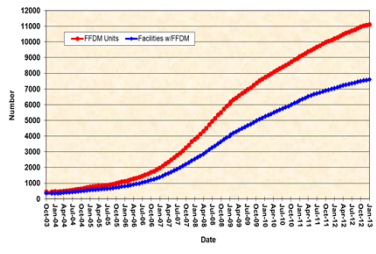

  
**ACR**<sup>®</sup>
  
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**RADIOLOGY**
  
 QUALITY IS OUR IMAGE

## MQSA and ACR Digital Breast Tomosynthesis Mammography Accreditation

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

### US FFDM Mammography Facilities and Units

US Full-Field Digital Mammography Units and Facilities  
(as of each month)



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%

10

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

1. 20%

2. 40%

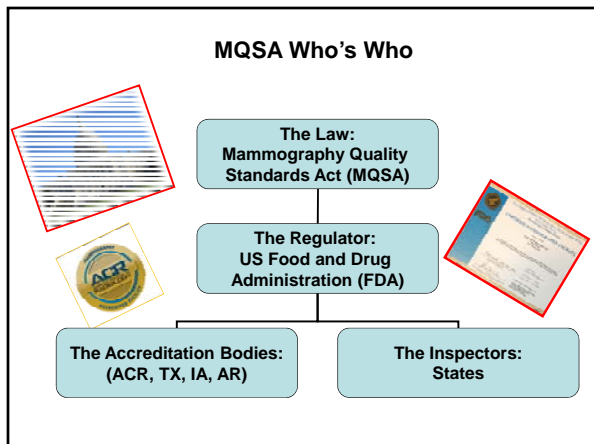
3. 66%

4. 88%

5. 100%


Answer: 4. 88%

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



### 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


  
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## 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")



www.acr.org

Mammography Accreditation

Program Requirements

It is required that you carefully read the Mammography Accreditation Program Requirements for a summary of the accreditation process before applying for accreditation.

The ACR Mammography Accreditation Program. Ten Years of Excellence Since MQSA - MQSA Certified Mammography Facilities and Accredited Mammography Units

Frequently Asked Questions (FAQ)

- Mammography Accreditation Program FAQ

New Mammography Facility Application Package

New mammography facilities may use this package to apply for accreditation. Please note that these documents are for facilities that have never applied with the American College of Radiology for mammography accreditation.

- New Mammography Facilities Application Package

HOME EDUCATION QUALITY & SAFETY ADVOCACY MEMBERSHIP RESEARCH NEWS & PUBLICATIONS MEETINGS & COURSES

Home / Quality & Safety / Accreditation / Mammography / Application Package

### New Mammography Facility Application Package

Please 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
- Unit Mammography Facilities Letter
- Entry - Renewal Application Instructions

Submit these documents:

- Entry - Renewal Application Checklist
- Entry Application
- Mammography Accreditation Survey Agreement
- MQSA Information Release Authorization
- MQSA Requirements for Mammography Equipment Checklist

Submit applicable medical physicist forms:

- Medical Physicist Equipment Evaluation and Annual Survey forms

CONTACT US

Phone 800-221-6440  
Fax 703-640-8176  
Email mamm-accred@acr.org

ACR Mammography Accreditation Program  
1801 Preston White Dr  
Reston, VA 20191

ACR MAMMOGRAPHY RESOURCES

- Breast Imaging Resources
- FDA Mammography Home Page
- MQSA Policy Guidance Help System
- BRACIS Atlas
- Breast Imaging Center of Excellence
- Free participation for BRICC facilities at the National Mammography Database
- Assistance for CMS Mammography Accreditation Issues
- Accreditation Newsletters

