Update on the ACR FFDM QC Manual

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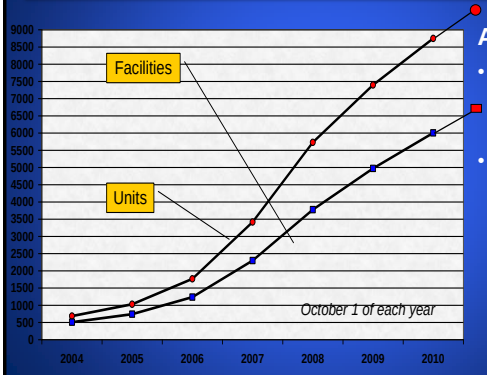
AAPM 2011 – Vancouver, Canada

FFDM in the US



As of 7/1/11

- 9,674 units at 6,714 facilities
- Over 79% of all units in US are FFDM

FDA Approved ACR to Accredit

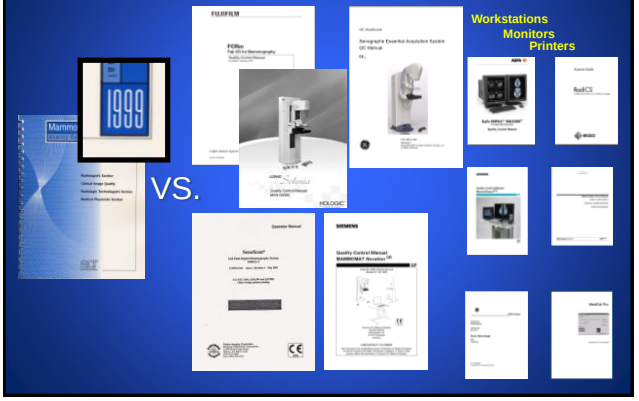
- GE
  - 2000D, DS, Essential
- Fischer
  - SenoScan
- Lorad
  - Selenia
- Siemens
  - Novation, Inspiration
- Fuji
  - FCRm (computed radiography)
- Carestream
  - DirectView (computed radiography)
- *Sectra Microdose – FDA Approved 4/28/2011
  - *In process of getting approval from FDA to accredit

- **Hologic Digital Breast Tomosynthesis (DBT) System approved for sale in US (Feb 2011)**

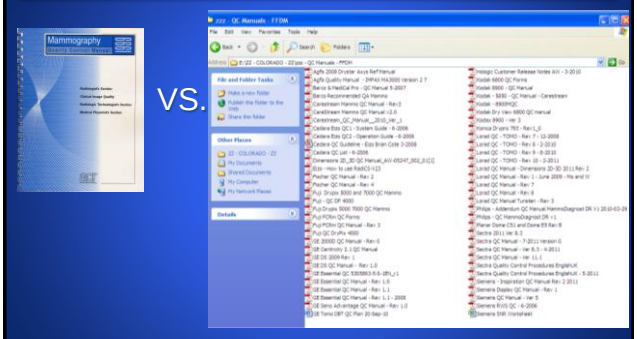
FDA's Current FFDM QC Requirements

- Follow latest version of mfr's QC manual procedures for unit tested
  - Lorad (Hologic) allows facility to follow any of their manuals
- Meet mfr's performance standards
- Failures must be fixed before use on patients
  - Most mfrs applied for alternative standards to allow 30 days for some QC tests

ACR FFDM QC Manual



ACR FFDM QC Manual



All of the above may vary with QC manual revisions of same manufacturer/model

ACR FFDM QC Manual Project

- ACR Subcommittee on Quality Assurance
  - Clinical Representatives
  - MITA Representatives
  - ACR Representatives

ACR Subcommittee on Quality Assurance

- Clinical Representatives
  - Eric Berns, PhD – University of Colorado - **Chair**
  - Chris Adent-Delaney, RT - Northwestern Memorial Hospital
  - Jay Baker, MD – Duke University Medical Center
  - Lawrence Bassett, MD – UCLA Medical Center
    - Chair, Joint Committee on Breast Imaging for Appropriateness Criteria and Guidelines
  - Shelli Dixon, RT – The Women's Imaging Center of Denver
  - R. Edward Hendrick, PhD – University of Colorado Hospital
  - Debra Monticciolo, MD – Texas A&M Health Sciences Center
    - Chair of ACR Accreditation Program Chairs
    - Chair of ACR Mammography Accreditation
  - Douglas Pfeiffer, MS – Boulder Community Hospital
  - Margarita Zuley, MD – University of Pittsburgh Medical Center

Subcommittee on Quality Assurance

- MITA Representatives
  - Gail Rodriguez, PhD - MITA
  - John Sandrik, PhD (Ret.) – GE Medical Systems
  - Robert Uzenoff - FUJIFILM Medical Systems
  - Stephen Vastagh – (Ret.) - MITA
  - Moustafa Zerhouni – Computerized Imaging References Systems
- ACR Representatives
  - Marion Boston, RT – Manager, ACR Breast Imaging Accreditation
  - Priscilla Butler, MS – Senior Director, ACR Breast Imaging Accreditation Programs

ACR FFDM QC Manual Project

- Subcommittee Charge:
  - Design ACR Accreditation Phantom for FFDM
  - Write QC Manual for ACR FFDM Mammography Accreditation Program

ACR FFDM QC Manual Project

- Subcommittee Goals:
  - Standardize all QC tests for all digital manufacturers
  - Standardize test frequencies
  - Standardize performance criteria

ACR FFDM QC Manual Project

- Subcommittee Goals:
  - QC Tests:
    - Tests come from a variety of sources (MQSA, ACR SFM, ACRIN DMIST, Manufacturer's QC programs, MITA, European Guidelines, subcommittee clinical experience, etc.)
    - Clinically relevant
    - User friendly
  - This manual will become basis of new regulations

