Update on MQSA and Mammography Accreditation

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MQSA - Who's Who

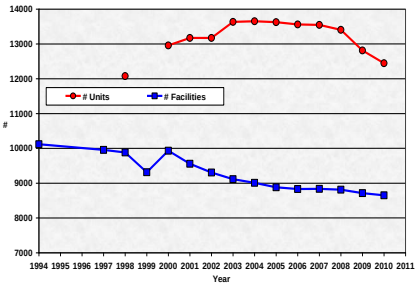
The Law: Mammography Quality Standards Act (MQSA)

The Regulator: US Food and Drug Administration (FDA)

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

The Inspectors: States

US Mammography Facilities and Units (October 1 each year)



In 2000

- 12,956 units at 9933 facilities
- 1.3 units/facility

As of 4/1/11

- 12,313 units at 8641 facilities
- 1.42 units per facility
- 5% drop in units/15% drop in facilities since 2000

MQSA and New Units

- **What you must do before examining patients on a new unit depends on**
  - **If you are a brand new facility**
  - **If you installed a new unit at an already accredited facility**

If You Are a Brand New Facility - Before You May Examine Patients

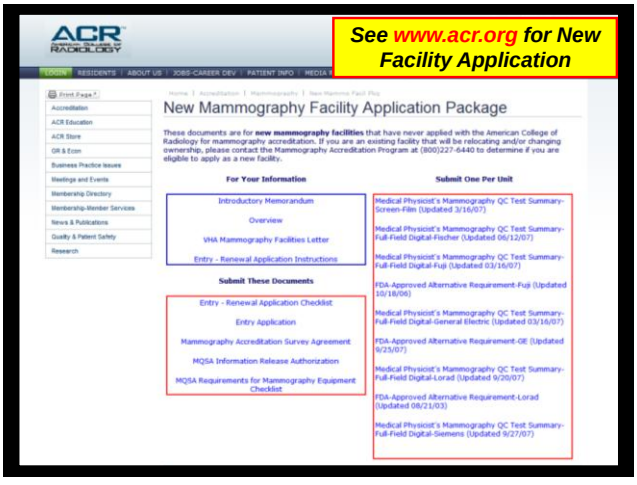
- Your medical physicist must
  - Do all FDA-required Equipment Evaluation tests
  - All tests must pass
- You must send ACR
  - A complete Entry Application
  - Equipment Evaluation Pass/Fail results
  - Fees
- Then…

If You Are a Brand New Facility - Before You May Examine Patients

- ACR staff must
  - Review and approve complete application and Equipment Evaluation
  - Notify FDA (or state certifier) OK to send MQSA certificate (or interim notice)
- There's more…

If You Are a Brand New Facility - Before You May Examine Patients

- You must physically have a
  - 6-month provisional MQSA certificate (or interim notice)
- Timing
  - Getting the MQSA certificate takes approximately 4 days from the time facility submits complete documentation to ACR
  - Recommend scheduling Equipment Evaluation 1 week before examining patients (including "applications")



If Your Facility Is Already Accredited - Before You May Examine Patients

- You must call ACR for appropriate application materials
- Your medical physicist must
  - Do all FDA-required Equipment Evaluation tests
  - All tests must pass
- You must send ACR
  - A complete Entry Application
  - Equipment Evaluation Pass/Fail results
  - Fees
- Then…

If Your Facility Is Already Accredited - Before You May Examine Patients

- ACR staff must
  - Review and approve complete application and Equipment Evaluation
  - Notify FDA (or state certifier)
- However…

If Your Facility Is Already Accredited - Before You May Examine Patients

- You do not have to wait for a response from ACR to use the new unit for mammography
  - Your facility already has a current MQSA certificate
- Beware of the catch if installing facility's 1st digital unit:
  - CMS will not reimburse if they don't have notification from FDA that you are approved for digital
  - Call ACR to be sure we have received and reviewed your complete application and transmitted it to the FDA before using the new digital unit

Medical Physicist's QC

- Medical physicist must complete ACR's summary forms
  - MQSA Requirements for Mammography Equipment (checklist)
  - Medical Physicist's Mammography QC Test Summary (FFDM mfr-specific)

