Site Readiness and Reimbursement

Hologic Proprietary Information for Training Purposes in U.S. Only - October 2011 MED-00013

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Mammography Accreditation and MQSA Certification

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Why ACR Accreditation?

- Validation of quality
- Peer process
  - Judy Destouet, M.D. – current chair, Committee on Mammography Accreditation
- Educational process
- MQSA requires accreditation for all mammography facilities (screening and diagnostic)
- Patient confidence
  - Facilities meet the highest standards of their profession

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Mammography Accreditation and MQSA Certification

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History

- 1987 – ACR’s voluntary Mammo Accreditation Program
- 1992 – President Bush signs the Mammography Quality Standards Act
- 1994 – FDA’s Interim Rules requires all mammography facilities in the US to be accredited, certified and inspected; QC regs mirror the ACR requirements
- 1999 – FDA’s Final Rules went into effect with new detailed requirements, including direct patient notification

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When Do the MQSA Certificate and Accreditation Expire?

- ACR expiration dates on certificate and unit label
- Against the law to perform mammography without a current MQSA certificate
- Medicare will not reimburse under expired certificate

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Meet All Application Deadlines

- Renewal notices sent out 8 months prior to accreditation expiration
  - ACR must receive the complete entry application within 6 months prior to expiration
- You have 45 calendar days to return completed testing to ACR
  - This guarantees completion of the review process before accreditation expiration

1999 ACR Quality Control Manual

- Aid for meeting FDA rules
- Consistent with MQSA requirements
- Additional recommendations for further quality improvement
- Meeting ACR recommendations not required for accreditation

ACR Image Reviewers

- 85 radiologists and 35 medical physicists qualified under MQSA
- In clinical (or physics) practice across the US
- Board certified
- 5+ years of experience in accreditation modality
- Participate in formal training program
- May not review images from the same state

4. The ACR staff employees 25 full-time clinical image reviewers and 15 phantom image reviewers at their Reston, VA office to ensure quick turn around of your accreditation images.

TRUE or FALSE

6. ACR radiologist reviewers assume that clinical images submitted for accreditation are

A. Examples of your facility's best work
B. Examples of your facility's typical work
C. Benign cases
D. Reviewed by your facility's mammography QC technologist
E. A and C

Phantom Image Quality Evaluation

- Phantom Image Reviewers use same criteria in ACR QC Manual
- Subtract artifacts if they appear
  - Fiber-like
  - Speck-like
  - Mass-like

- Mass: 33 segments of the circle must be visible for a full point
- Speck: 34 segments for the entire circle to be visible
- Fiber: 16 (the entire, unbroken length of the fiber must be visible)
Follow Instructions Submitting Clinical Images

- Examples of facility’s best work
- Supervising radiologist should review & approve images
- Submit “negative” images
  - BI-RADS assessment category 1 (“nothing to comment on...breasts are symmetrical...no masses, architectural disturbances or suspicious calcifications”)
  - ACR will accept BI-RADS assessment category 2 (“benign”) with prior approval & report
- Do NOT use models or volunteers

8. The major reason for failure of ACR accreditation is

A. Excessive patient dose
B. Poor phantom image quality
C. Poor clinical image quality (Positioning)
D. Processor QC (more than 3 data points outside of control limits without corrective action)

7. The radiologist reviewers will not review clinical images submitted for accreditation that are not adequately fatty or dense.

TRUE or FALSE

Different Breast Densities (BI-RADS) Present Different Imaging Challenges

- Comp Cat 1 (<25% glandular)
- Comp Cat 2 (25-50% glandular)
- Comp Cat 3 (51-75% glandular)
- Comp Cat 4 (>75% glandular)

Clinical Image Quality Evaluated in Eight Categories

- Positioning*
- Compression
- Exposure level
- Contrast
- Sharpness
- Noise
- Artifacts
- Exam ID

- Review evaluation criteria in “Clinical Image Evaluation” section of 1999 QC Manual before submitting images

(*Primary reason for accreditation failure)
9. Your facility does not pass accreditation after the initial application. (The clinical images were not acceptable.) You must immediately cease performing mammography.

