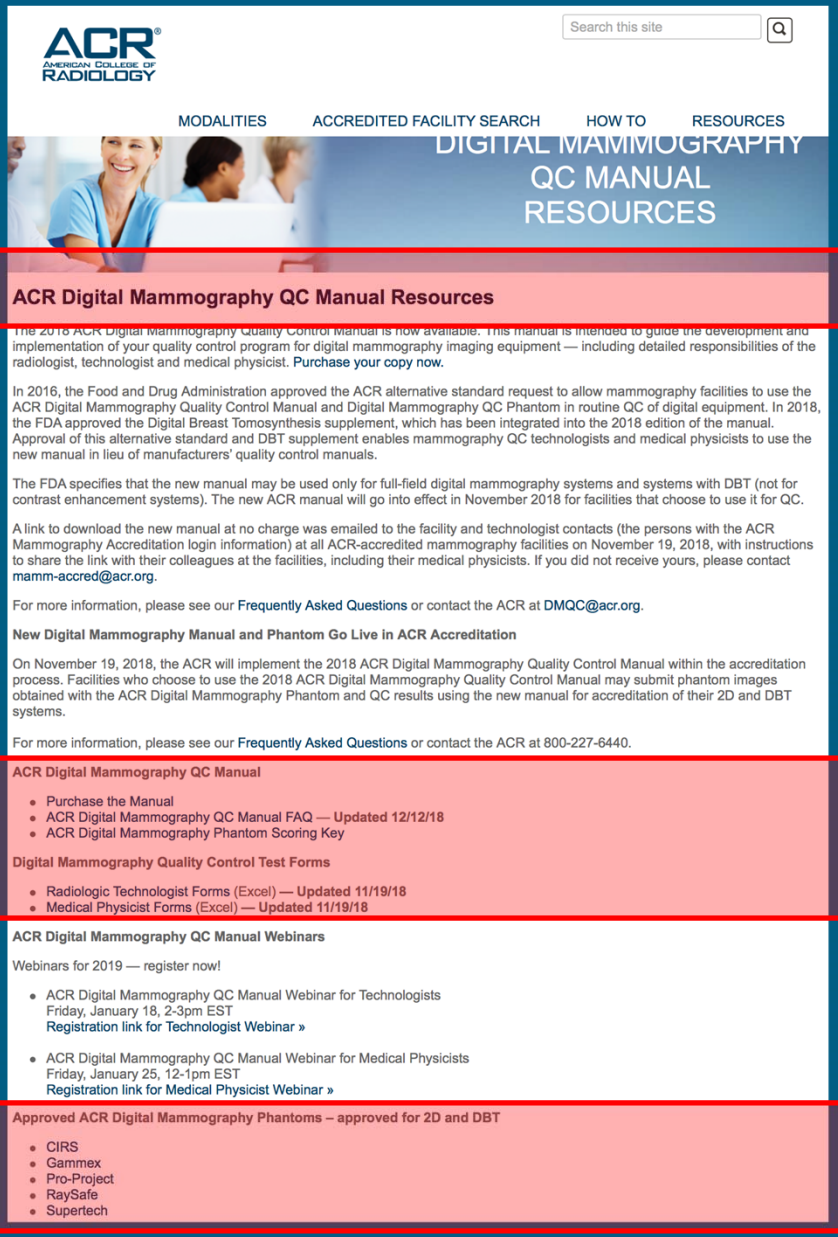
Resources

ACR Mammography Accreditation Website



Resources

ACR Digital Mammography QC Manual Resources webpage



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MODALITIES ACCREDITED FACILITY SEARCH HOW TO RESOURCES

DIGITAL MAMMOGRAPHY QC MANUAL RESOURCES

ACR Digital Mammography QC Manual Resources

The 2018 ACR Digital Mammography Quality Control Manual is now available. This manual is intended to guide the development and implementation of your quality control program for digital mammography 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 ACR Digital Mammography Quality Control Manual and Digital Mammography QC Phantom in routine QC of digital equipment. In 2018, the FDA approved the Digital Breast Tomosynthesis supplement, which has been integrated into the 2018 edition of the manual. Approval of this alternative standard and DBT supplement enables 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 and systems with DBT (not for contrast enhancement systems). The new ACR manual will go into effect in November 2018 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 November 19, 2018, with instructions to share the link with their colleagues at the facilities, including their medical physicists. If you did not receive yours, please contact mamm-accred@acr.org.

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

New Digital Mammography Manual and Phantom Go Live in ACR Accreditation

On November 19, 2018, the ACR will implement the 2018 ACR Digital Mammography Quality Control Manual within the accreditation process. Facilities who choose to use the 2018 ACR Digital Mammography Quality Control Manual may submit phantom images obtained with the ACR Digital Mammography Phantom and QC results using the new manual for accreditation of their 2D and DBT systems.

For more information, please see our Frequently Asked Questions or contact the ACR at 800-227-6440.

ACR Digital Mammography QC Manual

- Purchase the Manual
- ACR Digital Mammography QC Manual FAQ — **Updated 12/12/18**
- ACR Digital Mammography Phantom Scoring Key

Digital Mammography Quality Control Test Forms

- Radiologic Technologist Forms (Excel) — **Updated 11/19/18**
- Medical Physicist Forms (Excel) — **Updated 11/19/18**

ACR Digital Mammography QC Manual Webinars

Webinars for 2019 — register now!

- ACR Digital Mammography QC Manual Webinar for Technologists
  Friday, January 18, 2-3pm EST
  Registration link for Technologist Webinar »
- ACR Digital Mammography QC Manual Webinar for Medical Physicists
  Friday, January 25, 12-1pm EST
  Registration link for Medical Physicist Webinar »

Approved ACR Digital Mammography Phantoms – approved for 2D and DBT

- CIRS
- Gammex
- Pro-Project
- RaySafe
- Supertech

Resources:

- The QC Manual itself – reading the instructions may help!
- The ACR Mammography Accreditation Website
  - In particular, the FAQ's contain all the latest information that are most helpful to facilities
- Training Webinar(s) and handout
- Call the ACR!

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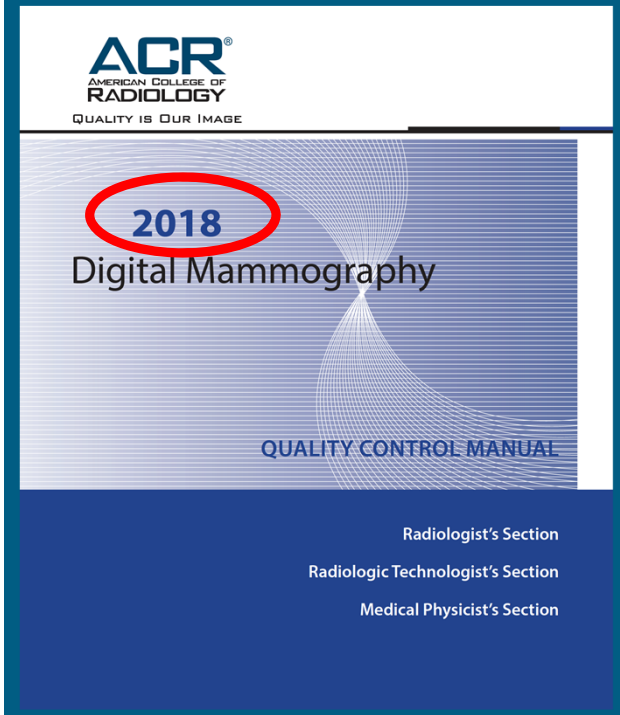
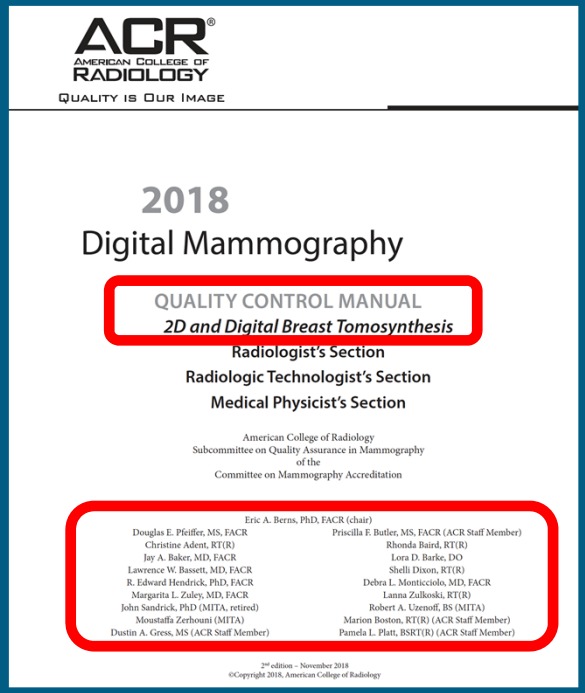
The 2018 ACR Digital Mammography Quality Control Manual





***Link for free download sent to all ACR mammography accredited facilities**

Digital Mammography Quality Control Tests
Medical Physicist's Tests (2D and DBT)

Important: Before a facility may start using the procedures in the ACR Digital Mammography QC Manual for the first time on a unit, the medical physicist must first conduct an annual survey of the digital mammography unit and display devices using the manual and the ACR Digital Mammography Phantom.

Note: *Complete Facility, Unit and Test Equipment Data tab first to populate facility information into forms*

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. DBT Z Resolution	MEE and Annual	Within 30 days
4. Spatial Resolution	MEE and Annual	Within 30 days
5. DBT Volume Coverage	MEE and Annual	Before clinical use
6. Automatic Exposure Control System Performance	MEE and Annual	Within 30 days
7. Average Glandular Dose	MEE and Annual	Before clinical use
8. Unit Checklist	MEE and Annual	Critical: before clinical use; less critical: w/in 30 days
9. Computed Radiography *(if applicable)*	MEE and Annual	Before clinical use
10. Acquisition Workstation (AW) Monitor QC	MEE and Annual	W/in 30 days; before clinical use for severe defects
11. Radiologist Workstation (RW) Monitor QC	MEE and Annual	W/in 30 days; before clinical use for severe defects
12. Film Printer QC *(if applicable)*	MEE and Annual	Before clinical use
13. Evaluation of Site's Technologist QC Program	MEE and Annual	Within 30 days
14. Evaluation of Display Device Technologist QC Program	MEE and Annual	Within 30 days
15. Manufacturer Calibrations *(if applicable)*	MEE and Annual	Before clinical use
16. Collimation Assessment	DBT-MEE and Annual DM-MEE and Troubleshooting	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
Troubleshooting - Ghost Image Evaluation	Troubleshooting	Before clinical use
Troubleshooting - Viewbox Luminance	Troubleshooting	NA

** Corrective action for MEEs must be performed before clinical use.*

Summary Report Forms

Medical Physicist's ACR DM QC Test Summary

Mammography Technique Chart

Medical Physicist QC Letter for the Radiologist

Supplemental Forms

Facility, Unit and Test Equipment Data

QC Equipment List - Medical Physicist

ACR Digital Mammography (DM) Phantom (may use facility's phantom)	Dosimeter
0.1 mm aluminum sheets	Lead sheet or equivalent
Hi-resolution bar pattern - 2 to 10 lp/mm	Photometer to measure luminance
2, 4, 6 and 8 cm thick acrylic, BR-12 or BR-50 sheets	Thin metal ruler (for CR)
kV meter	Coins, ready-pack film, electronic collimation test tools, or equivalent

