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Digital Mammography Quality Control and Accreditation

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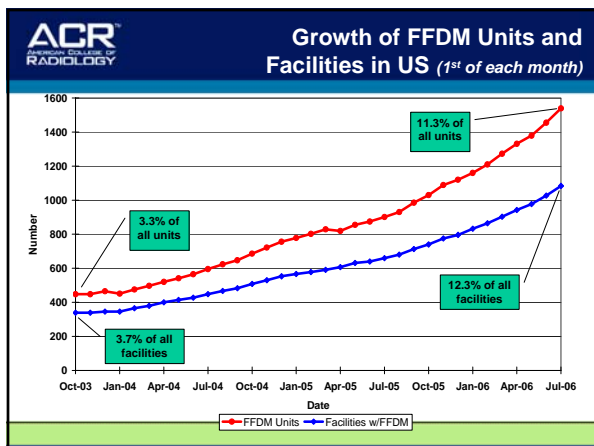
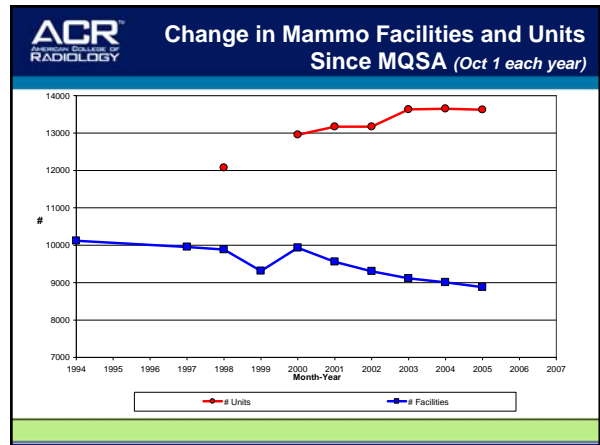
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Current Status of Mammography in the US, Including Full-Field Digital Mammography (FFDM)

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Mammography in the US (July 1, 2006)

- All
 - 13,582 units
 - 8840 facilities
- ACR-accredited (or undergoing accreditation)
 - 13,300 units (97.9%)
 - 8515 facilities (96.3%)
- Iowa, Arkansas and Texas accredit the rest



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Can Digital Mammography Co-Exist with MQSA and the FDA Regulations?

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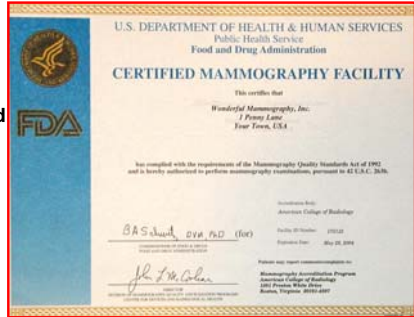
FDA Office of Device Evaluation Approves FFDM Systems

- GE Senographe 2000D - January 28, 2000
- Soft copy interpretation for GE - November 16, 2000
- Fischer SenoScan - September 25, 2001
- Lorad Selenia Amorphous Selenium Direct-Capture - October 2, 2002
- GE Senographe DS - February 19, 2004
- Siemens Mammomat Novation DR - August 20, 2004
- GE Senographe Essential - April 11, 2006
- Fuji FCRm - July 10, 2006

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A Different FDA Office Writes the Mammography Regulations

- Office of Communication, Education and Radiation Programs
- Regs apply to
 - Facilities AND
 - Accrediting bodies



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FDA Requirements for Facilities

- Facilities with FFDM units must meet FDA regs for QC (among other things)
- 900.12(e)(6) QC Tests-Other Modalities: *“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 this section”*
- The *“image receptor manufacturer”* would be GE, Fischer, Lorad, Siemens or Fuji

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FDA Requirements for Accrediting Bodies

- 900.3 Application for approval as an accreditation body: *“The applicant shall furnish to FDA...detailed description of the applicant’s accreditation review and decision making process, including... procedures for performing accreditation and reaccreditation clinical image review...procedures for performing phantom image review... procedures for assessing mammography equipment evaluations and surveys”*
- Accrediting bodies **must apply to FDA for approval before they may accredit any new FFDM manufacturer or model**