ACR FFDM QC Manual Project

- Subcommittee Goals:
  - Update critical component of the ACR MAP
    - Account for all past, present, and future FFDM systems
    - Reasonable and appropriate for mass implementation
    - Eliminate unnecessary complicated procedures & analysis
    - Maximize user experience
      - Especially for Techs & Rads & Facilities
  - Theme
    - Measurements be made with external equipment
      - Dosimeters, photometers, etc.
    - Minimal software requirements
      - CNR & SNR

ACR FFDM QC Manual Project

- Subcommittee Goals:
  - Ensure that accredited systems
    - Provide acceptable image quality
    - While meeting or exceeding MQSA requirements
  - Facilities (and Radiologists)
    - Can feel confident that their system is performing in accordance with ACR requirements
    - Are familiar with, and confident with their understanding of, their ACR FFDM QC Program

The QC Manual

ACR Digital QC Manual

- Structure of Manual:
  - Radiologist's Section
  - Clinical Image Quality Section
  - Radiologic Technologist's Section
  - Medical Physicist's Section
  - Educational, Guidance, and Troubleshooting Section
  - Glossary
  - References
  - Index

What Will Be New?

- Radiologist Section
  - Image ID regulations
  - Hanging protocols (left vs. right)
  - Monitor and viewing conditions guidance
  - Section on diagnostic tools for analyzing poor images
  - How to score the ACR FFDM Phantom
  - Guides for understanding their role and responsibility for overseeing the QC program

What Will Be New?

- Tech Section
  - Enhanced positioning and image quality section
  - New Test: Monitor QC for the Radiologist
  - New Test: Facility QC Review
  - New Format: Corrective Action Log
  - New Documentation: Facility Equipment Inventory
  - Instructions for Mobile Units
  - Eliminating calculations (Yet to be determined)

What Will Be New?

- Medical Physicist Section
  - Include tests procedures and forms for all ACR and MQSA QC Tests
  - Will include guidance on how to test
    - Multiple units (FFDM's, AW's, RW's, Printers, etc)
    - Multiple facilities
  - Procedures for evaluating and documenting Tech QC

What Will Be New?

- Medical Physicist Section
  - Theme: providing better documentation and communication
    - Single MP Summary Form
      - For Facility, ACR, State and MQSA Inspectors
      - Include an Action Item Summary
    - MP form for Tech for 0perating Levels and QC instructions
    - MP letter to the Radiologist
    - MP to use same Corrective Action Log form as Techs

What Will Be New?

- Facility
  - Guidance on how to handle multiple units at multiple locations.
  - Guidance on who/what/when tests need to be performed when “major” and “minor” repairs are performed on unit.
  - Facility QC Review (Tech Test) – Quarterly

ACR Digital QC Manual

Technologist QC Tests

Test Number	Name	Minimum Frequency	Required Corrective Action
1	ACR Phantom Image Quality	Weekly	Before Clinical Use
2	Acquisition Workstation (AW) Monitor QC	Weekly	Before Clinical Use
3	Radiologist Workstation (RW) Monitor QC	Weekly	Before Clinical Use
4	Laser Printer QC	Weekly	Before Clinical Use
5	Viewbox Cleanliness	Weekly	Before Clinical Use
6	Visual Checklist	Monthly	Before Clinical Use
7	Repeat Analysis	Quarterly	Within 30 Days
8	Monitor QC for the Radiologist	Quarterly	Before Clinical Use
9	Facility QC Review	Quarterly	Not Applicable
10	Compression Force	Semiannual	Before Clinical Use
11	Manufacturer Detector Calibration (If Applicable)	Per Mfr Recommendation	Before Clinical Use
	Supplemental Forms		
	Corrective Action Log		
	Facility Equipment Inventory Form		

ACR Digital QC Manual

Medical Physicists QC Tests

Test Number	Name	Minimum Frequency	Required Corrective Action
1	ACR Phantom Image Quality	Annual	Before Clinical Use
2	Ghost Image Evaluation	Annual	Before Clinical Use
3	Spatial Resolution	Annual	Before Clinical Use
4	Automatic Exposure Control System Performance	Annual	Before Clinical Use
5	Collimation Assessment	Annual	Within 30 Days
6	kVp Accuracy and Reproducibility	MEE Only	Before Clinical Use
7	Beam Quality (Half-Value Layer) Assessment	Annual	Within 30 Days
8	Average Glandular Dose	Annual	Before Clinical Use
9	Unit Checklist	Annual	Before Clinical Use
10	Evaluation of Site’s Technologist QC Program	Annual	Within 30 Days
11	MQSA Equipment Requirements	MEE Only	Before Clinical Use
12	Computed Radiography (If Applicable)	Annual	Before Clinical Use
13	Acquisition Workstation (AW) Monitor QC	Annual	Before Clinical Use
14	Radiologist Workstation (RW) Monitor QC	Annual	Before Clinical Use
15	Laser Printer QC	Annual	Before Clinical Use
16	Viewbox Luminance and Room Illuminance	Annual	Before Clinical Use
17	Evaluation of Off-Site Technologist QC Program (If Applicable)	Annual	Before Clinical Use

ACR Digital QC Manual

Medical Physicists QC Tests

Test Number	Name
	Supplemental Forms
1	Medical Physicist Summary Report
2	Technologist Operating Level Information and QC Instruction Form
3	Medical Physicist Summary Letter for the Radiologist
4	Mammography Corrective Action Log
5	Technologist Pre-Inspection Interview Form
6	Technique Chart