Medical Physicist's QC

- Forms provides ACR with needed pass/fail information
  - If medical physicist passes test, ACR accepts it
  - If she fails test, ACR requests corrective action
  - If she writes "NA," "see comments" (or anything other than pass or fail), ACR will follow-up; accreditation will be delayed
- Significantly different formats (even if they contain all the necessary information) will delay review

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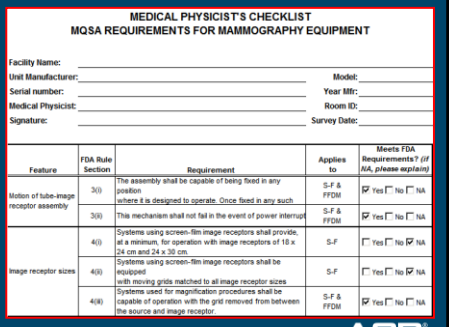
Download Medical Physicist Summary Forms

- www.acr.org
- In Excel format
- Required for Equipment Evaluation report
- Addresses 900.12(b) of the FDA regulations
- Same for S-F and FFDM



MEDICAL PHYSICIST'S CHECKLIST
MQSA REQUIREMENTS FOR MAMMOGRAPHY EQUIPMENT

Facility Name: _____
Unit Manufacturer: _____ Model: _____
Serial number: _____ Year Mfr: _____
Medical Physicist: _____ Room ID: _____
Signature: _____ Survey Date: _____

Feature	FDA Rule Section	Requirement	Applies to	Meets FDA Requirements? (if NA, please explain)
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	S-F & FFDM	☑ Yes ☐ No ☐ NA
	3(ii)	This mechanism shall not fail in the event of power interrupt	S-F & FFDM	☑ Yes ☐ No ☐ NA
Image receptor sizes	4(i)	Systems using screen-film image receptors shall provide, at a minimum, for operation with image receptors of 18 x 24 cm and 24 x 30 cm.	S-F	☐ Yes ☐ No ☑ NA
	4(ii)	Systems using screen-film image receptors shall be equipped with moving grids matched to all image receptor sizes	S-F	☐ Yes ☐ No ☑ NA
	4(iii)	Systems used for magnification procedures shall be capable of operation with the grid removed from between the source and image receptor.	S-F & FFDM	☑ Yes ☐ No ☐ NA

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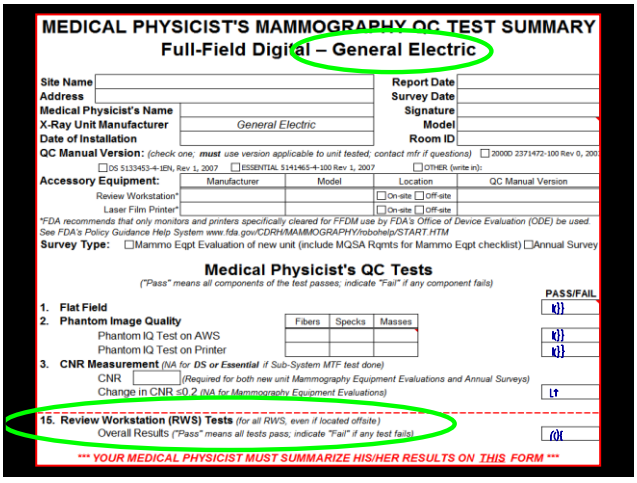

MEDICAL PHYSICIST'S MAMMOGRAPHY QC TEST SUMMARY
Full-Field Digital – General Electric

Site Name | Report Date
Address | Survey Date
Medical Physicist's Name | Signature
X-Ray Unit Manufacturer: General Electric | Model
Date of Installation | Room ID

QC Manual Version: *(check one; **must** use version applicable to unit tested; contact mfr if questions)* ☐ 2000D 2371472-100 Rev 0, 200-DS 5133453-4-1EN, Rev 1, 2007 ☐ ESSENTIAL 5141465-4-100 Rev 1, 2007 ☐ OTHER (write in):

Accessory Equipment:	Manufacturer	Model	Location	QC Manual Version
Review Workstation*			☐ On-site ☐ Off-site	
Laser Film Printer*			☐ On-site ☐ Off-site	

*FDA recommends that only monitors and printers specifically cleared for FFDM use by FDA's Office of Device Evaluation (ODE) be used. See FDA's Policy Guidance Help System www.fda.gov/CDRH/MAMMOGRAPHY/robohelp/START.HTM