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If No FDA-Approved Accreditation Program - FDA has “Interim” Process

- Must follow in order to legally perform mammography
- FFDM system is temporarily exempt from accreditation
- Must submit application to FDA to extend MQSA certificate to new FFDM unit
- Option only available to certified facilities with other accredited units (either screen-film or digital)
 - some flexibility
 - A facility with only a newly-approved FFDM unit may legally operate if certified sister site with accredited units is in same inspectional jurisdiction
- Call FDA-Denise Robinson-for info
 - (240)-276-3278
 - DENISE.ROBINSON@FDA.HHS.GOV
- Right now, only applies to Fuji FCRm

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FDA Approved ACR to Accred

- GE
 - 2000D
 - DS
 - Essential (July 15, 2006)
- Fischer
 - Senoscan
- Lorad
 - Selenia
- Siemens
 - Novation
- Facilities accrediting these new FFDM units may have **“stand-alone” digital systems**
 - No screen-film unit required on site
 - No need to “link” with sister accredited and certified facility in same inspectional jurisdiction

New FDA Guidance on FFDM

Impacts both facilities and accreditation bodies

FDA Policy Guidance Help System #9 – Issued April 19, 2006 – Recordkeeping

- Transmitting images for final interpretation
 - Original or lossless compressed FFDM data – OK, *if acceptable by receiving party*
 - Lossy compressed FFDM data – Not OK
- Retention of digital mammograms
 - Original or lossless compressed FFDM data – OK
 - Lossy compressed FFDM data – Not OK
 - Hardcopy film of final interpretation quality – OK

FDA Policy Guidance Help System #9 – More Recordkeeping

- Digitizing screen-film images
 - For retention purposes – Not OK
 - For final interpretation – Not OK
 - For comparison purposes – OK, *if interpreting physician deems it acceptable*; FDA also suggest digitizers be cleared by FDA for mammo
- Transferring digital mammograms
 - Must be able to provide *hardcopy of final interpretation quality*
 - Softcopy original or lossless compressed images, *if acceptable by receiving party*
- Charging for hardcopies
 - 1st – no
 - Subsequent – yes (actual costs)

FDA Policy Guidance Help System #9 – Printers and Monitors

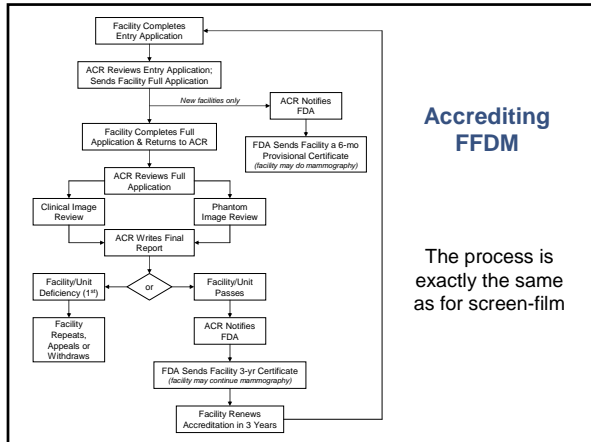
- FDA-required image annotation (view & laterality, pt name and ID, etc)
 - All must be visible on each displayed image in the standard or default display
 - May be switched off
 - Must be on each hardcopy image
- Printers & monitors
 - FDA *recommends* only using printers & monitors that were approved by their Office of Device Evaluation (ODE) for FFDM
 - It is legal to use those not approved
 - All must comply with a QA program substantially the same as recommended by the *image receptor* manufacturer
 - Must pass (or be able to pass) accreditation clinical image review

FDA Policy Guidance Help System #9 – Required Medical Physicist Testing

Equipment Evaluations on FFDM Components

Item/Repair	MP Involvement
Bucky & detector replacement	MP must evaluate in person
Bucky (but not detector) replacement	MP must oversee
Any detector replacement or repair	MP must evaluate in person
Software modifications	MP must evaluate in person (some alternative standards otherwise)
Monitor (display) or printer replacement	Must follow FFDM mfr's QC manual

ACR Accreditation and FFDM



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Before a New Facility May Examine Patients