Table 2. Required Tests for Imaging Modes Used on 2D and DBT Systems

Test	Imaging Modes to Test			
	System Used for Both 2D and DBT Acquisition			System Used for DBT Acquisition Only
	2D	2D w/Add-on DBT Device	DBT	DBT
Technologist Tests				
1. ACR DM Phantom Image Quality	✓*	✓	✓	✓ & 2D*
2. Computed Radiography Cassette Erasure (*if applicable*)	✓*			
3. Compression Thickness Indicator	✓*	✓*		✓*
4. Visual Checklist	✓*	✓	✓	✓
5. Acquisition Workstation Monitor QC	✓*			✓*
6. Radiologist Workstation Monitor QC	✓*			✓*
7. Film Printer QC (*if applicable*)	✓*			✓*
8. Viewbox Cleanliness (*if applicable*)	✓*			✓*
9. Facility QC Review	✓*	✓	✓	✓
10. Compression Force	✓*	✓*		✓*
11. Manufacturer Calibrations (*if applicable*)	✓*	✓	✓	✓
Medical Physicist Tests				
1. Mammography Equipment Evaluation (MEE)	✓*			✓*
2. ACR DM Phantom Image Quality	✓*	✓	✓	✓ & 2D*
3. DBT Z Resolution			✓	✓
4. Spatial Resolution	✓*	✓	✓	✓
5. DBT Volume Coverage			✓	✓
6. Automatic Exposure Control System Performance	✓*	✓	✓	✓
7. Average Glandular Dose	✓*	✓	✓	✓
8. Unit Checklist	✓*	✓	✓	✓
9. Computed Radiography (*if applicable*)	✓*			
10. Acquisition Workstation Monitor QC	✓*			✓*
11. Radiologist Workstation Monitor QC	✓*			✓*
12. Film Printer QC (*if applicable*)	✓*			✓*
13. Evaluation of Site's Technologist QC Program	✓*	✓	✓	✓
14. Evaluation of Display Device Technologist QC Program	✓*			✓*
15. Manufacturer Calibrations (*if applicable*)	✓*	✓	✓	✓
16. Collimation Assessment	✓*	✓*	✓	✓
MEE or Troubleshooting - Beam Quality (Half-Value Layer [HVL]) Assessment	✓*TF			✓*TF
MEE or Troubleshooting - kVp Accuracy and Reproducibility	✓*TF			✓*TF

**Follow the procedures and frequency outlined for 2D QC*

TFHVL and kVp tests must include kVp, target, and filter combinations used for DBT

Tech Tests

Digital Mammography Quality Control Tests
Radiologic Technologist's Tests (2D and DBT)

Important: Before a facility may start using the procedures in the ACR Digital Mammography QC Manual for the first time on a unit, the medical physicist must first conduct an annual survey of the digital mammography unit and display devices using the manual and the ACR Digital Mammography Phantom.

Note: *Complete Facility, Unit and Test Equipment Data tab first to populate facility information into forms*

Test*	Minimum Frequency**	Corrective Action Timeframe***
ACR Digital Mammography Phantom Image Quality	Weekly	Before clinical use
CR Cassette Erasure *(if applicable)*	Weekly	Before clinical use
Compression Thickness Indicator	Monthly	Within 30 days
Visual Checklist	Monthly	Critical: before clinical use; less critical: w/in 30 days
Acquisition Workstation (AW) Monitor QC	Monthly	W/in 30 days; before clinical use for severe defects
Radiologist Workstation (RW) Monitor QC	Monthly	W/in 30 days; before clinical use for severe defects
Film Printer QC *(if applicable)*	Monthly	Before clinical use
Viewbox Cleanliness *(if applicable)*	Monthly	Before clinical use
Facility QC Review	Quarterly	Not applicable
Compression Force	Semiannual	Before clinical use
Manufacturer 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.*

**** Corrective action for MEEs must be performed before clinical use.*

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
- Compression Thickness Indicator - after each move and prior to interpretation
- 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	Scale	Appropriate monitor cleaning materials
Densitometer	Towels	

Table 2. Required Tests for Imaging Modes Used on 2D and DBT Systems

Tech Tests

Test	Imaging Modes to Test			
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5. Acquisition Workstation Monitor QC	✓*			✓*
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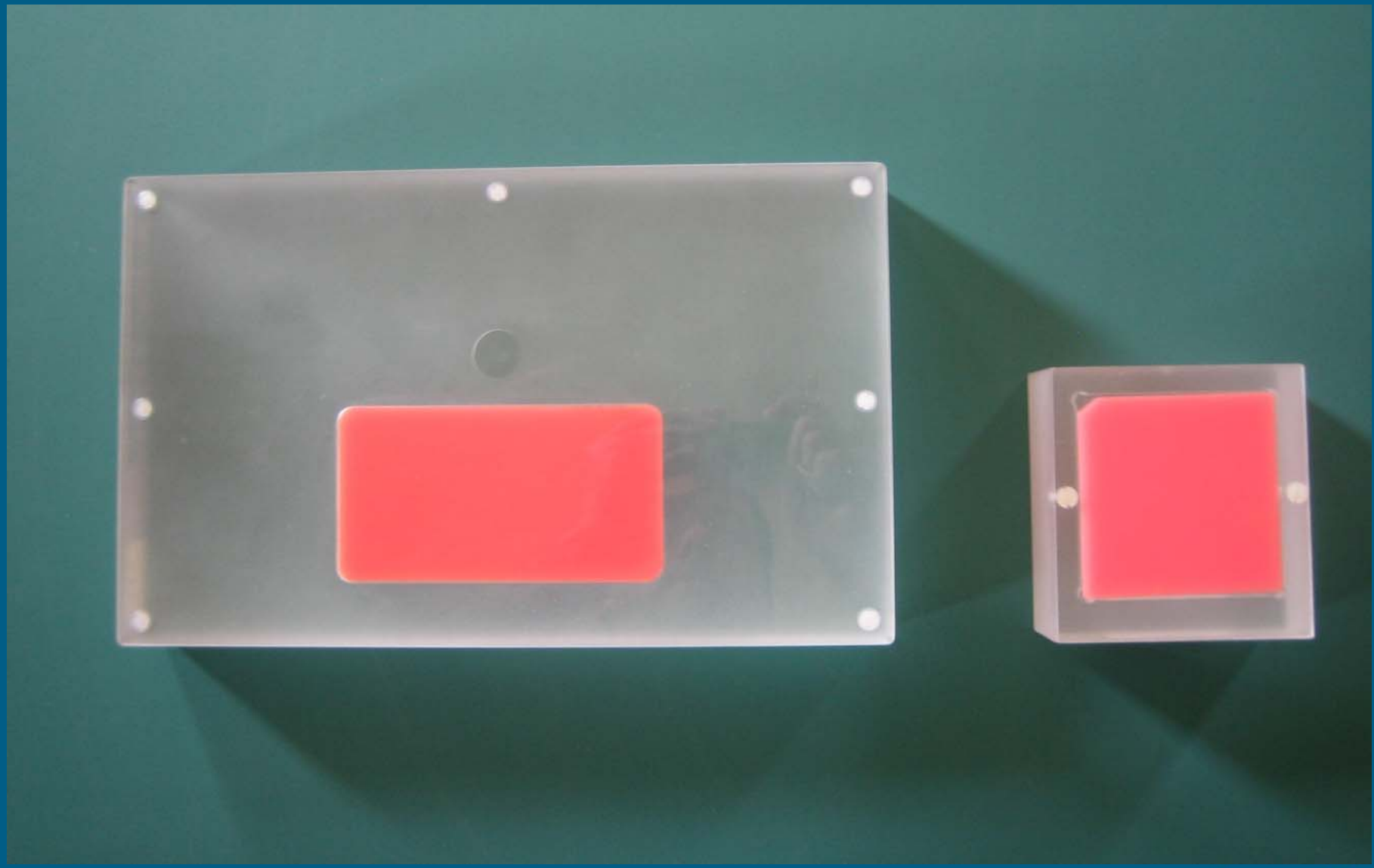
7. Film Printer QC (*if applicable*)	✓*			✓*
8. Viewbox Cleanliness (*if applicable*)	✓*			✓*
9. Facility QC Review	✓*	✓	✓	✓
10. Compression Force	✓*	✓*		✓*
11. Manufacturer Calibrations (*if applicable*)	✓*	✓	✓	✓

**Follow the procedures and frequency outlined for 2D QC*

[TF]HVL and kVp tests must include kVp, target, and filter combinations used for DBT

The ACR DM Phantom



The ACR DM Phantom

***Phantom must be purchased from an approved vendor (listed on the ACR Website)**

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DIGITAL MAMMOGRAPHY QC MANUAL RESOURCES

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ACR Digital Mammography QC Manual

- Purchase the Manual
- ACR Digital Mammography QC Manual FAQ — **Updated 12/12/18**
- ACR Digital Mammography Phantom Scoring Key

Digital Mammography Quality Control Test Forms

- Radiologic Technologist Forms (Excel) — **Updated 11/19/18**
- Medical Physicist Forms (Excel) — **Updated 11/19/18**

ACR Digital Mammography QC Manual Webinars

Webinars for 2019 — register now!

- ACR Digital Mammography QC Manual Webinar for Technologists
  Friday, January 18, 2-3pm EST
  Registration link for Technologist Webinar »
- ACR Digital Mammography QC Manual Webinar for Medical Physicists
  Friday, January 25, 12-1pm EST

