ACR Accreditation Update in Mammography

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**No financial disclosures to report*

Overview

- ACR Topics
- Requirements Today
- What's Coming For Tomorrow

MQSA - Who's Who

The Law:
Mammography Quality Standards Act (MQSA)

The Regulator:
US Food and Drug Administration (FDA)

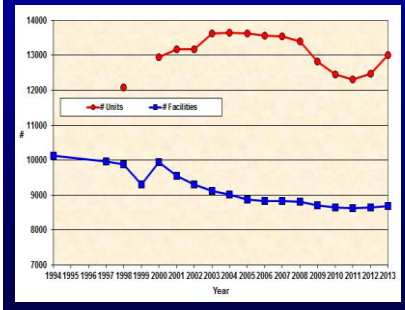
The Accreditation Bodies:
(ACR, TX, IA, AR)

The Inspectors:
States

Introduction

- 4 Accrediting Bodies (AB's)
  - ACR
  - Arkansas
  - Iowa
  - Texas
- 12 approved Mfr's
- ~31 FDA approved units

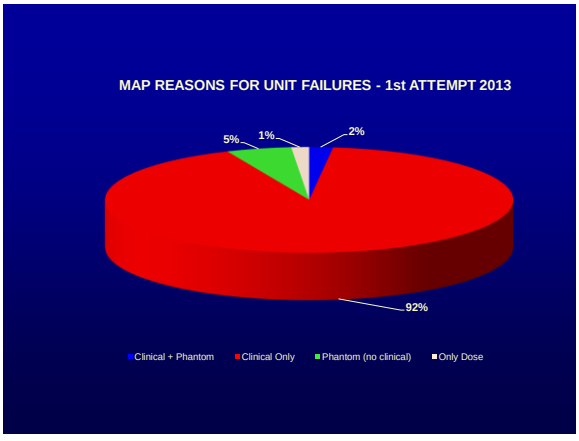
US Mammography Facilities and Units (October 1 each year)



In 2000
- 12,956 units
- 9933 facilities

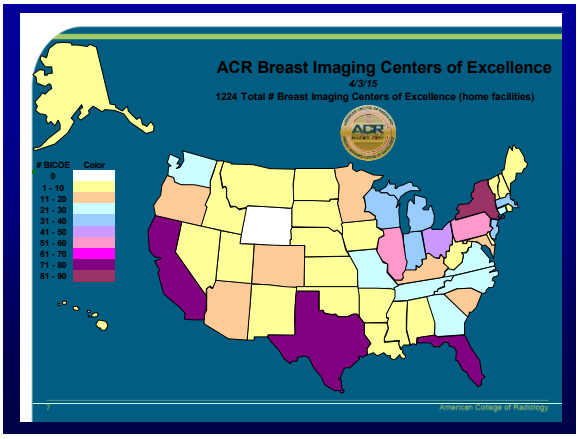
As of 7/1/15
- 14,737 units at
- 8,741 facilities

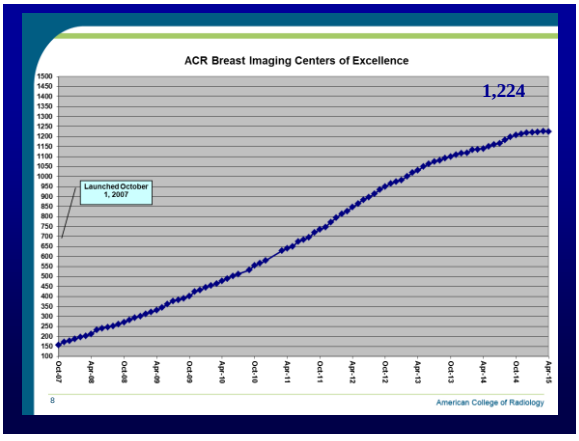
- Increase in units by 1,781
- Drop in facilities by 1,192
- 97% are digital
- Only 446 SFM left



ACR Breast Imaging Centers of Excellence
BICOE

- A center must be fully accredited in:
  - **Mammography** by ACR (or FDA-approved state accrediting body)
  - **Stereotactic** Breast Biopsy by the ACR
  - **Breast Ultrasound** by the ACR (including the Ultrasound-Guided Breast Biopsy module)
  - **Breast MRI** (**Effective Jan 1, 2016**)





Stereo Credits for MP's

Q. In order to obtain continuing education credit for stereotactic breast biopsy, must the coursework be specifically designed for stereotactic breast biopsy?

