MQSA and ACR Digital Breast Tomosynthesis Mammography Accreditation

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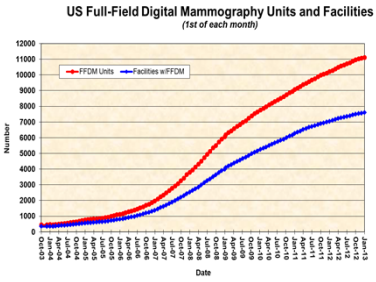
FDA Liaison, ACR Breast Imaging Accreditation Program

US FFDM Mammography Facilities and Units



In 2000
- 12,956 units at 9933 facilities
- 1.3 units/facility

As of 1/1/13
- 12,466 units at 8641 facilities
- 11115 FFDM Units – 89%
- 7590 facilities with FFDM – **88%**

1. As of January 1, 2013, what percent of facilities are FFDM?

0% 1. 20%
0% 2. 40 %
0% 3. 66%
0% 4. 88%
0% 5. 100%

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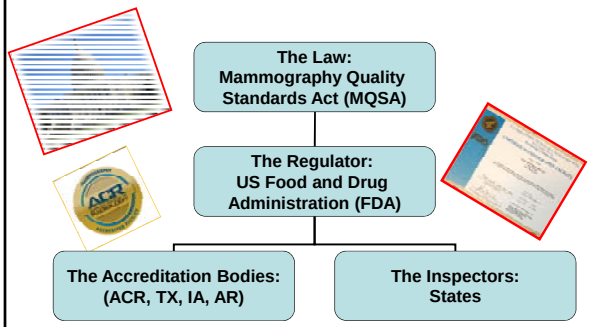
1. As of January 1, 2013, what percent of facilities are FFDM?

1. 20%
2. 40%
3. 66%
4. 88%
5. 100%

Answer: 4. 88%

Ref: National Statistics (MQSA), MQSA Policy Guidance Help System, www.fda.gov

MQSA Who's Who



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 the unit has an approved AB under MQSA**

What About Units Without An Accreditation Program

- Since February 2011, FDA has cleared 13 FFDM or DBT units for use in mammography facilities:
  - Hologic Selenia Dimensions DBT*
  - Philips (Sectra) MicroDose L30
  - Hologic Selenia Encore**
  - Siemens Mammomat Inspiration Pure**
  - Planned Nuance and Nuance Excel*
  - GE Senographe Care**
  - Fuji Aspire HD
  - Giotto Image 3D – 3DL
  - Fuji Aspire CR**
  - Agfa CR
  - Konica Minolta Xpress

* No AB accredits at this time

** Approved for use under existing manufacturer's manual

MQSA - Who's Who When a Unit Doesn't Have An AB

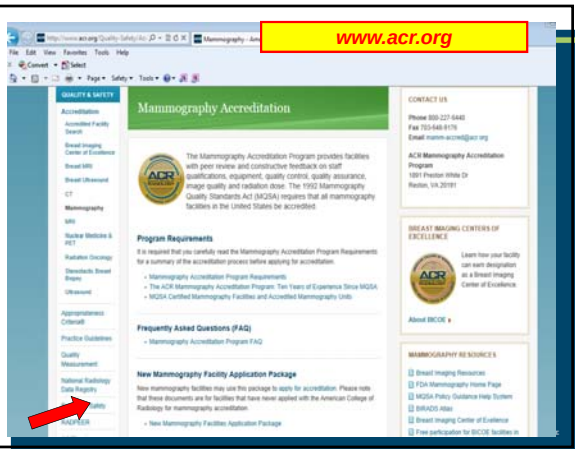
- FDA acts as the AB
- For FFDM and CR systems without an AB, the facility will apply directly to the FDA through the Certificate Extension Program
- For DBT the facility must apply to the FDA for the DBT portion of the system and to the AB for the 2D

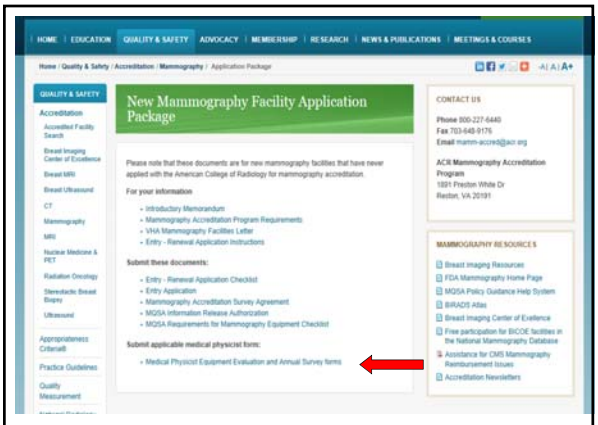
If You Are a Brand New Facility - Before You May Examine Patients

