Update on MQSA and ACR Mammography Accreditation

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

MQSA - Who's Who

The Law: Mammography Quality Standards Act (MQSA)

The Regulator: US Food and Drug Administration (FDA)

The Accreditation Bodies: (ACR, TX, IA, AR)

The Inspectors: States

US Mammography Facilities and Units (October 1 each year)

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

As of 12/1/11
- 12,287 units at 8617 facilities
- 5% drop in units/13% drop in facilities since 2000

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 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”)
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...

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
Tips for Passing Accreditation

- Clinical image (fatty and dense breast)
  - Phantom image
  - Dose (<300 mRads)
- Hard copy QC
  - Film processor
  - Laser printer (see mfr QC manual)
- Criteria the same for digital as with screen-film

Clinical Image Quality Evaluation - FFDM

- Positioning
- Compression
- Exposure level
- Contrast
- Sharpness
- Noise
- Artifacts
- Exam ID
  - Must be present
  - OK under HIPAA
Reasons for Clinical Failure – still the major reason for failure with FFDM

<table>
<thead>
<tr>
<th>Imaging Category</th>
<th>Failure Rate (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Positioning</td>
<td>20</td>
</tr>
<tr>
<td>Exposure</td>
<td>15</td>
</tr>
<tr>
<td>Compression</td>
<td>14</td>
</tr>
<tr>
<td>Sharpness</td>
<td>13</td>
</tr>
<tr>
<td>Contrast</td>
<td>13</td>
</tr>
<tr>
<td>Artifacts</td>
<td>11</td>
</tr>
<tr>
<td>Labeling</td>
<td>8</td>
</tr>
<tr>
<td>Noise</td>
<td>5</td>
</tr>
</tbody>
</table>

Why Did This Digital Case Fail Accreditation?

Failure due to positioning and missing tissue

Phantom Image Quality Evaluation

- Follow ACR testing instructions
  - Expose at technique for 4.2 cm breast
- Process image as done for clinical images
- Window and level to best show test objects
- Scoring criteria
  - 4 largest fibers
  - 3 largest speck groups
  - 3 largest masses
  - Be sure to subtract for artifacts

For Digital, ACR Only Accepts Hardcopy for Accreditation

- Phantom
  - Do not zoom or rotate
  - Print as close to “true size” as possible (within ±25%)
- Clinical
  - Must be of “final interpretation quality”
  - Entire breast must fit on image; no “tiling”
  - Print as close to “true size” as possible
  - Must contain patient ID information
- Lead interpreting physician must review and approve all hardcopy images

ACR Mammography Accreditation Program Pass Rates

Facilities Not Passing Accreditation on 1st Attempt
Reasons - 2010

- Clinical
- Phantom
- Clinical Only
- Phantom (no clinical)
- Only Image
- Only Processor

88%
Where to Go for Help on Digital QC, MQSA Certification and ACR Accreditation

We Tell Facilities that Their Medical Physicist Is Their Friend

• Talk with her before the annual survey
  – Let her know if you have equipment or QC problems/questions
• Talk with her after you receive the report
  – Make sure you understand all results, recommendations and timeframes
• Talk with her during the year any time you have questions or concerns about equipment performance
  – Show clinical images illustrating the problem (physicists like pictures too)

Contact FFDM Manufacturer for QC Assistance

<table>
<thead>
<tr>
<th>FFDM Mfr</th>
<th>Website</th>
</tr>
</thead>
<tbody>
<tr>
<td>Carestream</td>
<td><a href="http://www.carestreamhealth.com">www.carestreamhealth.com</a></td>
</tr>
<tr>
<td>GE</td>
<td><a href="http://www.gehealthcare.com">www.gehealthcare.com</a></td>
</tr>
<tr>
<td>Fuji</td>
<td><a href="http://www.fujimed.com">www.fujimed.com</a></td>
</tr>
<tr>
<td>Lorad</td>
<td><a href="http://www.hologic.com">www.hologic.com</a></td>
</tr>
<tr>
<td>Philips (Sectra)</td>
<td><a href="http://www.healthcare.philips.com">http://www.healthcare.philips.com</a></td>
</tr>
<tr>
<td>Planned</td>
<td><a href="http://www.planned.com">www.planned.com</a></td>
</tr>
<tr>
<td>Siemens</td>
<td><a href="http://www.medical.siemens.com">www.medical.siemens.com</a></td>
</tr>
</tbody>
</table>

Validation Film Checks and On-Site Surveys – Required by FDA

• Random film checks - 3% of facilities accredited each year
  – Clinical case from an ACR-designated day
  – Phantom image
  – Dosimeter
• Random on-site surveys – for ACR, at least 50 each year
  – Visit by ACR radiologist reviewer, medical physicist reviewer and ACR staff (mammo tech)