DBT Credits for MP's

U.S. Food and Drug Administration
Protecting and Promoting *Your* Health

Frequently Asked Questions about DBT and MQSA Training Requirements

Mammographic Modalities and MQSA Training Requirements

Q. Is digital breast tomosynthesis (DBT) a mammographic modality under MQSA?

Q. Do the modality training requirements apply to recently graduated radiology residents, fellows, radiologists providing *locum tenens* services, consulting medical physicists, and mammography technologists providing *per diem* services?

Q. What are the "unique features" of a particular DBT system?

Status of Prior Training

Q. What is the status of training received prior to the FDA approval of the GE and Siemens DBT systems?

FDA DBT Approval Process

MQSA Facility Certification Extension Requirements for Digital Breast Tomosynthesis (DBT) System

NOTE 1: Under MQSA, each manufacturer's Digital Breast Tomosynthesis system is currently considered a separate new mammographic modality, and the personnel requirements for new modality training apply.

NOTE 2: In order to use the tomosynthesis portion of the unit, the facility must apply to FDA to have its certificate extended to include that portion of the unit. **The certification extension only applies to the DBT portion of the unit.** The facility must have the 2D portion of the unit accredited by one of the accreditation bodies already approved to accredit the 2D portion.

Requirements:

1: Manufacturers name of FFDM-DBT unit: _____

2. Facility Status Information

a. Facility Name and FDA Facility ID Number

b. FDA Certificate Expiration Date

c. Current Accreditation Body for the 2D unit

d. Accreditation Expiration Date

e. Facility Contact Person for DBT unit

f. Contact Person's Title

g. Contact Person's Telephone, Fax, E-mail

h. Facility Address

i. Facility Owner

3. DBT Unit Identification

a. Machine Manufacturer

b. Machine Model

c. Year of Manufacture

d. Serial Number

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FDA DBT Approval Process

e. Accreditation Body Unit Number

4. DBT Digital Image Receptor Identification (if interchangeable)

a. Receptor Manufacturer

b. Receptor Model

c. Year of Manufacture

d. Serial Number (if applicable)

5. Identification of Printer for Hard Copy Interpretation (mandatory even for facilities performing only soft copy interpretation)

a. Printer Manufacturer

b. Printer Model

c. Year of Manufacture

d. Serial Number

6. Final Interpretation Review Monitor Identification (if soft copy display is available)

a. Monitor Manufacturer

b. Monitor Model

c. Year of Manufacture

d. Serial Number

7. Phantom Identification

a. Phantom Manufacturer

b. Phantom Model

8. Hardcopy phantom image (3D mode) must be included when submitting application.

9. Personnel Qualifications

a. Interpreting Physicians who are qualified to interpret DBT mammograms (see Qualified Personnel)

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FDA DBT Approval Process

b. Radiological Technologists who are qualified to perform DBT mammography examinations and the manufacturer recommended quality assurance tests (see Qualified Personnel)

c. Medical Physicists who are qualified to perform equipment evaluations and/or surveys of DBT mammography units (Qualified Personnel)

10. Complete Detailed report of Mammography Equipment Evaluation (MEE) (must have been conducted in accordance with 900.12(e)(10) within the 6 months prior to the request for use approval) **must be included when submitting application.**

a. Statement that equipment performance, as required under the following sections of the MQSA final regulation 21 CFR 900.12(b), is met:

(1) Prohibited Equipment
(2) Specifically Designed for Mammography
(3) Motion of Tube-Image Receptor Assembly
(4)(iii) Removable Grid (if applicable to the DBT system used) (5) Beam Limitation and Light Fields
(6) Magnification
(7) Focal Spot Selection
(8) Compression
(9) Technique Factor Selection and Display
(10) Automatic Exposure Control

b. The results of quality control tests as required under the following sections of the MQSA final regulations 21CFR 900.12(e):

