Basics of Breast Imaging Accreditation

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Introduction
Introduction - What I’m going to Talk About

• Brief history of ACR accreditation, MQSA and MIPPA
• Mammography Accreditation Program
• Stereotactic Breast Biopsy Accreditation Program
• Breast Ultrasound Accreditation Program
• Breast MRI Accreditation Program
• Breast Imaging Centers of Excellence
Introduction – ACR Accreditation History

• 1966 - First Practice Accreditation Program
• 1987 – Mammography
• 1987 – Radiation Oncology
• 1995 – Ultrasound
• 1996 – Stereotactic Breast Biopsy
• 1997 – MRI
• 1998 – Breast Ultrasound
• 1999 – Nuclear Medicine
• 2002 – CT and PET
• 2010 – Breast MRI
Accreditation Program Development & Oversight

- ACR Commission on Quality and Safety - Jacqueline Bello, MD, Chair
- Committee on Accreditation Program Chairs
  - Anthony Scuderi, MD, Chair
- Modality Accreditation Program Committee
  - Develops requirements and clinical image quality criteria
  - Oversees the program and updates as necessary
  - Trains and oversees radiologist clinical image reviewers
- Modality Accreditation Program Subcommittee on Physics
  - Develops QC requirements and phantom image quality criteria
  - Oversees the QC program and updates as necessary
  - Trains and oversees medical physicist phantom image reviewers
- Clinical and phantom image reviewers – evaluates facility image quality
- ACR accreditation staff – implements the program
Accreditation Program Elements

• Personnel Qualifications
  – Interpreting physician
  – Imaging technologist
  – Medical physicist

• Equipment

• Quality Control
  – Acceptance testing/equipment evaluations and annual surveys
  – Routine QC

• Quality Assurance
  – Medical audits, or
  – Physician peer-review and outcome data

• Reporting

• Accreditation Testing
  – Clinical image quality
  – Phantom image quality
ACR Accreditation Process

Generally same for all programs
New – ACR Accreditation Website
Modality Web Pages

- Program requirements
- Frequently asked questions
- How to register/log in
- Gathering data
Introduction – Mammography Quality Standards Act (MQSA)

• 1992 – Mammography Quality Standards Act signed into law
• 1994 – FDA’s Interim Rules required all mammography facilities in the US to be accredited, certified and inspected
• 1999 – FDA’s Final Rules went into effect with new detailed requirements, including direct patient notification
• The law requires periodic reauthorization by Congress (last done in 2004)
MQSA Who’s Who

The Law: MQSA

The Regulator: FDA

The Accrediting Body: ACR, TX, IA, AR

The Inspectors: States
Mammography in the US (as of 3-1-2016)

- 15,713 units at 8,740 certified facilities
- 98% of all units in US are digital
- Over 20% have tomo
Introduction – What Do FDA Regs Cover?

- Personnel requirements
  - Interpreting physicians
  - Radiologic technologists
  - Medical physicists

- Equipment requirements

- Medical records and mammography reports
  - Final assessment categories
  - Communication of results to patients
  - Communication of results to health care providers
  - Recordkeeping
  - Mammographic image identification

- Quality assurance
  - Responsible individuals
  - Maintaining records
  - Equipment tests

- Mammography medical outcomes audits

- Mammography of patients with implants

- Consumer complaints

- Clinical image quality

- Additional mammography review and patient notification
Does MQSA Apply to Me or My Practice?