Approved ACR Digital Mammography Phantoms – approved for 2D and DBT

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- Gammex
- Pro-Project
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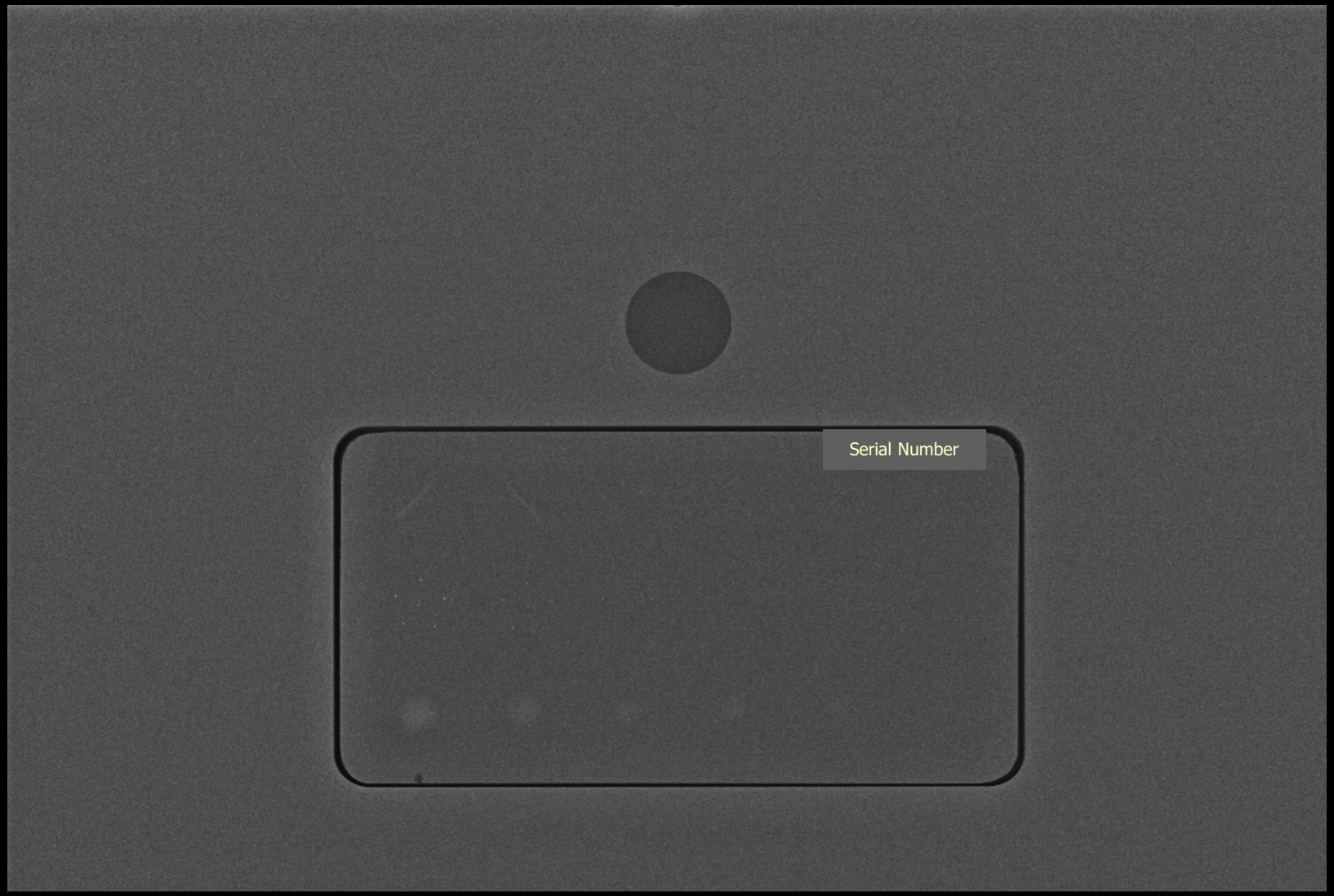

Serial Number

Pass Criteria: 2 Fibers, 3 Specks, 2 Masses

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

Transition – BIG PICTURE

- In order to transition to the new manual, a mammo unit must have an annual physics survey – we'll call this the unit's transition survey.
- Once the mammo unit has its transition survey, it is now in the new QC program and Tech's can begin performing the new ACR DM QC tests.
- The mammo unit's transition survey starts the one-year clock on the display devices requiring their transition surveys.
- Until each display device has a transition survey, it must continue on its existing manufacturer's QC program.
- Upon having its (display device) transition survey, a display device is then in the new QC program and the Tech can begin performing the new ACR DM QC tests.
- Each display device needs to have its transition survey within a year of the mammo unit.
- After each transition survey by the Physicist (for either a unit or display device) the Technologists should begin the ACR DM QC Tests and this date should be noted in the QC books. At this time, Manufacturer QC may be stopped (as ACR QC will be performed going forward).

Transition – Practical Steps (recommendation)

- **1.** Order/buy a phantom (*from and approved vendor*).
- **2.** Organize a meeting with relevant Lead Techs, Facility Managers, Medical Physicists (MP), and Lead Interpreting Physician (LIP) to develop an implementation plan and schedule.
- **3. To begin, an MP must test a unit and/or display device using the ACR QC program BEFORE the Tech can start Tech QC.**
- **4.** After the MP tests a unit and/or display device the tech must start ACR QC (and this date should be documented in the QC book).
- **5.** The ACR does not need to be notified. This information will be reviewed by your MQSA Inspector during your annual inspection(s).
- **6.** For display devices, it's the same process, MP tests using ACR QC, then, Techs follow with ACR QC.
- **7.** After the first unit is tested by the MP, all display devices have 12 months to be tested using the ACR program. In the meantime, facilities should continue with Mfr QC for the displays.
- **8. BIG NOTE: The key to successful transition comes from the initial group meeting where you develop a schedule to make sure each unit and/or display device is having the proper QC methodology being performed (Mfr vs. ACR).**
  - **There may be overlap where you're performing ACR on a unit before a display, or, where it's the display(s) that have been tested before all the units are tested. As long as you have one large DM phantom image acquired from MP testing on a single unit, you can use this phantom for display testing across multiple display devices.**

Transition – Practical Steps

- **One way to transition (an example):**
  - Have MP and Lead Tech(s) meet and train each other on how to perform and document correctly each test (on Units and display devices). This includes determining what kind of unit(s) you have (2D, DBT, Add-on DBT, etc) and which tests need to be performed. Once this is established, it will simplify everything.
  - Have Lead Tech, Manager, and LIP meet to review QC Tests and the new Quarterly QC Review Test. Orient the LIP to the tests and their overall responsibilities of Mammography QC for their facility.
  - Have Tech's start performing ACR QC on selected devices (Unit and RW) for, perhaps 1-3 months before MP does ACR Testing. This would mean you're running parallel Tech testing (Mfr & ACR). Note this is not that burdensome and worth the investment to ensure seamless transition.
  - At the end of Tech ACR QC trial period, have MP and Tech review the documented QC and ensure correct.
  - Have the MP test a Unit for ACR QC. Next day have Tech start (continue) ACR QC on this unit.
  - Document in the QC book the day ACR QC officially starts. (**Note** it must start with MP testing of a unit and/or display device.
- (**Note #2**: this may have to be scaled depending on how many units/RW's/facilities)

Transition – MP Points

- Learn the tests yourself (from the QC Manual)
- Teach the Techs
  - *Reassure* them the ACR DM QC Program will be less time, less burdensome, and why it's an improved program.
  - *Remind* them that once they convert to the ACR DM QC program it will **completely replace** the Mfr QC program(s).
  - *Inform* them of the sequence of transitioning (Unit testing first, then Tech testing follows).
  - *Introduce* the new phantom.
  - *Teach* how to score the new phantom (and that there's no more subtracting for artifacts).
  - *Teach* how to visually evaluate for artifacts.
- Make an overall schedule for all units and displays

Medical Physicist's ACR DM QC Test Summary

Facility Name _____ **MAP ID-Unit#** _____ - _____

Address _____ **Room ID** _____

_____ **Report Date** _____

Survey Date _____

X-Ray Unit Manufacturer _____ **Model** _____

Control Panel Serial # _____ **Manufacture Date** _____ **Installation Date** _____

DM Unit Type: ☐ Digital radiography (DR) ☐ Computed radiography (CR) ☐ Digital Breast Tomosynthesis (DBT)

Unit Use: ☐ Diagnostic and screening mammography ☐ Diagnostic only ☐ Screening only

Survey Type: ☐ Mammography equipment evaluation (MEE) - Full ☐ MEE - Partial ☐ Annual survey

Equipment Tested: ☐ DM unit ☐ AW monitor ☐ RW monitor ☐ Viewbox ☐ Printer Other: _____

Oversight Level: ☐ Medical physicist on-site ☐ Medical physicist oversight

Quality Control Manual Used for Survey and Facility QC: *2018 ACR Digital Mammography QC Manual (with 2D and DBT QC)*

Medical Physicist _____ **Signature** _____

QC Test Results

Test	Pass/Fail* 2D**	2D Add-on DBT	DBT	CA
Medical Physicist Tests				
1. Mammography Equipment Evaluation - MQSA Reqs				
2. ACR DM Phantom Image Quality				
3. DBT Z Resolution				
4. Spatial Resolution				
5. DBT Volume Coverage				
6. Automatic Exposure Control System Performance				
7. Average Glandular Dose				
8. Unit Checklist				
9. Computed Radiography *(if applicable)*				
10. Acquisition Workstation Monitor QC				
11. Radiologist Workstation Monitor QC				
12. Film Printer QC *(if applicable)*				
13. Evaluation of Site's Technologist QC Program				
14. Evaluation of Display Device Technologist QC Program				
15. Manufacturer Calibrations *(if applicable)*				
16. Collimation Assessment				
MEE/Troubleshooting - Beam Quality (HVL) Assessment				
MEE/Troubleshooting - kVp Accuracy and Reproducibility				
Troubleshooting - Ghost Image Evaluation				
Troubleshooting - Viewbox Luminance				
Technologist QC Evaluation				
1. ACR DM Phantom Image Quality				
2. Computed Radiography Cassette Erasure *(if applicable)*				
3. Compression Thickness Indicator				
4. Visual Checklist				
5. Acquisition Workstation Monitor QC				
6. Radiologist Workstation Monitor QC				
7. Film Printer QC *(if applicable)*				
8. Viewbox Cleanliness *(if applicable)*				
9. Facility QC Review				
10. Compression Force				
11. Manufacturer Calibration *(if applicable)*				
Optional - Repeat Analysis				

Your Phantom Results - 2D

Fiber (≥ 2.0) ☐
Speck grp (≥ 3.0) ☐
Mass (≥ 2.0) ☐
AGD (≤ 3.0 mGy) ☐

Your Phantom Results - DBT

Fiber (≥ 2.0) ☐
Speck grp (≥ 3.0) ☐
Mass (≥ 2.0) ☐
AGD (≤ 3.0 mGy) ☐

** "Pass" means all components of test passes; "Fail" means any or all components fail; if "CA" checked, see Corrective Action Summary*
*** or DBT aquistition only*