Survey Type: ☐ Mammo Eqpt Evaluation of new unit (include MQSA Rqmts for Mammo Eqpt checklist) ☐ Annual Survey

Medical Physicist's QC Tests
("Pass" means all components of the test passes; indicate "Fail" if any component fails)

	Fibers	Specks	Masses	PASS/FAIL
1. **Flat Field**				
2. **Phantom Image Quality**				
Phantom IQ Test on AWS				
Phantom IQ Test on Printer				
3. **CNR Measurement** *(NA for **DS or Essential** if Sub-System MTF test done)*				
CNR		*(Required for both new unit Mammography Equipment Evaluations and Annual Surveys)*		
Change in CNR ≤0.2 *(NA for Mammography Equipment Evaluations)*				
15. **Review Workstation (RWS) Tests** *(for all RWS, even if located offsite)*				
Overall Results *("Pass" means all tests pass; indicate "Fail" if any test fails)*				

*** YOUR MEDICAL PHYSICIST MUST SUMMARIZE HIS/HER RESULTS ON THIS FORM ***

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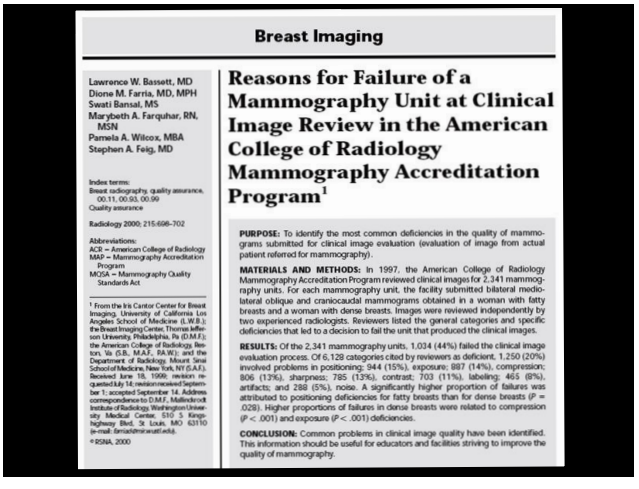
Tips for Passing Accreditation

Accreditation Testing

- Clinical image (fatty and dense breast)
  - Phantom image
  - Dose (<300 mrads)
- Hard copy QC
  - Film processor
  - Laser printer (see mfr QC manual)
- Criteria the same for digital as with screen-film

Clinical Image Quality Evaluation - FFDM

- Positioning
- Compression
- Exposure level
- Contrast
- Sharpness
- Noise
- Artifacts
- Exam ID
  - Must be present
  - OK under HIPAA



Breast Imaging

Reasons for Failure of a Mammography Unit at Clinical Image Review in the American College of Radiology Mammography Accreditation Program[1]

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Index terms:
Breast, radiography, quality assurance, 00.11, 00.93, 00.99
Quality assurance

Radiology 2000; 215:698–702

Abbreviations:
ACR = American College of Radiology
MAP = Mammography Accreditation Program
MQSA = Mammography Quality Standards Act

[1] From the Iris Cantor Center for Breast Imaging, University of California Los Angeles School of Medicine (L.W.B.); the Breast Imaging Center, Thomas Jefferson University, Philadelphia, Pa (D.M.F.); the American College of Radiology, Reston, Va (S.B., M.A.F., P.A.W.); and the Department of Radiology, Mount Sinai School of Medicine, New York, NY (S.A.F.). Received June 18, 1999; revision requested July 14; revision received September 1; accepted September 14. Address correspondence to D.M.F., Mallinckrodt Institute of Radiology, Washington University Medical Center, 510 S. Kingshighway Blvd, St. Louis, MO 63110 (e-mail: farriad@msnotes.wustl.edu).

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PURPOSE: To identify the most common deficiencies in the quality of mammograms submitted for clinical image evaluation (evaluation of image from actual patient referred for mammography).

MATERIALS AND METHODS: In 1997, the American College of Radiology Mammography Accreditation Program reviewed clinical images for 2,341 mammography units. For each mammography unit, the facility submitted bilateral mediolateral oblique and craniocaudal mammograms obtained in a woman with fatty breasts and a woman with dense breasts. Images were reviewed independently by two experienced radiologists. Reviewers listed the general categories and specific deficiencies that led to a decision to fail the unit that produced the clinical images.

