

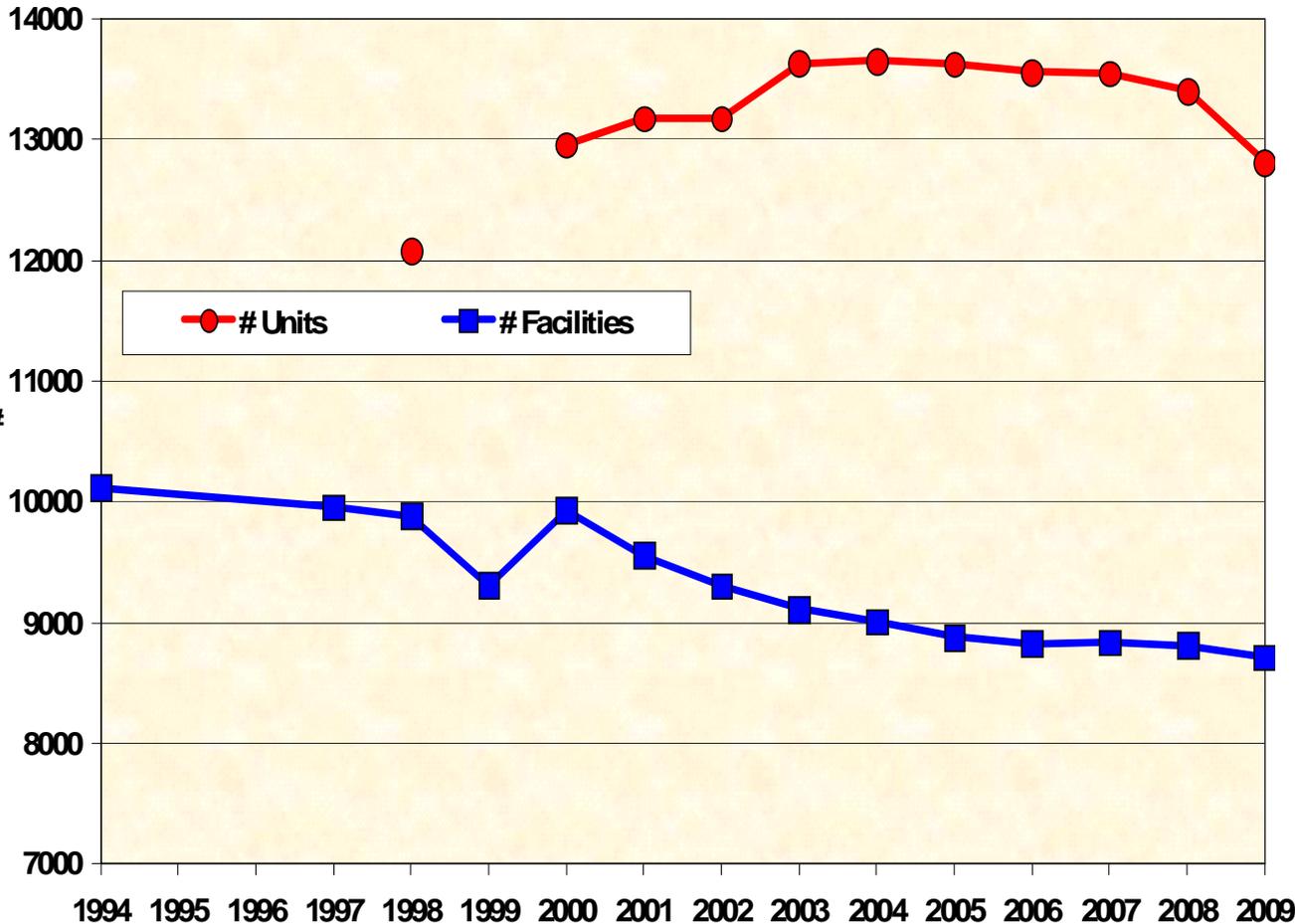
ACR Full-Field Digital Mammo QA Manual

**Priscilla F. Butler, M.S.
Senior Director, ACR Breast Imaging
Accreditation Programs**

- **Digital's impact on mammography in the US**
- **Digital mammography QC – as it exists now**
- **Digital mammography QC – as we hope it will exist in the future**
- **Some general thoughts**