Medical Physicist's Section

4z. MP FORMS_2018-11-19.xlsx

1. Mammography Equipment Evaluation (MEE)

Facility Name _____ **MAP ID-Unit#** *(00000-00)* _____ - _____

Mfr & Model _____ **Room ID** _____

Survey Date _____

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

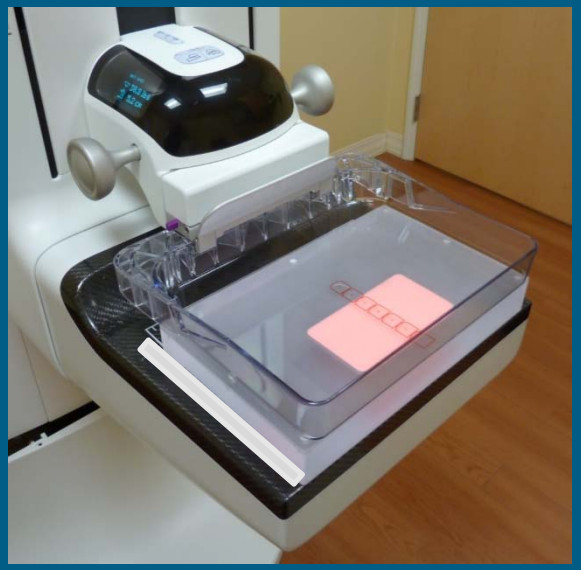
Feature	FDA Rule	Requirement	Meets? Yes/No/NA
Motion of tube-image receptor assembly	3(i)	The assembly shall be capable of being fixed in any position where it is designed to operate. Once fixed in any such position, it shall not undergo unintended motion.	
	3(ii)	This mechanism shall not fail in the event of power interruption.	
Image receptor sizes	4(iii)	Systems used for magnification procedures shall be capable of operation with the grid removed from between the source and image receptor.	
Light fields	5	For any mammography system with a light beam that passes through the X-ray beam-limiting device, the light shall provide an average illumination of not less than 160 lux (15 ft-candles) at 100 cm or the maximum source-image receptor distance (SID), whichever is less.	
Magnification	6(i)	Systems used to perform noninterventional problem-solving procedures shall have radiographic magnification capability available for use by the operator.	
	6(ii)	Systems used for magnification procedures shall provide, at a minimum, at least one magnification value within the range of 1.4 to 2.0.	
Focal spot selection	7(i)	When more than one focal spot is provided, the system shall indicate, prior to exposure, which focal spot is selected.	
	7(ii)	When more than one target material is provided, the system shall indicate, prior to exposure, the preselected target material.	
	7(iii)	When the target material and/or focal spot is selected by a system algorithm that is based on the exposure or on a test exposure, the system shall display, after the exposure, the target material and/or focal spot actually used during the exposure.	
Application of compression	8(i)(A)	Each system shall provide an initial power-driven compression activated by hands-free controls operable from both sides of the patient.	
	8(i)(B)	Each system shall provide fine adjustment compression controls operable from both sides of the patient.	
Compression paddle	8(ii)(A)	Systems shall be equipped with different sized compression paddles that match the sizes of all full-field image receptors provided for the system.	
	8(ii)(B)	Compression paddle shall be flat and parallel to the breast support table and shall not deflect from parallel by more than 1.0 cm at any point on the surface of the compression paddle when compression is applied.	
	8(ii)(C)	Equipment intended by the manufacturer's design to not be flat and parallel to the breast support table during compression shall meet the manufacturer's design specifications and maintenance requirements.	
	8(ii)(D)	Chest wall edge of the compression paddle shall be straight and parallel to the edge of the image receptor.	
	8(ii)(E)	Chest wall edge may be bent upward to allow for patient comfort but shall not appear on the image.	
Technique factor selection and display	9(i)	Manual selection of mAs or at least one of its component parts (mA and/or time) shall be available.	
	9(ii)	The technique factors (kVp and either mA and seconds or mAs) to be used during an exposure shall be indicated before the exposure begins, except when AEC is used, in which case the technique factors that are set prior to the exposure shall be indicated.	
	9(iii)	Following AEC mode use, the system shall indicate the actual kVp and mAs (or mA and time) used during the exposure.	
Lighting**	14	The facility shall make special lights for film illumination, i.e., hot-lights, capable of producing light levels greater than that provided by the view box, available to the interpreting physicians.	
Film masking devices**	15	Film masking devices that can limit the illuminated area to a region equal to or smaller than the exposed portion of the film are available to all interpreting physicians interpreting for the facility.	
Beam quality assessment	*	Must meet the specifications of FDA's Performance Standards for Ionizing Radiation Emitting Products (Part 1020.30)	
kVp accuracy & reproducibility	*	The mean kVp must not differ from the nominal by more than + 5% of the nominal kVp.	
	*	The coefficient of variation must be ≤0.02.	
Collimation assessment	*	If sum of left plus right edge deviations or anterior plus chest edge deviations exceeds 2% of SID, seek service adjustment.	
	*	If X-ray field exceeds image receptor at any side by more than + 2% of SID or if X-ray field falls within image receptor on the chest wall side, seek service adjustment.	
	*	If chest-wall edge of compression paddle is within the image receptor or projects beyond the chest-wall edge of the image receptor by more than 1% of SID, seek service correction.	
		Overall Pass/Fail	

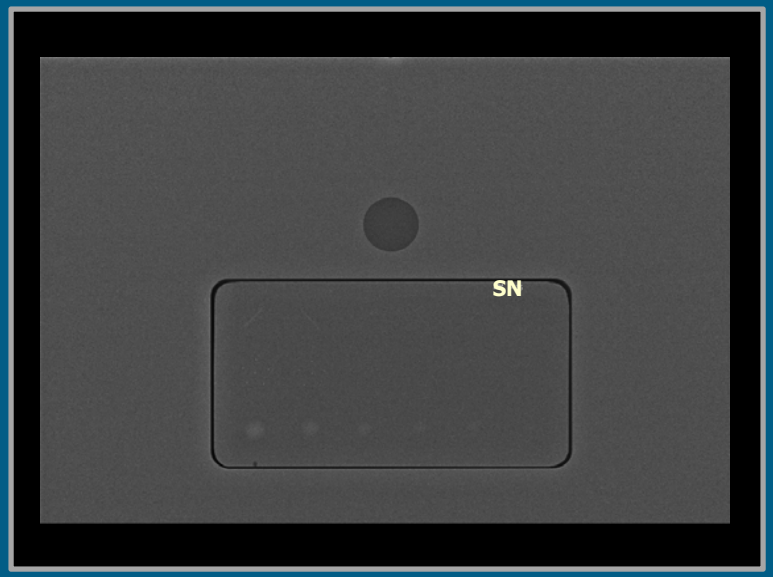
** ACR adoption for MEEs of pertinent sections in FDA Rule 900.12(e)(5) that apply to annual testing of screen-film only*

*** NA is acceptable if 1) no hard copy interpretations are made, 2) no hard copy comparisons are made or 3) for new units at existing facilities if these were previously evaluated and have not changed*

Medical Physicist's Section

Mammo QC Test Forms_Physicists_Excel.xlsx





2. ACR DM Phantom Image Quality

Facility Name Breast Center USA | **MAP ID-Unit#** *(00000-00)* 54321 - 01
Mfr & Model Manf AA Unit BB | **Room ID** Room 1
ACR DM Phantom Mfr and S/N 123-999 | **Survey Date** January 25, 2019

Phantom Setup

Equipment: ACR DM Phantom *(required)*

Follow procedure in the Technologist's ACR Technique & Procedure Summaries:
- Use clinical technique for typical screening exam of 4.2 cm 50/50 breast
- Largest IR & paddle, 5 daN or 12 lbs, score on AW
- Adjust W/L to optimize test objects, zoom & pan entire image

WL _____ WW _____
- For DBT, scroll to best slice/slab to visualize test objects

Slice/slab # _____
Phantom patient name: _____
Phantom patient ID: _____

Phantom Setup:
AEC mode: _____
Paddle size (IR size): _____
Paddle type (reg or flex): _____
View or selected image: _____
Compression force: _____
AEC cell position (if avail): _____
Target/filter (if app): _____ kVp (if app): _____
Density setting (if app): _____
Mag factor (mag mode only): 1.8
Image sent to which PACS? _____

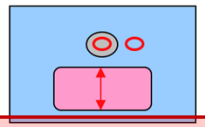
	Image Mode (2D, 2D w/Add-on DBT, DBT)	2D	DBT				Mag Mode 2D
Resulting Techniques *(if available)*	Target/filter	W/Rh	W/Al				
	Image receptor size	L	L				
	kVp	28	29				
	mAs	102.0	49.0				
	Unit-indicated AGD (mGy)	1.25	1.48				
ACR DM Phantom Evaluation	Artifacts P/F	P	P				
	Fiber score	5.0	4.0				
	Speck group score	4.0	4.0				
	Mass score	4.0	4.0				
	Phantom P/F	P	P				
SNR & CNR Raw Image *(does not apply to DBT)*	DC offset *(if applicable)*	50.0					
	Mean cavity signal	336					
	Mean background signal	319.5					
	Std dev of background	5.47					
	Calculated SNR	49.27					
	Calculated CNR	3.02					
	SNR ≥ 40.0 (P/F)	P					
	CNR ≥ 2.0 (P/F)	P					
Distance Measurement	Parallel to A-C axis (mm)	74	74				
	Meas = 70.0 ±14.0 mm (P/F)	P	P				
	Overall Pass/Fail						

CNR from MEE (If avail; does not apply to MEEs) | CNR Lower Limit (85% of MEE) | CNR ≥ -15% of MEE (P/F)

Initiated (or updated) technologist's ACR Technique and Procedure Summaries form _____

Analysis

	Full Point	Half Point
Fibers	≥ 8 mm long	≥5 & <8 mm
Specks	4 - 6 specks	2 - 3 specks
Masses	≥ ¾ border	≥ ½ & < ¾ border



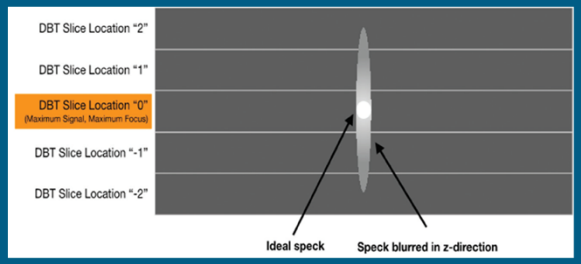
$$SNR = \frac{(Mean\ Bkgd\ Signal - DC\ offset)}{Std\ Dev\ of\ Bkgd}$$

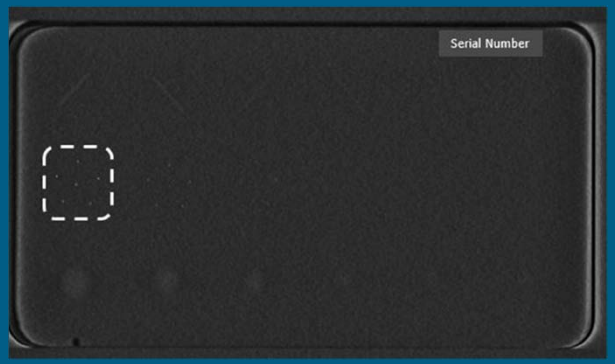
$$CNR = \frac{(Mean\ Cavity\ Signal - Mean\ Bkgd\ Signal)}{Std\ Dev\ of\ Bkgd}$$

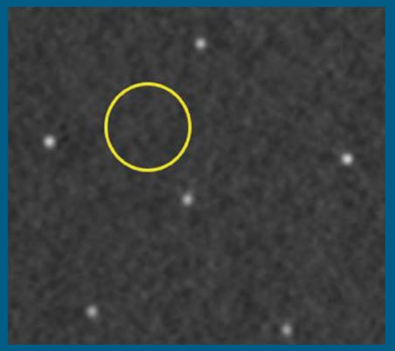
Action Limits

Required: ACR 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.
2D Only - MEE & Annual: SNR must be ≥ 40.0; CNR ≥ 2.0. Annual: CNR must be ≥ 85% of MEE.
Measured wax insert distance must be 70.0 ± 14.0 mm.

Timeframe: Failures of required items must be corrected before clinical use.