TRUE or FALSE

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10. Your accredited facility just installed a new unit. You must ___ before you examine patients with that unit

A. Have you medical physicist conduct an Equipment Evaluation on the unit
B. Correct all problems identified during the Equipment Evaluation
C. Send ACR the accreditation application and Equipment Evaluation results for the new unit
D. All of the above

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Accreditation Attempts

<table>
<thead>
<tr>
<th>Attempt</th>
<th>Result</th>
<th>Facility Options</th>
</tr>
</thead>
<tbody>
<tr>
<td>1st</td>
<td>NOT GRANTED</td>
<td>1st Deficiency Facility may continue mammography with unit.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• REPEAT not acceptable area(s) (if &gt;2 months on certificate),</td>
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<tr>
<td></td>
<td></td>
<td>• REINSTATE by retesting all areas (if &lt;2 months on certificate),</td>
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<tr>
<td></td>
<td></td>
<td>• APPEAL or</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• WITHDRAW</td>
</tr>
<tr>
<td>2nd</td>
<td>NOT GRANTED</td>
<td>2nd Deficiency = 1st Failure ACR recommends facility cease mammography.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• REINSTATE by retesting all areas (with corrective action),</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• APPEAL (may not operate until the appeal is complete) or</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• WITHDRAW</td>
</tr>
<tr>
<td>3rd</td>
<td>NOT GRANTED</td>
<td>3rd Deficiency = 2nd Failure ACR recommends that facility cease mammography.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• REINSTATE after SOSS,</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• APPEAL (may not operate until the appeal is complete) or</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• WITHDRAW</td>
</tr>
</tbody>
</table>

Clinical Image Quality Evaluation Will Not Differ

• Hard copy images only/changed now to both are acceptable Electronic/hard copy
• Evaluate the same 8 attributes as screen-film
  - Positioning
  - Compression
  - Exposure
  - Contrast
  - Sharpness
  - Noise
  - Artifacts
  - Labeling
• ACR radiologists reviewing FFDM images are digital-qualified under MQSA

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Phantom Image Quality Evaluation Will Not Differ

• Hard copy images/Electronic Submission
• Scoring is the same as screen-film
  - Fibers
  - Specks
  - Masses
  - Subtraction for artifacts
• ACR medical physicists reviewing FFDM images are digital-qualified under MQSA

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Personnel Requirements are Different for FFDM

- Interpreting physician
- Medical physicist
- Radiologic technologist

Interpreting Physician (FFDM)

- Initial training
  - 8 hours (doesn’t need to be Cat I)
  - Special training courses
  - Mfr applications training
  - Graduate training
  - Hands-on training (e.g., soft copy interpretation)
- Exemptions
  - If began interpreting before 4/28/99
  - Either document or attest
- Continuing education
  - 6 Cat I CME’s every 36 months

Medical Physicist (FFDM)

- Initial training
  - 8 hours
  - Special training courses
  - Mfr applications training
  - RT training
  - Include hands on training (e.g., QC testing)
- Exemptions
  - If began using FFDM before 4/28/99
  - Either document or attest
- Continuing education
  - No # specified
  - Include CEU’s in FFDM every 36 months

The Future

- ACR is working with equipment manufacturers to develop a harmonized, evidence-based set of QC tests, test frequencies and performance criteria
- Benefit from the ACRIN/DMIST experience

Know When Your Accreditation and MQSA Certification Expire

- Make every effort to stay within our timeframe
- If you don’t submit your accreditation materials to us in a timely manner, we may have to fail your facility for non-compliance
- Our expiration date is on your ACR certificate and unit decal
- FDA and ACR are synchronizing dates
Radiologists:

- Don’t assume everything is OK
- Radiologist is responsible for everything that impacts the interpretation of the patients’ films
- Lead interpreting physician has responsibility to ensure that the QA program meets all requirements
  - ACR recommends that you review your facility’s QC at least quarterly
- Review and approve all accreditation materials (including clinical images)
- ACR sends all accreditation materials to the lead interpreting physician (he/she signs all survey agreements)

Medical Physicists:

- The medical physicist has responsibility over QC
- Talk with the technologists and radiologists; ask them about problems and concerns; have them show you
- Verbally explain your report to the facility staff
- Be aware of the new ACR Equipment Evaluation requirements for accreditation

Mammography Technologists:

- Keep your radiologist(s) informed and involved
- The lead interpreting physician has the responsibility of ensuring that the quality assurance program meets all MQSA requirements
- Be sure he/she reviews all accreditation materials (including clinical images) before sending them to the ACR

FDA Required Breast Tomosynthesis Training

On any new mammography technology, such as breast tomosynthesis, the Mammography Quality Standards Act (MQSA) (http://fda.gov/Radiation-EmittingProducts/MammographyQualityStandardsActandProgram/FacilityCertificationandInspection/ucm114148.htm) requires that all health care professionals obtain eight hours of training prior to using new mammography technology on patients.