US Mammography Facilities and Units

(October 1 each year)



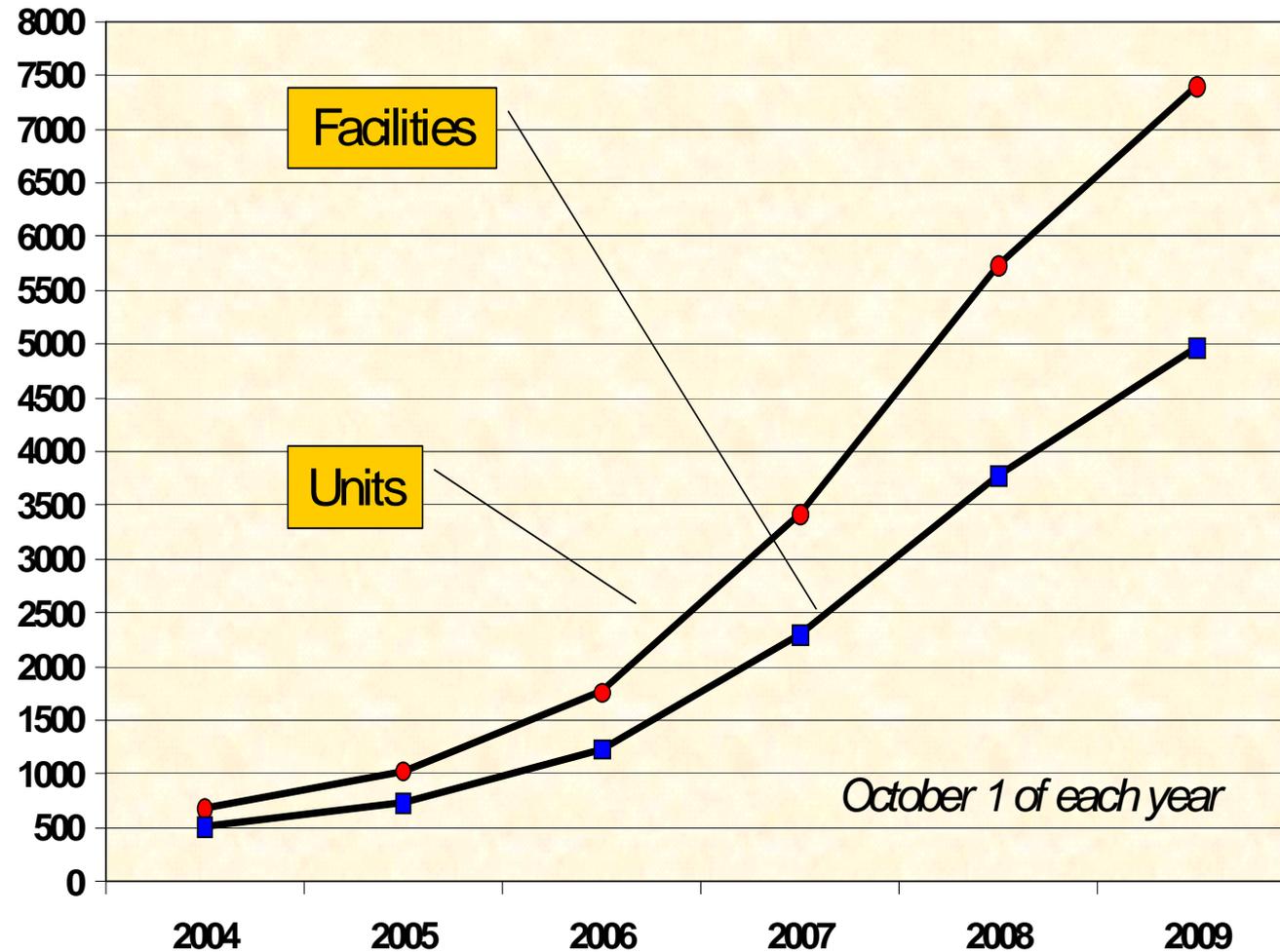
In 2000

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

As of 9/1/10

- 12,412 units at 8646 facilities
- 1.44 units per facility
- 4% drop in facilities/13% drop in units since 2000

Look at the Growth of FFDM in the US!