ACR Digital QC Manual

Tech & MP	
Test Number	Name
Educational and Example Forms	
1	Complete set of forms with example data, scores, and calculations
2	ACR Phantom Scoring Guide
3	SNR & CNR Calculation Guide
4	Monitor Test Pattern Evaluation Guide
5	Printed Film Evaluation Guide
6	FFDM Artifact Guide

The ACR FFDM Phantom

Design Summary

- Phantom Design Principles
  - Base on existing ACR Accreditation Phantom
  - Similar imaging and scoring to current SFM phantom
  - Can be used on both SFM & FFDM
  - Total attenuation matched to current SFM phantom
    - Similar thickness
    - Similar total dose
  - Permits testing of 3.0 mGy dose limit

Design Summary

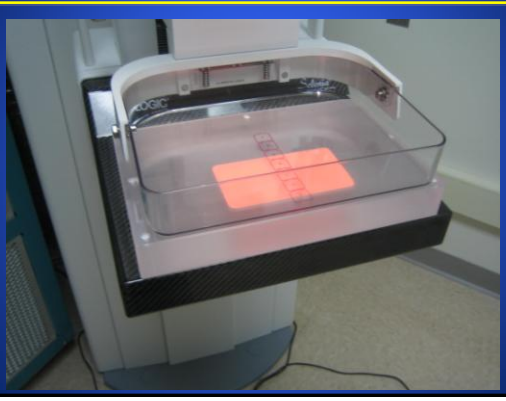
- Phantom Design Principles
  - Cover all (or most) of detector on all digital systems
  - Single exposure results in all relevant information
  - All evaluation (including artifacts) can be done at one WW, WL
  - Provide detailed specifications to manufacturer's
- Manufacturing will be open to all qualifying vendors
  - Must receive approval from ACR (ACR will test sample phantom)

Design Summary

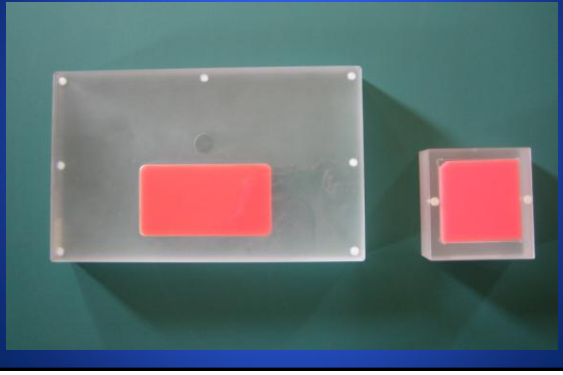
- Differences from screen-film phantom
  - Eliminate subtraction for artifacts
  - Add "Fail" for artifacts
  - Improve specific rules for scoring
  - Change pass/fail criteria from
    - 4,3,3
    - To: 2,3,2
    - **But, objects are the same (effective) size as SFM Phantom

The ACR FFDM Phantom

The ACR FFDM Phantom



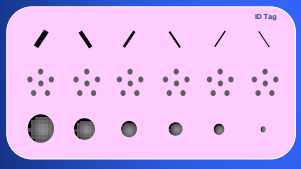
The ACR FFDM Phantom vs. SFM ACR Phantom



