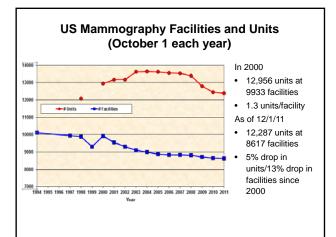
Update on MQSA and ACR Mammography Accreditation

QUALITY IS OUR IMAGE

Pamela L. Platt, BSRT(R)(M)(CV) FDA Liaison, ACR Breast Imaging Accreditation Program





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
- 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")



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RADIOLOGY QUALITY IS CUR IMAGE		acr.org			
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ACR Hote	Mammography				
Accrisitization Home		needing fewer clicks			
Disgram Requirements					
FAGE	ACR	Mammography Accreditation Program			
Nev Matteringraph Pacity Application Package					
Personnel, Teeling and GC Forms					
Bangre Lay Report Letters	Program Requirements				
Renoutement	it is previously that uses exceed the local the	Nammography Acceditation Program Requirements for a summary of the			
LTHE.	accreditation process before applying for				
Neve	Mammography Accreditation Program R	anguirements.			
threast imaging Center of Econierce	The ACR Mammography Accreditation P	Program: Ten Years of Experience Since MQSA			
Contact Lis	MOSA Certified Mammography Facilities	s and Accredited Mammography Units			
Additional Resources	MOSA and Accreditation for Full-Field D				
Mannopraphy Quality Control	Frequently Asked Questions	(FAQs)			
Manual	Club here for the Mammography Acceditation Program FAQs				
	New Mammography Facility Application Package				
	New mammography facilities may click mammography facilities that have never	here to apply for accreditation. Please note that these documents are for new in applied with the American College of Radiology for mammography accreditation.			
	Personnel, Testing and QC F	orms			
	The facility will usually submit the comp convenience, additional copies may be	s with testing materials to the facility after the initial application has been processed, letted hard-copies at the same time they submit their images for review. For your proted by clicking on the links below. If you have any questions about which forms a checking and instructions in vour acceleration testing backase.			

New Mammography Facility Application Package
New mammography facilities may click here to apply for accreditation. Pease note that these documents are for new mammography facilities that have never applied with the American College of Radiology for mammography accreditation.
For your information
Introductory Memorandum
Mammography Accreditation Program Requirements
VHA Mammography Facilities Letter
Entry - Renewal Application Instructions
Submit these documents:
Entry - Renewal Application Checklist
Entry Application
Mamnography Accreditation Survey Agreement
MQSA Information Release Authorization
MOSA Requirements for Mammography Equipment Checklist
Submit one per unit:
Medical Physicist's Mammography GC Test Summary-Screen-Film (Updated 10/25/10)
Medical Physicist's Mammography QC Test Summary-Full-Field Digital-Fischer (Updated 10/26/10)
Medical Physicist's Mammography QC Test Summary-Full-Field Digital-Full (Updated 10/26/10)
Medical Physicist's Mammography GC Test Summary-Full-Field Digital-General Electric (Updated 10/26/10)
Medical Physicial's Mammography GC Test Summary-Full-Field Digital-Lorad (Updated 11/23/10)
Medical Physicist's Mammography GC Test Summary-Full-Field Digital-Siemens (Updated 10/20/10)
Medical Physicist's Mammography QC Test Summary-Full-Field Digital-Carestream (Updated 2/2/11)

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
- 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
 But there is a catch if you are installing your 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)
- 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

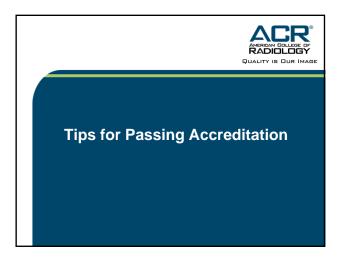


Download Medical Physicist Summary Forms

	• www.acr.org	м	MEDICAL PHYSICIST'S CHECKLIST MQSA REQUIREMENTS FOR MAMMOGRAPHY EQUIPMENT				
	 In Excel format Required for 	Facility Name: Unit Manufacturer: Serial number: Medical Physicist: Signature:			Mode Year Mh Room IC Survey Date		
	Equipment	feature	FDA Rule Section	Requirement	Applies to	Meets FDA Requirements? (if NA, please explain)	
	Evaluation report	Noton of tube-image receptor assembly	200	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		
		receptor assembly	3(8)	This mechanism shall not fail in the event of power interrupt	S-F & FTDM	P tes E to E NA	
	 Addresses 900.12(b) of the FDA 	Image receptor sizes	4(0	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.	5.F		
			400	Systems using screen-film image receptors shall be equipped with moving grids matched to all image receptor sizes.	5.7		
	regulations		4(8)	Systems used for magnification procedures shall be capable of operation with the grid removed from between the source and image receptor.	S-F & FFDM		
	 Same for S-F and FFDM 					ADIOLOGY	

