

The New MQSA Rules & New ACR Recommendations

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Priscilla F. Butler
Director, Breast Imaging Accreditation Program

Objectives

- Mammo accreditation under MQSA
- ACR Mammo Accreditation Program - the process
- FDA's Final Rules - the high points
- 1999 ACR Mammo QC Manual - what's new and what's not

Mammography Accreditation Under MQSA

Mammography Quality Standards Act (MQSA)

- Establish standards for mammography facilities
 - Equipment, personnel and practices, including QA
- Establish standards for accrediting bodies
 - Accreditation body quality standards for facilities must be equivalent to MQSA final rules
 - Essentially same criteria as original voluntary program with some differences

Facility Requirements Under MQSA

- Legislation called for all mammography (screening and diagnostic) facilities to be
 - Accredited
 - Certified
 - Inspected
- System of checks and balances
 - Some duplication of activities

- Mostly complementary

Accrediting Bodies Responsibilities

- Facility standards review
- Clinical image review
- Physics survey review
- On-site visits
- Mechanism to deal with complaints
- Reporting and record keeping
- Maintain reasonable fees

ACR Mammo Accreditation Program - The Process

Similar Process for all Programs

1) Entry Application

- Basic info on facility, examinations, equipment, personnel
- Survey agreement (conditions to participate)
- Physician's release (allows ACR to serve as AB for facility)
- Fee (\$900 for 1st unit; \$800 for others)

Similar Process for all Programs

2) Full Application

- Detailed info on facility, practice, examinations, policies and procedures, equipment, personnel
- Quality control data
 - Image procedure quality test materials
 - Clinical
 - Phantom (most programs)
 - Dose (x-ray programs)

Similar Process for all Programs

3) Final Report

- Testing results

- Recommendations for improvement
- Pass
 - 3-year accreditation certificate
- Deficiency or failure
 - Reapply
 - Appeal

The ACR MAP Process: Accreditation/ Reaccreditation

Accreditation Required for Certification, Deadlines Are Essential

- Initial testing materials 45 days
- Reapplication materials 20 days
- Letter of appeal 30 days
 - Re-submit films originally evaluated
 - No new films are acceptable

Reaccreditation

- ACR sends notice 8 months in advance
- Facility should apply 6 months before expiration
- All units at the same time

The ACR MAP Process: Reapplication/Appeal after 1st Deficiency

The ACR MAP Process: Reinstatement after Failure (2nd Deficiency)

Annual Updates

- Personnel changes
- Equipment changes

- Quality control logs
- Physicist report

Equipment Change

- Notify ACR at time of Annual Update about:
 - New processor
 - Change in processing techniques
 - Screen-film combination

Equipment Change

- New unit at accredited site > 12 months left on certificate
 - Physicist report
 - Clinical images
 - 6 months to achieve accreditation
- New unit at accredited < 12 months left on certificate
 - Initiate reaccreditation

validation

- Random film checks
- Random on-site surveys

Random Film Checks

- ACR specifies data for facility to provide
 - 1 set of mammograms
 - Phantom image
 - Dose measurement by TLD
 - Processor data

On-Site Surveys

- Goals
 - Education
 - Validation
- Types
 - Random
 - Scheduled

- The team
 - Radiologist
 - Medical physicist
 - ACR staff person

On-Site Survey: Radiologist's Role

- Team leader
- Evaluates clinical image quality
- Consults with radiologist regarding clinical interpretation
- Evaluates follow-up logs

On-Site Survey: Medical Physicist's Role

- Equipment verification
- Reviews annual physicist report
- Reviews & scores phantom images
- Images phantom and dosimeter
- Reviews & evaluates all QC logs

On-Site Survey: ACR Staff Member's Role

- Verifies application data
- Reviews federal, state & local licensure or certification
- Schedules on-site visit
 - ACR staff member has ARRT(M)
 - Reviews positioning with technologists

Personnel Requirements under the MQSA Final Rules

Interpreting Physician

**Medical Physicist
Radiologic Technologist**

- Initial qualifications
- Continuing education
- Continuing experience
- Reestablishing qualifications