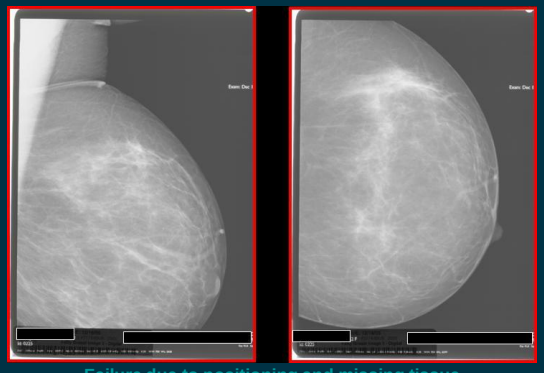
RESULTS: Of the 2,341 mammography units, 1,034 (44%) failed the clinical image evaluation process. Of 6,128 categories cited by reviewers as deficient, 1,250 (20%) involved problems in positioning; 944 (15%), exposure; 887 (14%), compression; 806 (13%), sharpness; 785 (13%), contrast; 703 (11%), labeling; 465 (8%), artifacts; and 288 (5%), noise. A significantly higher proportion of failures was attributed to positioning deficiencies for fatty breasts than for dense breasts ($P = .028$). Higher proportions of failures in dense breasts were related to compression ($P < .001$) and exposure ($P < .001$) deficiencies.

CONCLUSION: Common problems in clinical image quality have been identified. This information should be useful for educators and facilities striving to improve the quality of mammography.

Reasons for Clinical Failure – still the major reason for failure with FFDM

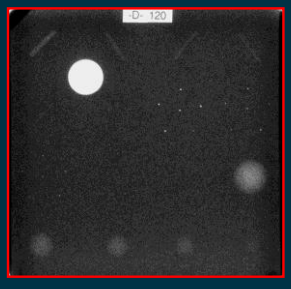
Imaging Category	Failure Rate (%)
Positioning	20
Exposure	15
Compression	14
Sharpness	13
Contrast	13
Artifacts	11
Labeling	8
Noise	5

Why Did This Digital Case Fail Accreditation?



Failure due to positioning and missing tissue

Phantom Image Quality Evaluation



- Follow ACR testing instructions
  - Expose at technique for 4.2 cm breast
- Process image as done for clinical images
- Window and level to best show test objects
- Scoring criteria
  - 4 largest fibers
  - 3 largest speck groups
  - 3 largest masses
  - Be sure to subtract for artifacts

For Digital, ACR Only Accepts Hardcopy for Accreditation

- **Phantom**
  - **Do not zoom or rotate**
  - **Print as close to "true size" as possible (w/in +/- 25%)**
  - **Do not send in 14X17 images**
- **Clinical**
  - **Must be of "final interpretation quality"**
  - **Entire breast must fit on image; no "tiling"**
  - **Print as close to "true size" as possible**
  - **Must contain patient ID information**
- **Lead interpreting physician must review and approve all hardcopy images**

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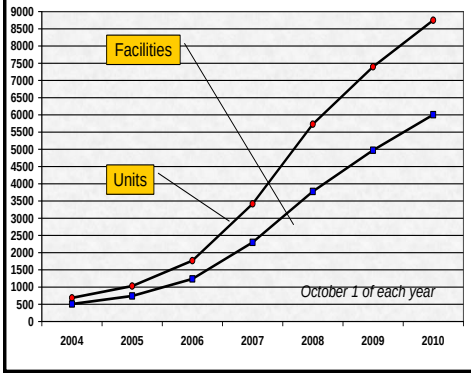
Look at the Growth of FFDM in the US!



