2018 Digital Mammography QC Manual

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**No financial disclosures to report*

Overview

- ***Why***
  - The benefits of the ACR QC Digital Mammography Program
- ***When***
  - Strategy and steps to transition to the new program
- ***How***
  - Overview of the phantom & QC tests
  - How to perform a few select QC tests

MQSA - Who's Who

The Law:
Mammography Quality Standards Act (MQSA)

The Regulator:
US Food and Drug Administration (FDA)

The Accreditation Bodies:
(ACR, TX, AR)

The Inspectors:
States

ACR Mammography Accreditation Program Statistics as of July 1, 2019

- 8,663 Accredited Mammography Facilities (61% have DBT)
  - ~7,200 CT facilities
  - ~7,200 MR facilities
- 20,545 Accredited Mammography Units
  - 12,841 2D (and 7,667 have DBT = 20,545)
  - ~10,000 CT units
  - ~9,200 MR units
- 37 SFM units left….

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.

ACR DM QC Manual Project

– **Subcommittee Goals:**

- – Standardize all QC tests for all digital mfrs
- – Standardize test frequencies
- – Standardize performance criteria
- – To make QC tests clinically relevant and operator-friendly

Why should we switch?

Performing tests are more efficient:

- 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, the ACR QC tests provide a better quality evaluation of the entire system.

Why should we switch?

Highlights for Medical Physicist tests:

- ACR Phantom
  - Can now fail for artifacts
  - Phantom covers majority of detector area
  - Evaluate SNR & 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 evaluation 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
  - Method (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 (using 2D method)
- Facilities
  - QC program is structured for modern facilities (with multiple **units**, multiple **RW's**, and at multiple **facilities**)

Why else should we switch?

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

Why should we switch?

Non-obvious reasons and benefits of switching

- Demonstrate the Medical Physicists value and expertise
- Re-establishes the relationship of the MP with the Tech, Rad, and Facility
- Establishes the MP as the QC leader and the go-to resource
- Establishes communication directly with the Lead Interpreting Radiologist
- Establishes communication directly with the Facility (including the Quarterly QC Meetings)

Resources

ACR Mammography Accreditation Website

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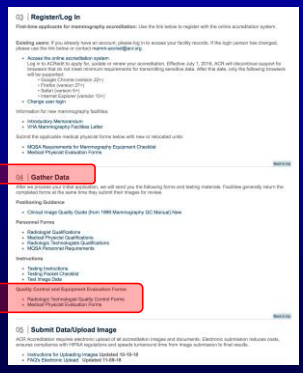
Resources

ACR Mammography Accreditation Website



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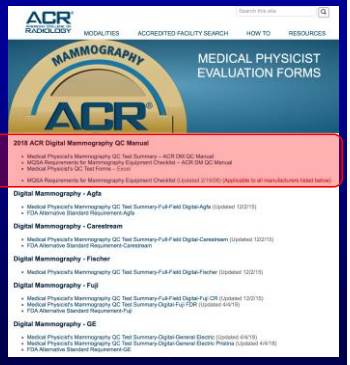
Resources

ACR Mammography Accreditation Website



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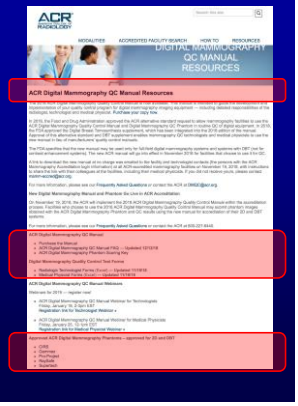
Resources

ACR Digital Mammography QC Manual Resources webpage



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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!

Transition to ACR Mammography Program

- Transition to ACR Mammography Program:
  - Step 1: Obtain a DM Phantom
  - Step 2: Discuss transition plan with facility (and timeline)
  - Step 3: MP tests unit(s) and workstation(s)
  - Step 4: Tech(s) begins testing on unit(s) and workstation(s)

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).

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Transition – Practical Steps (recommendation)

- 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.