(4)(iii) Compression Device Performance
(5)(i) Automatic Exposure Control Performance (if applicable to the DBT system used) (5)(ii) Kilovoltage Peak Accuracy and Reproducibility
(5)(iii) Focal Spot Condition (Resolution) (5)(iv) Beam Quality and Half-Value Layer
(5)(v) Breast Entrance Air Kerma and AEC Reproducibility (if applicable to the DBT system used) (5)(vi) Dosimetry
(5)(vii) X-Ray Field/Light field/Image receptor/Compression paddle alignment
(5)(ix) System Artifacts
(5)(x) Radiation Output
(5)(xi) Decompression (or alternative standards allowed for these requirements) (6) Quality Control Tests – Other Modalities (Facilities must perform all DBT manufacturer recommended quality control tests including the medical physicist's tests for Soft Copy Display system)

c. The results of the phantom image quality tests, including a sample image
d. If any of the requirements in 8 a, b, or c are not met, submit documentation of successful corrective action
e. If any of the requirements in 8 a or b are not performed, explain why the requirement is not applicable

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FDA DBT Approval Process

f. Date of the MEE
g. Name and address of the physicist(s) who performed the MEE

11. DBT Manufacturer's Quality Control Program

a. Name of the Quality Control Manual
b. Year published
c. Revision number, if not the original
d. Printing number, if not the original

12. Signature of facility contact person for the DBT unit _____

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FDA DBT Approval Process

Qualified Personnel

Interpreting Physicians

PERSONNEL QUALIFICATIONS: INTERPRETING PHYSICIANS WHO ARE QUALIFIED TO INTERPRET DBT MAMMOGRAMS

List the current interpreting physicians who:

(1) meet all the requirements of 21 CFR 900.12(a)(1) "Mammography Quality Standards; Final Rule" that became effective on April 28, 1999; and

(2) have 8 hours of initial new-modality training in DBT, either including or supplemented by training in the unique features of the specific manufacturer's DBT system.

* Supporting documentation for these requirements will be checked during annual MQSA inspections.

Radiologic Technologists

PERSONNEL QUALIFICATIONS: RADIOLOGIC TECHNOLOGISTS WHO ARE QUALIFIED TO PERFORM DBT MAMMOGRAMS

List the current radiologic technologists who:

(1) meet all the requirements of 21 CFR 900.12(a)(3) "Mammography Quality Standards; Final Rule" that became effective on April 28, 1999; and

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FDA DBT Approval Process

(2) have 8 hours of initial new-modality training in DBT, either including or supplemented by training in the unique features of the specific manufacturer's DBT system.

* Supporting documentation for these requirements will be checked during annual MQSA inspections.

Medical Physicists

PERSONNEL QUALIFICATIONS: MEDICAL PHYSICISTS WHO ARE QUALIFIED TO PERFORM DBT SURVEYS

List the current medical physicists who:

(1) meet all the requirements of 21 CFR 900.12(a)(3) "Mammography Quality Standards; Final Rule" that became effective on April 28, 1999; and

(2) have 8 hours of initial new-modality training in DBT, either including or supplemented by training in the unique features of the specific manufacturer's DBT system.

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FDA DBT Approval Process

* Supporting documentation for these requirements will be checked during annual MQSA inspections.

Lead Interpreting Physician Attestation to Staff Personnel Qualifications

To the best of my knowledge and my belief, the information provided in this document is true and correct. I understand that FDA may request additional information to substantiate the statements made in the document. I understand that knowingly providing false informations in a matter within the jurisdiction of an agency of the United States could result in criminal liability, punishable by up to $10,000 fine and imprisonment of up to five years, or civil liability under MQSA, or both.

Signature (Lead Interpreting Physician) _____

Print Name _____ _____

Date _____

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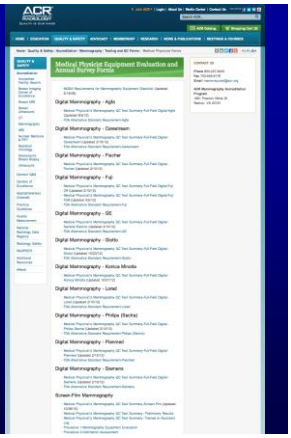
Before You Begin

- Qualifications
  - Initial
    - Master's or Bachelor's Pathway's
    - Board Certification
    - 8 hours of training in mammography (e.g. digital)
  - Continuing Experience
    - 2 Facilities & 6 Units over a 24-month Period
    - 15 CME's in mammography in a 36-month period