The ACR FFDM Phantom

Wax Insert Comparison

FFDM



SFM

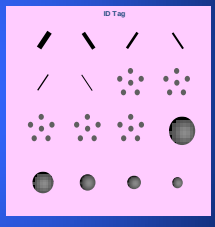


Image of Entire Phantom

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

Expanded view of Wax Insert

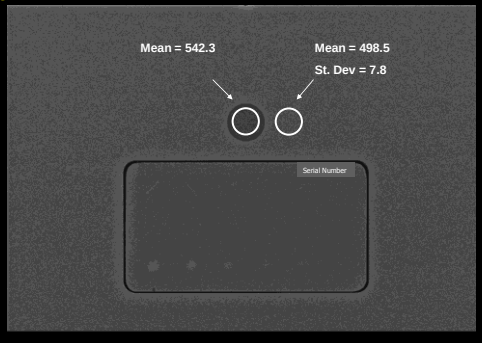
Expanded view of Wax Insert

Expanded view of Wax Insert With Pass/Fail criteria

Pass Criteria: 2 Fibers, 3 Specks, 2 Masses

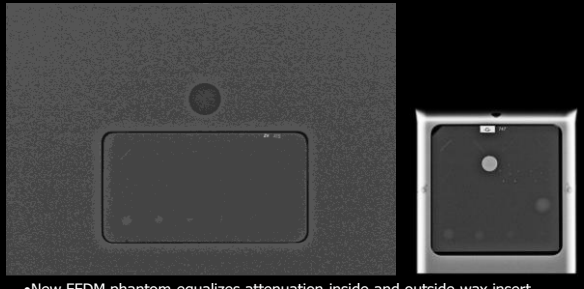
Image of Entire Phantom

CNR



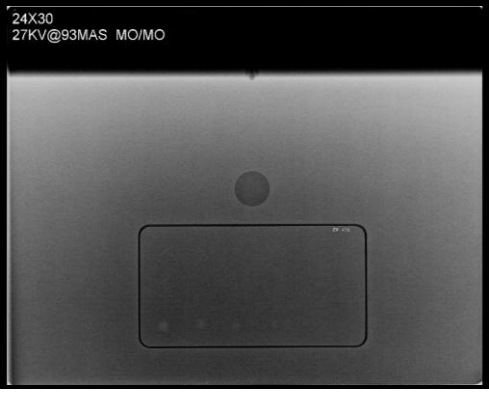
The ACR FFDM Phantom

Effects of Thickness Equalization

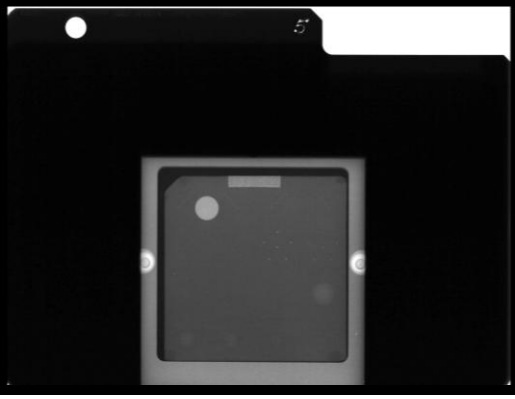


- New FFDM phantom equalizes attenuation inside and outside wax insert.
- This permits evaluation of artifacts over entire phantom area with same WW and WL used to score test objects.

The ACR FFDM Phantom
CR 24x30



The ACR Prototype
Screen-Film 18x24



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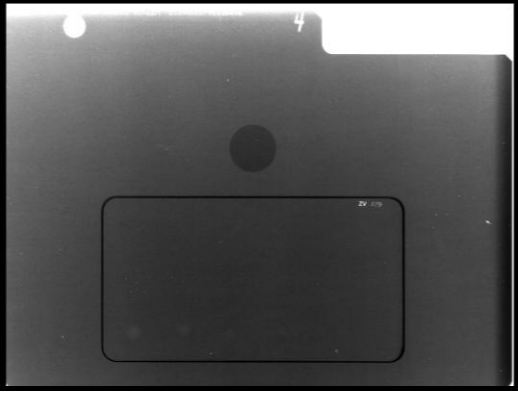
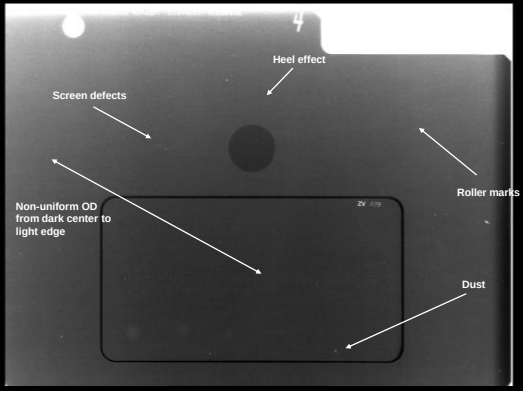
Screen-Film 18x24



The ACR Prototype
Screen-Film 18x24



Design Summary

- Measurements using the FFDM Phantom
  - Phantom used in
    - 3 of 11 Tech tests
    - 12 of 24 Tech sub-tests
    - 7 of 17 Physicists tests
    - 19 of 48 Physicist sub-tests

50% Tech Tests

41% Physics Tests

AEC Technique Comparison

	Lorad – Mo		Lorad - W		Fuji CR 18 x 24 cm		Fischer	
Mode	Auto-Filter		Auto-Filter		AA		Auto-Technique	
Phantom	FFDM	SFM	FFDM	SFM	FFDM	SFM	FFDM	SFM
Compression Thickness (cm)	5.2	5.2	5.2	5.2	4.0	4.0	5.74	4.05
Target/Filter	Mo/Mo	Mo/Mo	W/Rh	W/Rh	Mo/Mo	Mo/Mo	W/Al	W/Al
kVp	29	29	28	28	27	27	31	27
mAs	66.4	65.4	92.5	97.6	90	89	177 mA	158 mA
Machine Reported Dose (mGy)	1.64	1.61	1.03	1.08	**	**	0.954	1.211

Manual Technique Signal Comparison

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

ACR Digital QC Manual

- Benefits of Phantom Design
  - Provides view of entire detector – artifact evaluation
  - W/L optimized for test objects optimizes for artifact eval
  - Finer gradations of test objects
  - Test objects go to smaller sizes
  - AGD measurement & limit same as SFM – Meets MQSA
  - Provides single image/exposure for evaluation(s)
  - Minimal training (~ 25,000 Techs currently trained)
  - Provides basis for monitor and laser printer QC
  - ACR Physics Reviewers
    - Can see scores and artifacts on single submitted film (or image)
    - Do not need different WW/WL settings

The QC Tests

ACR FFDM QC Manual

Required Full Field Digital Mammography Quality Control Tests

Technologist Tests

Test #	Test Name	Test Element	Minimum Frequency[1]	Performance Criteria	Corrective Action Time Limit[2]	Comments
1	ACR Phantom Image Quality (Acquisition Workstation)	Phantom Average Glandular Dose (AGD) Check	•Weekly •After relevant service	•Machine reported AGD must be ≤ 3.0 mGy	Immediately	NA if AGD is NA
		Automatic Exposure Control Consistency	•Weekly •After relevant service	•Machine reported AGD must be within ± 0.20 mGy of Operating Level (OL)	Immediately	OL value obtained from MP, use mAs if AGD is NA
		Artifact Evaluation	•Weekly •After relevant service	•No clinically significant artifacts	Immediately	
		Phantom Scoring – Acquisition Workstation	•Weekly •After relevant service	•Fibers ≥ 2.0 •Masses ≥ 3.0 •Specks ≥ 2.0	Immediately	

[1] Daily and weekly tests must be performed on all days/weeks that the component of the mammography system is used.
[2] Problems must be corrected within the specified time limit; after that, further examinations may not be performed nor any images printed or interpreted using the component of the mammography system that failed the test.