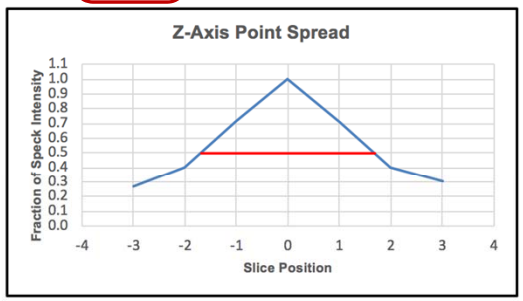
***This test may require evaluation downstream from AW if AW can't provide ROI capabilities**

3. DBT Z Resolution

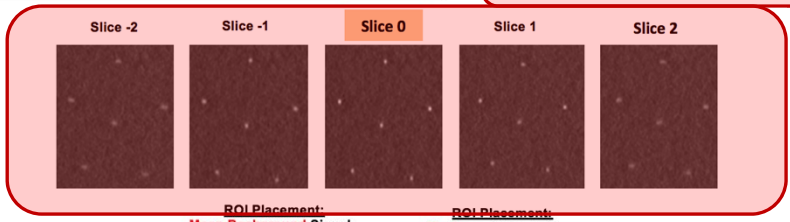
Facility Name Breast Center USA
Mfr & Model Manf AA Unit BB
MAP ID-Unit# *(00000-00)* 54321 - 01
Room ID Room 1
Survey Date January 25, 2019

Procedure
Equipment: DBT image from ACR DM Phantom Image Quality test
MEE Date: 1/20/18
MEE Baseline FWHM: 3.28

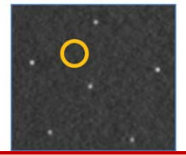
Slice #	Relative Slice Location	Maximum Speck Signal: Center Speck	12:00 Speck	2:00 Speck	5:00 Speck	7:00 Speck	10:00 Speck	Ave Max Signal	Mean Background Signal
	-3	459	442	444	428	433	445	442	373
	-2	470	478	463	473	456	502	474	373
	-1	542	574	539	562	530	583	555	374
	0	549	683	638	651	596	637	626	374
	1	494	596	589	544	532	552	551	373
	2	459	493	491	459	468	475	474	372
	3	445	453	468	440	444	449	450	373



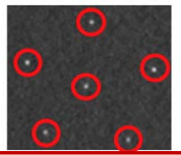
Z-Res Diff (Ave Max - Background Mean)	△ Z-Res Diff relative to DBT Slice 0
68.55	0.27
100.38	0.40
181.43	0.72
252.07	1.00
178.47	0.71
101.92	0.40
76.73	0.30
Current FWHM	3.37 mm
MEE Baseline FWHM	3.28 mm
% Change (Current vs MEE)	2.7%
Overall Pass/Fail	Pass



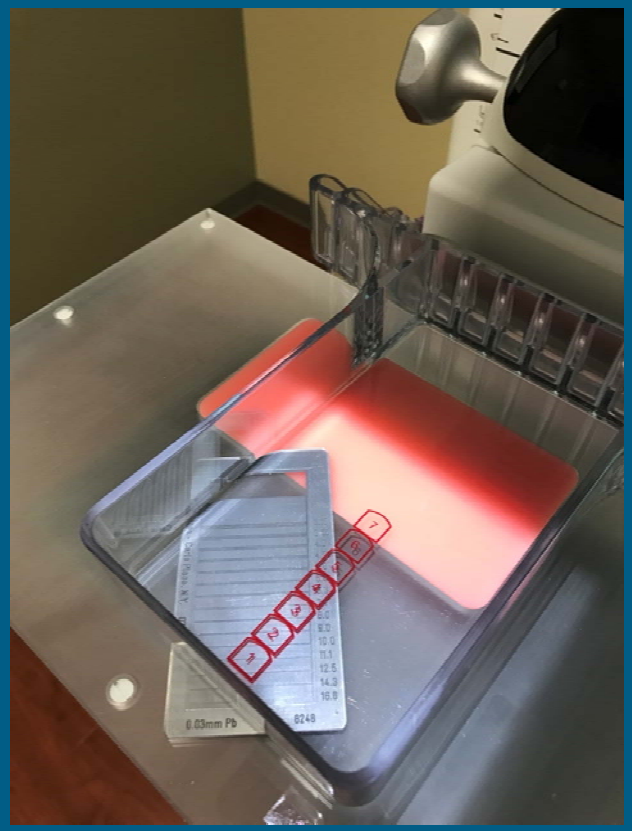
ROI Placement:
Mean Background Signal - Next to Center Speck



ROI Placement:
Maximum Signal - Over Each Speck



Action Limits
Required: Annual Survey: FWHM must be within ±30% of the baseline (MEE) value. MEE: No action limit.
Timeframe: Failures must be corrected within 30 days.



4. Spatial Resolution

Facility Name Breast Center USA
Mfr & Model Manf AA Unit BB
MAP ID-Unit# *(00000-00)* 54321 - 01
Room ID Room 1
Survey Date January 25, 2019

Procedure

Equipment: ACR DM Phantom, line-pair test tool

Place ACR DM Phantom reversed on breast support (wax insert away from chest edge)

Place bar pattern on top of phantom and under paddle at ~45°

Lightly compress paddle to touch bar pattern

Acquire "raw" images using manual mode closest to ACR DM Phantom technique

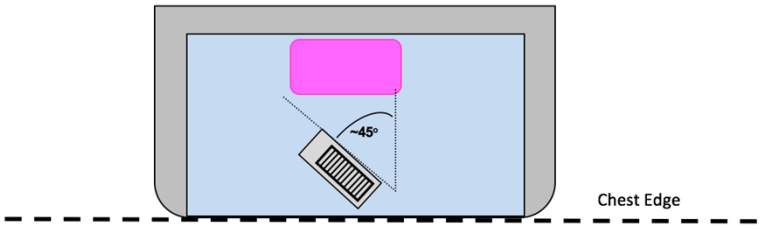
Phantom Setup:
Paddle size (IR size):
Paddle type (reg or flex):

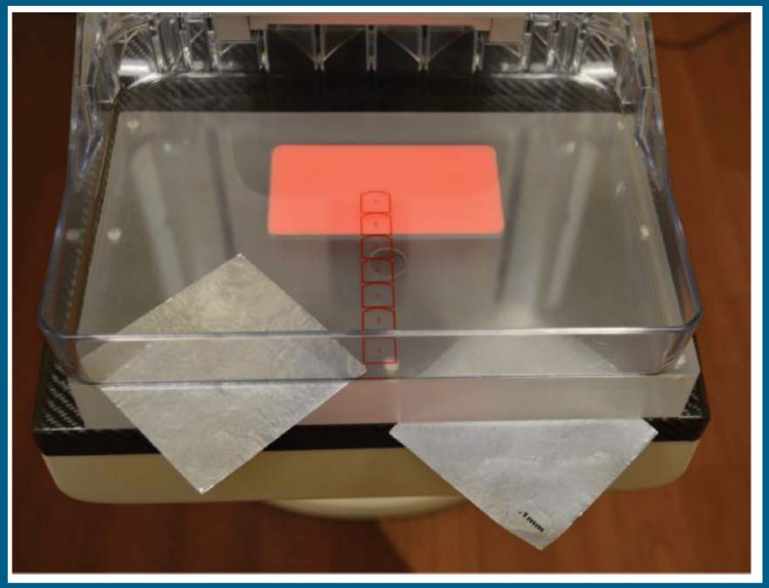
	Image Mode *(2D, 2D w/Add-on DBT, DBT)*	2D	DBT		Mag Mode 2D
Setup Techniques	Mag factor	Contact			1.8
	Target/filter	W/Rh	W/Al		W/Rh
	kVp	28	28		28
	mAs	100	50		45
Spatial Resolution Score	Line-pair score	8.0	4.0		8.0
	Overall Pass/Fail	**Pass**	**Pass**		**Pass**

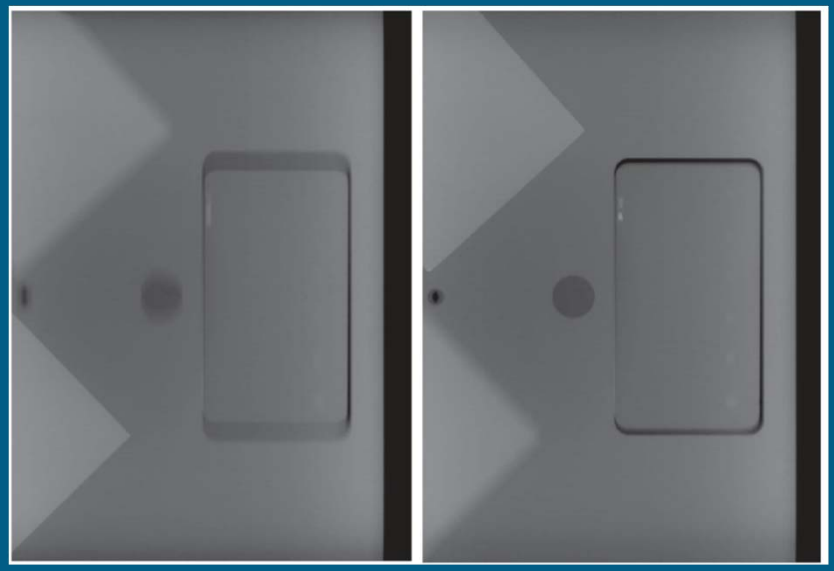
Action Limits

Required: For 2D, spatial resolution must be ≥ 4.0 lp/mm for contact mode and 6.0 lp/mm for magnification mode.
For DBT, spatial resolution must be ≥ 2.0 lp/mm for contact mode.

Timeframe: Failures must be corrected within 30 days; for MEEs, before clinical use.







5. DBT Volume Coverage

Facility Name	Breast Center USA	**MAP ID-Unit#** *(00000-00)*	54321 - 01
Mfr & Model	Manf AA Unit BB	**Room ID**	Room 1
		Survey Date	January 25, 2019

Procedure	**Equipment:** ACR DM Phantom, 2 sheets of 0.1 mm Al	**Phantom Setup:**
	Place ACR DM Phantom on breast support in the usual position	Paddle size (IR size):
	Place Al sheets on top and bottom of DM phantom, diagonally across chest wall	Paddle type (reg or flex):
	Acquire DBT image of phantom	
	View reconstructed image and verify that both Al sheets are in focus within the volume	

		Contact Mode
Setup Techniques	Mag factor	Contact
	Target/filter	W/Ag
	kVp	28
	mAs	102
Results (Yes/No/NA)	Lower Al sheet in focus within the volume	Yes
	Upper Al sheet in focus within the volume	Yes
	Overall Pass/Fail	**Pass**

Action Limits	**Required:**	Both sheets must be focused in volume
	Timeframe:	Failures must be corrected before clinical use.

6. Automatic Exposure Control System Performance

Image Mode *(2D, 2D w/Add-on DBT, DBT)*: 2D

Facility Name: Breast Center USA
Mfr & Model: Manf AA Unit BB
MAP ID-Unit# *(00000-00)*: 54321 - 01
Room ID: Room 1
Survey Date: January 25, 2019

Procedure

Equipment: 2, 4, 6, 8 cm of BR-12, BR-50 or acrylic
Install small paddle (reg or flex) (Use large if small not available)
Use regular or flex paddle used for most clinical imaging
Set thickness at actual thickness of phantom (2, 4, or 6 cm)
Acquire images using clinical techniques
SNR data must be obtained from raw image
Magnification stand, if used clinically for 2D

Phantom Setup:
Paddle size (IR Size):
Paddle type (reg or flex):
AEC cell position (if avail):
Mag setting: 1.8
Mfr DC offset, if app: 50.000
Other settings:

AEC Thickness Tracking

		Setup Techniques		Resultant Techniques				Signal and Noise Measurements			
Mode	Thick-ness (cm)	AEC Mode	Density setting	Target/ Filter	kVp	mAs	Other	Mean Bkgd Signal	Std Dev of Bkgd	DC Offset (if app)	SNR
Contact	2	Auto-Filter	**	W/Rh	25	49		320.00	4.50	50.00	60.00
Contact	4	Auto-Filter	**	W/Rh	28	85		332.00	4.90	50.00	57.55
Contact	6	Auto-Filter	**	W/Rh	31	192		365.00	5.10	50.00	61.76
Contact	8	Auto-Filter	**	W/Ag	32	237		550.00	5.30	50.00	94.34
Mag*	4	Auto-Filter	**	W/Rh	29	94		450.00	4.20	50.00	95.24

*2D only

Analysis

$$SNR = \frac{(Mean\ Bkgd\ Signal - DC\ offset)}{Std\ Dev\ of\ Bkgd}$$

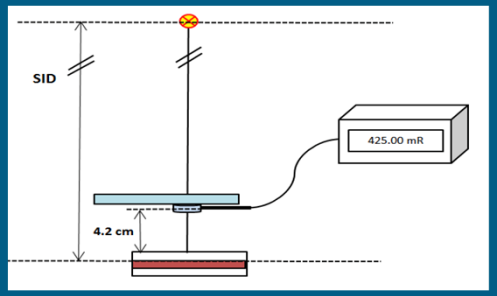
			MEE and Annual		Annual			
Mode	Thick-ness (cm)	SNR	Lowest Limit for SNR	Pass/Fail	MEE SNR	Lower Limit	Upper Limit	SNR within ±15% of MEE (P/F)
Contact	2	60.0			58.0	49.3	66.7	P
Contact	4	57.6	40.0	P	61.0	51.9	70.2	P
Contact	6	61.8			63.0	53.6	72.5	P
Contact	8	94.3			96.0	81.6	110.4	P
Mag*	4	95.2			92.0	78.2	105.8	P
*2D only							Overall Pass/Fail	Pass

Action Limits

Required: MEE and Annual: SNR must be ≥ 40.0 for 4.0 cm in contact mode.
Annual: SNR must be within ±15% of MEE over the clinically used phantom thickness and imaging modes.