As of 9/1/10

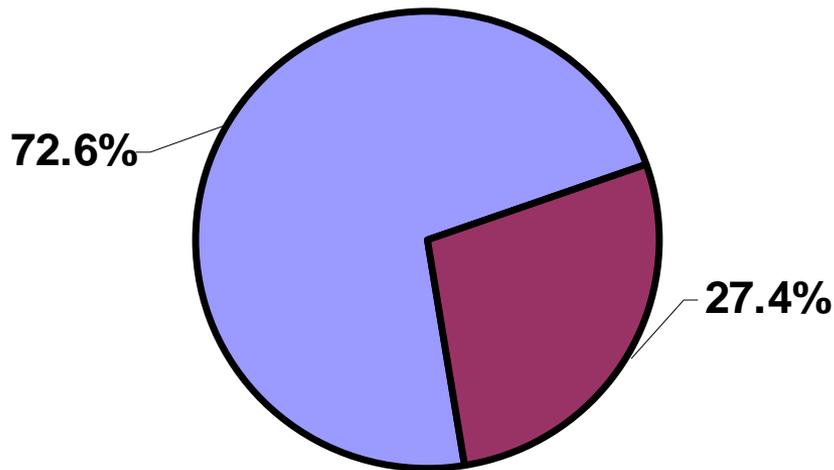
- Significant increase since 2005 ACRIN result
- 8614 units at 5903 facilities
- Over 68% of all units in US are FFDM

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

	# Units*	Overall	
		Pass	Deficient
Screen-Film	19,854	89.0%	11.0%
FFDM	5085	93.3%	6.7%

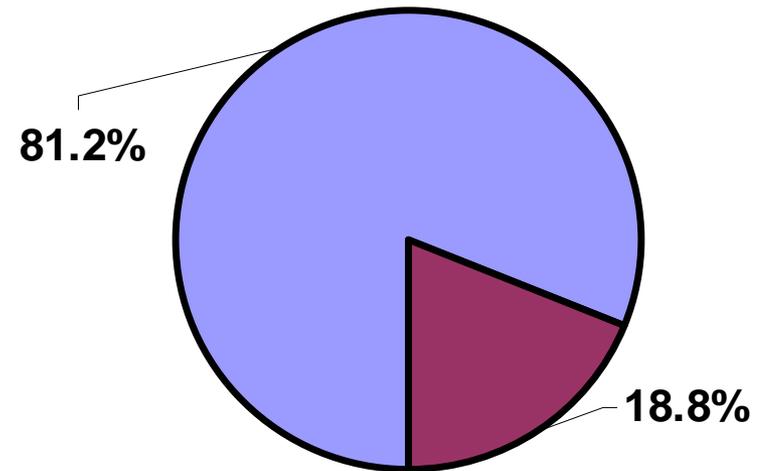
**1st attempt for both initials and renewals; 2/15/03 – 4/24/08*

1st Attempt Screen-Film Deficiencies (2/15/03 - 4/24/08)



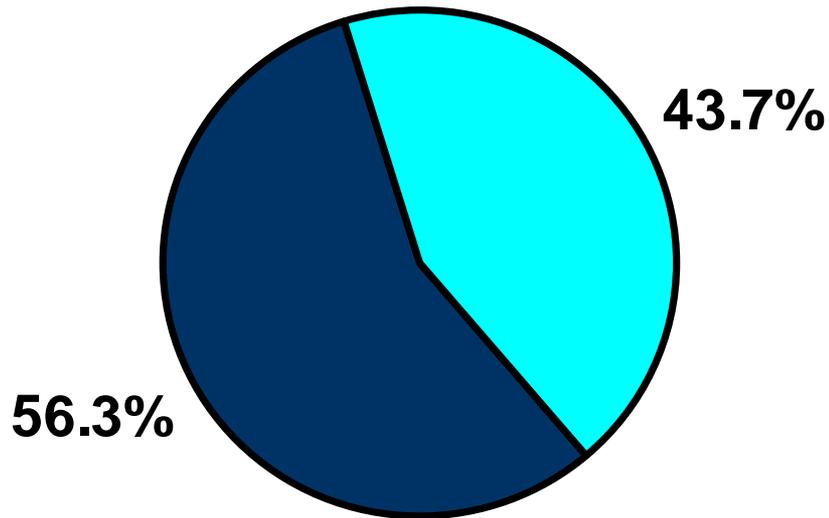
■ Clinical ■ Phantom

1st Attempt FFDM Deficiencies (2/15/03 - 4/24/08)