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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 there's no more subtracting for artifacts).
  - *Teach* how to visually evaluate for artifacts.
- Make an overall schedule for all units and displays

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Important FAQ's

The American College of Radiology Digital Mammography QC Manual: Frequently Asked Questions
(Revised 06/10/2019; new and updated items in red)

- Contrast Enhanced Mammography (CEM)
- Units with CEM can use the ACR manual for 2D and DBT applications, but must use manufacturer QC for CEM applications

Important FAQ's

The American College of Radiology Digital Mammography QC Manual: Frequently Asked Questions

(Revised 06/10/2019; new and updated items in red)

Q. If a facility chooses to use the ACR Digital Mammography QC Manual for their digital mammography unit, do they need to notify the ACR?

A. No. They may do so without notifying the ACR. Facilities should submit the appropriate documentation and testing materials using the QC manual during their normal accreditation cycle.

Q. If a facility chooses to use the ACR Digital Mammography QC Manual for their digital mammography unit, do they need to notify their MQSA inspector?

A. No. However, the facility should document the date they transitioned to the ACR Digital Mammography QC Manual in their QC records (e.g., their Corrective Action Log).

Important FAQ's

The American College of Radiology Digital Mammography QC Manual: Frequently Asked Questions

(Revised 06/10/2019; new and updated items in red)

Q. Is a full mammography equipment evaluation (MEE) required to begin using the ACR Digital Mammography QC Manual for 2D and DBT?

A. No, an ***annual survey*** is required for facilities transitioning from a manufacturer's QC program to the ACR DM QC Manual. ***However***, **MEE** test data obtained under the facility's previous QC program should be maintained and available for baseline, comparison, and troubleshooting purposes until those tests are performed for the first time under the ACR Digital Mammography QC procedures. If data for the MEE tests are not available for baseline, comparison, and troubleshooting purposes, a full MEE must be done in order to make those data available.

Important FAQ's

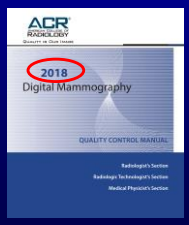
The American College of Radiology Digital Mammography QC Manual: Frequently Asked Questions

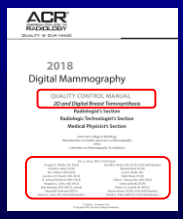
(Revised 06/10/2019; new and updated items in red)

Q. While performing SNR during my survey I noticed a discrepancy in the manual. On page 170, the Performance Criteria and Corrective Actions section states that "The SNR *must* be ≥40.0 for the 4.0 cm phantom in the DBT mode." However, the Precautions and Caveats section also states, "It is recognized that the SNR is not strictly defined for DBT images." Which is correct?

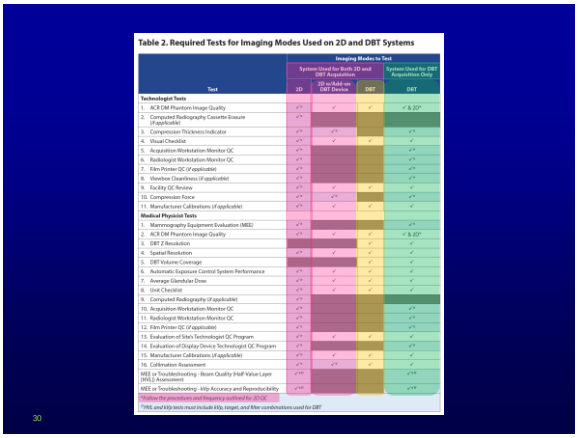
A. The ACR recognizes that this is a typographical error in the manual, and it will be corrected in a revision. The SNR Performance Criteria and Corrective Actions should state, "The SNR *must* be ≥40.0 for the 4.0 cm phantom in the 2D Contact mode." For DBT, the SNR is not strictly defined.