Timeframe: Failures must be corrected within 30 days; for MEEs, before clinical use.

*This test may require evaluation downstream from AW if AW can't provide ROI capabilities



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.

7. Average Glandular Dose

Facility Name	Breast Center USA	**MAP ID-Unit#** *(00000-00)*	54321 - 01
Mfr & Model	Manf AA Unit BB	**Room ID**	Room 1
ACR DM Phantom Mfr & S/N	123-999	**Survey Date**	January 25, 2019

Procedure	**Equipment:** Dosimeter	Dosimetry system:	Dosimeter Mfr/Mod
	ACR DM Phantom	Calibration date:	1/1/19
	Use the technique from the ACR DM Phantom image page.	Correction factor, if app:	1
	Measure mR/mAs or total exposure for dose calculation(s).	SID (cm):	70
	Make exposure measurements at 4.2 cm		

	Imaging Mode *(2D, 2D w/Add-on DBT, DBT)*	**2D**	**DBT**			
Technique Factors Resulting From ACR DM Phantom Acquisition	ACR DM Phantom equivalent breast thickness (cm)	4.2	4.2			
	ACR DM Phantom material	Acrylic	Acrylic			
	AEC mode	Auto Filter	Auto Filter			
	Target/filter	W/Rh	W/Al			
	kVp	28	29			
	mAs	104	51			
Exposure Data (at skin surface)	Measured HVL (mm Al)	0.541	0.518			
	mAs setting for manual exposure measurement	100.0	100.0			
	Exposure #1 (mR)	472.0	1062.0			
	Exposure #2 (mR)	472.0	1062.0			
	Exposure #3 (mR)	472.0	1062.0			
	Average exposure (mR)	472.0	1062.0			
	Exposure/mAs at skin entrance (mR/mAs)	4.7	10.6			
	Total exposure (mR)	490.9	541.6			
AGD Calculation D = Kgcs	Average entrance exposure - K (mR)	490.9	541.6			
	g-factor x c-factor x (8.76 mGy/R)	2.660	2.551	0.000	0.000	0.000
	s-factor	1.042	1.082			
	Computed AGD (mGy)	1.36	1.50			
AGD Result	**Pass/Fail**	**Pass**	**Pass**			
Indicated vs. Calculated AGD *(if avail)*	Unit-indicated AGD from DM Phantom image (mGy)	1.39	1.52			
	% Difference	**2.2%**	**1.7%**			
	Indicated within ±25% of measured?	**Pass**	**Pass**			

Action Limits	**Required:**	AGD for a single cranio-caudal view of the ACR DM Phantom in either 2D or DBT mode 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.

8. Unit Checklist

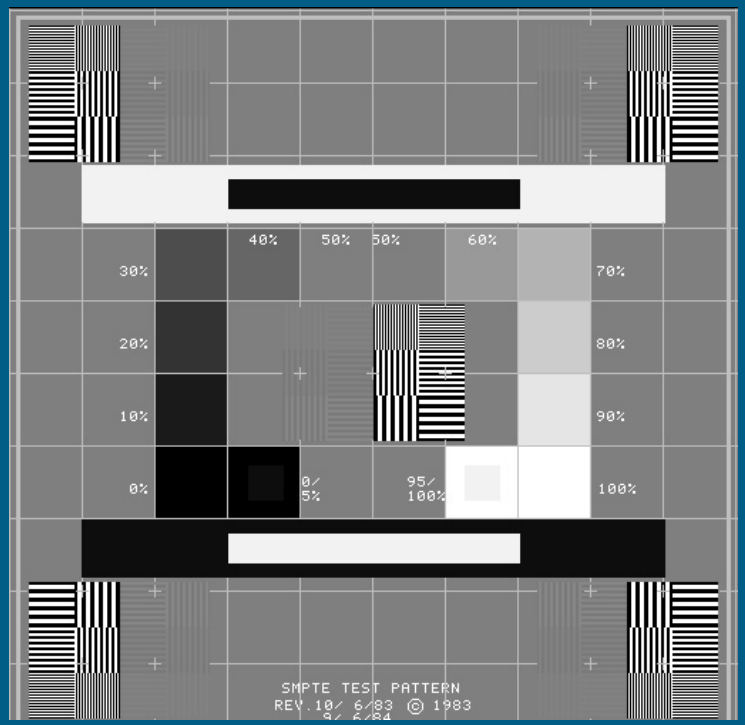
Facility Name Breast Center USA
Mfr & Model Manf AA Unit BB
MAP ID-Unit# *(00000-00)* 54321 - 01
Room ID Room 1
Survey Date January 25, 2019

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 (if applicable).	
6. Image receptor is held securely by assembly in any orientation (if applicable).*	
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. Autodecompression 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. DBT assembly moves as designed through its range of motion.*	
16. Operator technique charts are current and posted.	
17. Other:	
18. Other:	
19. Other:	
20. 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.

10. *Acquisition Workstation (AW) Monitor QC*

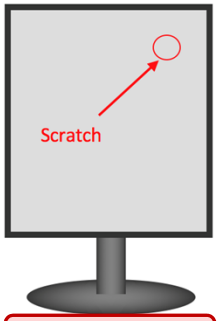


Facility Name	ACR Webinar	**MAP ID-Unit#** *(00000-00)*	99999 - 01
Mfr & Model	Unit Mfr A Unit Model ABC	**Room ID**	Room 1
Medical Physicist	MP Name Jane Doe	**Survey Date**	December 6, 2016
Signature			

Procedure	**Equipment:** Luminance meter **Note:** Some of these QC tests may or may not be possible to perform depending on the monitor QC capabilities Test Pattern Image Quality: Use TG18-QC, SMPTE or other relevant pattern (if available) Luminance Check: TG 18 LN8-01 & LN8-18 test patterns, or others that provide measure of L_{min} & L_{max} (if available)

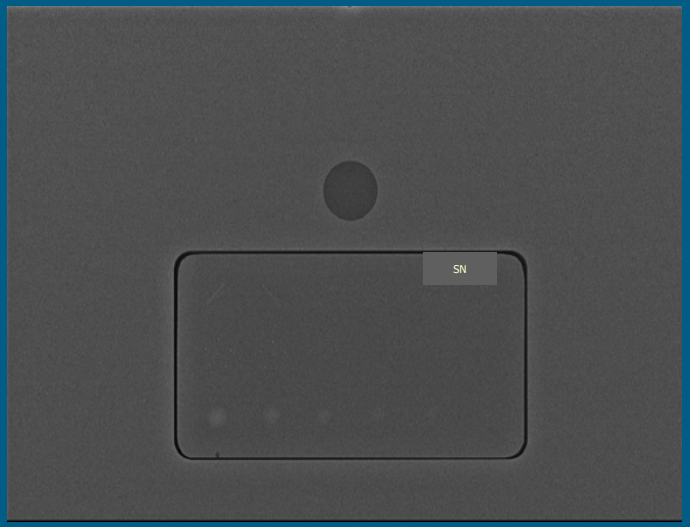
Monitor manufacturer:	**Model:**	Monitor Model A
	Monitor serial number	321
	Monitor date of manufacture	12/1/16
Monitor Condition	Significant findings P/F	F
Test Pattern Image Quality *(if available)*	Test pattern centered appropriately?	Yes
	0%-5% contrast boxes visible?	Yes
	95%-100% contrast boxes visible?	Yes
	Alphanumerics sharp and legible?	Yes
	3 "Quality Control" patches visible (TG18)?	NA
	Line-pair images distinct (center)?	Yes
	Line-pair images distinct (corners)?	Yes
	Grayscale ramps smooth *(if avail)* ?	Yes
	Test pattern P/F	Pass
Luminance Check *(if available)*	Measured Luminance minimum (cd/m^2)	NA
	Mfr recommendation for L_{min} *(if avail)*	NA
	L_{min} meets mfr recommendation ±30%?	NA
	Measured Luminance maximum (cd/m^2)	NA
	Mfr recommendation for L_{max} *(if avail)*	NA
	L_{max} meets mfr recommendation ±10%?	NA
	Luminance check P/F	NA
DICOM GSDF	W/in ±10% of targeted contrast response P/F *(if avail)*	NA
Mfr Automated Test	Most recent set of mfr automated tests P/F	NA
	Overall Pass/Fail	Fail

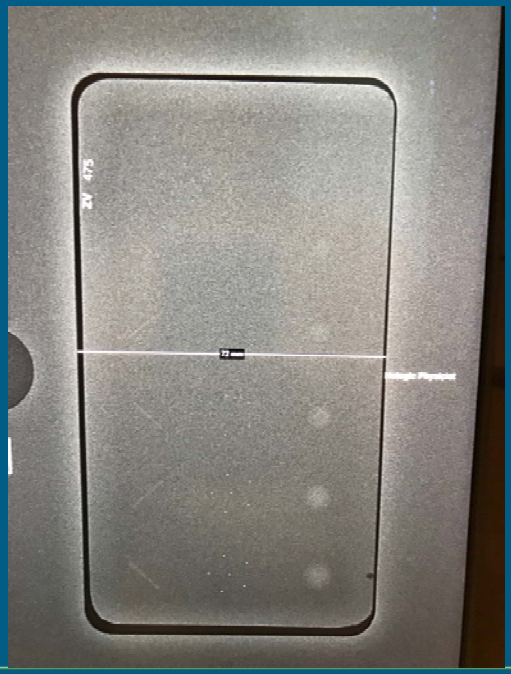
Significant findings indicated on figure below



Luminance Uniformity	
Center	NA
Upper Left	NA
Upper Right	NA
Lower Left	NA
Lower Right	NA
Max	
Min	
% Diff	
P/F	NA

Action Limits	**Required:**	Any identified screen blemish that could interfere with clinical information must be removed. Test pattern image quality must pass all visual tests. L_{min} must be within ±30% of mfr specifications (or, if not available ≤1.5 cd/m^2). L_{max} must be within ±10% of mfr specifications (or, if not available ≥150 cd/m^2). Luminance uniformity must be ≤30% GSDF measured contrast response must be within ±10% of targeted contrast response. Mfr's automated tests must pass mfr specifications (if 1 test fails, indicate "F").
	Timeframe:	Significant monitor cleanliness defects must be corrected before clinical use; all other required tests must be corrected within 30 days.