ACR's Accreditation Portal
www.acr.org

Currently working on online application and image submission process
FDA Definitions

- Consumer - person complaining about a 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

Also Watch

- DXIMGMEDPHYS@HERMES.GWU.EDU
- AAPM Newsletter
ACR’s Serious Consumer Complaint Policy – Accredited Facilities

- Report unresolved serious complaints to the ACR as soon as possible

ACR’s Serious Consumer Complaint Policy – Consumers

- May report serious complaints to ACR if not been adequately addressed by facility
- May not be anonymous
- Must be in writing (either via mail or email) and include:
  - Consumer’s name, address, telephone number and signature
  - Name and location of the ACR-accredited facility where the mammogram was performed
  - Description of complaint
  - Copies of any supporting documentation

ACR Consumer Complaint History

- Over 10 years experience (1997 – 2009)
- Hundreds of consumer complaints received… examples:
  - Excessive compression
  - Excessive wait times
  - Excessive fees
  - Cannot obtain old films
  - Front desk staff/technologist/manager was rude
- Non-serious complaints
  - Refer back to facility
  - ACR assists with film transfer issues
- 147 of a serious nature

ACR Mammography Accreditation Program

Serious Consumer Complaints

Types of Serious Consumer Complaints Investigated by ACR: 1997 - 20010

- No Lay Summary and/or Physician Report w/in 30 Days - Example
  - Complaint
    - Many patients complained exams had not been interpreted in over a month
    - Facility refused to address complaints
    - Facility closed
No Lay Summary and/or Physician Report w/in 30 Days - Example

- ACR investigation
  - Many unsuccessful attempts to contact facility by phone or mail
  - Unopened investigation letters were returned
  - ACR referred complaint to FDA

- Resolution
  - FDA and state took legal action against the owner of the facility
  - Facility finally made films available to patients
  - ACR revoked the facility’s accreditation

Injury & Unqualified Personnel – Example

- Complaint
  - Severe pain and bi-lateral lacerations of both breasts
  - Technologist not qualified
  - Patient told tech, “you are hurting me” and tech said, “I know”
  - Not satisfied with facility’s response to her complaint (nothing done about tech’s actions)
  - Physician advised her to use Neosporin and pain relievers

- ACR investigation
  - Facility’s actions to resolve patient’s complaint
  - Policies for consumer complaints, positioning and compression
  - QC records for compression tests
  - Qualifications for technologist

- Response and resolution by facility
  - Tech documented patient did not mention pain during exam
  - Documentation of all correspondence with patient
  - Provided QC and personnel documentation
  - Updated and provided all requested policies
  - New policy to document patient’s skin condition prior to exam

Missed Cancer & Poor Image Quality - Example

- ACR investigation
  - Facility’s actions to resolve patient’s complaint
  - Policies for consumer complaints, medical audit and reporting findings to patients and physicians
  - Evidence that facility reviewed patient’s mammogram after learning of the missed cancer
  - Radiologist’s qualifications
  - Participate in Additional Mammography Review (AMR)

- Response and resolution by facility
  - Documentation of correspondence with patient
  - Updated and provided all requested policies
  - Could not review mammogram since patient checked it out
  - Provided personnel documentation
  - Failed AMR (corrective action subsequently taken)
Other – Example

- Complaint
  - Businessman intermittently received mammography reports intended for local referring physicians through home fax machine
  - Complained to facility numerous times
  - No results

Other – Example

- ACR investigation
  - Facility’s actions to resolve complaint
  - Policies for consumer complaints and reporting findings to physicians
- Response and resolution by facility
  - Documentation of correspondence with complainant
  - Updated and provided all requested policies
  - Error due to human error (reports manually faxed)
  - Made staff aware of problem
  - Implemented new RIS with automatic faxing

Recurring Themes

- Physician did not receive report within 30 days or at all
- Patient did not receive lay letter within 30 days or at all
- Pain and injuries from compression
- Facility closed with no provision to provide old films to patients
  - “The doctor would not talk with me”
  - “I don’t want anyone else to go through what I did”

Lessons to Learn

- Don’t ignore complaints from patients...your customers
- Talk with your patients...listen to your patients
- Analyze complaints to find opportunities for quality improvement
- Use your risk management resources
- You can address many complaints to the patient’s satisfaction
- You will not be able to satisfy everyone

We Also Get Compliments

Why Medical Physicists Should Join the ACR

- Raise awareness of the important contributions medical physicists make to the radiology profession
  - Nationally
  - In your home town
- Be part of the significant influence ACR has in state and local government
- Serve on critical ACR committees and subcommittees that eventually affect your practice