### 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:			Model:	
Unit Manufacturer:			Year Mfg.:	
Serial number:			Room ID:	
Medical Physicist:			Survey Date:	
Signature:				
Feature	FDA Rule Section	Requirement	Applies to	Meets FDA Requirements? (If NA, please explain)
Station of tube image receptor assembly	300	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"/> N/A
	300	The mechanism shall not fail in the event of power interruption	S-F & FFDM	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A
Image receptor sizes	400	Systems using screen-film image receptors shall provide, at a minimum, for operation with image receptors of 18 x 24 cm and 24 x 36 cm.	S-F	<input type="checkbox"/> Yes <input type="checkbox"/> No <input checked="" type="checkbox"/> N/A
	400	Systems using screen-film image receptors shall be equipped with heavy grids matched to all image receptor sizes.	S-F	<input type="checkbox"/> Yes <input type="checkbox"/> No <input checked="" type="checkbox"/> N/A
	400	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"/> N/A



### 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 compared)	Weekly	
8. MTF Measurement	DSE/essential Weekly; 20000-Monthly	
9. AOP Mode and SNR	Monthly	
10. Visual Checklist	Monthly	
11. Repeat Analysis	Quarterly	
12. Analysis of Fuser 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




### ACR Forms are Manufacturer Specific

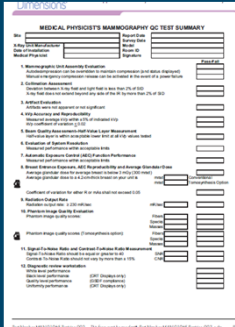



Quality Control Manual  
Selenia Dimensions 2D FFDM  
Selenia Dimensions DBT

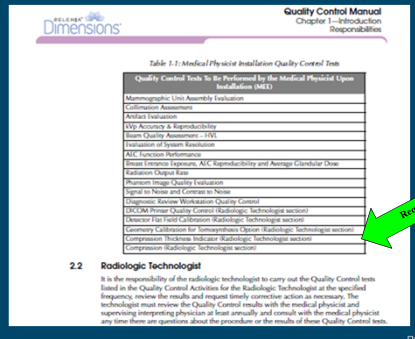
HOLOGIC MAN-01965




### Hologic Medical Physicist QC Test Summary

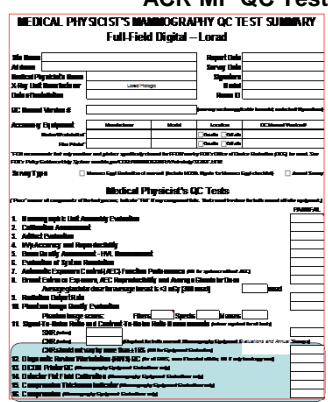
### Quality Control Test Required by MP at MEE



Review at MEE



### 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 QC Tests**

Test	Date
1. Mammograph Unit Assembly Evaluation	2011
2. Computed Tomography	2011
3. Annual Evaluation	2011
4. MQSA Annual and Intermediate	2011
5. Image Quality Assessment - IQA II (Intermediate)	2011
6. Evaluation of System Operation	2011
7. Additional System Evaluation (QC) (Frequency: 1/yr or as required)	2011
8. Breast Unit or Computer Aided Detection and Average Member Class	2011
9. Additional System Evaluation	2011
10. Phantom Image Quality Evaluation	2011
11. Image Quality Assessment - IQA II (Intermediate)	2011
12. Image Quality Assessment - IQA II (Intermediate)	2011
13. Image Quality Assessment - IQA II (Intermediate)	2011
14. Image Quality Assessment - IQA II (Intermediate)	2011
15. Image Quality Assessment - IQA II (Intermediate)	2011
16. Image Quality Assessment - IQA II (Intermediate)	2011
17. Image Quality Assessment - IQA II (Intermediate)	2011
18. Image Quality Assessment - IQA II (Intermediate)	2011
19. Image Quality Assessment - IQA II (Intermediate)	2011
20. Image Quality Assessment - IQA II (Intermediate)	2011

- 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 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.