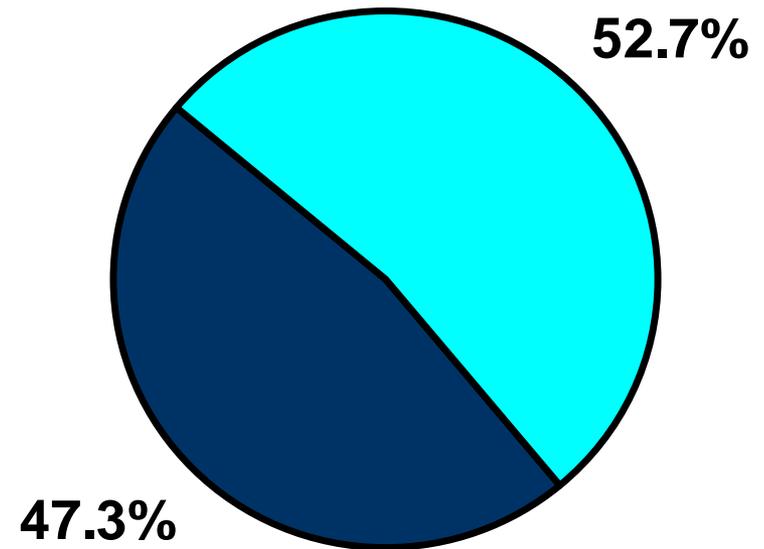
■ Clinical ■ Phantom

Screen-Film Clinical Deficiencies



■ Dense ■ Fatty

FFDM Clinical Deficiencies



■ Dense ■ Fatty

Phantom Images and Dose

	# Units	Average Scores			Ave Dose* (mrads)
		Fibers	Specks	Masses	
Screen-Film	19,854	4.71	3.61	3.75	163.7
(SD)		(0.47)	(0.39)	(0.40)	(31.0)
FFDM	5085	5.01	3.90	4.12	129.7
(SD)		(0.55)	(0.31)	(0.40)	(42.2)

**as measured by TLD*

Dose with FFDM is 20% lower than S-F

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

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

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

- **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

- 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

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)

- **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 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

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

Have Your Medical Physicist Download 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:		_____		
Medical Physicist:		_____		
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	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> NA
	3(ii)	This mechanism shall not fail in the event of power interrupt	S-F & FFDM	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> 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	<input type="checkbox"/> Yes <input type="checkbox"/> No <input checked="" type="checkbox"/> NA
	4(ii)	Systems using screen-film image receptors shall be equipped with moving grids matched to all image receptor sizes	S-F	<input type="checkbox"/> Yes <input type="checkbox"/> No <input checked="" type="checkbox"/> 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	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> NA

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, 2003
 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*			<input type="checkbox"/> On-site <input type="checkbox"/> Off-site	
Laser Film Printer*			<input type="checkbox"/> On-site <input type="checkbox"/> 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)

1. **Flat Field**

PASS/FAIL
Pass

2. **Phantom Image Quality**

Phantom IQ Test on AWS
Phantom IQ Test on Printer

Fibers	Specks	Masses

Pass
Pass

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)

NA

15. **Review Workstation (RWS) Tests** (for all RWS, even if located offsite)