• Yes, if you
  – Conduct screening mammography
  – Conduct diagnostic mammography
  – Interpret mammograms

• No, if you conduct or interpret
  – Stereotactic breast biopsies or other interventional procedures
  – Breast ultrasound
## Physician Qualifications Under MQSA

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<tr>
<th>Initial Qualifications</th>
<th>Cont Exp</th>
<th>Cont Ed</th>
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<tr>
<td>Medical license. Board certified or 2 months full-time training before 1999 or 3 months full-time training after 1999</td>
<td>960 exams in 24 months</td>
<td>15 Cat I CME in 36 months</td>
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<td>Cat I CME in mammo (at least 15 hours in 3 years prior to qualifying date)</td>
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<tr>
<td>• Qualifying before 1999 - 40 hours</td>
<td></td>
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<tr>
<td>• Qualifying after 1999 - 60 hours</td>
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<tr>
<td>Initial interpreting experience</td>
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<tr>
<td>• Qualifying before 1999 - 240 exams w/in 6 months (under direct supervision if after 1994)</td>
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<tr>
<td>• Qualifying after 1999 - 240 exams under direct supervision w/in 6 months prior to qualifying*</td>
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<tr>
<td>Each modality (i.e., digital, tomo): 8 hours training</td>
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*Required Initial Experience May Depend on When Boards Were Passed*

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<th>Initial Experience</th>
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<tr>
<td><strong>For residents graduating before 2014:</strong></td>
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<tr>
<td>• If passed boards at first allowable time - interpret 240 exams under direct supervision within any 6 months in last 2 years of residency</td>
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<tr>
<td>• If not - interpret 240 exams under direct supervision w/in 6 months prior to qualifying</td>
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<tr>
<td><strong>For residents graduating 2014 or later:</strong></td>
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<tr>
<td>• 240 exams in any 6 month period of last 2 years of residency</td>
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What Residents and Fellows Should Know about FDA’s Interpreting Physician Requirements?

- Get letter from residency program director before you leave
- See FDA’s Policy Guidance Help System for sample
Introduction – The Medicare Improvements for Patients and Providers Act (MIPPA)

• MIPPA passed in 2008; effective 2012
• Accreditation is required for providers that bill for CT, nuclear medicine, PET and MRI (including breast MRI) under part B of the Medicare Physician Fee Schedule
  – Hospitals are exempt from this requirement since hospitals generally are not paid under the physician fee schedule
• ACR, IAC and RadSite approved as accrediting organizations
Mammography Accreditation Program (MAP)

As of March 2016 – 11687 accredited units at 8267 facilities
Mammography Accreditation Program

- *Brett Parkinson, MD*, Chair, Committee on Mammography Accreditation
- Unit based (clinical and phantom images from each unit)
  - Clinical
  - Phantom
  - QC/medical physics evaluation
- Online applications
- Upload images for review
MAP Clinical Images

• Submit screening examinations, not diagnostic
  – 1 Fatty case (4 views)
  – 1 Dense case (4 views)
• No volunteers
• Final interpretation quality – no copies or digitized film images
• Send examples of best work
MAP - Phantom Images

- Only submit one image
- Use clinical technique
  - Follow manufacturers-specific instructions for exposure
- Dosimeter no longer required
  - Dose assessment done by your medical physicist
Mammography Accreditation, MQSA and New Units

- Mammography is special
- What you must do before examining patients on a new unit depends on
  - If you are a brand new facility
  - If are an existing accredited and certified 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)

• Wait, 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”)
If Your Facility Is Already Accredited - Before You May Examine Patients

- Contact the ACR
- Your medical physicist must do all FDA-required Equipment Evaluation tests
  - All tests must pass
- 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)
- But note...
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
MQSA and Consumer Complaints

- Consumer - person complaining about 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
ACR Consumer Complaint History

• Over 15 years experience (1997 – 2015)
• Hundreds of consumer complaints received... examples:
  – Excessive compression
  – Excessive wait times
  – Excessive fees
  – Cannot obtain old images
  – Front desk staff/technologist/manager was rude
• Non-serious complaints
  – Refer back to facility
  – ACR assists with film transfer issues
• Only 175 of a serious nature
Types of Serious Consumer Complaints Investigated by ACR: 1997 - 2015

- Poor Image Quality: 17 cases (6.4%)
- Missed CA: 29 cases (11.0%)
- Unqualified Personnel: 33 cases (12.5%)
- No Lay Summary and/or Physician Report within 30 Days: 55 cases (20.8%)
- Injury: 49 cases (18.6%)
- Other: 81 cases (30.7%)
ACR Mammography QC Manual