Physician - Initial Qualifications

- Licensed
- Board certified, OR
 - At least 3 mo training in interpretation, radiation physics effects, and protection
- 60 hrs Cat I CME in mammo
 - 15 hrs w/in 3 years prior to meeting initial requirements
- Read 240 exams under supervision w/in 6 mo prior to meeting initial requirements
- 8 hrs training in new modality before use

Physician - Initial Qualifications

Exemption

- If qualified under Interim Rules
 - Considered to have met initial qualifications
 - Must meet continuing education and education requirements

Newly Graduated Residents Exception

- 240 mammograms in 6 months during last 2 years of residency
- Must pass the board at first allowable time

Physician - Continuing Education and Experience

- 15 hrs of Category I every 3 years
 - 6 hrs in each modality
- 960 mammograms over 24 months

Medical Physicist - Initial Qualifications

- Certified by ABR or ABMP in an appropriate specialty OR licensed or approved by a state
- Master's degree or higher in a physical science
- 20 semester hours of physics
- 20 contact hours of training in conducting surveys of mammo facilities
- Surveys of at least 10 units/1 facility (under supervision if after 4/28/99)
- 8 hrs training in new modality before surveying

Medical Physicist- Alternative Initial Qualification

- By April 28, 1999 qualified under Interim Rules
- Bachelor's degree or higher in a physical science
- 10 semester hours of physics
- 40 contact hours of training in conducting surveys of mammo facilities
- Surveys of at least 20 units/1 facility
- 8 hrs training in new modality before surveying

Radiological Technologist - Initial Qualifications

- Certified by ARRT or ARCI OR state licensed in general radiography
- 40 hrs training in breast anatomy & physiology, positioning & compression, QA/QC techniques, imaging of patients with breast implants
- 25 mammo examinations under direct supervision
- 8 hrs training in new modality before use

Rad Tech - Initial Qualifications Exemption

- If qualified under Interim Rules
 - Considered to have met initial qualifications
 - Must meet continuing experience and education requirements

Equipment Requirements: Motion of Tube-Image Receptor Assembly

- The assembly shall be capable of being fixed in any position where it is designed to operate. Once fixed in any such position, it shall not undergo unintended motion
- This mechanism shall not fail in the event of power interruption

Equipment Requirements: Image Receptor Sizes

- Systems using screen-film image receptors shall provide, at a minimum, for operation with image receptors of 18x24 cm and 24x30 cm
- Systems using screen-film image receptors shall be equipped with moving grids matched to all image receptors provided

Equipment Requirements: Application of Compression

- Each system shall provide for initial power-driven compression activated by hands-free controls operable from both sides of the patient (10/28/02)
- Each system shall provide fine adjustment compression controls operable from both sides of the patient (10/28/02)

Equipment Requirements: Compression Paddle

- Systems shall be equipped with different sized compression paddles that match the sizes of all full-field image receptors provided for the system
- The compression paddle shall be flat and parallel to the breast support table, etc
- The chest wall edge of the compression paddle shall be straight and parallel to the edge of the image receptor

Equipment Requirements: Technique Factor Selection and Display

- Following AEC mode use, the system shall indicate the actual kVp and mAs (or mA and time) used during the exposure

Equipment Requirements: Automatic Exposure Control

- The positioning or selection of the detector shall permit flexibility in the placement of the detector under the target tissue. The size and the available positions of the detector shall be clearly indicated at the x-ray input surface of the breast compression paddle. The selected position of the detector shall be clearly indicated

Equipment Requirements: Film Masking Devices

- Facilities shall ensure that film masking devices that can limit the illuminated area to a region equal to or smaller than the exposed portion of the film are available to all interpreting physicians interpreting for the facility

Quality Assurance - Responsibilities Under MQSA

- Lead interpreting physician
 - Ensures all QA requirements are met
- Interpreting physicians
 - Follows corrective action procedures when asked to interpret poor quality images
 - Participates in medical outcomes audit
- Medical physicist
 - Annual survey of mammo equipment
 - Oversees equipment-related QA practices

Quality Assurance - Responsibilities Under

MQSA (cont.)