- Medical physicist must do all FDA-required Equipment Evaluation tests and they must pass
- Facility must send ACR the Entry Application, fees and your Equipment Evaluation Pass/Fail results
 - ACR staff reviews and approves complete application and Equipment Evaluation and notifies FDA (or state certifier)
- Facility must receive 6-month provisional MQSA certificate (or interim notice)
 - Not more than 4 days from the time facility submits required documentation to ACR
- Recommend scheduling Equipment Evaluation 1 week before examining patients (including “applications”)

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Before an Accredited Facility May Examine Patients on a New Unit

- Medical physicist must do all FDA-required Equipment Evaluation tests and they must pass
- Facility must send ACR the application, fees and your Equipment Evaluation Pass/Fail results
- Facility does not have to wait for a response from ACR to use the new unit for mammography
 - Facility already has a current MQSA certificate
- **Beware if you have digital**, 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 your FFDM application and transmitted it to the FDA before using

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FFDM Equipment Evaluations, Annual Surveys and QC

FDA regulations require facilities to follow FFDM manufacturer's QC – this makes life interesting for everyone

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Mfr QC Manuals Are All Very Different Example: Technologist Tests

Frequencies

Test	Soft Copy Display	SNR	Flat Field	MTF/ Sys Res
GE	Monthly	Monthly	Weekly	Monthly
Fischer	Daily	Weekly	Weekly	Monthly
Lorad	Weekly	Weekly	Bi-weekly	Not required
Siemens	Daily	Not required	Weekly	Not required

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

Test Names

Test	Flat Field	SNR	MTF/ Sys Res	Soft Copy Display
GE	"Flat Field"	"AOP Mode and SNR"	"MTF" or "Sub-System MTF"	"Monitor Calibration"
Fischer	"Flat Field"	"Phantom Image Acquisition"	"System Resolution/Scan Speed Uniformity"	"Image Display Monitor(s) Check"
Lorad	"Artifact Evaluation"	"SNR"	"Evaluation of System Resolution"	"Diagnostic Review Workstation QC"
Siemens	"Detector Calibration"	"SNR"	"Spatial Resolution"	7 tests listed individually

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FDA's FFDM QC Requirements

- Follow latest version of mfr's QC manual procedures for unit tested
- Meet mfr's performance standards
- Failures must be fixed before use on patients (no more 30 days)
 - GE & Lorad applied for alternative standards to allow 30 days for some Annual Survey tests

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ACR's FFDM QC Requirements

- Same as FDA's
- ACR suggests using mfr's data forms (including laser printer QC)
- Medical physicist **must** complete ACR's summary forms
 - MQSA Requirements for Mammography Equipment (checklist)
 - Medical Physicist's Mammography QC Test Summary form
 - Available on ACR website in Excel

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ACR's QC Summary Forms

- FFDM manufacturer-specific, similar to screen-film version
- Provides ACR with essential pass/fail information in a standard format with no fluff
 - If medical physicist passes test, ACR accepts it
 - If medical physicist fails test, ACR requests documentation of corrective action
 - If medical physicist writes "N/A," "see comments" (or anything other than pass or fail), ACR will follow-up with facility and accreditation will be delayed
- In 2005, ACR staff reviewed over 1200 Equipment Evaluation reports for new units and over 4000 Annual Survey reports for renewals
 - Different formats (even if they contain all the necessary information) will delay review

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3rd Party Components used with the FFDM Unit

Life gets even more interesting

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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
GE	2000D, DS, Essential	Follow the laser printer mfr's QC
Fischer	SenoScan	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)

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Monitors and Workstations

- FDA MQSA regs state facilities 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 has informed the ACR that
 - 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 (on FDA website)
 - ??? have been approved for FFDM

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Download Summary Forms from ACR Website (www.acr.org)

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

MEDICAL PHYSICIST'S CHECKLIST
MQSA REQUIREMENTS FOR MAMMOGRAPHY EQUIPMENT

Facility Name: _____
 Unit Manufacturer: _____ Model: _____
 Medical Physicist: _____ Room #: _____
 Signature: _____ Date: _____