As of 4/1/11

- **9387 units at 6523 facilities**
- **Over 76% of all units in US are FFDM**

FDA Approved ACR to Accredit

- GE
  - 2000D, DS, Essential
- Fischer
  - SenoScan
- Lorad
  - Selenia
- Siemens
  - Novation
- Fuji
  - FCRm (computed radiography)
- Carestream
  - DirectView

- Hologic Digital Breast Tomosynthesis (DBT) System approved for sale in US (Feb 2011)
- On 4/28 FDA approved the Sectra Microdose Mammography L30 for sale the US

Digital Breast Tomosynthesis (DBT) System Accreditation

- Accreditation Bodies (ABs) cannot accredit the DBT modality portion of the unit because they do not have the capability to review DBT images
- Facilities with DBT must apply for accreditation of Selenia Dimensions 2D aspect of AND
- Apply to FDA to extend its certification to include DBT
  - Submit additional DBT testing results and other documentation directly to FDA for review and approval

ACR's Current FFDM QC Requirements

- Same as FDA's
- Which are the same as the manufacturer's
- ACR suggests using manufacturer's data forms

Manufacturer's FFDM QC Requirements – They Vary…A Lot

- By manufacturer and model
  - Some tests same but names different
  - Some tests not required by some manufacturers
  - Frequencies vary
  - Procedures vary
  - Pass/fail criteria
- All of the above may vary with QC manual revisions of same manufacturer/model

QC, Equipment Evaluation, and Annual Survey Conduct and Review

- Confusing for technologists with multiple manufacturers (or single manufacturer but multiple models or software versions) at same facility
- Confusing for medical physicists surveying multiple facilities with different equipment for same reasons
- Confusing for accreditation staff and inspectors to review for same reasons
- Examples…

Mfr QC Manuals Are All Very Different Example: Technologist Tests-Frequencies

Test	Monitor Cleaning	SNR and/or CNR	Flat Field	MTF/ Sys Res
GE	Daily	Monthly	Weekly	Monthly (2000D) Weekly (DS, Essential)
Fischer	Not in QC	Weekly	Weekly	Monthly
Fuji	Not req'd	Weekly	Not req'd	Not req'd
Lorad	Not req'd	Weekly	Weekly	Not req'd
Siemens	Daily (Syngo)	Weekly	Weekly	Not req'd

Mfr QC Manuals Are All Very Different Example: Medical Physicist Tests-Names

Test	Flat Field	SNR and/or CNR	MTF/Sys Res
GE	*Flat Field*	*AOP Mode and SNR; CNR*	*MTF or Sub-System MTF*
Fischer	*Flat Field*	*Phantom Image Acquisition*	*System Resolution/Scan Speed Uniformity*
Fuji	*System Artifact Evaluation*	*AEC System Performance; Interplate Consistency*	*System Resolution*
Lorad	*Artifact Evaluation*	*SNR; CNR*	*Evaluation of System Resolution*
Siemens	*Detector Uniformity and Artifact Detection*	*SNR; CNR*	*Spatial Resolution*

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
  - GE, Lorad and Fuji applied for alternative standards to allow 30 days for some QC tests

Laser Film Printers

- FDA recommends only using printers cleared by FDA's Office of Device Evaluation for FFDM (but may legally use others)
- Facility must have access to a laser printer (either on-site or someplace else)
- Printer must exist and be tested by MP before the facility performs mammography

Laser Film Printer QC

FFDM Mfr	Model	FFDM Mfr's Printer QC Instructions
Fischer	SenoScan	Follow the laser printer mfr's QC
Fuji	FCRm	Follow the laser printer mfr's QC
GE	2000D, DS, Essential	Follow the laser printer mfr's QC
Lorad	Selenia	Follow the Lorad Selenia QC Manual
Siemens	Mammomat Novation DR	Follow the laser printer mfr's QC (but conduct QC every day you print)

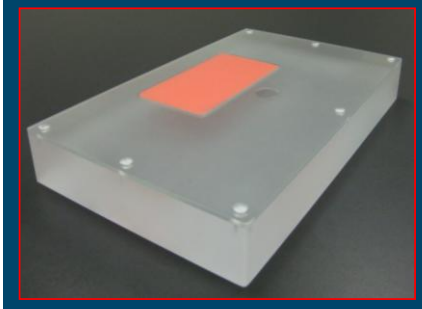
Monitors and Workstations

- FDA MQSA regs: must comply with a QA program substantially the same as recommended by the FFDM manufacturer (i.e., GE, Fischer, Lorad, Siemens, Fuji)
  - Impractical; sometimes impossible since some is software-based
- FDA says
  - If the monitor/workstation has been approved by FDA's ODE for FFDM, the monitor's QC manual is "substantially the same" and facilities may follow
  - If monitor was not approved by FDA ODE for FFDM facilities must follow one by FFDM mfr
- FDA ODE approved monitors/workstations
  - Over 500 approved total
  - ??? have been approved for FFDM