ACR FFDM QC Manual

Required Full Field Digital Mammography Quality Control Tests

Technologist Tests

Test #	Test Name	Test Element	Minimum Frequency[1]	Performance Criteria	Corrective Action Time Limit[2]	Comments
2	Acquisition Workstation QC	Monitor Cleanliness	•Weekly •After relevant service	•Monitor(s) must be clean	Immediately	
		Test Pattern Evaluation	•Weekly •After relevant service	•Visual evaluation must pass (SMPTE or TG18)	Immediately	On monitors where test pattern is available
		Manufacturer's Recommended QC Tests	•Per Manufacturer	•Per Manufacturer	Per Manufacturer	Mfr's test(s) established by MP (if Applicable)

[1] Daily and weekly tests must be performed on all days/weeks that the component of the mammography system is used.
[2] Problems must be corrected within the specified time limit; after that, further examinations may not be performed nor any images printed or interpreted using the component of the mammography system that failed the test.

ACR FFDM QC Manual

Required Full Field Digital Mammography Quality Control Tests

Technologist Tests

Test #	Test Name	Test Element	Minimum Frequency[1]	Performance Criteria	Corrective Action Time Limit[2]	Comments
3	Radiologist Workstation QC	Monitor Cleanliness	•Weekly •After relevant service	•Monitor(s) must be clean	Immediately	
		Test Pattern Evaluation	•Weekly •After relevant service	•Visual evaluation must pass (SMPTE or TG18)	Immediately	
		Artifact Evaluation	•Weekly •After relevant service	•No clinically significant artifacts	Immediately	
		ACR Phantom Scoring	•Weekly •After relevant service	•Fibers ≥ 2.0 •Masses ≥ 3.0 •Specks ≥ 2.0	Immediately	
		Manufacturer's Recommended QC Tests	•Per Manufacturer	•Per Manufacturer	Per Manufacturer	Mfr's test(s) established by MP (If Applicable)

[1] Daily and weekly tests must be performed on all days/weeks that the component of the mammography system is used.
[2] Problems must be corrected within the specified time limit; after that, further examinations may not be performed nor any images printed or interpreted using the component of the mammography system that failed the test.

ACR FFDM QC Manual

Required Full Field Digital Mammography Quality Control Tests

Technologist Tests

Test #	Test Name	Test Element	Minimum Frequency[1]	Performance Criteria	Corrective Action Time Limit[2]	Comments
4	Laser Printer QC	Artifact Check	•Weekly •After relevant service	•No clinically significant artifacts	Immediately	
		ACR Phantom Scoring	•Weekly •After relevant service	•Fibers ≥ 2.0 •Masses ≥ 3.0 •Specks ≥ 2.0	Immediately	
		Background Optical Density Check	•Weekly •After relevant service	•Background OD must be within ± 0.15 OD of OL	Immediately	OL value give by MP
		Contrast Optical Density Check	•Weekly •After relevant service	•Density difference (DD) must be within – 0.05 of OL	Immediately	OL value give by MP
		Dmax Optical Density Check	•Weekly •After relevant service	•≥ 3.5 OD	Immediately	

[1] Daily and weekly tests must be performed on all days/weeks that the component of the mammography system is used.
[2] Problems must be corrected within the specified time limit; after that, further examinations may not be performed nor any images printed or interpreted using the component of the mammography system that failed the test.

ACR FFDM QC Manual

Required Full Field Digital Mammography Quality Control Tests

Technologist Tests

Test #	Test Name	Test Element	Minimum Frequency[1]	Performance Criteria	Corrective Action Time Limit[2]	Comments
5	Viewbox Cleanliness Check	Viewboxes Clean	•Weekly •After relevant service	Document all cleaning procedures and frequencies	Immediately	
6	Visual Checklist	Visual Checklist	•Monthly •After relevant service	Must pass all tests	Immediately	
7	Repeat Analysis	Repeat Analysis	Quarterly	If the total repeat changes from previously determined rate by more than 2.0% of the total images included in the analysis, the reason(s) for the change must be determined	≤ 30 days of test date	

[1] Daily and weekly tests must be performed on all days/weeks that the component of the mammography system is used.
[2] Problems must be corrected within the specified time limit; after that, further examinations may not be performed nor any images printed or interpreted using the component of the mammography system that failed the test.

ACR FFDM QC Manual

Required Full Field Digital Mammography Quality Control Tests

Technologist Tests

Test #	Test Name	Test Element	Minimum Frequency[1]	Performance Criteria	Corrective Action Time Limit[2]	Comments
8	Monitor QC For The Radiologist	Imaging Chain Spot Check	Quarterly	Must pass all tests	Immediately	
9	Facility QC Review	QC Review with Lead Interpreting Physician & Facility Manager	Quarterly	QC review signed by lead interpreting physician, facility manager, and QC technologist	NA	
10	Compression Force	Compression Force	•Semi-annually •After relevant service	•Initial power drive max force between 25 and 45 lbs (11.1 and 20.0 decanewtons)	Immediately	
11	Manufacturer Detector Calibration (If App).	Manufacturer Detector Calibration	•Per Manufacturer Recommendation	•Per Manufacturer Recommendation	Immediately	

[1] Daily and weekly tests must be performed on all days/weeks that the component of the mammography system is used.
[2] Problems must be corrected within the specified time limit; after that, further examinations may not be performed nor any images printed or interpreted using the component of the mammography system that failed the test.