• Screen-film
  – R. Edward Hendrick, PhD
• Guided MQSA QC regulations
• Precursor to other modality QC manuals
ACR Digital Mammography QC Manual

• Eric Berns, PhD, Chair
• Goals
  – Standardize QC tests for all digital mfrs
  – Standardize test frequencies
  – Standardize performance criteria
• FDA approved ACR’s alternative standard request – Feb 2016
  – Will allow facilities to use under MQSA
• Available late spring 2016
Stereotactic Breast Biopsy Accreditation Program (SBBAP)

As of March 2016 –
1588 accredited units at 1459 facilities
Stereotactic Breast Biopsy Accreditation

- **Leonel Vasquez, MD**, Chair, Committee on Stereotactic Breast Biopsy Accreditation
- Unit-based
- Personnel requirements and responsibilities vary depending on the practice setting
  - Collaborative
  - Independent
SBBAP - Collaborative Setting

- Radiologists *and* surgeons conduct biopsy procedures
- Joint responsibility for:
  - Patient selection
  - QA (including medical audit, number of biopsies performed, etc.)
- Radiologist responsible for
  - Interpretation
  - QC/QA oversight
  - Technologist and Physicist supervision
SBBAP - Independent Setting

• Radiologists or surgeons conduct biopsy procedures

• Physician responsibilities
  – Patient selection
  – QA (including medical audit, number of biopsies performed, etc.)
  – QC/QA oversight
  – Technologist and medical physicist supervision
Stereotactic Breast Biopsy Accreditation

• Clinical case material
  – 1 calcification Bx case
  – Corresponding mammograms
  – Specimen image

• Devices
  – Gun-needle
  – Vacuum suction
  – Other FDA-approved core Bx devices

• Send examples of best work

• Criteria
  – Accurate needle positioning of Bx probe in relation to the target
Breast Ultrasound Accreditation Program (BUAP)

As of March 2016 – 2178 accredited facilities
Breast Ultrasound Accreditation

- Jean Paquelet, MD, Chair, Committee on Breast Ultrasound Accreditation
- Facility-based
- Submit examples of best work
- Breast ultrasound
  - Simple cyst, and
  - Solid mass
BUAP – Ultrasound-Guided Breast Biopsy

• Ultrasound-guided breast Bx module
  – Core needle Bx
    ✓ Gun-needle or
    ✓ Vacuum suction
  – Fine needle aspiration cytology
  – Accurate needle positioning of Bx probe in relation to the target at specified stage of procedure for the probe being used
BUAP - Physics Requirements

• Most recent annual physics survey
• Corrective documentation for any performance problems
Breast MRI Accreditation Program (BMRAP)

As of March 2016 – 1756 accredited units at 1599 facilities
Breast MRI Accreditation

- **Elsie Levin, MD** and **Ed Hendrick, PhD**, Co-Chairs, Committee on Breast MRI Accreditation
- Unit-based
- Facility must have the capacity to perform mammographic correlation, directed breast ultrasound, and MRI-guided intervention, OR
- Create a referral arrangement with a cooperating facility that could provide these services
  - Recommend that cooperating facility be accredited by the ACR in breast MRI (not required)
BMRAP - Equipment Requirements

• No requirement for minimum field strength
• MR Equipment must:
  – Have a dedicated, bilateral breast coil
  – Be capable of simultaneous, bilateral, imaging
  – Meet all state and federal performance requirements, including:
    ✓ Maximum static magnetic field strength
    ✓ Maximum rate of change of magnetic field strength (dB/dt)
    ✓ Maximum RF power deposition (specific absorption rate)
    ✓ Maximum auditory noise levels
BMRAP - Testing

• 1 bilateral breast MRI case
  – 1 known, enhancing, biopsy-proven CA in breast
• Must include 4 sequences (and only these 4):
  – T2-weighted/bright fluid series
  – Multi-phase T1-weighted series
    ✓ Pre-contrast T1
    ✓ Early phase post-contrast T1
    ✓ Delayed phase post-contrast T1
  – Aurora units only require 3 sequences
    ✓ Pre-contrast T1 is same as T2-weighted/bright fluid series
• QC/Physics evaluation (including breast coil testing)
Breast Imaging Centers of Excellence (BICOE)
What is BICOE?