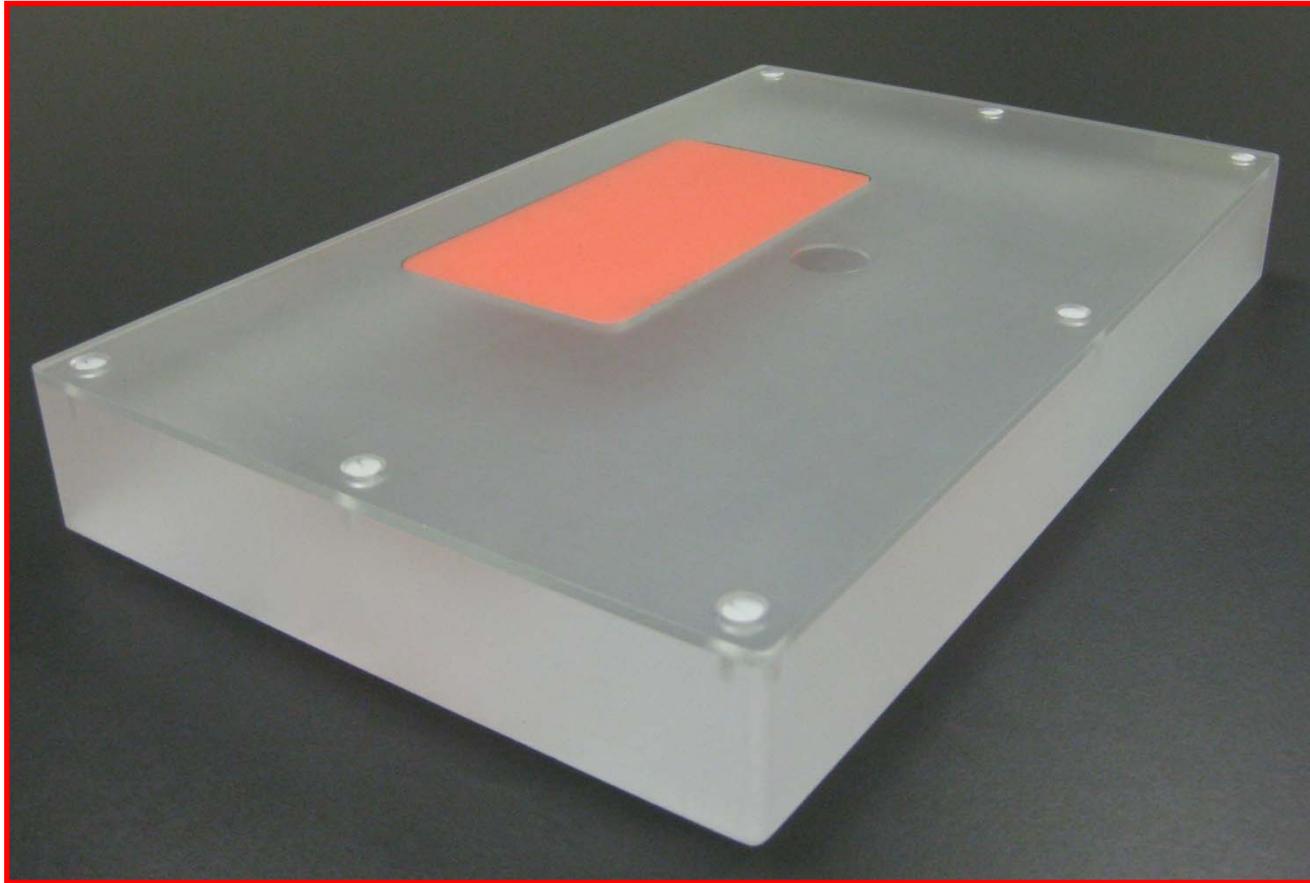
Overall Results ("Pass" means all tests pass; indicate "Fail" if any test fails)