11. *Radiologist Workstation (RW) Monitor QC*

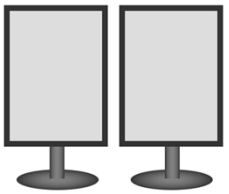
Facility Name	ACR Webinar	**MAP ID-Unit#** *(00000-00)*	99999 - 01
Workstation ID	Workstation #1	**Survey Date**	December 6, 2016
Medical Physicist	MP Name Jane Doe	**Signature**	

Procedure

Equipment: ACR DM Phantom Image, luminance meter
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
Test Pattern Image Quality: Use TG18-QC, SMPTE or other relevant pattern
Luminance: TG 18 LN8-01, LN8-18 & TG 18 UNL80 test patterns or other relevant test patterns

		Monitor manufacturer: / Model:	Left*	Right*
		Monitor serial number	100230	100231
		Monitor date of manufacture	12/1/16	1/1/16
Ambient Light		Are ambient light conditions adequate for DM?	Yes	
Monitor Condition		Significant findings P/F	P	P
ACR DM Phantom Evaluation		Artifacts P/F	P	P
		Fiber score	5.0	5.0
		Speck group score	4.5	4.5
		Mass score	4.0	4.0
		Phantom P/F	P	P
Distance Measurement		Parallel to A-C axis (mm)	72.0	72.0
		Meas = 70.0 ±14.0 mm (P/F)	P	P
Test Pattern Image Quality		Test pattern centered appropriately?	Yes	Yes
		0%-5% contrast boxes visible?	Yes	Yes
		95%-100% contrast boxes visible?	Yes	Yes
		Alphanumerics sharp and legible?	Yes	Yes
		3 "Quality Control" patches visible (TG18)?	Yes	Yes
		Line-pair images distinct (center)?	Yes	Yes
		Line-pair images distinct (corners)?	Yes	Yes
		Grayscale ramps smooth?	Yes	Yes
		Test pattern P/F	P	P
Luminance Check		Measured Luminance minimum (cd/m^2)	0.75	0.09
		Mfr recommendation for L_{min} *(if avail)*	1.0	1.0
		L_{min} meets mfr recommendation ±30%?	P	F
		Measured Luminance maximum (cd/m^2)	502.3	495.3
		Mfr recommendation for L_{max} *(if avail)*	500	500
		L_{max} meets mfr recommendation ±10%?	P	P
		Luminance check P/F	P	P
DICOM GSDF *(if avail)*		W/in ±10% of targeted contrast response P/F	P	P
Mfr Automated Test		Most recent set of mfr automated tests P/F	P	P
		Overall Pass/Fail	**Pass**	**Pass**

Significant findings indicated on figures below



**Left and right monitors; complete additional forms if more than 2 monitors used*

Luminance Uniformity

Monitor	Left	Right
Center	425.0	433.0
Upper L	432.0	415.0
Upper R	444.0	455.0
Lower L	420.0	446.0
Lower R	415.0	435.0
Max	444.0	455.0
Min	415.0	415.0
% Diff	6.8	9.2
P/F	P	P

Luminance Matching

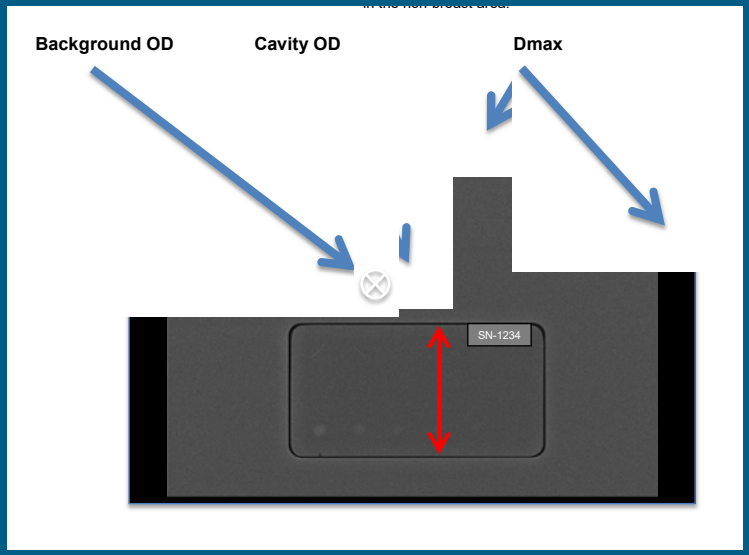
P/F	P

Action Limits

Required:
- Any identified monitor blemish that could interfere with clinical information must be removed.
- ACR 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 ±14.0 mm.
- Test pattern image quality must pass all visual tests.
- L_{min} must be within ±30% of mfr specifications (or, if not available ≤1.5 cd/m^2).
- L_{max} must be within ±10% of mfr specifications (or, if not available ≥420 cd/m^2).
- Luminance uniformity must be ≤30%; luminance matching must be ≤20%.
- GSDF measured contrast response must be within ±10% of targeted contrast response.
- Mfr's automated tests must pass mfr specifications (if 1 test fails, indicate "F").

Recommended:
- Ambient light conditions should be appropriate for mammography; max of 45 lux is recommended.

Timeframe:
- Phantom must pass and significant monitor cleanliness defects must be corrected before clinical use; all other required tests must be corrected within 30 days.



12. *Film Printer QC (if applicable)*

Facility Name	ACR Webinar	**MAP ID-Unit#** *(00000-00)*	99999 - 01
Printer ID	Printer #1	**Survey Date**	December 6, 2016
Medical Physicist	MP Name Jane Doe	**Signature**	

Procedure

Applicability: If film printer is used clinically for mammography (i.e., for interpretation and to provide images to referring physicians and patients)

Equipment: Densitometer

Print an ACR DM Phantom image acquired from any DM unit within facility network, preferably one MP has just acquired.

Do not change window/level settings from acquired image prior to printing.

Print the phantom image from the workstation/computer typically used to print clinical films.

Dmax should be measured either at extreme left or right edge of film or at extreme non-chest wall edge.

Film Printer Manufacturer	Kodak	**Film Printer Serial Number**	1235695
Film Printer Model	8900	**Film Printer Date of Manufacture**	12/1/05
Workstation for printing	Tech Workstation #3	**DM ID or workstation ID**	Room 1

		Film size	**8 x 10**	
ACR DM Phantom		Artifacts P/F	P	
		Fiber score	5.0	
		Speck group score	4.5	
		Mass score	4.0	
		Phantom P/F	P	
Back-ground		Bkgd OD *(Outside cavity)*	1.85	
		Bkgd OD ≥ 1.6 (P/F)	P	
Contrast		Cavity OD	2.10	
		Bkgd OD *(use value from above)*	1.85	
		Contrast = Cavity OD - Bkgd OD	0.25	
		Contrast ≥0.1 (P/F)	P	
Dmax		D_{max} OD	3.75	
		D_{max} OD ≥3.1 (P/F)	P	
Distance Measurement		Parallel to A-C axis (mm)	72.0	
		Meas = 70.0 ±14.0 mm (P/F)	P	
		Overall Pass/Fail	**Pass**	

Action Limits

Required: ACR 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.

Background OD must be ≥1.6 (1.7 to 2.2 is recommended; approx 2.0 is optimal).

Contrast (Cavity OD - Background OD) must be ≥0.1.

D_{max} must be ≥3.1 (≥3.5 is recommended).

Measured distance of wax insert must be 70.0 ±14.0 mm.

Timeframe: Failures of required items must be corrected before printing of clinical images.

13. Evaluation of Site's Technologist QC Program

Facility Name Breast Center USA
Mfr & Model Manf AA Unit BB
MAP ID-Unit# *(00000-00)* 54321 - 01
Room ID Room 1
Survey Date January 25, 2019

Radiologic Technologist's Quality Control Tests	Frequency	Test Performed, Analyzed & Documented	Missing Data	Incorrect Scoring or Calculations	Missing Corrective Action Documentation	Other	Comments
1. ACR DM Phantom Image Quality	Weekly	✓					
			Tech Score		MP Score		
Medical physicist comparison scores of latest phantom image:	Fiber		5.0		5.0		
	Speck group		4.0		4.0		
	Mass		4.0		4.0		
	Artifacts		P		P		
2. CR Cassette Erasure *(if app)*	Weekly						
3. Comp Thickness Indicator	Monthly	✓					
4. Visual Checklist	Monthly	✓					
5. AW Monitor QC	Monthly	✓					
9. Facility QC Review	Quarterly	✓					
10. Compression Force	Semiannual	✓					
11. Mfr Calibrations *(if app)*							
Optional - Repeat Analysis	As Needed						
Optional - System QC for Radiologist	NA						
Optional - Radiologist IQ Feedback	NA						
Corrective Action Log documentation adequate?	Yes						

Overall Pass/Fail for Performance of Technologist QC Program Pass

Additional Comments:

Action Limits		
	Required:	MQSA regulations [FDA Rule 900.12(d)(1)(iii) 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 a) no significant missing data, b) the tests must be analyzed without gross errors, and c) appropriate corrective action for failures must be taken (and documented). See test procedures for more information.
	Timeframe:	Failures must be corrected within 30 days.

14. *Evaluation of Display Device Technologist QC Program*

Facility Name	ACR Webinar	**MAP ID-Unit#** *(00000-00)*	99999 - 01
Medical Physicist	MP Name Jane Doe	**Display Device Location**	Outpatient Reading Center - Smith Street
Signature		**Survey Date**	December 6, 2016

Display Device ID & Room	Display Device Description (RW, Printer, Viewbox)	Test Performed, Analyzed & Documented Incorrectly	Missing Data	Incorrect Scoring or Calculations	Missing Corrective Action Documentation	Mfr Automated Tests (if Applicable)	Other	Comments	P/F
Example: Mammography reading room	RW	✓	✓	✓	✓			Discussed with manager	P
Workstation 1	RW	✓							P
Workstation 2	RW	✓							P
Workstation 3	RW	✓							P
Laser Printer - Basement File Room	Printer	✓							P
Corrective Action Log documentation adequate?	Yes								
								Overall Pass/Fail for Performance of Display Device Technologist QC Program	**Pass**

Additional Comments:

Action Limits	**Required:**	MQSA regulations [FDA Rule 900.12(d)(1)(iii) 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 a) no significant missing data, b) the tests must be analyzed without gross errors, and c) appropriate corrective action for failures must be taken (and documented). See test procedures for more information.
	Timeframe:	Failures must be corrected within 30 days.