Feature	FDA Rule Section	Requirement	Applies to	Meets FDA Requirements? (if NA, please explain)
Motion of tube-image receptor assembly	30)	The assembly shall be capable of being fixed in any position where it is designed to operate. Once fixed in any such position, it shall not undergo unintended motion.	S-F & FFDM	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> NA
	30)	This mechanism shall not fail in the event of power interruption.	S-F & FFDM	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> NA
Image receptor sizes	40)	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	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> NA
	40)	Systems using screen-film image receptors shall be equipped with moving grids matched to all image receptor sizes provided.	S-F	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> NA
	40)	Systems used for magnification procedures shall be capable of operation with the grid removed from between the source and image receptor.	S-F & FFDM	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> NA

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Medical Physicist's Mammography QC Test Summary Forms

- Use for both Equipment Evaluations and Annual Surveys
- Addresses 900.12(e) of the FDA regulations
- All have been revised in July 2006 to further streamline
- Excel format
 - Built-in P/F drop-downs
- Use the one for your digital unit manufacturer
 - General Electric
 - Fischer
 - Lorad
 - Siemens
- Check version of manufacturer's QC manual used
- Single overall** review workstation assessment

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 231472-100 Rev 0, 2003
 5133483-2-100 Rev 1, 2005 5133483-2-100 Rev 1, 2005 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, but the use of others is also legal. See FDA's Policy Guidance Help System Modification Document #9 (page 27).

Survey Type: Mammography Evaluation of new unit (include MQSA Rqmts for Mammography checklist) Annual Survey

Medical Physicist's QC Tests

1. Flat Field PASS/FAIL
 2. Phantom Image Quality
 Phantom IQ Test on AWS
 Phantom IQ Test on Printer

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)

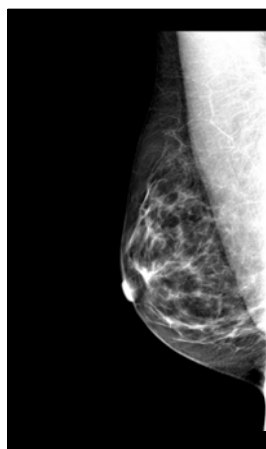
*FDA requires that all RWS comply with a QC program that is substantially the same as that recommended by the image receptor manufacturer. If the RWS has been approved by the FDA's ODE for FFDM, the FDA considers the RWS's QC manual to be "substantially the same" and you may follow it for QC. Check with the RWS manufacturer for their system's FDA clearance status and their QC manual. If the RWS has not been approved by the FDA's ODE for FFDM, you must follow the QC manual provided by the image receptor manufacturer. (In this case, check with the image receptor manufacturer for their required tests.)

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

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Off-Site Laser Printers and Workstations

- Facilities must submit copy of medical physicist's Equipment Evaluation/Annual survey results with accreditation application
- Tests may have been done at a different time than the tests done on the facility's unit
 - But may not be greater than 14 months older than the date of the accreditation application

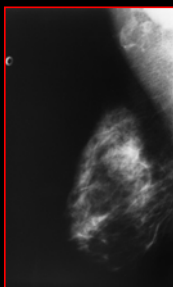


**Accreditation Testing:
Must Pass**

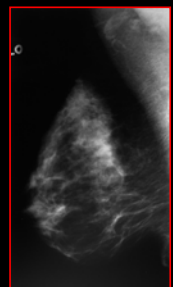
- Clinical image review (fatty and dense breast)
- Phantom image review
- Dose (<300 mrad)
- Processor QC or
- Laser QC for FFDM
 - Follow your mfr QC manual

**Clinical Image Quality Evaluated in 8
Categories**

- Positioning*
- Compression
- Exposure level
- Contrast
- Sharpness
- Noise
- Artifacts
- Exam ID



Bad

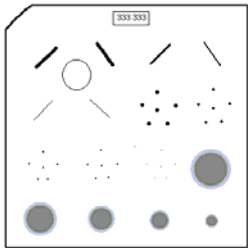


Good

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Phantom Image Quality Evaluation


- Expose at technique for 4.2 cm breast
- Must see
 - 4 largest fibers
 - 3 largest speck groups
 - 3 largest masses
- Subtract for artifacts
- Applies to both screen-film and FFDM