Site Name				Report			
Address				Survey			
Medical Physicist's Name				Signature			
X-Ray Unit Manufacturer General Date of Installation		I EROCIFIC		Room ID			
QC Manual Version: (check on	He; must use version ap v 1, 2007 ESSENTIAL				f questions OTHER (write		71472-100 Rev 0, 2
Accessory Equipment:	Manufacturar		ndel	Locatio			ual Version
	manufactorer		oues	Cocato		QC man	Call Version
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	This is Required; There	e Have Been Issues			
	Evaluation of Technolo	ogist QC Program			
	New units: Medical physicists must review the technologist QC program within 45 days of installation and complete this section as the facility may submit this form along with the entire Mammography Equipment Evaluation report to the ACR with their phantom and images. Renewing units: Medical physicists must complete this section as part of the unit's annual survey.				
		FREQUENCY	PASS/FAIL		
1.	Monitor Cleaning	Daily			
2.	Darkroom Cleanliness (if applicable)	Daily			
3.	Processor QC (if applicable)	Daily			
	Flat Field	Weekly			
5.	Phantom Image Quality CNR	Weekly			
6.	CNR	Weekly			
7.	Viewbox and Viewing Conditions (NA if no hardcopy interprete	d or compared Weekly			
B .	MTF Measurement	DS/Essential-Weekly; 2000D-Monthly			
9.	AOP Mode and SNR	Monthly			
10.	Visual Checklist	Monthly			
11.	Repeat Analysis	Quarterly			
12.	Analysis of Fixer Retention (if applicable)	Quarterly			
	Compression Force	Semi-annually			
14.	Darkroom Fog (if applicable)	Semi-annually			
15.	Review Workstation QC-Overall (NA if only hardcopy read)	See FDA guidance			
16.	Laser Film Printer QC (GE requires laser printer mfr's manual)	Printer mfr recommendations			
17.	Mobile Unit Quality Control (if applicable)	After every move			

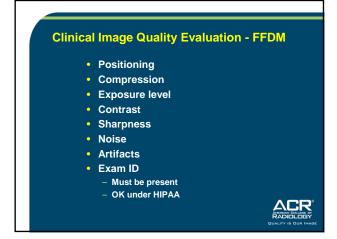


Accreditation Testing

- Clinical image (fatty and dense breast)
 ___Phantom image
 - Dose (<300 mrads)
- Hard copy QC

ò.

- Film processor
- Laser printer (see mfr QC manual)
- Criteria the same for digital as with screen-film

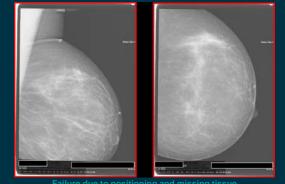


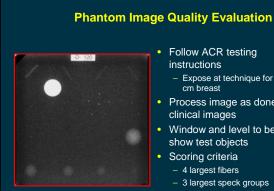
Breast Imaging				
Lawrence W. Bassett, MD Dione M. Farria, MD, MPH Swatt Bansal, MS Marybeth A. Farquhar, RN, MSN Pamela A. Wilcox, MBA Stephen A. Feig, MD Index terms: Breat actography: gaility amerance. 00.11, 0.033, 0.059	Reasons for Failure of a Mammography Unit at Clinical Image Review in the American College of Radiology Mammography Accreditation Program ¹			
Calify service Backings 2000: 121:668-702 Attendency 2000: 121:668-702 Attendency 2000: 121:668-702 Backeton (Calify Calify Calify Backeton (California) Backeton (California) B	PURPOSE. To identify the most common ideliancial in the quality of mammon- grams submitted for clinical image evaluation (aduation of image from actual patient referred for mammography). MATTERNAS AND METHODS: In 1997, the Annotan College of Badelogy Mammography subcriteration (aduation in the image in the image in the intervel obligation in the image in the image in the image in the intervel obligation of the image in the image in the image in the intervel obligation of the image in the image in the image in the image intervel of the image in the image in the image in the image intervel of the image in the image in the image in the image intervel of the image in the image in the image in the image in the image in the image in the image in the image in the image intervel of the image in the			