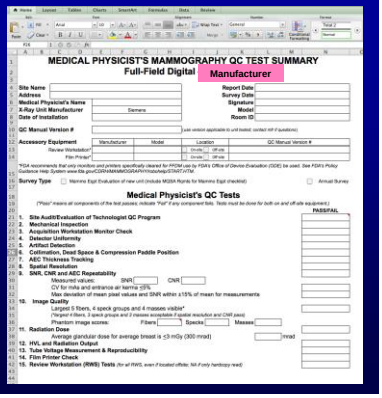
Introduction

- ACR Accreditation Program



Introduction

- ACR Accreditation Program

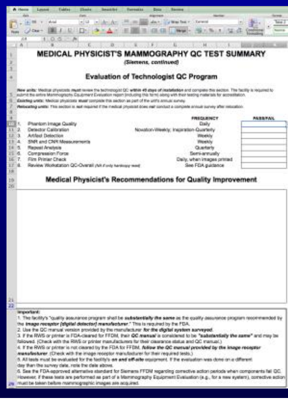


Introduction

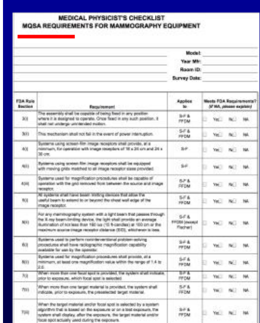
- ACR

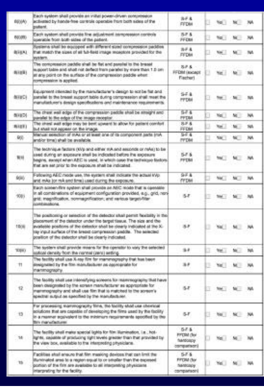
  Accreditation

  Program



Introduction





Introduction

- Golden Rules
  - Still must use Manufacturer's QC Manual
    - May refer to Monitor & Printer Manufacturers' QC
    - Multimodality Workstations may have own separate QC
    - Printers may have their own QC

Introduction

- Tips from ACR……
  - Always get latest version of ACR Summary Forms from Web
  - Verify you're using correct Mfr QC Manual version
  - Record the correct Mfr QC Manual version on your report
  - Make sure you perform all tests in the Mfr QC Manual!

The ACR FFDM Phantom Prototype

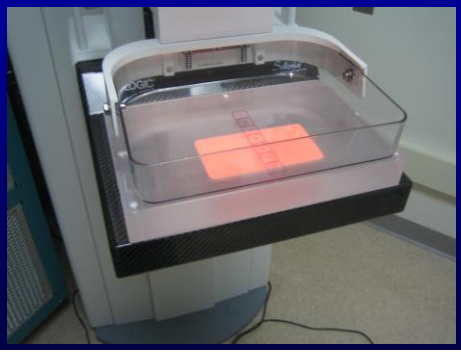


Image of Entire Phantom

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

Wax Insert

Expanded view of Wax Insert

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

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

The ACR DM Phantom

- Summary
  - Permits testing of the MQSA 3.0 mGy dose limit (Single CC view) – Similar thickness and dose
  - **Eliminate** subtraction for artifacts
  - **Add** "Fail" for artifacts
  - New pass/fail criteria from
    - 4,3,3 → 2,3,2
    - **But, objects are the same (effective) size as SFM Phantom
  - Can be used on both SFM & FFDM (…. Important b/c of CR)
  - Build on experience of QC techs and physicists at ~8,700 US facilities who already know how to use and score the existing phantom (~24,000 Techs)