ACR FFDM QC Manual Project

- Eric Berns, Ph.D., chair, Subcommittee on QA
- Subcommittee includes medical physicists, radiologists, MITA representatives and technologists
- Standardize QC tests, performance criteria and frequencies across all systems
  - Will apply to all manufacturers and models
  - New phantom to be more applicable to digital (but usable with screen-film)

New ACR FFDM Phantom (prototype)



- Smaller fibers, specks and masses
- But P/F criteria (size) will be same
- Larger to cover entire detector
- AEC response better
- Permits artifact evaluation
- To be used with most tests

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New ACR FFDM Phantom (prototype)

ACR FFDM QC Phantom

- Developed with assistance and input from several MITA phantom and equipment manufacturers
- Still a prototype
- Will not be commercially available for use in accreditation until the FDA reviews and approves it along with the manual

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New Manual Technologist QC Tests (draft)

- Fewer tests and written to be "tech friendly"
  - Still undergoing field testing by committee and manufacturers
- More pictures
- Excel forms downloadable from website – may be completed on paper or via computer

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New Manual Technologist QC Tests-I (draft)

- Monitor Cleanliness (weekly)
- ACR Phantom Image Quality – multipurpose (weekly)
  - Technique evaluation
  - Compression thickness
  - Dose display
  - Contrast-to-noise
  - Artifacts
  - Scoring
- Laser Printer QC – done with phantom (weekly)
  - Scoring
  - Artifacts
  - Optical density
  - No graphing (record data on chart)

New Manual Technologist QC Tests-II (draft)

- Monitor QC - AWS and RWS (weekly)
  - Phantom evaluation (scoring and artifacts)
  - AAPM TG-18 test pattern
  - Built in automatic tests (if available from manufacturer)
- Viewbox Cleanliness Check – same (weekly)
- Visual Checklist (monthly)
- Repeat Analysis (quarterly)
- Compression Force (semi-annual)
- Detector Calibration (optional)
- Quarterly QC Review

New Manual Technologist QC Tests-III (draft)

- QC Review – new (quarterly)
  - To enhance communication among key mammography personnel
  - Reviewers
    - ✓QC technologist
    - ✓Facility manager
    - ✓Supervising radiologist
  - Review
    - ✓Technique chart
    - ✓QC in the last quarter
    - ✓Corrective action

New Manual Medical Physicist Tests (draft)

- Excel forms downloadable from website – designed to be completed via computer (with calculations built in)
- New summary form designed for radiologist (in addition to main summary form)

New Manual Medical Physicist Tests-I (draft)

- ACR Phantom Image Quality (Acquisition Workstation)
  - Phantom scoring
  - Artifacts
  - SNR
  - CNR
  - Geometric accuracy
- Ghost Image Evaluation
- Automatic Exposure Control System Performance

New Manual Medical Physicist Tests-II (draft)

- Spatial Resolution
  - Bar pattern
- Collimation Assessment
  - Traditional method,
  - Ready pack film/paper, or
  - Electronic device
- kVp Accuracy and Reproducibility
  - For Mammography Equipment Evaluations only (not annually)

New Manual Medical Physicist Tests-III (draft)

- Beam Quality (Half-Value Layer) Assessment
- Average Glandular Dose
  - Phantom
  - 2 cm attenuator
  - 6 cm attenuator
- Unit Checklist

New Manual Medical Physicist Tests-IV (draft)

- Monitor QC
  - Acquisition station monitor
  - Radiologist work station monitors
  - Use phantom image and AAPM TG-18
  - Must consider diverse practice patterns
- Laser Printer QC
  - Use phantom image and AAPM TG-18
  - Must consider diverse practice patterns
- Evaluation of Site's Technologist QC Program
  - MPs need to play a stronger role
- Computed Radiography Tests

ACR FFDM QC Manual – 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 2010 for review by FDA
  - When final, ACR will apply for FDA alternative standard
  - Alternative standard will allow facilities to use this instead of the manufacturer's manuals