- 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")





What About a New Facility with A DBT System

- Follow the same instructions for a new facility
- Submit the 2D application to the AB
- Submit the DBT application to the FDA

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

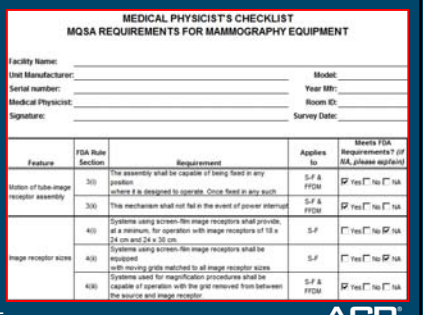
- You do not have to wait for a response from ACR to use the new unit for mammography
  - Your facility already has a current MQSA certificate
- But there is a catch if you are installing your 1st digital unit
  - CMS will not reimburse if they don't have notification from FDA that you are approved for 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
- In Excel format
- Required for Equipment Evaluation report
- Addresses 900.12(b) of the FDA regulations
- Same for S-F and FFDM

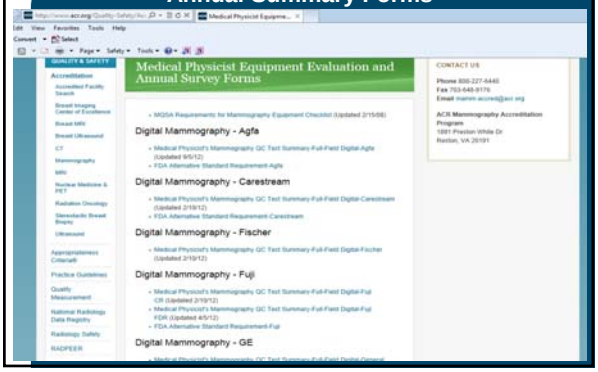


MEDICAL PHYSICIST'S CHECKLIST
MQSA REQUIREMENTS FOR MAMMOGRAPHY EQUIPMENT

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

Medical Physicist Equipment Evaluation & Annual Summary Forms



This is Required With Testing Materials; There Have Been Issues

Evaluation of Technologist QC Program

New units: Medical physicists ***must*** review the technologist QC program within 45 days of installation and complete this section so that the facility may submit this form along with the entire Mammography Equipment Evaluation report to the ACR with their phantom and clinical 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	
4. Flat Field	Weekly	
5. Phantom Image Quality	Weekly	
6. CNR	Weekly	
7. Viewbox and Viewing Conditions *(NA if no hardcopy interpreted or comparec*	Weekly	
8. 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	
13. 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	

Medical Physicist's QC For FDA

- Medical physicist must complete summary forms
  - MQSA Requirements for Mammography Equipment (checklist)
  - Medical Physicist's Mammography QC Test Summary (FFDM mfr-specific)
  - The ACR does not provide a form for DBT on our website because we do not accredit DBT at this time
- Forms provided need pass/fail information
  - If medical physicist passes test, test accepted
  - If she fails test, requests corrective action
  - If she writes "NA," "see comments" (or anything other than pass or fail), will follow-up; and approval letter will be delayed
- Significantly different formats (even if they contain all the necessary information) will delay review

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ACR Forms are Manufacturer Specific

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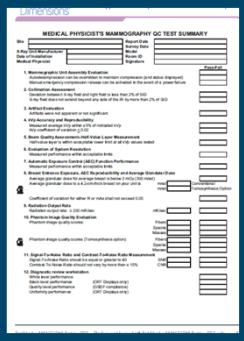
Hologic Medical Physicist QC Test Summary



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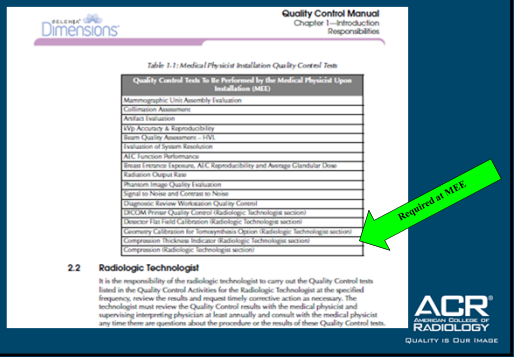
Quality Control Test Required by MP at MEE