PERSONNEL QUALIFICATIONS: RADIOLOGIC TECHNOLOGISTS WHO ARE QUALIFIED TO PERFORM DBT MAMMOGRAMS

List the current radiologic technologists who:

1. Meet all the requirements of 21 CFR 900.12(a)(3) "Mammography Quality Standards: Final Rule" that became effective on April 28, 1999; and
2. Have 8 hours of initial new-modality training in DBT, either including or supplemented by training in the unique features of the specific manufacturer’s DBT system.

New Mammographic Modality Training

- Interpreting Physicians and Medical Physicist and Radiologic Technologists are required to have 8 hours of training in FFDM system(s) before providing services independently using the system
- Similar to a SFM requirement, the Quality Control (QC) technologist at a facility using an FFDM unit must be a qualified radiologic technologist who also meets the training requirement for performing FFDM examinations

Qualified Radiologic Technologist

- Certified by:
  - American Registry of Radiologic Technologists (ARRT), or
  - American Registry of Clinical Radiologic Technologists, or
  - Licensed to perform general radiographic procedures in a state
- AND
- 40 hours of training in mammography including:
  - Training in breast anatomy and physiology, positioning and compression, QA/QC techniques, and imaging of patients with breast implants, and
  - 25 mammography examinations under direct supervision of an appropriate MQSA-qualified individual
Mammographer

- 8 hours of training in using a mammographic modality (e.g., digital, tomosynthesis), before beginning to use that modality independently.

- Continuing Experience: Perform 200 mammographic examinations over a 24-month period

- Continuing Education: 15 category 1 CEU's in mammography during 36 months. Once certified in mammography, Registered Technologists (R.T.s) must complete 24 Category A or A+ continuing education (CE) credits each biennium — a two-year period that begins at the start of his or her birth month.

New Mammographic Modality Training

- Medical physicists are required to have 8 hours training in surveying FFDM system(s) before conducting independent surveys and/or equipment evaluations

- Hands-on training is strongly recommended

- Continuing Experience — Survey 2 mammography facilities and 6 mammography units over a 24-month period.

- Continuing Education — 15 CME/CEU's in mammography in a 36-month period

Tomosynthesis Training

- Radiologists - 8 hours of new modality training for tomosynthesis

- Physicists - 8 hours of new modality training for tomosynthesis

- Technologists - 8 hours of new modality training for tomosynthesis

Tomosynthesis Training for Radiologists:

- Radiologists must meet all MQSA requirements

- Radiologist will need 8 hours of training in the interpretation of breast tomosynthesis will be offered through non-CME courses

- PERSONNEL QUALIFICATIONS: INTERPRETING PHYSICIANS WHO ARE QUALIFIED TO INTERPRET DBT MAMMOGRAMS

- List the current interpreting physicians who:

  - (1) meet all the requirements of 21 CFR 900.12(a)(1) "Mammography Quality Standards; Final Rule" that became effective on April 28, 1999, and

  - (2) have 8 hours of initial new-modality training in DBT, either included or supplemented by training in the unique features of the specific manufacturer’s DBT system.
Tomosynthesis Training for Physicists

- Physicists must meet all MQSA requirements.
- 8 hours of new modality training for tomosynthesis will be offered. During installation, training will provide five hours of Quality Control training by a qualified field service engineer.
- Physicists will be able to obtain 3 hours of this training online or in a live setting prior to an install
- Additional 5 hours may be obtained with the FE during the install
- They could also spend 8 hours with the FE if they choose
- www.MTMI.net

Tomosynthesis Site Readiness

Once you have 8 hours Tomo Training
Peer to peer

- peer to peer review, but must be specific topics

Tomosynthesis Training for Technologists

- Technologists must be MQSA certified
- Technologists must have received 8 hours of training in FFDM before 8 hours of instruction for tomosynthesis

- PERSONNEL QUALIFICATIONS: MEDICAL PHYSICISTS WHO ARE QUALIFIED TO PERFORM DBT SURVEYS
- List the current medical physicists who:
  - (1) meet all the requirements of 21 CFR 900.12(a)(3) "Mammography Quality Standards; Final Rule" that became effective on April 28, 1999; and
  - (2) have 8 hours of initial new-modality training in DBT, either including or supplemented by training in the unique features of the specific manufacturer’s DBT system.