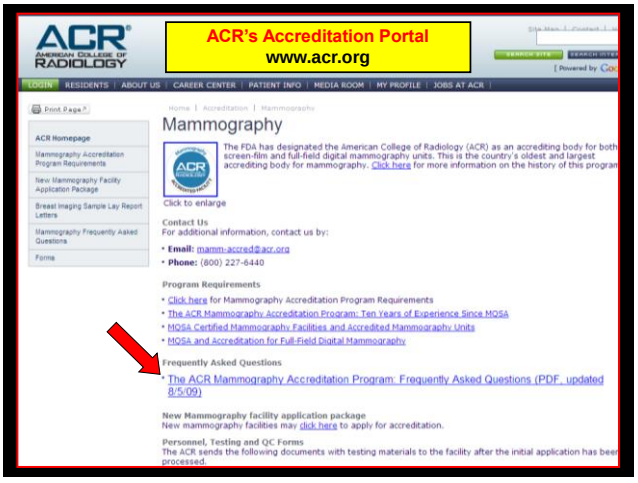
Where to Go for Help on Digital QC, MQSA Certification and ACR Accreditation

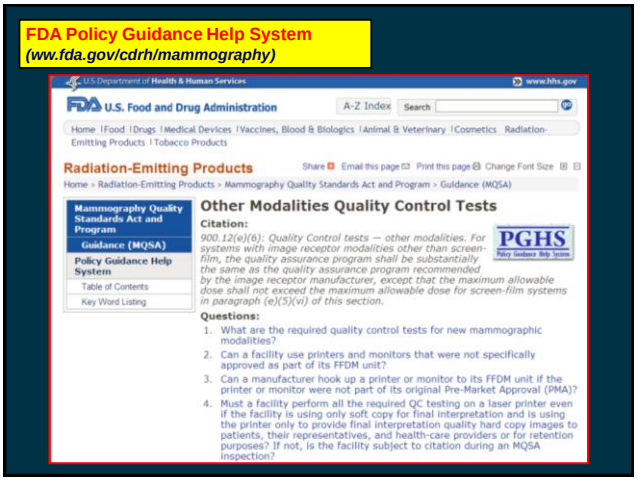
We Tell Facilities that Their Medical Physicist Is Their Friend

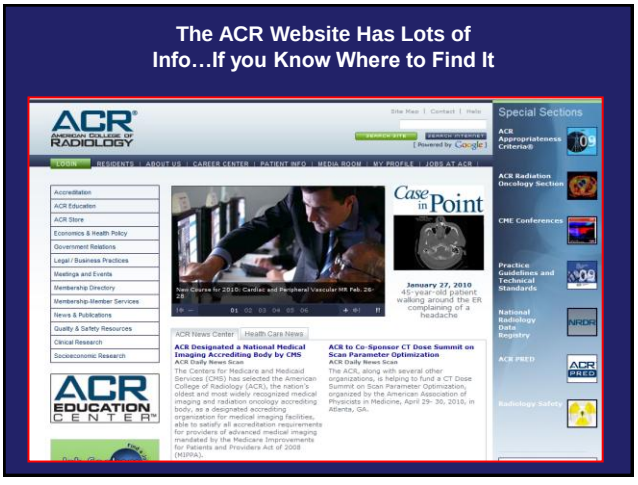
- Talk with her before the annual survey
  - Let her know if you have equipment or QC problems/questions
- Talk with her after you receive the report
  - Make sure you understand all results, recommendations and timeframes
- Talk with her during the year any time you have questions or concerns about equipment performance
  - Show clinical images illustrating the problem (physicists like pictures too)

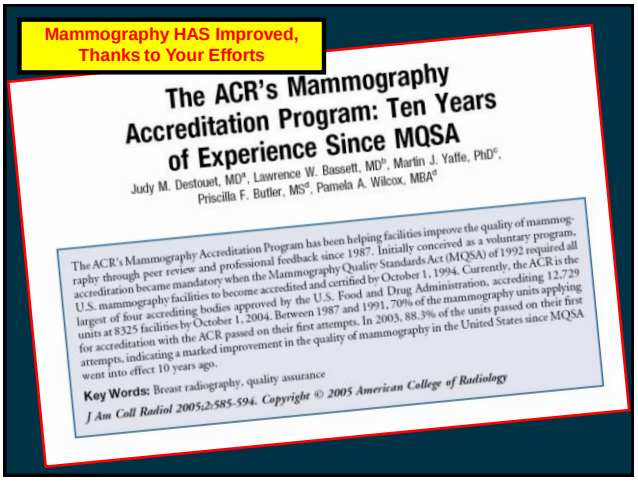
Contact FFDM Manufacturer for QC Assistance

