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%

Answer: 4. 88%

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 Mammmomat 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
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 Equipment Evaluation & Annual Summary Forms
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 mr-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

Hologic Medical Physicist QC Test Summary

Quality Control Test Required by MP 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
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

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 the AB accredits the DBT

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

Answer: 5. None of the above

Ref: Facility Certification and Inspection, Digital Accreditation, MQSA Policy Guidance

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

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
4. A facility may begin 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


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**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/RadiationEmittingProducts/MammographyQualityStandardsActandProgram/FacilityCertificationandInspection/ucm243765.htm](http://www.fda.gov/RadiationEmittingProducts/MammographyQualityStandardsActandProgram/FacilityCertificationandInspection/ucm243765.htm)

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**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

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**DBT Accreditation**

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  - Expects mammography to be in our on-line database by ACredit by summer 2013
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- Facility will need to accredit both modalities, the FFDM and DBT portion of the unit

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**Hologic Technical Support**

Sign up to download QC Manuals


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**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

ACR Voluntary Breast Imaging Accreditation Programs

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

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
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 FFDM Manufacturer for QC Assistance

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<thead>
<tr>
<th>FFDM Mfr</th>
<th>Website</th>
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<tbody>
<tr>
<td>Carestream</td>
<td><a href="http://www.carestreamhealth.com">www.carestreamhealth.com</a></td>
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<td>GE</td>
<td><a href="http://www.gehealthcare.com">www.gehealthcare.com</a></td>
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For ACR Breast Imaging Information

ACR’s Accreditation Portal

www.acr.org

Currently working on online application and image submission process.

Look for Position Statements

ACR's Accreditation Portal

www.acr.org

More Help

ACR’s Accreditation Portal

www.acr.org
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?