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?**





- Expose at technique for 4.2
- Process image as done for
- Window and level to best show test objects

- 3 largest speck groups
- 3 largest masses - Be sure to subtract for
- artifacts

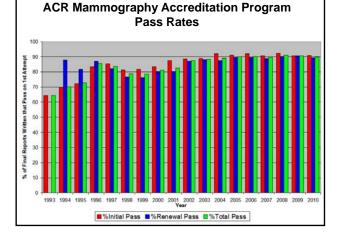
For Digital, ACR Only Accepts Hardcopy for Accreditation

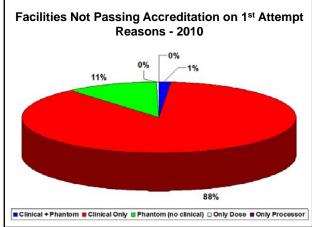
Phantom

- Do not zoom or rotate
- Print as close to "true size" as possible (w/in +/- 25%)
- 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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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)

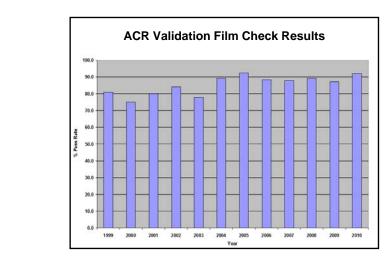


Contact FFDM Manufacturer for QC Assistance

FFDM Mfr	Website
Carestream	www.carestreamhealth.com
GE	www.gehealthcare.com
Fuji	www.fujimed.com
Lorad	www.hologic.com
Philips (Sectra)	http://www.healthcare.philips.com
Planmed	www.planmed.com
Siemens	www.medical.siemens.com

Validation Film Checks and On-Site Surveys – Required by FDA Random film checks - 3% of facilities accredited

- each year
- Clinical case from an ACR-designated day
- Phantom image
- Dosimeter
- Random on-site surveys for ACR, at least 50 each year
 - Visit by ACR radiologist reviewer, medical physicist reviewer and ACR staff (mammo tech)



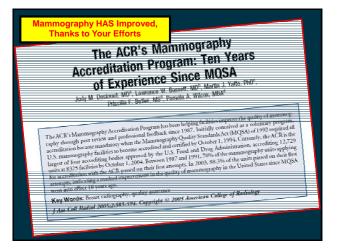


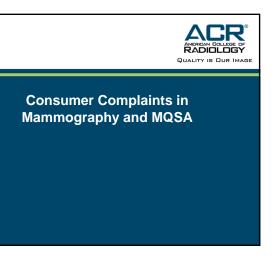


Also Watch

DXIMGMEDPHYS@HERMES.GWU.EDU **AAPM Newsletter**







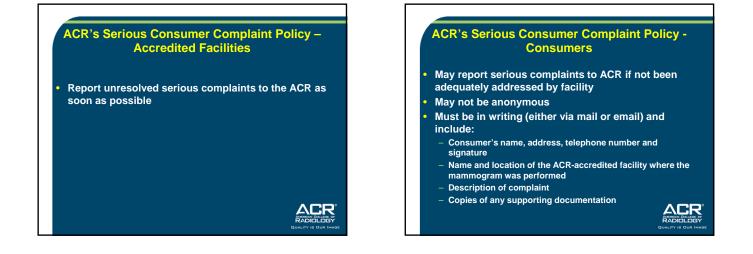
FDA Definitions

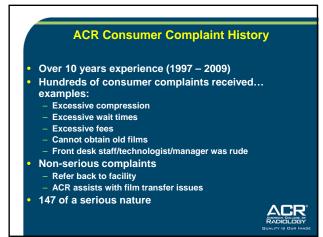
- Consumer person complaining about a mammography exam
 - Includes patient or patient's representative (e.g., family member or referring physician)
- Serious complaint report of a serious adverse event
- Serious adverse event
 - One that may significantly compromise clinical outcomes One for which a facility fails to take appropriate corrective action in a timely manner
 - Examples: poor image quality, missed cancers, use of unqualified personnel, failure to send mammography reports or lay summaries within 30 days.