- QC technologist
 - QC tech must be identified by the facility
 - Responsible for all QA activities not assigned to lead interpreting physician or medical physicist
 - Other qualified personnel may conduct QC tasks but the QC tech must ensure they are done as required

Quality Control - Final Rules What's New

- Phantom images required weekly
- Radiation output rate measured by medical physicist
- Infection control procedures
- Equipment evaluations before use of new equipment (and before some repair)
- Some new test conditions and performance criteria
- New corrective action requirements

Immediate Corrective Action

- Processor QC
- Phantom image quality
- Darkroom fog
- Screen-film contact
- Compression
- Average glandular dose

Corrective Action Within 30 Days

- Repeat analysis
- Fixer retention
- Most physicist tests (unit assembly evaluation, collimation assessment, system resolution, AEC system performance, uniformity of screen speed, artifact evaluation, kVp accuracy and reproducibility, HVL, breast exposure and AEC reproducibility, radiation output rate)

Medical Physicist's Annual Survey Report Must

- Include summary and recommendations for corrective action
- Be sent to facility within 30 days of survey date
 - Physicist should let facility know ASAP if problems were found
- Be dated and signed by qualified medical physicist performing or supervising survey
- Include names of individuals under direct supervision

Equipment Evaluation

- Required when
 - New unit or processor installed
 - Unit or processor is disassembled and reassembled at same or new location
 - Major component of unit or processor is changed or repaired (e.g., x-ray tube, collimator, filter or AEC replaced)
- Correct before using for mammography
- Performed by medical physicist or under direct supervision of medical physicist

1999 ACR Mammography Quality Control Manual

What's New and What's Not

1999 ACR Quality Control Manual

- Published in March 99
- Radiologist's Section
- Clinical Image Quality
- Radiological Technologist's Section
- Medical Physicist's Section
- Glossary

Throughout the Manual

- New MQSA requirements outlined
- QC procedures revised to be consistent with these requirements
- ACR recommendations are clearly delineated from the MQSA

requirements

- Only MQSA requirements must be met for accreditation

Radiologist's Section

- Introduction
- Radiologist's Responsibilities
- Medical Physicist's Responsibilities
- Radiological Technologist's Responsibilities
- Specimen Radiography
- Conclusion
- References

Clinical Image Quality

- Patient Positioning and Compression
 - revised labeling
 - most else the same
- Clinical Image Evaluation
 - new
- References

Clinical Image Evaluation

- Technical assessment of clinical images by radiologist
- Feedback to technologists
- Criteria for evaluating quality
- Good and poor clinical images

Radiological Technologist's Section

- Introduction
- Important Points
- Mammography Quality Control Tests
 - Monitoring Developer Temperature & Replenishment Rate in Processors
- Mobile Mammography
 - new
- Infection Control
 - new
- References

“Whadaya mean my phantom's gotta pass before I do patients?”

- New table describing MQSA's minimum frequencies and times for

corrective action

“I’ve gotta have a physicist do *what* before I use the unit again?”

- Guidance for MQSA-required equipment evaluation

Radiological Technologist’s Section - Important Points

- More emphasis on appropriate optical densities, adequately short exposure times and proper viewing conditions
- Monthly, etc, checklist revised to allow for data and comments

“My processor QC mid-density step has gotta be *what*?”

- MD step should be the one with OD closest to but not less than 1.2
- Processor QC chart allows room for more remarks
- Guidance on when to re-establish processor QC operating levels
- Revised Crossover Procedure

“Whadaya mean I gotta do the phantom weekly?”