The 2018 ACR Digital Mammography Quality Control Manual





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



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	

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Tech Tests

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*)	✓*	✓	✓	✓

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

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

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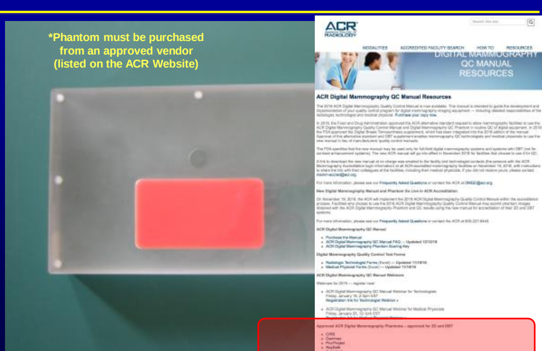
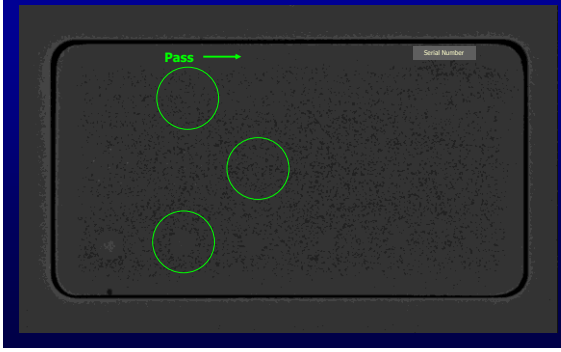
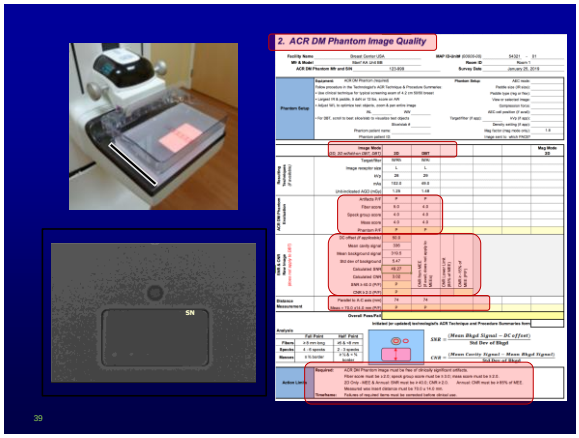
The ACR DM Phantom

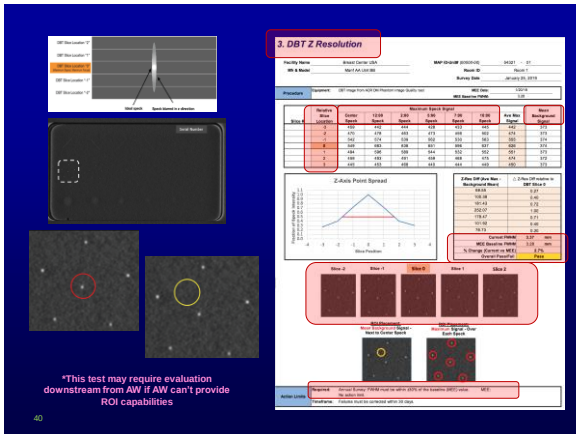


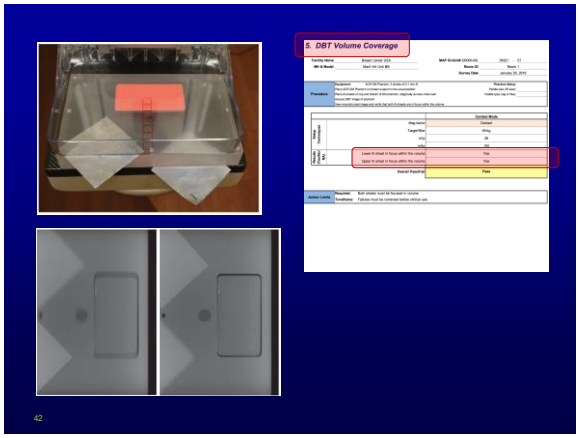
Pass Criteria: ***2 Fibers, 3 Specks, 2 Masses***