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FFDM Instructions for Phantom (Exposure Control Mechanism Differs for Each Mfr)

- Some manual
- Some AEC
 - e.g., GE exposure control is impacted by the thickest/densest part of the breast
 - Accreditation phantom rim and TLD holder result in higher exposure than 4.2 cm breast
- Process image as done for clinical images
- Window and level to best show test objects
- Do not zoom or rotate



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For Digital, ACR Only Accepts Hard Copy for Accreditation

- Phantom
 - Print as close to “true size” as possible
 - Do not rotate
- Clinical
 - Must be of “primary interpretation quality”
 - Entire breast must fit on image; no “tiling”
 - Print as close to “true size” as possible
- Film size – prefer small format, rather than 14 x 17 (but will accept)
- Clinical and phantom images must be reviewed and approved by lead interpreting physician before sending them to the ACR

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The Future of Digital Quality Control

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ACR Subcommittee on Digital Mammography

- Under ACR Committee on Mammography Accreditation
- Members

– Martin Yaffe, Ph.D., chair	R. Edward Hendrick, Ph.D.
– Kalpana Kanal, Ph.D.	Mark Williams, Ph.D.
– Lawrence Bassett, M.D.	Debra Monticciolo, M.D.
– Julienne Greenberg, M.D.	Murray Rebner, M.D.
– Valerie Andolina, R.T.	Mary Ann Chorlton, R.T.
– Doug Pfeiffer, M.S.	Ellen Mendelson, M.D.
– Priscilla Butler, M.S., staff	Marion Boston, R.T., staff
- Develop accreditation processes for FFDM
- Develop a FFDM QC manual

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ACR FFDM QC Manual Project

- Standardize QC tests, performance criteria and frequencies across all systems
 - Will apply to all manufacturers and models
 - Earlier draft is being streamlined to be clearer and more “tech friendly”
 - Currently undergoing more revisions before pilot testing
 - When ready, draft will be sent to manufacturers for their input before it is final
- When final, ACR will apply for FDA alternative standard
 - When approved, facilities will have the option of following ACR QC or manufacturer’s QC

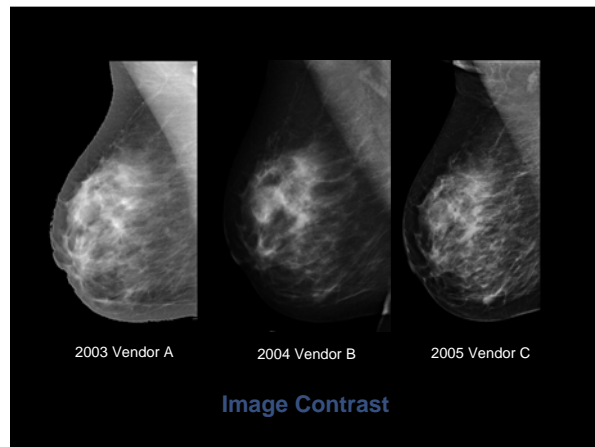
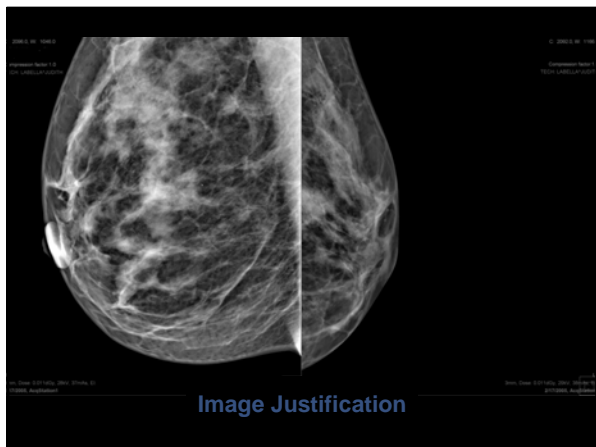
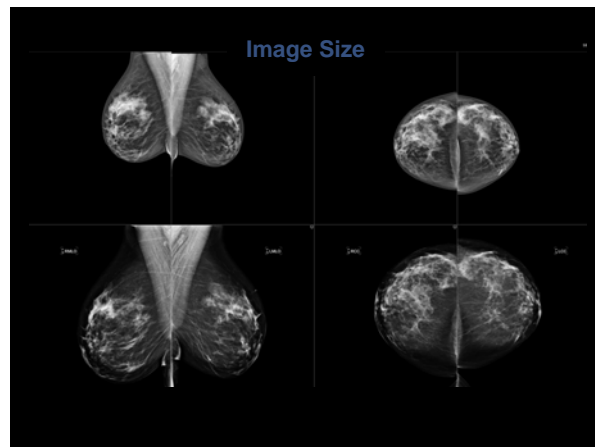
- Tech QC
 - Laser printer QC (dry lasers) – monthly sensitometry – ACRIN data shows it rarely fails
 - Darkroom fog test – eliminate
 - MTF/System Resolution – only for systems with moving parts (e.g., slot-scan, CR) – quarterly
- Medical Physicist QC
 - Eliminate annual kVp testing – ACRIN data shows it never fails with modern generators