Lead Interpreting Physician Attestation to Staff Personnel Qualifications

- To the best of my knowledge and my belief, the information provided in this document is true and correct. I understand that FDA may request additional information to substantiate the statements made in the document. I understand that knowingly providing false information in a matter within the jurisdiction of an agency of the United States could result in criminal liability, punishable by up to $10,000 fine and imprisonment of up to five years, or civil liability under MQSA, or both.
- Signature (Lead Interpreting Physician) ____________________________
- Print Name _________________________________________________________________________
- Date ________________________________________________________________________________

February 2011
Accreditation

- The 2D portion of the unit is accredited using standard FFDM procedures
  - ACR, SAR, SIA, and STX
- The DBT portion of the unit must apply to and be approved by the FDA for extension of their certificates to include the use of a DBT unit
  - MQSA Facility Certification Extension Requirements for Hologic Digital Breast Tomosynthesis

MQSA Accreditation

- No approved accrediting bodies for Tomosynthesis as yet
- To become breast tomosynthesis certified your site must apply to the MQSA for a 3D extension certification. Once application is sent for breast tomosynthesis approval, it will take about 14 days for MQSA to process and approve/deny the request.

Coordination of On-Site Tomosynthesis Training

Before applications can take place, radiologists must have completed their tomosynthesis 8 hour of interpretation training. Remember application specialist will not be allowed to train radiologist in DBT the way they could in 2D.

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

NOTE 1: For MQSA purposes, Digital Breast Tomosynthesis is a new mammographic modality separate from Full Field Digital Mammography.

NOTE 2: In order to use the tomosynthesis portion of the unit, the facility must apply to FDA to have its certificate extended to include that portion of the unit. The certification extension only applies to 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.

Certification Extension Program

Facilities must have either the provisional or final FFDM MQSA certification (site MAP I.D.) before applying for Tomosynthesis extension certification.

Questions please contact:
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Certification Extension Program
Division of Mammography Quality and Radiation Program
FDA/CDRH/OCER
10903 New Hampshire Avenue WO66-4621
Silver Spring, MD 20903-0002
Phone: 301-796-5710 Fax: 301-847-8502

2D & Tomosynthesis Dimensions Unit Accreditation

Facilities must have either the provisional or final FFDM MQSA certification (site MAP I.D.) before applying for Tomosynthesis extension certification.

Radiologist 8 hours training prior to interpreting images

Physicist 3 hours online training

Install System

Physicists testing for 2D & tomosynthesis - Receives 5 hrs tomosynthesis training credit

2D paperwork submitted to ACR

- Provisional MQSA accreditation received
- Applications training for 2D to satisfy 8 hours if needed
- 2D imaging may begin

Tomosynthesis paperwork submitted to FDA

- 14 days to receive tomosynthesis certification extension
- Applications training for tomosynthesis to satisfy 8 hours needed

Site has 45 days from provisional MQSA accreditation to apply for final accreditation
Facilities must have either the provisional or final FFDM MQSA certification (site MAP I.D.) before applying for Tomosynthesis extension certification.

- Radiologist 8 hours training prior to interpreting images
- Physicist 3 hours on-line training
- Install System Tomosynthesis Option
- Physicists testing for Tomosynthesis Receives 5 hrs Tomosynthesis training credit
- Tomosynthesis paperwork submitted to FDA
- 14 days to receive tomosynthesis certification extension
- Applications training for tomosynthesis to satisfy 8 hours needed

Billing Options for Breast Tomosynthesis

- Breast tomosynthesis performed in conjunction with digital mammography is appropriately reported with the unlisted diagnostic procedure code 76499 to describe breast tomosynthesis and one of the HCPCS Level II “G” codes (G0202, G0204, or G0206) to describe the full-field digital mammography performed. If computer-aided detection (CAD) also is performed, it should be reported separately using one of the mammography CAD codes, 77051 (CAD performed in conjunction with diagnostic mammography) or 77052 (CAD performed in conjunction with screening mammography).