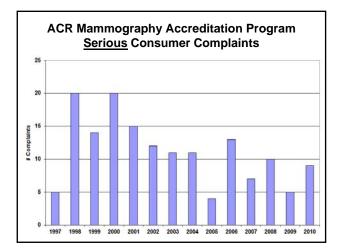


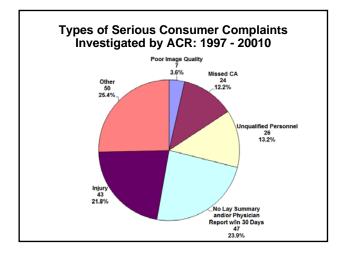
Facility's Responsibilities

- Have a documented system for collecting and resolving consumer complaints
- Maintain a record of each serious complaint for at least 3 years
- Provide consumer with directions for filing serious complaints with their accreditation body if facility is unable to resolve it to the consumer's satisfaction
- Report unresolved serious complaints to the accreditation body in a manner and timeframe specified by the accreditation body









No Lay Summary and/or Physician Report w/in 30 Days - Example

Complaint

- Many patients complained exams had not been interpreted in over a month
- Facility refused to address complaints
- Facility closed

No Lay Summary and/or Physician Report w/in 30 Days - Example

- ACR investigation
 - Many unsuccessful attempts to contact facility by phone or mail
 - Unopened investigation letters were returned
 - ACR referred complaint to FDA
- Resolution
 - FDA and state took legal action against the owner of the facility
 - Facility finally made films available to patients
 - ACR revoked the facility's accreditation

Injury & Unqualified Personnel – Example

Complaint

- Severe pain and bi-lateral lacerations of both breasts
- Technologist not qualified
- Patient told tech, "you are hurting me" and tech said, "I know
- Not satisfied with facility's response to her complaint (nothing done about tech's actions)
- Physician advised her to use Neosporin and pain relievers



Injury & Unqualified Personnel – Example

ACR investigation

- Facility's actions to resolve patient's complaint
- Policies for consumer complaints, positioning and compression
- QC records for compression tests
- **Qualifications for technologist**
- Response and resolution by facility
- Tech documented patient did not mention pain during exam
- Documentation of all correspondence with patient
- Provided QC and personnel documentation
- Updated and provided all requested policies
- New policy to document patient's skin condition prior to exam



Missed Cancer & Poor Image Quality - Example

Complaint

- Cancer missed due to poor image quality
- Radiologist at another facility interpreting subsequent mammogram that discovered the cancer remarked that positioning of previous mammogram was poor

Missed Cancer & Poor Image Quality - Example

ACR investigation

- Facility's actions to resolve patient's complaint
- Policies for consumer complaints, medical audit and reporting findings to patients and physicians
- Evidence that facility reviewed patient's mammogram after learning of the missed cancer
- Radiologist's qualifications
- Participate in Additional Mammography Review (AMR)



Missed Cancer & Poor Image Quality - Example

Response and resolution by facility

- Documentation of correspondence with patient
- Updated and provided all requested policies
- Could not review mammogram since patient checked it out
- Provided personnel documentation
- Failed AMR (corrective action subsequently taken)



ACR

Other – Example

Complaint

- Businessman intermittently received mammography reports intended for local referring physicians through home fax machine
- Complained to facility numerous times
- No results

ΔCR

Other – Example ACR investigation Facility's actions to resolve complaint - Policies for consumer complaints and reporting findings to physicians Response and resolution by facility Documentation of correspondence with complainant

- Updated and provided all requested policies - Error due to human error (reports manually faxed)
- Made staff aware of problem
- Implemented new RIS with automatic faxing

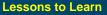


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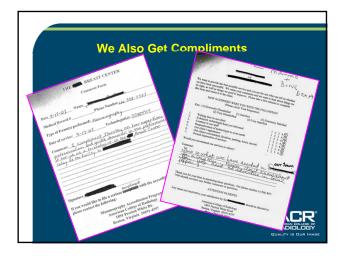
Recurring Themes

- Physician did not receive report within 30 days or at all
- Patient did not receive lay letter within 30 days or at all
- Pain and injuries from compression
- Facility closed with no provision to provide old films to patients
- "The doctor would not talk with me"
- "I don't want anyone else to go through what I did"





- Don't ignore complaints from patients...your customers
- Talk with your patients...listen to your patients
- Analyze complaints to find opportunities for quality improvement
- Use your risk management resources
- You can address many complaints to the patient's satisfaction
- You will not be able to satisfy everyone



Why Medical Physicists Should Join the ACR Raise awareness of the important contributions medical physicists make to the radiology profession - Nationally - In your home town Be part of the significant influence ACR has in state and local government Serve on critical ACR committees and subcommittees that eventually affect your practice ACR