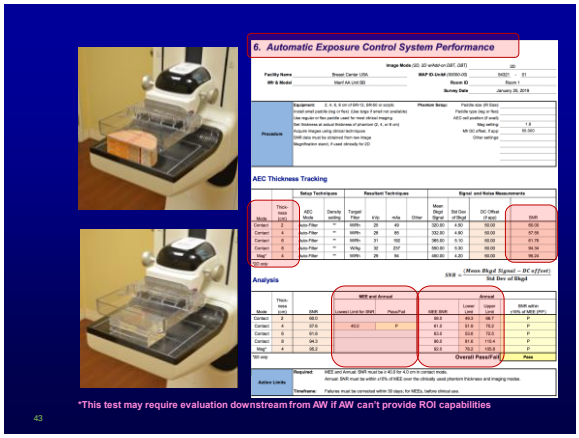
Equivalent to SFM Phantom: ***4 Fibers, 3 Specks, 3 Masses***






3. DBT Z Resolution
Z-Axis Point Spread
*This test may require evaluation downstream from AW if AW can't provide ROI capabilities
40


5. DBT Volume Coverage
42


6. Automatic Exposure Control System Performance
AEC Thickness Tracking
Analysis
*This test may require evaluation downstream from AW if AW can't provide ROI capabilities
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Typo

- AEC Performance Criteria

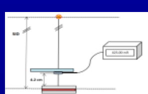
MEE and Annual Surveys

2D

The SNR *must* be ≥40.0 for the 4.0 cm phantom in ~~the DBT~~ mode.

Annual Surveys

The SNR must be within ±15% of the last MEE's SNR for each thickness and mode tested. (This component of the test does not apply to MEEs.)



$D = Kgcs$

D = Mean Glandular Dose

K = Entrance surface air kerma

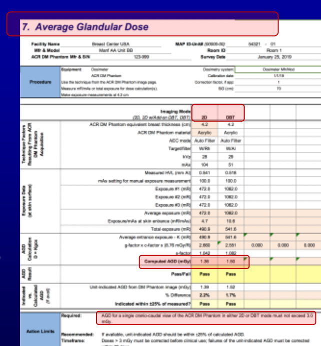
g = glandularity of 50%

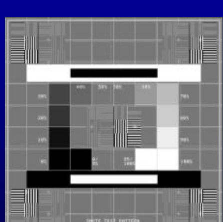
c = corrects for difference in composition (age dependent)

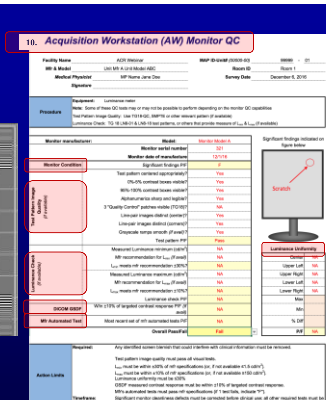
s = X-ray spectrum correction (Target/Filter)

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.







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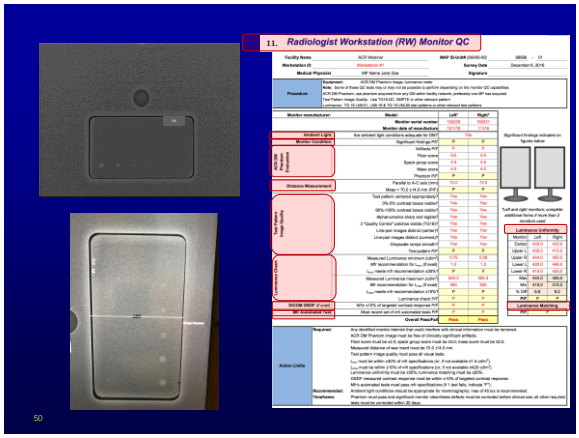