Questions??

Billing Options for Breast Tomosynthesis

- Reported with the unlisted diagnostic procedure code 76499 to describe breast tomosynthesis
- One of the HCPCS (Healthcare Common Procedure Coding System) Level II “G” codes (G0202, G0204, or G0206) to describe the full-field digital mammography performed.
- If computer-aided detection (CAD) also is performed, it should be reported separately using one of the mammography CAD codes, 77051 (CAD performed in conjunction with diagnostic mammography) or 77052 (CAD performed in conjunction with screening mammography).

Billing Options for Breast Tomosynthesis

- Digital breast tomosynthesis (DBT) has been assigned new billing codes and reimbursement rate values in the final rule for the calendar year (CY) 2015 Medicare Physician Fee Schedule (MPFS).

In response to a request from the American College of Radiology (ACR), the Current Procedural Terminology (CPT) Editorial Panel created three new codes (77061, 77062, and 77063) for CY 2015 to describe the physician work and practice expense associated with screening and diagnostic DBT. However, the Centers for Medicare & Medicaid Services (CMS) recommends in the 2015 MPFS that only 77063, (screening digital breast tomosynthesis, bilateral) be used at this time in conjunction with the digital screening mammography code G0202. The recommendation is based on a Food & Drug Administration requirement that a 2-D mammogram accompany a DBT when used for screening purposes.
Billing Options for Breast Tomosynthesis

• In lieu of using the new diagnostic DBT CPT codes (77061, 77062), CMS created a new add-on G code (G0279) to be used with the existing digital diagnostic mammography codes (G0204, G0206) to reflect the work of tomosynthesis when provided with diagnostic digital mammography. Therefore, the stand-alone diagnostic DBT codes have been replaced by add-on codes, leaving no means to report diagnostic DBT when it is reported separately from a full-field digital mammogram (FFDM).

• The ACR argued before the RUC that surveying mammography along with DBT would preclude an accurate valuation of DBT. DBT and mammography involve different technologies, different work, different practice expenses and often different patients. Because DBT is a new technology, the data regarding utilization, site of service and specialty remain to be seen. To include DBT as simply part of the mammography code family is premature and may eventually prove to be inaccurate. The ACR plan is to re-review the DBT family in three years per the conventional Relativity Assessment Workgroup schedule for the re-review of new technologies.

Note: Patients will not be responsible for any co-pays associated with the new screening DBT codes. The screening tomosynthesis add-on code, 77063, would be subject to the same co-insurance/deductible policies as other screening mammography services. Code G0279 relates to a diagnostic procedure; therefore, it would not follow the same policies as those established for the screening studies.

In A Nut Shell

• 77061 Digital breast tomosynthesis diagnostic; unilateral + 77062 bilateral breast diagnostic (Do not report 77061, 77062 in conjunction with 76376, 76377, 77057)
77063 Screening digital breast tomosynthesis, bilateral (List separately in addition to code for primary procedure) (Do not report 77063 in conjunction with 76376, 76377, 77055, 77056) (Use 77063 in conjunction with 77057)
• Multiple radiology societies requested three new Category I codes to describe diagnostic (77061 and 77062) and screening (77063) digital breast tomosynthesis procedures. Current mammography codes do not include the added physician work or practice expense involved in digital breast tomosynthesis and, therefore, new codes were needed to describe these additional resources. Currently under the CMS FAQ issued in November 2013, tomosynthesis is not separately billable. The publication of Medicare’s Final Rule for 2015 this November will, we hope, clarify billing for tomosynthesis.

Prices for manufactures machines

• Pricing for Full-Field Digital Mammography:
  - Low: $175,000
  - High: $435,000
  - Average Price: $273,940
• System Service Support Prices
  - Low: $29,500
  - High: $59,575
  - Average Price: $43,290

• Pricing for Digital Breast Tomosynthesis:
  - Low: $399,400
  - High: $551,900
  - Average Price: $462,010
• System Service Support Prices
  - Low: $42,000
  - High: $78,910
  - Average Price: $53,990