ACR FFDM QC Manual

Required Full Field Digital Mammography Quality Control Tests

Medical Physicist's Tests

No.	Test Name	Test Element	Minimum Frequency[1]	Action Limits	Corrective Action Time Limit[2]	Comments
1	ACR Phantom Image Quality (Acquisition Workstation)	Artifact Evaluation	•Annually •After relevant service	No clinically significant artifacts	Immediately	•All clinical target/filter combinations •Contact and Mag modes
		Phantom Scoring – Acquisition Workstation	•Annually •After relevant service	•Fibers ≥ 2.0 •Masses ≥ 3.0 •Specks ≥ 2.0	Immediately	
		Exposure Duration	•Annually •After relevant service	•Total exposure time for the ACR Phantom must be ≤ 2.0 seconds	≤ 30 days of test date	
		Signal-to-Noise Ratio Measurement	•Annually •After relevant service	•SNR must be ≥ 40	Immediately	Action Limit TBD during pilot testing
		Contrast-to-Noise Ratio Verification	•Annually •After relevant service	•CNR TBD	Immediately	Action Limit TBD during pilot testing
		Distance Measurement Check	•Annually •After relevant service	•70 mm ± 7.0 mm	≤ 30 days of test date	Applicable if software provides measurement tool

[1] All tests must be done during the Mammography Equipment Evaluation (MEE) following installation of new systems; MEEs performed after equipment relocation or service must include relevant tests. Any MEE test failure must be corrected immediately.
[2] Problems must be corrected within the specified time limit; after that, further examinations may not be performed nor any images printed or interpreted using the component of the mammography system that failed the test.

ACR FFDM QC Manual

Required Full Field Digital Mammography Quality Control Tests

Medical Physicist's Tests

No.	Test Name	Test Element	Minimum Frequency[1]	Action Limits	Corrective Action Time Limit[2]	Comments
2	Ghost Image Evaluation	Ghost Image Evaluation	•Annually •After relevant service	•Ghost Image Value must be within ± 0.3	Immediately	
3	Spatial Resolution	Bar Pattern Evaluation – Contact & Mag Modes	•Annually •After relevant service	•See table in QC Forms	Immediately	
4	Automatic Exposure Control System Performance	SNR Thickness Tracking (2, 4, 6 cm, Large, Mag)	•Annually •After relevant service	•Must maintain signal value to within ± 10% of average	≤ 30 days of test date	
		Density Control Function (if applicable)	•Annually •After relevant service	•Each step should result in 12% to 15% change in mAs & mean signal value	≤ 30 days of test date	

[1] All tests must be done during the Mammography Equipment Evaluation (MEE) following installation of new systems; MEEs performed after equipment relocation or service must include relevant tests. Any MEE test failure must be corrected immediately.
[2] Problems must be corrected within the specified time limit; after that, further examinations may not be performed nor any images printed or interpreted using the component of the mammography system that failed the test.

ACR FFDM QC Manual

Required Full Field Digital Mammography Quality Control Tests

Medical Physicist's Tests

No.	Test Name	Test Element	Minimum Frequency[1]	Action Limits	Corrective Action Time Limit[2]	Comments
5	Collimation Assessment	X-ray Field & Detector Alignment	•Annually •After relevant service	•X-ray field does not extend beyond IR by more than 2% of SID •X-ray field extends all the way to chest wall	≤ 30 days of test date	Measured for largest paddle only
		Light Field & X-ray Field Alignment	•Annually •After relevant service	•Light field & X-ray field alignment (Length or Width) must not exceed 2% of SID	≤ 30 days of test date	CR must measure at both IR sizes
		Compression Paddle Alignment	•Annually •After relevant service	•Chest edge of compression paddle must not extend beyond chest-wall edge of IR by more than 1% of SID	≤ 30 days of test date	
6	kVp Accuracy and Reproducibility	kVp Accuracy and Reproducibility	•Only upon installation •After relevant service	•Must be accurate within ± 5% of the indicated kVp at -Lowest clinical kVp that can be measured by a kVp test device -Most commonly used clinical kVp -Highest available clinical kVp •Coefficient of variation must be ≤0.02	Immediately	

[1] All tests must be done during the Mammography Equipment Evaluation (MEE) following installation of new systems; MEEs performed after equipment relocation or service must include relevant tests. Any MEE test failure must be corrected immediately.
[2] Problems must be corrected within the specified time limit; after that, further examinations may not be performed nor any images printed or interpreted using the component of the mammography system that failed the test.

ACR FFDM QC Manual

Required Full Field Digital Mammography Quality Control Tests

Medical Physicist's Tests

No.	Test Name	Test Element	Minimum Frequency[1]	Action Limits	Corrective Action Time Limit[2]	Comments
7	Beam Quality (Half-Value Layer) Assessment	HVL	•Annually •After relevant service	Must meet upper and lower criteria in 1999 ACR Mammography QC Manual. *(note: both upper and lower criteria are important to maintain a check on beam quality in the recommended absence of routine kVp tests; if necessary, the MP may conduct kVp testing to investigate outliers)*	≤ 30 days of test date	
8	Average Glandular Dose	Average Glandular Dose Measurement	•Annually •After relevant service	•AGD delivered during a single cranio-caudal view of an attenuator simulating the attenuation of a standard breast must be ≤ 3.0 mGy (0.3 rad) per exposure	Immediately	
		Machine Indicated Average Glandular Dose (AGD) Check	•Annually •After relevant service	•Machine reported AGD must be within ± 25% of measured AGD	≤ 30 days of test date	

[1] All tests must be done during the Mammography Equipment Evaluation (MEE) following installation of new systems; MEEs performed after equipment relocation or service must include relevant tests. Any MEE test failure must be corrected immediately.
[2] Problems must be corrected within the specified time limit; after that, further examinations may not be performed nor any images printed or interpreted using the component of the mammography system that failed the test.