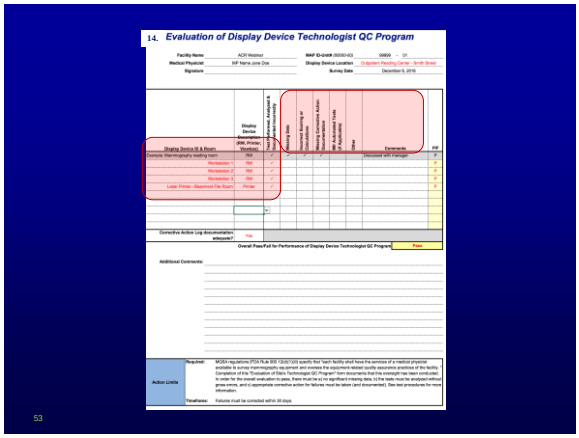

Major Component Service, Upgrade, Replacement & Repair

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***
Compression Device	Adjustment	N	Oversight
	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.

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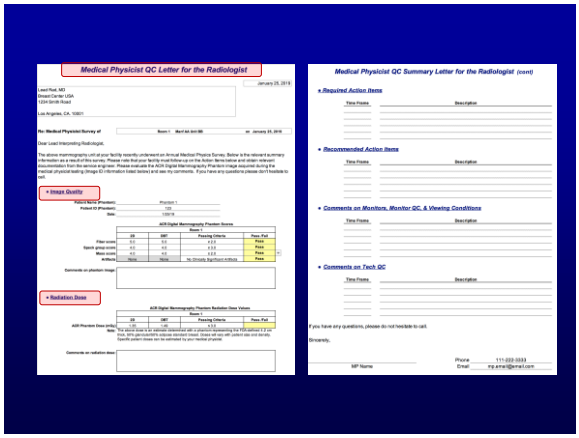
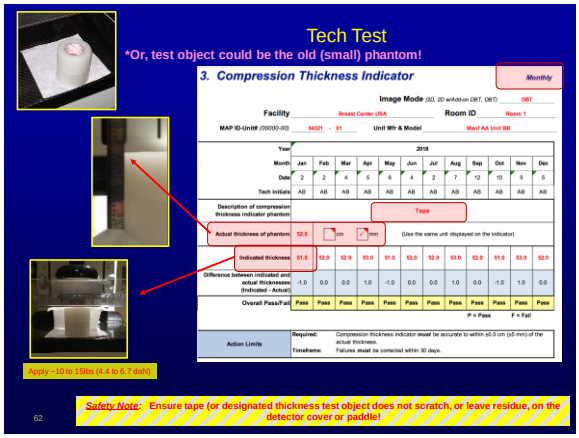

Medical Physicist QC Letter for the Radiologist
Medical Physicist QC Summary Letter for the Radiologist (cont)
• Required Action Items
• Recommended Action Items
• Comments on Monitors, Monitor QC, & Viewing Conditions
• Comments on Tech QC
• Image Quality
• Radiation Dose