- A demonstration of excellence in breast imaging for facilities by successfully achieving ACR Accreditation in Mammography, Stereotactic Breast Biopsy, Breast Ultrasound (including Ultrasound-Guided Breast Biopsy module) and Breast MRI
- Recognizes breast imaging centers’ dedication to improving women’s health by participating in rigorous quality assurance programs and undergoing peer review
Why Choose BICOE?

• Marketing tool for your practice (sample press release available)

• BICOE seal appears on ACR Accredited Facility Search

• Free participation in the Nat’l Mammography Database
BICOE Criteria

• Must be fully accredited in all breast imaging accreditation programs to receive BICOE designation
  – Mammography (*ACR or FDA-approved state accrediting body*)
  – ACR Stereotactic Breast Biopsy
  – ACR Breast Ultrasound, including Ultrasound-Guided Breast Biopsy
  – ACR Breast MRI
BICOE - New

- Effective January 1, 2016, existing BICOE facilities must be accredited in Breast MRI by the ACR or be associated with a facility with this accreditation
  - BICOE facilities were given 2 years notice
- After January 1, 2016, facilities applying for BICOE designation must be accredited in Breast MRI by the ACR or be associated with a facility with this accreditation
Single Location “Centers” – Designation is Automatic!

- No need to apply
- BICOE designation is automatically applied to facility
- BICOE Certificate will be sent to facility for display
- Sample news release available for facilities on ACR website for marketing
“Centers” with Multiple Locations also Eligible...but Call Us!

Home Location
1891 Preston White Dr, Reston, VA
Accredited in:
MAP and SBBAP

Affiliate Location
1818 Market St, Philadelphia, PA
Accredited in:
BUAP and BUAP-UGBB

Affiliate Location
505 9th St, Washington, DC
Accredited in:
MAP and BUAP
ACR Breast Imaging Centers of Excellence
3/14/16
973 Total # Breast Imaging Centers of Excellence (home facilities)
In Conclusion
Does Accreditation (and Regulation) Matter?
The ACR’s Mammography Accreditation Program: Ten Years of Experience Since MQSA

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The ACR’s Mammography Accreditation Program has been helping facilities improve the quality of mammography through peer review and professional feedback since 1987. Initially conceived as a voluntary program, accreditation became mandatory when the Mammography Quality Standards Act (MQSA) of 1992 required all U.S. mammography facilities to become accredited and certified by October 1, 1994. Currently, the ACR is the largest of four accrediting bodies approved by the U.S. Food and Drug Administration, accrediting 12,729 units at 8325 facilities by October 1, 2004. Between 1987 and 1991, 70% of the mammography units applying for accreditation with the ACR passed on their first attempts. In 2005, 88.3% of the units passed on their first attempts, indicating a marked improvement in the quality of mammography in the United States since MQSA went into effect 10 years ago.

Key Words: Breast radiography, quality assurance

Mammography Accreditation Pass Rates

Before 1994, over 30% of units failed; 31% of these did not reapply but continued to operate.

After MQSA in 1994, 30% of units failed, but regs required them to reapply and pass in order to operate.

Steady improvement in pass rates.
Thank you!

• To our accredited facilities and their staff who care about early detection and accurate diagnose

• To our many dedicated volunteer expert radiologist and medical physicist committee members and reviewers

• To Theresa Branham, Director, Breast Imaging Accreditation and her crackerjack accreditation staff
Contact Us for More Info

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