### 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



### 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



4. A facility may be 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

10

4. A facility may be 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](http://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](mailto: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

- 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



### Hologic Technical Support

Sign up to download QC Manuals

The screenshot shows the Hologic website's technical support page. It features a navigation menu at the top, a main heading 'Sign up to download QC Manuals', and a registration form. The form includes fields for 'First Name', 'Last Name', 'Email', and 'Phone', along with checkboxes for 'I agree to the terms and conditions' and 'I agree to receive newsletters'. A 'Log In' button is also visible. Below the form, there are links for 'Product Support' and 'Technical Document Downloads'. The ACR logo is in the bottom right corner.

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

### Hologic Quick Links

The screenshot shows the Hologic website's quick links section. It features a navigation menu at the top, a main heading 'Hologic Quick Links', and a list of links. The links are organized into two columns: 'Medical Professionals' and 'Digital Breast Tomosynthesis'. The 'Medical Professionals' column includes links for 'Product Support', 'Technical Document Downloads', 'Registration', 'Log In', 'Forgot your password?', and 'Sign Up'. The 'Digital Breast Tomosynthesis' column includes links for 'Hologic Training Courses for Technologists', 'Hologic Training Courses for Medical Physicists', 'Hologic Training Courses for Radiation Therapists', and 'Hologic Training Courses for Radiologists'. The ACR logo is in the bottom right corner.

- 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](http://www.acr.org/accreditation/bicoe.aspx)



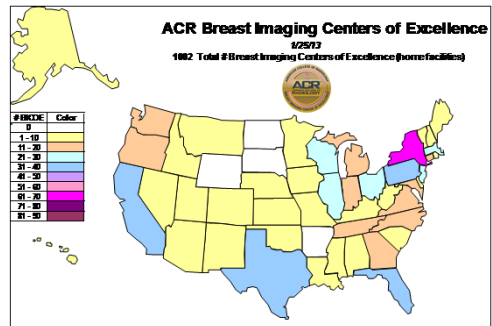
### ACR Voluntary Breast Imaging Accreditation Programs

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



45

### 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



### 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
- 0% 5. Mammography, Breast Ultrasound & Breast MRI Accreditation

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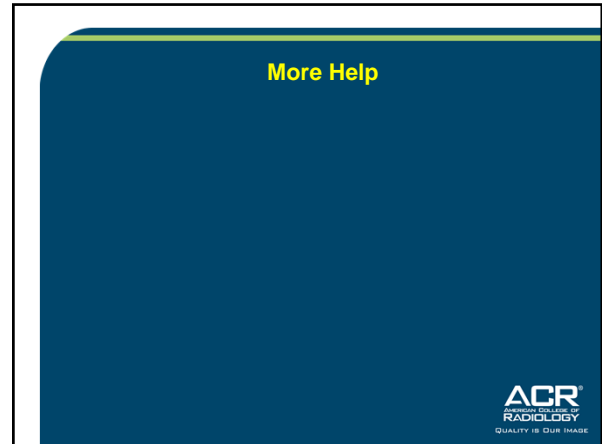


**5. To achieve the BICOE designation a center must be accredited in**

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

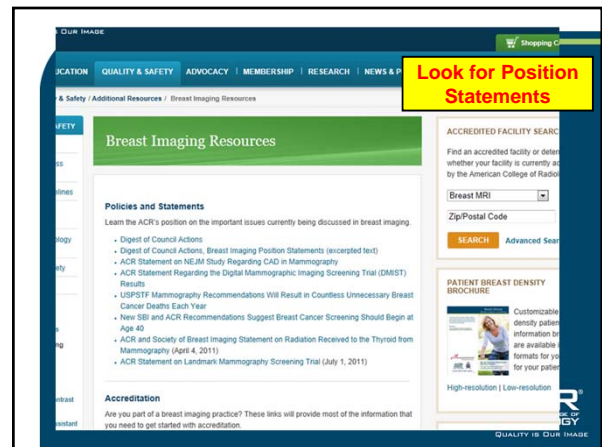
Answer: Mammography, Stereotactic Breast Biopsy & Breast Ultrasound Accreditation

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



**Contact FFD 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**  
 (www.fda.gov/cdrh/mammography)

**Other Modalities Quality Control Tests**

**Citation:**  
 900.22(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?

**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 ?