- MQSA requires phantom test to be weekly instead of monthly
- Recommends phantom background OD to be >1.40
- Revised to allow emulsion lot #'s to be tracked & now room for more remarks

Phantom Images

- Test & evaluation procedures revised so that 3 density measurements are made instead of 2
- Same in Medical Physicist’s Section

Phantom Images

- Phantom diagrams illustrate phantom scoring criteria
- Same in Medical Physicist’s Section

Radiological Technologist’s Section - Mobile

Mammography

- New section
- On-board processing
 - evaluate phantom images & take corrective action after each relocation & before patients examined
- Processing not immediately accessible
 - Phantom film sent to central site for processing before patients examined, or
 - Radiation output or post-exposure mAs compared to acceptable operating level

Radiological Technologist's Section Infection Control

- New section
- General procedure
 - Straighten mammo rooms between patients
 - Wipe patient contact surfaces with facility-approved disinfectant after each exam
 - Wash hands between patients
 - Linens for single patient use only
 - Wash drips on floor with facility approved disinfectant
- Isolation patients

Medical Physicist's Section

- Introduction
- Mammography Quality Control Tests
 - Assessing the Mammo Site's QC Program
- Summary Report Forms
- Data Recording and Analysis Forms
- MQSA Requirements for Mammo Equipment
 - new
- Slit Camera Evaluation of Focal Spot Performance
 - no longer routine QC
- References

Medical Physicist's Section - Mammography QC Tests

- Mammo unit assembly checklist modified
 - autodecompression override
 - manual emergency compression release
- Collimation assessment
 - x-ray field should not fall within the IR by > 2% on either left or right side, or
 - by > 4% on anterior side

Medical Physicist's Section - Mammography QC Tests

- AEC system performance
 - streamlined to test clinically used techniques
- Uniformity of screen speed
 - evaluate cassette/screen artifacts at same time
- Image quality evaluation
 - consistent with Rad Tech Section
- kVp accuracy & reproducibility
 - measurements @ highest available & lowest clinically-used kVp (that can be measured by meter)

“Whadaya mean I gotta measure radiation output rate? And what the #!%\$! is “air kerma”?”

- New MQSA-required measurement
 - air kerma (mGy/s) = exposure rate (mR/s) x a CF
- Included in Breast Entrance Exposure test
- 800 mR/s (ACR; MQSA in 2002)
- 13 mR/s (MQSA in 1999)

“But the viewboxes look bright!”

- Test moved from appendix to list of ACR recommended tests
 - not required by MQSA
- Viewbox luminance greater than 3000 cd/m² (nit)
- Room illuminance less than 50 lux

“Ya mean I should measure more than one

HVL?"

- Recommended to measure HVL's for range of kVp-target-filter settings used clinically (in addition to most common)
- New "C" value to determine W/Rh upper limit

Data Recording and Analysis Forms

- Updated
- Includes both ACR recommended performance criteria & MQSA required limits
- Both the physicist and tech QC forms available on the ACR website (www.acr.org)

MQSA Requirements for Mammography Equipment

- New section
- Checklist format
- Recommended that medical physicist help facility determine if equipment is compliant with new rules

"Is it OK if I send them the medical physicist's report when I get back from Nepal?"

- 30 days to send report (MQSA)
- Physicist's QC Test Summary
 - ACR recommendations P/F
 - MQSA regulation P/F
 - Corrective action time-frames
- Preliminary Results form to leave on site
- Physicist Trainee or Assistant log

More Info from FDA on the MQSA Final Rules

- Quality Mammography Standards; Final Rules (October 28, 1997)
- FDA Facility Hotline: (800) 838-7715
- *Mammography Matters* (FDA newsletter)
- www.fda.gov/cdrh/dmqrp.html

- Guidance documents
- How to prepare for MQSA inspections

ACR Help for Accredited Facilities in Meeting MQSA Final Rules

- ACR Bulletin articles (12/97, 1/98, 8/98, 10/98, 4/99)
- ACR letter to facilities about direct reporting to patients
- ACR letter to members about meeting MQSA Final Rules
- 1999 ACR Mammography QC Manual
- Help line: (800) 227-6440
- Or check out our website at www.acr.org

The End

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PLEASE SEE ACR WEBSITE
FOR CURRENT FORMS**