ACR FFDM QC Manual

Required Full Field Digital Mammography Quality Control Tests

Medical Physicist's Tests

No.	Test Name	Test Element	Minimum Frequency[1]	Action Limits	Corrective Action Time Limit[2]	Comments
9	Unit Checklist	Unit Evaluation	Annually	Must pass all tests	≤ 30 days of test date	
10	Evaluation of Site's Technologist QC Program	Evaluation of Site's QC	Annually	•Tech QC tests pass MP review and corrective action documented correctly	≤ 30 days of test date	
11	MQSA Equipment Requirements	MQSA Equipment Requirements	•Upon installation (MEE) •After relevant service	Must meet MQSA requirements	Immediately	MQSA Equipment Requirements
12	Computed Radiography Tests (if applicable)	SNR Inter-plate Consistency	•Annually •After relevant service	•Variation in mAs must be within ± 10 of average •Variation in SNR must be within ± 15% of average	Immediately	
		Artifact Evaluation on All Cassettes	•Annually •After relevant service	•All plates - no clinically significant artifacts	Immediately	
		CR Reader Scanner Performance	•Annually •After relevant service	•Edges on must appear smooth with no jagged edges	Immediately	

[1] All tests must be done during the Mammography Equipment Evaluation (MEE) following installation of new systems; MEEs performed after equipment relocation or service must include relevant tests. Any MEE test failure must be corrected immediately.
[2] Problems must be corrected within the specified time limit; after that, further examinations may not be performed nor any images printed or interpreted using the component of the mammography system that failed the test.

ACR FFDM QC Manual

Required Full Field Digital Mammography Quality Control Tests

Medical Physicist's Tests

No.	Test Name	Test Element	Minimum Frequency[1]	Action Limits	Corrective Action Time Limit[2]	Comments
13	Acquisition Workstation QC	Monitor Screen Evaluation	•Annually •After relevant service	•Monitor screen must be free of scratches, defects, fingerprints, dust, or marks that may impede image interpretatoin.	Immediately	
		Defective Pixel Check	•Annually •After relevant service	•Monitors must be free of any defective pixels that may impede image interpretation	Immediately	
		Test Pattern Evaluation	•Annually •After relevant service	•Test pattern visual evaluation must pass (TG18-QC or SMPTE)	Immediately	Applies only if monitor is capable of test
		Luminance Check (Black and White Level, Luminance Ratio)	•Annually •After relevant service	•Mfr Recommendations •Typically: Lmin < 1.0 cd/m² •Typically: Lmax ≥ 450 cd/m² •Lum Ratio > 250	Immediately	Applies only if monitor is capable of test
		Luminance Uniformity	•Annually •After relevant service	•<30% difference from average for CRT Recommendations •<10% difference from average for LCD	Immediately	Applies only if monitor is capable of test
		DICOM Gray-Scale Display Function (GSDF) Check	•Annually •After relevant service	•Error rate < ± 10% of GSDF	Immediately	Applies only if monitor is capable of test
		Manufacturer's Recommended QC Tests	•Annually •After relevant service	•Per Manufacturer	Per Manufacturer	MP to decide if Mfr QC tests apply to FFDM

[1] All tests must be done during the Mammography Equipment Evaluation (MEE) following installation of new systems; MEEs performed after equipment relocation or service must include relevant tests. Any MEE test failure must be corrected immediately.
[2] Problems must be corrected within the specified time limit; after that, further examinations may not be performed nor any images printed or interpreted using the component of the mammography system that failed the test.

Medical Physicist's Tests

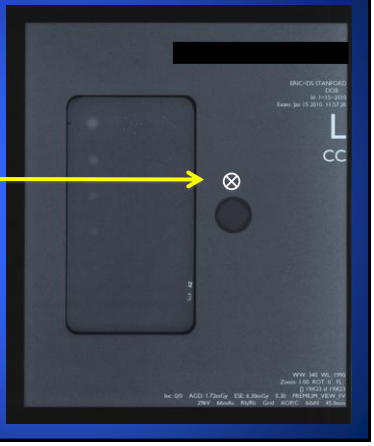
No.	Test Name	Test Element	Minimum Frequency[1]	Action Limits	Corrective Action Time Limit[2]	Comments
14	Radiologist Workstation QC	Monitor Screen Evaluation	•Annually •After relevant service	Screen must be free of scratches, defects, fingerprints, dust, or marks that may impede image interpretation.	Immediately	
		Defective Pixel Check	•Annually •After relevant service	Monitors must be free of any defective pixels that may impede image interpretation	Immediately	
		Test Pattern Evaluation	•Annually •After relevant service	Test pattern visual evaluation must pass (TG18-QC)	Immediately	
		ACR Phantom Scoring & Artifact Check	•Annually •After relevant service	•Fibers ≥ 2.0 •Masses ≥ 3.0 •Specks ≥ 2.0 •No clinically significant artifacts •Distance measured must be 70 mm ± 7.0 mm	Immediately	
		Clinical Image Check (Monitor Comparison)	•Annually •After relevant service	When same clinical image is on each monitor: •Background light levels must match •Color tone must match •Contrast must appear the same	≤ 30 days of test date	
		Ambient Light Conditions	•Annually •After relevant service	•Ambient light should be < 10 lux •Total darkness is not recommended	≤ 30 days of test date	
		Luminance Check (Black and White Level, Luminance Ratio)	•Annually •After relevant service	•Mfr Recommendations •Typically: Lmin < 1.0 cd/m² •Typically: Lmax ≥ 450 cd/m² •Lum Ratio > 250 •Right-Left Ratio for Lmin & Lmax < 10% difference	Immediately	
		Luminance Uniformity	•Annually •After relevant service	•< 30% difference from average for CRT •< 10% difference from average for LCD		
		Gray-Scale Display Function (GSDF) Check	•Annually •After relevant service	•Error rate < ± 10% of GSDF	Immediately	
		Manufacturer's Recommended QC Tests	•Annually •After relevant service	•Per Manufacturer	Per Manufacturer	MP to decide if Mfr QC tests apply to FFDM