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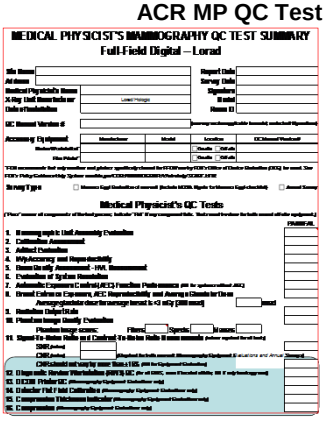
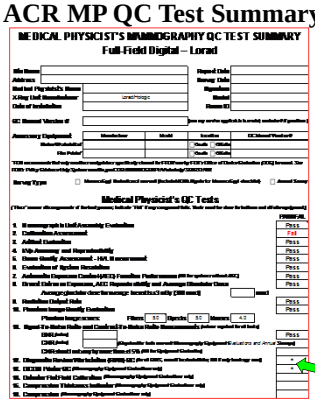
ACR MP QC Test Summary



- FDA requires the AB to review the MEE according to the manufacturer's QC Manual; not the manufacturer's QC Test Summary
- Please use the ACR MP QC Test Summary

ACR MP QC Test Summary – Reasons for Delay


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

- **Failure; no corrective action submitted**
- **Test outcome listed as ***
- **Test outcome listed as NA, when not appropriate**
- **RWS or Film Printer not listed**
- **Form not signed (required by MQSA)**

2. Why does the ACR request that medical physicist use our forms?

0% 1. Easier for staff to review
0% 2. Contains all the test required by the manufacturer's QC manual
0% 3. Contains all test required by FDA for AB's approval to accredit the unit
0% 4. List what test may be listed as "NA"
5. All of above

10

2. Why does the ACR request that medical physicist use our forms?

1. Easier for staff to review
2. Contains all the test required by the manufacturer's QC manual
3. Contains all test required by FDA for AB's approval to accredit the unit
4. List what test may be listed as "NA"
5. All of above

Answer: 5. All of above

Ref: ACR, Breast Imaging Center of Excellence Requirements, www.acr.org

Test that are specific to DBT

- **ACR does not need to see at this time, but must be included in information sent to FDA**

DBT Accreditation

- **New technology and need an established standard of care**
- **May need to establish new accreditation criteria for pass/fail clinical and phantom standards**
- **Must be able to review DBT in soft copy format**
  - **The ACR currently only accepts hard copy images for mammography accreditation**
  - **Expects mammography to be in our on-line database by ACRedit by summer 2013**
  - **Expect to pilot test soft copy mammography submission for accreditation in late 2013**
- **Facility will need to accredit both modalities, the FFDM and DBT portion of the unit**

FDA's Interim Process Certificate Extension Program

- **Exempt from accreditation (until a program is available)**
- **However, only facilities that are already accredited may apply for use (some flexibility here)**
  - **A facility may legally operate if they have a sister site is in same inspectional jurisdiction**
  - **Contact FDA for details**
- **Submit application and be approved by the FDA to extend MQSA certificate to the FFDM or DBT unit in order to legally operate**
- **Undergo annual inspections**
- **At this time no AB accredits the DBT**

3. What AB currently accredits the Hologic DBT System?

0% 1. ACR
0% 2. State of Arkansas
0% 3. State of Iowa
0% 4. State of Texas
0% 5. None of the above

10

3. What AB currently accredits the Hologic DBT System?

1. ACR
2. State of Arkansas
3. State of Iowa
4. State of Texas
5. None of the above

Answer: 5. None of above

Ref: Facility Certification and Inspection, Digital Accreditation, MQSA Policy Guidance Help System, www.fda.gov

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

- DBT is a new mammographic modality separate from FFDM under MQSA and all personnel must obtain 8 hours of new modality training prior to independent use
- In order to use the DBT portion of the unit, the facility must have the 2D portion of the unit accredited by one of the accreditation bodies already approved to accredit the Hologic Selenia Dimensions 2D, and
- The facility must apply to FDA to have its certificate extended for the DBT portion of the unit.

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FDA Application

- Facility Status Information
- Hologic Selenia Dimension DBT Unit Identification
- Identification of accessory components (film printer and RWS)
- List of qualified personnel who will work with DBT
- Copy of Equipment Evaluation by medical physicist (including sample phantom image)
- Technologists and medical physicists must follow manufacturer's QC procedures
- Submit first 6 months of QC (after starting mammography) w/in 9 months

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FDA Application

- FDA will review application
  - Facilities are being told approximately two week turn around time by FDA
- FDA will contact the AB if the facility does not have the corresponding unit showing up in the database
  - If the facility has not submitted the 2D application to the AB, the FDA will not proceed with the DBT application
- FDA will send Letter of Acceptance or Denial
  - A facility may not perform DBT until they have this letter