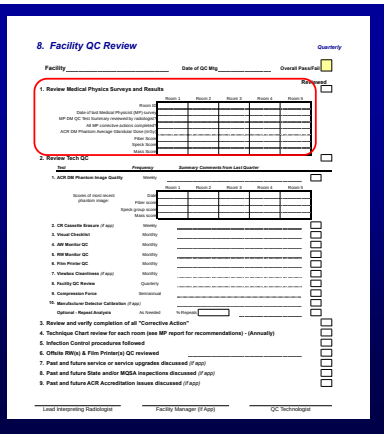
Technologist QC Tests

Test Number	Name	Minimum Frequency	Required Corrective Action
1	ACR DM Phantom Image Quality	Weekly	Before Clinical Use
2	CR Cassette Erasure (if applicable)	Weekly	Before Clinical Use
3	Visual Checklist	Monthly	As noted on form
4	Acquisition Workstation (AW) Monitor QC	Monthly	30 Days or Before Use for Severe Artifacts
5	Radiologist Workstation (RW) Monitor QC	Monthly	30 Days or Before Use for Severe Artifacts
6	Film Printer QC	Monthly	Before Clinical Use
7	Viewbox Cleanliness (if app)	Monthly	Before Clinical Use
8	Facility QC Review	Quarterly	Not Applicable
9	Compression Force	Semiannual	Before Clinical Use
10	Manufacturer Detector Calibration (If Applicable)	Per Mfr Recommendation	Before Clinical Use
	Optional - Repeat Analysis	As Needed	Within 30 days after analysis
	Optional – System QC for Radiologist	As Needed	30 Days or Before Use for Severe Artifacts
	Optional – Radiologist Image Quality Feedback	As Needed	Not applicable

Management Forms

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

Tech Tests



8. Facility QC Review — Quarterly

Facility _____ Date of QC Mtg _____ Overall Pass/Fail ☐

1. Review Medical Physics Surveys and Results — Reviewed ☐

	Room 1	Room 2	Room 3	Room 4	Room 5
Room ID					
Date of last Medical Physicist (MP) survey					
MP DM QC Test Summary reviewed by radiologist?					
All MP corrective actions completed?					
ACR DM Phantom Average Glandular Dose (AGD)					
Fiber Score					
Speck Score					
Mass Score					

2. Review Tech QC

Test	Frequency	Summary Comments from Last Quarter
1. ACR DM Phantom Image Quality	Weekly	
Scores of most recent phantom image:		Room 1 / Room 2 / Room 3 / Room 4 / Room 5; Date; Fiber score; Speck group score; Mass score
2. CR Cassette Erasure (if app)	Weekly	
3. Visual Checklist	Monthly	
4. AW Monitor QC	Monthly	
5. RW Monitor QC	Monthly	
6. Film Printer QC	Monthly	
7. Viewbox Cleanliness (if app)	Monthly	
8. Facility QC Review	Quarterly	
9. Compression Force	Semiannual	
10. Manufacturer Detector Calibration (if app)		
Optional - Repeat Analysis	As Needed	% Repeats

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)* ☐

_____ Lead Interpreting Radiologist

_____ Facility Manager (If App)

_____ QC Technologist

Tech Tests

Facility Offsite Display Locations

Facility ______________________ MAP ID# *(00000)* ________

Address

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

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Tech Tests

Facility Display Device QC Summary Checklist

Facility ______________________ MAP ID# *(00000)* ________

Address ______________________

Address ______________________

QC Summary information for display devices at this MAP ID

Physical Location at Facility/ ID Designation									
Device *(RW, film printer, viewbox)*									
Manufacturer									
Model									
Jan	Date								
	Tech Initials								
Feb	Date								
	Tech Initials								
Mar	Date								
	Tech Initials								
Apr	Date								
	Tech Initials								
May	Date								
	Tech Initials								
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Aug	Date								
	Tech Initials								
Sep	Date								
	Tech Initials								
Oct	Date								
	Tech Initials								
Nov	Date								
	Tech Initials								
Dec	Date								
	Tech Initials								
Medical Physicist Survey Date									
Medical Physicist Name(s)									

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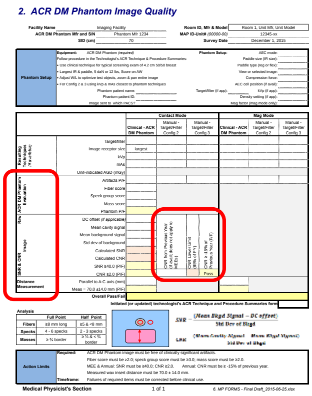
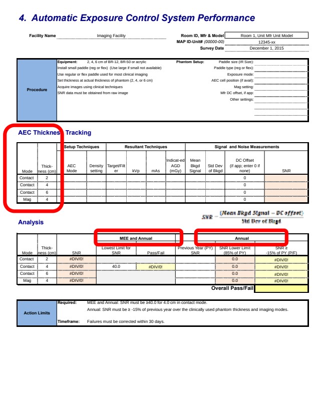
Medical Physicists QC Tests