FFDM Mfr	Website
GE	www.gehealthcare.com
Fuji	www.fujimed.com
Lorad	www.hologic.com
Siemens	www.medical.siemens.com


ACR's Accreditation Portal
www.acr.org
Mammography
The FDA has designated the American College of Radiology (ACR) as an accrediting body for both screen-film and full-field digital mammography units. This is the country's oldest and largest accrediting body for mammography. Click here for more information on the history of this program
Click to enlarge
Contact Us
For additional information, contact us by:
• Email: mamm-accred@acr.org
• Phone: (800) 227-6440
Program Requirements
• Click here for Mammography Accreditation Program Requirements
• The ACR Mammography Accreditation Program: Ten Years of Experience Since MQSA
• MQSA Certified Mammography Facilities and Accredited Mammography Units
• MQSA and Accreditation for Full-Field Digital Mammography
Frequently Asked Questions
• The ACR Mammography Accreditation Program: Frequently Asked Questions (PDF, updated 8/5/09)
New Mammography facility application package
New mammography facilities may click here to apply for accreditation.
Personnel, Testing and QC Forms
The ACR sends the following documents with testing materials to the facility after the initial application has been processed:


FDA Policy Guidance Help System
(ww.fda.gov/cdrh/mammography)
U.S. Food and Drug Administration
Radiation-Emitting Products
Other Modalities Quality Control Tests
Citation:
900.12(e)(6): Quality Control tests — other modalities. For systems with image receptor modalities other than screen-film, the quality assurance program shall be substantially the same as the quality assurance program recommended by the image receptor manufacturer, except that the maximum allowable dose shall not exceed the maximum allowable dose for screen-film systems in paragraph (e)(5)(vi) of this section.
Questions:
1. What are the required quality control tests for new mammographic modalities?
2. Can a facility use printers and monitors that were not specifically approved as part of its FFDM unit?
3. Can a manufacturer hook up a printer or monitor to its FFDM unit if the printer or monitor were not part of its original Pre-Market Approval (PMA)?
4. Must a facility perform all the required QC testing on a laser printer even if the facility is using only soft copy for final interpretation and is using the printer only to provide final interpretation quality hard copy images to patients, their representatives, and health-care providers or for retention purposes? If not, is the facility subject to citation during an MQSA inspection?


The ACR Website Has Lots of Info…If you Know Where to Find It
Special Sections
Case in Point
ACR Designated a National Medical Imaging Accrediting Body by CMS
ACR to Co-Sponsor CT Dose Summit on Scan Parameter Optimization
ACR EDUCATION CENTER


Mammography HAS Improved, Thanks to Your Efforts
The ACR's Mammography Accreditation Program: Ten Years of Experience Since MQSA
Judy M. Destouet, MD[a], Lawrence W. Bassett, MD[b], Martin J. Yaffe, PhD[c], Priscilla F. Butler, MS[d], Pamela A. Wilcox, MBA[d]
The ACR's Mammography Accreditation Program has been helping facilities improve the quality of mammography through peer review and professional feedback since 1987. Initially conceived as a voluntary program, accreditation became mandatory when the Mammography Quality Standards Act (MQSA) of 1992 required all U.S. mammography facilities to become accredited and certified by October 1, 1994. Currently, the ACR is the largest of four accrediting bodies approved by the U.S. Food and Drug Administration, accrediting 12,729 units at 8325 facilities by October 1, 2004. Between 1987 and 1991, 70% of the mammography units applying for accreditation with the ACR passed on their first attempts. In 2003, 88.3% of the units passed on their first attempts, indicating a marked improvement in the quality of mammography in the United States since MQSA went into effect 10 years ago.
Key Words: Breast radiography, quality assurance
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Radiation!

The ACR and Society of Breast Imaging Statement on Radiation Received to the Thyroid from Mammography

April 4, 2011

Some Americans have expre… to an erroneous media report, that the small amount of radiation… mammogram may significantly increase the likelihood… oncern simply is *not* supported in scientific

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