Major Component Service, Upgrade, Replacement & Repair

Item	Component	Major Repair	Medical Physicist Involvement
Automatic Exposure Control (AEC)	***AEC replacement***	***Y***	***On-site***
	AEC recalibration that effects dose	***Y***	***On-site***
	AEC sensor replacement	***Y***	***On-site***
	AEC circuit board replacement	***Y***	***On-site***
	Density control - internal adjustment*	N	Oversight
	Thickness compensation internal* adjustment	N	Oversight
Bucky Replacement	***AEC sensor also replace***	***Y***	***On-site***
	AEC sensor not replaced	N	Oversight
	DM detector also replaced	***Y***	***On-site***
	DM detector not replaced	N	Oversight
Collimator	***Replacement***	***Y***	***On-site***
	Reassembly with blade replacement	***Y***	***On-site***
	Adjustment	N	Oversight
Compression Device	Pressure adjustment	N	Optional
	Thickness scale accuracy adjustment but only if it affects AEC performance	N	Oversight
	Repair of auto decompression	N	Optional
Compression Paddle	Paddle (new to facility)	N	Oversight
	Deflection adjustment	N	Oversight
	Adjustment due to extension beyond allowable limit, or visible on images	N	Oversight
X-ray Unit	***Installation***	***Y***	***On-site***
	Reassembly	***Y***	***On-site***
	X-ray tube replacement	***Y***	***On-site***
	High voltage generator replacement	***Y***	***On-site***
	Filter replacement	***Y***	***On-site***
	Manufacturer's software upgrade or modifications	***Y***	***On-site***
	DM detector replacement or repair	***Y***	***On-site***
	kVp, mA or time internal* adjustments	N	Oversight
Display Devices	***New installation or replacement***	***Y***	***On-site***
	New video card or software upgrade	***Y***	***On-site***
	Relocation	N	Oversight
Computed Radiography (CR) and Photostimulable Phosphor (PSP) Plates	***New installation or replacement of CR reader***	***Y***	***On-site***
	Replacement of all PSP plates	***Y***	***On-site***
	One or 2 new PSP plates	N	Oversight

**Internal adjustments refer to equipment adjustments that typically cannot be made by the operator.*

Mammography Technique Chart

Image Mode *(2D, 2D w/Add-on DBT, DBT)*

Facility Name Breast Center USA
Mfr & Model Manf AA Unit BB
MAP ID-Unit# *(00000-00)* 54321 - 01
Room ID Room 1
Survey Date January 25, 2019

Screening/Diagnostic Digital Mammography

Compressed Breast Thickness	50% Fatty - 50% Dense Breast		
	AEC Mode	Target/Filter	kVp
< 3 cm			
3 to 5 cm			
5 to 7 cm			
> 7 cm			

Implant Displaced Mammography Views (Manual Technique)

Breast Size	Target/Filter	kVp	mAs
Small			
Medium			
Large			

ACR DM Phantom Technique (Weekly QC)

	Digital Mammography	DBT	2D w/DBT Fixture
AEC mode			
Paddle size (IR Size)			
Paddle type (reg or flex)			
View/selected image type			
Slice or Slab # (DBT only)			
Compression force			
AEC cell position *(if avail)*			
Target/filter *(if app)*			
kVp *(if app)*			
Density setting *(if app)*			

Medical Physicist QC Letter for the Radiologist

January 25, 2019

Lead Rad, MD
Breast Center USA
1234 Smith Road

Los Angeles, CA. 10001

Re: Medical Physicist Survey of Room 1 Manf AA Unit BB on January 25, 2019

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): Phantom 1
Patient ID (Phantom): 123
Date: 1/25/19

ACR Digital Mammography Phantom Scores

	Room 1			
	2D	DBT	Passing Criteria	Pass /Fail
Fiber score	5.0	5.0	≥ 2.0	Pass
Speck group score	4.0	4.0	≥ 3.0	Pass
Mass score	4.0	4.0	≥ 2.0	Pass
Artifacts	None	None	No Clinically Significant Artifacts	Pass

Comments on phantom image:

• Radiation Dose

ACR Digital Mammography Phantom Radiation Dose Values

	Room 1			
	2D	DBT	Passing Criteria	Pass /Fail
ACR Phantom Dose (mGy)	1.35	1.49	≤ 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:

Medical Physicist QC Summary Letter for the Radiologist *(cont)*

• 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

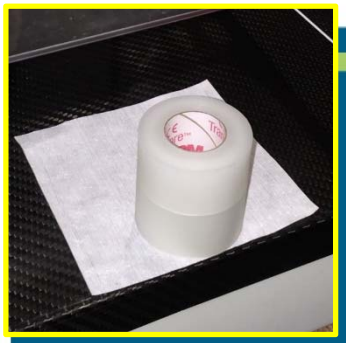
If you have any questions, please do not hesitate to call.

Sincerely,

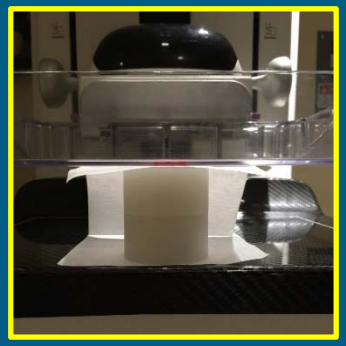
MP Name

Phone 111-222-3333
Email mp.email@email.com

Tech Test



*Or, test object could be the old (small) phantom!



Apply ~10 to 15lbs (4.4 to 6.7 daN)

3. Compression Thickness Indicator

Monthly

Image Mode *(2D, 2D w/Add-on DBT, DBT)* DBT

Facility Breast Center USA **Room ID** Room 1

MAP ID-Unit# *(00000-00)* 54321 - 01 **Unit Mfr & Model** Manf AA Unit BB

Year	2018											
Month	Jan	Feb	Mar	Apr	May	Jun	Jul	Aug	Sep	Oct	Nov	Dec
Date	2	2	4	5	6	4	2	7	12	10	5	5
Tech Initials	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB
Description of compression thickness indicator phantom	Tape											
Actual thickness of phantom	52.0	☐ cm	☑ mm	(Use the same unit displayed on the indicator)								
Indicated thickness	51.0	52.0	52.0	53.0	51.0	52.0	52.0	53.0	52.0	51.0	53.0	52.0
Difference between indicated and actual thicknesses (Indicated - Actual)	-1.0	0.0	0.0	1.0	-1.0	0.0	0.0	1.0	0.0	-1.0	1.0	0.0
Overall Pass/Fail	Pass	Pass	Pass	Pass	Pass	Pass	Pass	Pass	Pass	Pass	Pass	Pass

P = Pass F = Fail

Action Limits		
	Required:	Compression thickness indicator ***must*** be accurate to within ±0.5 cm (±5 mm) of the actual thickness.
	Timeframe:	Failures ***must*** be corrected within 30 days.

Safety Note: **Ensure tape (or designated thickness test object does not scratch, or leave residue, on the detector cover or paddle!**

9. Facility QC Review

Quarterly

Image Mode *(2D, 2D w/Add-on DBT, DBT)* DBT

Facility Breast Center USA **Date of QC Mtg** 1/18/19

1. Review Medical Physics Surveys and Results — Reviewed ✓

	Room 1	Room 2	Room 3	Room 4	Room 5
Room ID	1	2	3	4	5
Date of last Medical Physicist (MP) survey	1/10/19	1/11/19	1/12/19	1/13/19	1/14/19
MP DM QC Test Summary reviewed by radiologist?	Yes	Yes	Yes	Yes	Yes
All MP corrective actions completed?	Yes	Yes	Yes	Yes	Yes
ACR DM Phantom Average Glandular Dose (mGy)	1.23	1.25	1.34	1.45	1.00
Fiber Score	5.0	5.0	5.0	5.0	5.0
Speck Score	4.0	4.0	4.0	4.0	4.5
Mass Score	4.0	3.5	3.5	3.5	4.0

2. Review Tech QC ✓

Test	*Frequency*	*Summary Comments from Last Quarter*	
1. ACR DM Phantom Image Quality	Weekly		✓
2. CR Cassette Erasure *(if app)*	Weekly		✓
3. Compression Thickness Indicator	Monthly		✓
4. Visual Checklist	Monthly		✓
5. AW Monitor QC	Monthly		✓
6. RW Monitor QC	Monthly		✓
7. Film Printer QC	Monthly		✓
8. Viewbox Cleanliness *(if app)*	Monthly		✓
9. Facility QC Review	Quarterly		✓
10. Compression Force	Semiannual		✓
11. Manufacturer Calibrations *(if app)*			✓
Optional - Repeat Analysis	As Needed	% Repeats 2.1	✓

Scores of most recent phantom image:

	Room 1	Room 2	Room 3	Room 4	Room 5
Date	12/25/18	12/26/18	12/27/18	12/24/18	12/23/18
Fiber score	5.0	5.0	5.0	5.0	5.0
Speck group score	4.0	4.0	4.0	4.0	4.5
Mass score	4.0	3.5	3.5	3.5	4.0

3. Review and verify completion of all "Corrective Action" ✓
4. Technique 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)* ✓

***Participation not required to be "in person". Alternate methods for having meetings are permitted (telephone, skype, etc.)**

Facility Offsite Display Locations

Facility Breast Center USA **MAP ID#** *(00000)* 54321

Address Los Angeles, CA. 10001

Offsite Locations or Facilities Where Images are Interpreted for this Facility
(list facility name, address, and MAP ID)

Location or Facility Name	Address	MAP ID
Breast Center #1	1123 Smith Road Reston VA 12345	12345
Breast Clinic #2	9988 USA Street Washington DC, 33344	23456
Outpatient Imaging Center #3	5678 Santa Fe Road Santa Fe, NM 12345	34567

Facility Display Device QC Summary Checklist

Facility Breast Center #1 **MAP ID#** *(00000)* 54321

Address 1123 Smith Road

Address Reston VA 12345

QC Summary information for display devices at this MAP ID

Physical Location at Facility/ ID Designation		**Read Rm 1**	**Read Rm 2**	**Laser Print 1**	**Viewbox 1**	**Viewbox 2**			
Device *(RW, film printer, viewbox)*		RW	RW	Film Printer	Viewbox	Viewbox			
Manufacturer		Mfr A	Mfr A	Mfr B	Mfr C	Mfr C			
Model		Model 22	Model 22	Model A1	Model 771	Model 771			
Jan	Date	1/2/2016	1/2/2016	1/25/2016	1-24-20016	1/14/2016			
	Tech Initials	TI	TI	JJ	LT	LT			
Feb	Date	2/21/2016	2/1/2016	2/15/2016	2/12/2016	2/24/2016			
	Tech Initials	TI	TI	JJ	LT	LT			
Mar	Date								
	Tech Initials								
Apr	Date								
	Tech Initials								
May	Date								
	Tech Initials								
Jun	Date								
	Tech Initials								
Jul	Date								
	Tech Initials								
Aug	Date								
	Tech Initials								
Sep	Date								
	Tech Initials								
Oct	Date								
	Tech Initials								
Nov	Date								
	Tech Initials								
Dec	Date								
	Tech Initials								
Medical Physicist Survey Date		2/22/16	2/22/16	2/22/16	2/22/16	2/22/16			
Medical Physicist Name(s)		MP	MP	MP	MP	MP			

Why should we switch?

- Question: is it worth switching to the ACR Digital Mammography QC Program.

- Answer: Yes, for reasons such as ease of learning, ease of documentation, less tests, less time need for performing the tests, better forms, better handling of offsite equipment, better handling of multi-facility situations, better phantom, advantage of a singular QC program, and… most importantly, an overall superior program that focuses on quality while respecting the time and resources of mammography facilities and medical physicists.

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And now, the ACR Staff

If we don't get to your question, send them via email to dmqc@acr.org and we'll respond ASAP.