Fail

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

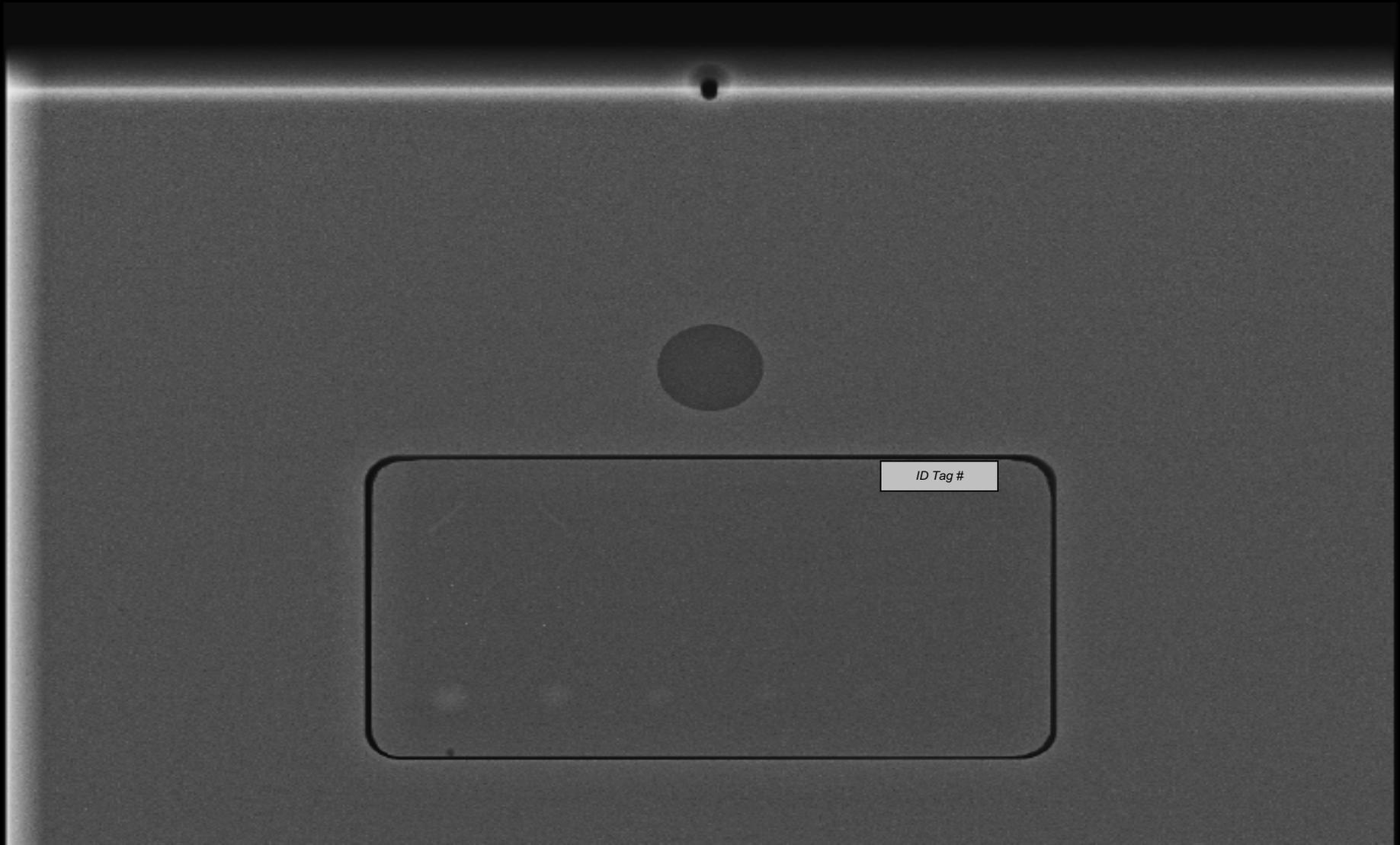
- **Eric Berns, Ph.D., chair, Subcommittee on QA**
- **Subcommittee includes medical physicists, radiologists, MITA representatives and technologists**
- **Standardize QC tests, performance criteria and frequencies across all systems**
 - **Will apply to all manufacturers and models**
 - **New phantom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

New ACR FFDM Phantom (prototype)



- Same scoring
- 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

New ACR FFDM Phantom (prototype)



- **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**

- **Fewer tests and written to be “tech friendly”**
 - Field tested in December 2009
- **More pictures**
- **Excel forms downloadable from website – may be completed on paper or via computer**

- **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)

- **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**

- **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*

- **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)**

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

- **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)

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

- **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**

- **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

- **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)

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

FDA Policy Guidance Help System

(www.fda.gov/cdrh/mammography)

Radiation-Emitting Products

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Mammography Quality Standards Act and Program

Guidance (MQSA)

Policy Guidance Help System

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[Key Word Listing](#)

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?

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Mammography



Click to enlarge

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.

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.





***“Toto, I don’t think we are in
Texas anymore.”***