Test #	Name	Minimum Frequency	Req'd Corr.Action
1	Mammography Equipment Evaluation & MQSA Requirements	MEE Only	Before Clinical Use
2	ACR DM Phantom Image Quality	Annual	Before Clinical Use
3	Spatial Resolution	Annual	Within 30 Days
4	Automatic Exposure Control System Performance	Annual	Within 30 Days
5	Average Glandular Dose	Annual	Before Clinical Use
6	Unit Checklist	Annual	Before Clinical Use**
7	Computed Radiography (If Applicable)	Annual	Before Clinical Use
8	Acquisition Workstation (AW) Monitor QC	Annual	Before Clinical Use**
9	Radiologist Workstation (RW) Monitor QC	Annual	Before Clinical Use**
10	Film Printer QC	Annual	Before Clinical Use
11	Evaluation of Site's Technologist QC Program	Annual	Within 30 Days
12	Evaluation of Off-Site Technologist QC Program (If App)	Annual	Within 30 Days
MEE or Troubleshooting Test Forms			
	Beam Quality (Half-Value Layer) Assessment	MEE or Troubleshooting	Before Clin or 30 D
	kVp Accuracy and Reproducibility	MEE or Troubleshooting	Before Clin or 30 D
	Collimation Assessment	MEE or Troubleshooting	Before Clin or 30 D
	Ghost Image Evaluation (Troubleshooting only)	Troubleshooting	Before Clinical
	Viewbox Luminance (Troubleshooting only)	Troubleshooting	**
Summary Report Forms			
	Medical Physicist DM QC Summary		
	Technique Chart (Clinical & Phantom)		
	Medical Physicist Summary Letter for the Radiologist		

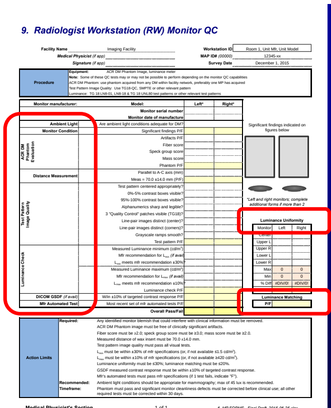
MP Tests



MP Tests

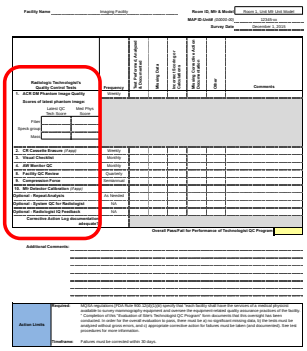


MP Tests



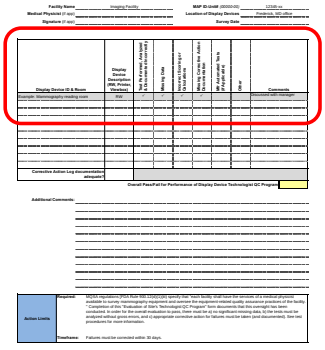
MP Tests

11. Evaluation of Site's Technologist QC Program



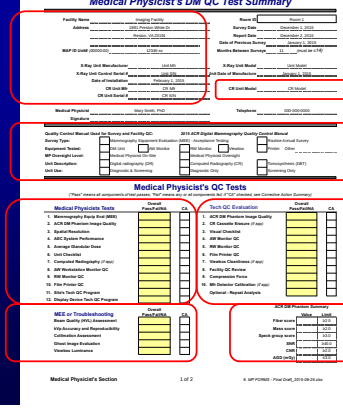
MP Tests

12. Evaluation of Display Device Technologist QC Program



MP Tests

Medical Physicist's DM QC Test Summary



What's Next

Status

- Final draft is in the submission process to the FDA for an alternative standard under current regulations
  - Alternative standard application must include a statement from MITA that use of the ACR Manual results in substantially the same clinical image quality as use of the manufacturer's manuals.
  - 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

End of Presentation

Questions?