Tech Test
*Or, test object could be the old (small) phantom!
3. Compression Thickness Indicator
Monthly
Apply ~10 to 15lbs (4.4 to 6.7 daN)
Safety Note: Ensure tape (or designated thickness test object does not scratch, or leave residue, on the detector cover or paddle!
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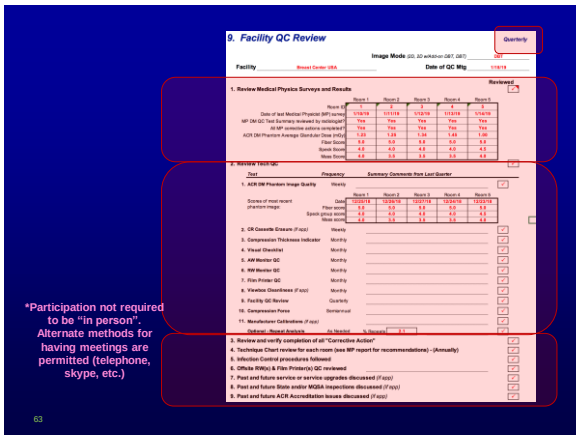
9. Facility QC Review
Quarterly
*Participation not required to be "in person". Alternate methods for having meetings are permitted (telephone, skype, etc.)
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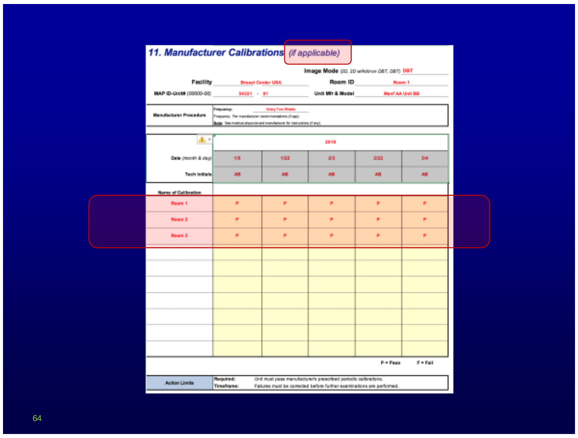
11. Manufacturer Calibrations
(if applicable)
Image Mode (2D, 2D w/Add-on DBT, DBT) DBT
Facility Breast Center USA
Room ID Room 1
MAP ID-Unit# (00000-00) 54321 - 01
Unit Mfr & Model Manf AA Unit BB
Manufacturer Procedure
2016
Date (month & day) 1/5 1/22 2/3 2/22 3/4
Tech Initials AB AB AB AB AB
Name of Calibration
Room 1 P P P P P
Room 2 P P P P P
Room 3 P P P P P
P = Pass F = Fail
Action Limits
Required: Unit must pass manufacturer's prescribed periodic calibrations.
Timeframe: Failures must be corrected before further examinations are performed.
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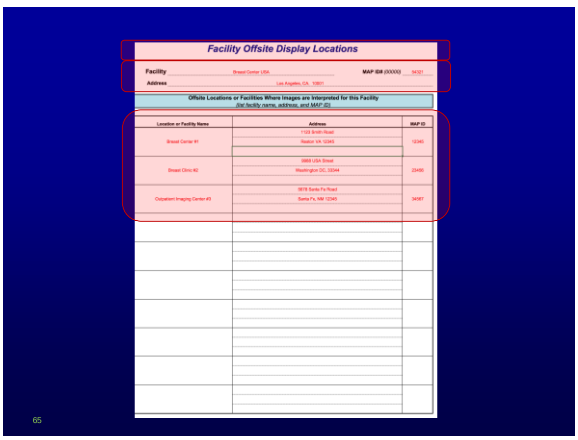
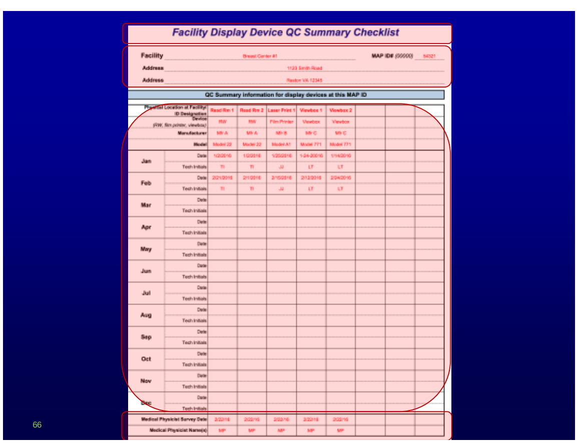

Facility Offsite Display Locations
Facility Breast Center USA
MAP ID# (00000) 54321
Address Los Angeles, CA 10801
Offsite Locations or Facilities Where Images are Interpreted for this Facility
(list facility name, address, and MAP ID)
Location or Facility Name
Address
MAP ID
Breast Center #1 1123 Smith Road Reston VA 12345 12345
Breast Clinic #2 9988 USA Street Washington DC, 33344 23456
Outpatient Imaging Center #3 5878 Santa Fe Road Santa Fe, NM 12345 34567
65


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
Feb
Mar
Apr
May
Jun
Jul
Aug
Sep
Oct
Nov
Dec
Date
Tech Initials
66

End of Presentation Questions?

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