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4. A facility may begging using the DBT system after

0% 1. they have training with Hologic
0% 2. the unit is assembled
0% 3. they submit an application to the ACR
0% 4. they submit an application to the FDA
0% 5. they receive the approval letter from the FDA

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4. A facility may begging using the DBT system after

1. they have training with Hologic
2. the unit is assembled
3. they submit an application to the ACR
4. they submit an application to the FDA
5. they receive the Approval Letter from the FDA

Answer: 5. They receive the Approval Letter from the FDA

Ref: Facility Certification and Inspection, Digital Accreditation, MQSA Policy Guidance Help System, www.fda.gov

FDA Certificate Extension Program

- **Submit to:**
  MQSA **Certification Extension Program**
  Division of Mammography Quality and Radiation Programs
  FDA/CDRH/OCER
  10903 New Hampshire Avenue WO66-4621
  Silver Spring, MD 20903-0002
  Phone: 301-796-5710 Fax: 301-847-8502
  Contact: Denise Robinson, denise.robinson@fda.hhs.gov
- **FDA Website:**
  - http://www.fda.gov/Radiation-EmittingProducts/MammographyQualityStandardsActandProgram/FacilityCertificationandInspection/ucm243765.htm

FDA Annual Inspection

- **FDA will treat the DBT system as a separate unit from the 2D FFDM system**
- **Inspector will verify the facility's Certificate Extension Approval Letter for DBT**
- **Inspector will verify all personnel New Modality Initial Training**
- **Will verify that appropriate DBT testing is being performed per the manufacturers QC manual for the medical physicist tests and the technologist**

DBT Accreditation

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Hologic Technical Support

Sign up to download QC Manuals

http://www.hologic.com/en/product-support/downloads/

Hologic Quick Links

- **Links to MQSA Certificate Extension Program**
- **Hologic Training Requirements**
- **Hologic Online Courses for Technologist**

Hologic Website for Patients

- Hologic reports DBT units in 47 states
- Approximately several hundred in DBT systems in use

Find a DBT Mammography Unit
http://pinkribbon.hologic.com/index.cfm?zipc

ACR Breast Imaging Centers of Excellence

- Initiated in October 2007
- A center must be fully accredited in:
  - Mammography by ACR (or FDA-approved state accrediting body)
  - Stereotactic Breast Bx by the ACR
  - Breast Ultrasound by the ACR (including the Ultrasound-Guided Breast Bx module)
- The ACR awards the designation at no additional fee to acknowledge the dedication of the center to improving women's health by participating in these rigorous quality assurance programs
- For more information, go to www.acr.org/accreditation/bicoe.aspx

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ACR Voluntary Breast Imaging Accreditation Programs

- Mammography - MAP (1987)
- Stereotactic Breast Biopsy – SBBAP (1996)
- Ultrasound-Guided Breast Biopsy (1998)
- Breast Ultrasound, with USGBB Module - BUAP (2000)
- Breast MRI – BMRAP (2010)

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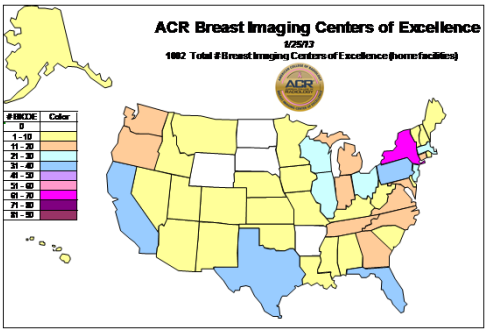
BICOE



Why BICOE

- Stereo Accreditation
  - October 2007
    - ✓Facilities - 456
    - ✓Units – 469
  - December 2012
    - ✓Facilities – 1175
    - ✓Units – 1219
- Breast Ultrasound Accreditation
  - October 2007
    - ✓Facilities – 633
  - December 2012
    - ✓Facilities - 1807

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5. To achieve the BICOE designation a center must be accredited in

0% 1. Mammography and Stereotactic Breast Biopsy Accreditation
0% 2. Mammography, Stereotactic Breast Biopsy & Breast Ultrasound Accreditation
0% 3. Mammography and Breast Ultrasound Accreditation
0% 4. Mammography, Stereotactic Breast Biopsy & Breast MRI Accreditation
5. Mammography, Breast Ultrasound & Breast MRI Accreditation

10

5. To achieve the BICOE designation a center must be accredited in

1. Mammography and Stereotactic Breast Biopsy Accreditation
2. Mammography, Stereotactic Breast Biopsy & Breast Ultrasound Accreditation
3. Mammography and Breast Ultrasound Accreditation
4. Mammography, Stereotactic Breast Biopsy & Breast MRI Accreditation
5. Mammography, Breast Ultrasound & Breast MRI Accreditation