Workstation Issues and IHE

Slides courtesy of:
Margarita Zuley, M.D.
Elizabeth Wende Breast Clinic
Rochester, NY

FFDM Workstation Problems

- Mix/match systems
- Content/display incompatibilities
 - Image size
 - Image orientation and justification
 - Image contrast adjustment
 - Background blackness maintenance
 - Annotation of identification and technical factor information
 - Display of CAD marks
- Negatively impacts radiologist productivity



www.acr.org – **NEW Accreditation Portal**



Accreditation Portal

- ACR Homepage
- Accreditation Index
- Accredited Facility Search
- Accreditation Programs
- Mammography**
- History
- Mammography Overview
- Facility Application Package
- Sample Lay Report Letters
- Apply for Accreditation
- FAQs
- Testing and QC Forms

Mammography Accreditation Program

Accreditation > 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 explore Program Overview

- [Click here](#) for Mammography Program Overview
- [The ACR Mammography Accreditation Program and MQSA](#)

Frequently Asked Questions

- [MQSA and FDA Regulations](#)
- [Click Mammography Accreditation](#)
- [The 1999 ACR Mammography Quality Control Manual](#)

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.

- [Click here](#) to view all Personnel Testing and QC Forms.

Useful Links

- [Why Get Accredited?](#)



Accreditation Portal

- ACR Homepage
- Accreditation Index
- Accredited Facility Search
- Accreditation Programs
- Mammography**
- History
- Mammography Overview
- Facility Application Package
- Sample Lay Report Letters
- Apply for Accreditation
- FAQs
- Testing and QC Forms

Mammography Frequently Asked Questions

Accreditation > Mammography > FAQs > Mammography Accreditation

- General
- [Applying for Accreditation](#)
- [Full Application and Testing](#)
- [Accreditation Testing Materials](#)
- [Adverse Accreditation Decisions](#)
- [Appealing an Adverse Accreditation Decision](#)
- [Inform Accreditation and MQSA certificate extensions](#)
- [New Units at an Accredited Facility](#)
- [Equipment Evaluations](#)
- [Annual Updates](#)
- [Validation Film Checks](#)
- [Accrediting Full-Field Digital Mammography \(FFDM\) Units](#)
- [Personnel](#)
- [Miscellaneous](#)


General FAQ

- 1.1. How many MQSA-certified mammography facilities and units are there in the United States?
- 1.2. How many MQSA-certified full-field digital mammography facilities and units are there in the United States?
- 1.3. How many mammography facilities and units are accredited by the ACR?
- 1.4. I have questions about my facility's accreditation. Where can I go for help?

Useful Links

- [Why Get Accredited?](#)
- [Apply for Accreditation](#)

1.1. How many MQSA-certified mammography facilities and units are there in the United States?
Current data on the number of MQSA-certified facilities and units may be obtained from




The ACR's Mammography Accreditation Program: Ten Years of Experience Since MQSA

Judy M. Destouet, MD^{*}, Lawrence W. Bassett, MD^{*}, Martin J. Yaffe, PhD^{*},
Priscilla F. Butler, MS^{*}, Pamela A. Wilcox, MBA^{*}

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 1,2729 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 attempt, 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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Thank-you

Any Questions?