Medical Physicist's Tests

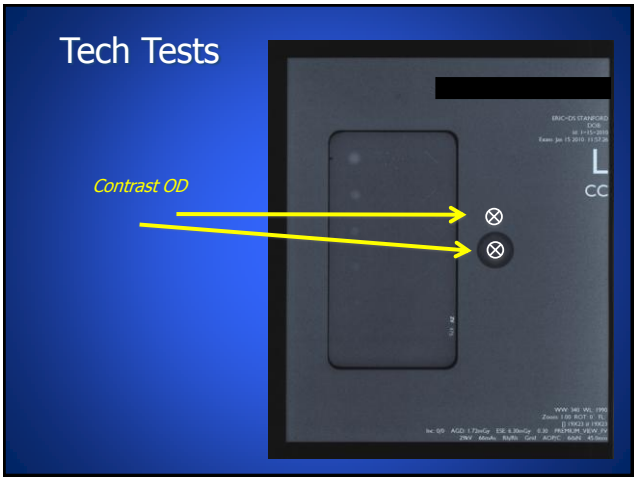
No.	Test Name	Test Element	Minimum Frequency[1]	Action Limits	Corrective Action Time Limit[2]	Comments
15	Laser Printer QC	ACR Phantom Artifact Evaluation	•Annually •After relevant service	No clinically significant artifacts	Immediately	
		ACR Phantom Scoring	•Annually •After relevant service	•Fibers ≥ 2.0 •Masses ≥ 3.0 •Specks ≥ 2.0	Immediately	
		ACR Phantom - Background Optical Density Check	•Annually •After relevant service	•Background OD must be > 1.4 OD •Background OD should be within ± 0.30 of 1.9 OD •Background OD must be within ± 0.15 OD of OL (if applicable)	Immediately	
		ACR Phantom - Contrast Optical Density	•Annually •After relevant service	•Contrast OD must be ≥ 0.10 OD •Contrast OD must be within ~ 0.05 of OL (if applicable)	Immediately	
		ACR Phantom - Dmax Check	•Annually •After relevant service	•≥ 3.5 OD	Immediately	
		ACR Phantom - Printed Size Check	•Annually •After relevant service	•Distance measured must be 70 mm ± 7.0 mm •Size of printed image appears to be correctly sized •Phantom appears to be correctly positioned on the film	Immediately	
		Test Pattern Check	•Annually •After relevant service	Test pattern must pass visual evaluation (TG-18)	Immediately	

Tech Tests

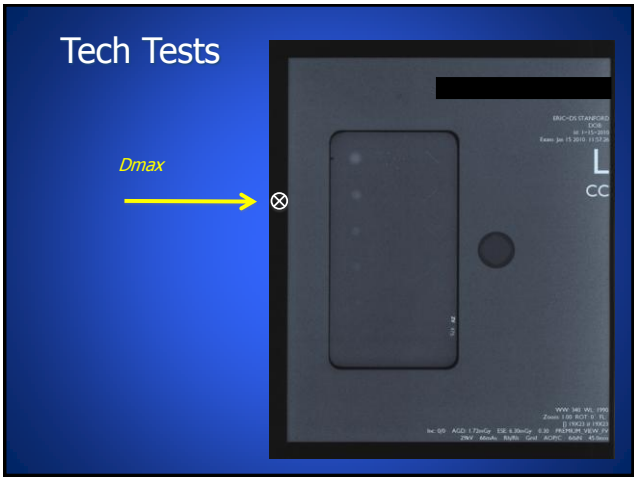
Background OD



Tech Tests



Tech Tests



Medical Physicist's Tests

No.	Test Name	Test Element	Minimum Frequency[1]	Action Limits	Corrective Action Time Limit[2]	Comments
16	Viewbox Luminance and Room Illuminance	Viewbox Luminance	•Annually •After relevant service	•ACR Recommends > 3,000 cd/m2	Immediately	
		Room Illuminance	•Annually •After relevant service	ACR Recommends: •Illuminance at surface ≤ 50 lux •Illuminance seen by observer ≤ 50 lux	Immediately	
17	Evaluation of Off-Site Technologist QC Program	Evaluation of Off-Site's QC	Annually	•Tech QC tests pass MP review and corrective action documented correctly	≤ 30 days of test date	

Summary

- QC Tests
  - We did take into consideration the following:
    - MQSA, ACR SFM Manual, ACRIN DMIST results, Manufacturer's QC programs (FFDM, CR, Monitor, Printer), MITA, European Guidelines, AAPM TG18, and others…
  - Subcommittee and others clinical experience

What's Next – The Approval Process

- When ready, draft will be sent to manufacturers for their input before it is sent to FDA
  - We hope manufacturers will adopt this manual
- Draft should be completed in 2011 for review by FDA
  - When final, ACR will apply for FDA alternative standard under current regulations
  - Alternative standard will allow facilities to use this instead of the manufacturer's manuals
  - Potential for ACR QC Manual to be basis for new MQSA Regulations

Preemptive Questions

- Cost of phantom?
  - Don't know. Reason to believe it will be affordable.
- Implementation and roll-out?
  - ACR to develop a plan to include some sort of training.
- When?
  - Can't be too soon! We're working double-time to get this completed.

Preemptive Questions

- Tomo?
  - Perhaps. Preliminary testing looks very promising.
    - Phantom does show objects in single plane
- CEDM?
  - Yet to be tested.

End of Presentation

Questions?