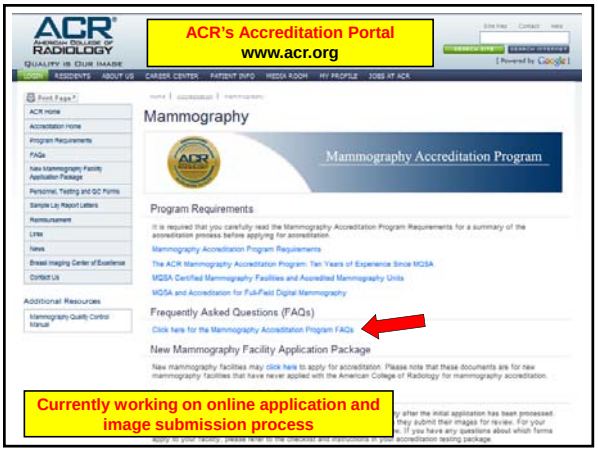
Answer: Mammography, Stereotactic Breast Biopsy & Breast Ultrasound Accreditation

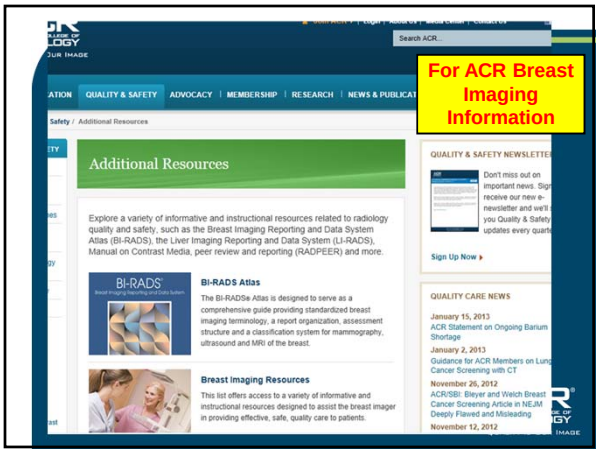
Ref: ACR, Breast Imaging Center of Excellence Requirements, www.acr.org

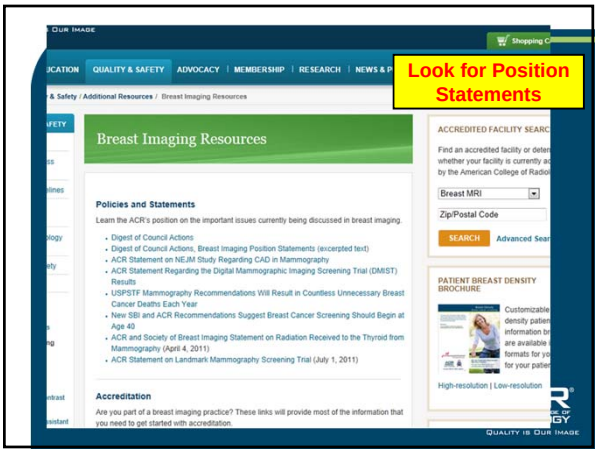
More Help

Contact FFDM Manufacturer for QC Assistance

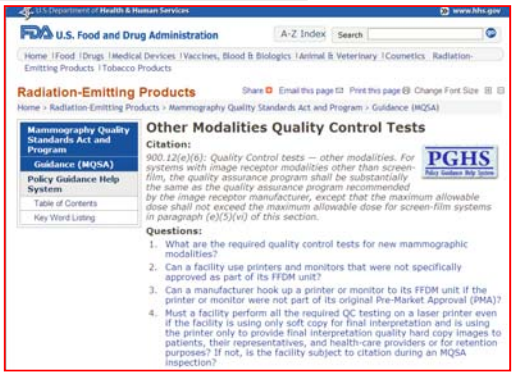
FFDM Mfr	Website
Carestream	www.carestreamhealth.com
GE	www.gehealthcare.com
Fuji	www.fujimed.com
Lorad	www.hologic.com
Philips (Sectra)	http://www.healthcare.philips.com
Planmed	www.planmed.com
Siemens	www.medical.siemens.com







FDA Policy Guidance Help System
(ww.fda.gov/cdrh/mammography)



Where Do We Go From Here

- **Developing on-line accreditation database for mammography – ACRedit**
- **Developing web-based submission for Clinical and Phantom Images – Triade**
- **In final stages of ACR QC Full-Field Digital Mammography Manual**
- **Accreditation program for DBT**
- **What's next - Breast CT ?**

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