QUALITY ASSURANCE AND EVALUATION

Dawn Derenburger, R.T.(R)(M)(ARRT), CRT
Consultant – Mammography Educators
www.mammographyeducators.com

Special thanks to Fabiola Perez, RTRM for her contributions to this presentation.

Objectives

- Become familiar with the regulatory agencies and laws that govern the field of mammography.
- Define Quality Control and Quality Assurance.
- Review mandated requirements set forth by mammography regulatory agencies.

Regulating Mammography

As mammography became the standard of care, it was necessary to eliminate the great variations in mammography quality across the country and from one facility to the next.

Regulating Mammography

Congress set out to establish national quality standards for mammography.

Regulating Mammography

- Congress enacted the Mammography Quality Standards Act into Law on October 27,1992.
- Congress delegated the FDA to develop and implement MQSA regulations.
- Enforcement began on October 1, 1994.
- Annual inspections of facilities began in January,1995.

Regulatory Agencies

- FDA (Food and Drug Administration)
  - Mammography Quality Standards Act (MQSA)
- American College of Radiology (ACR)
  - Entity approved by the FDA to oversee, accredit and evaluate facilities set forth by the Mammography Quality Standards Act (MQSA)

MQSA Policy Guidance

- Interprets the regulations and helps facilities comply with final regulations.
- Electronic searchable help system became available in November, 1998.

PGHS
Policy Guidance Help System

MAMMOGRAPHY EDUCATORS

MQSA – Final Regulations

- Final regulations became effective April 28, 1999
- Written by FDA
- National Quality Standards for mammography services
- Force of the Law

MAMMOGRAPHY EDUCATORS

MQSA

- Meet quality standards for equipment, personnel, radiation dose, quality assurance, medical audit and outcomes, record keeping and reporting.
- Be accredited by an FDA-approved accrediting body (Dept. of Veterans Affairs is exempt).

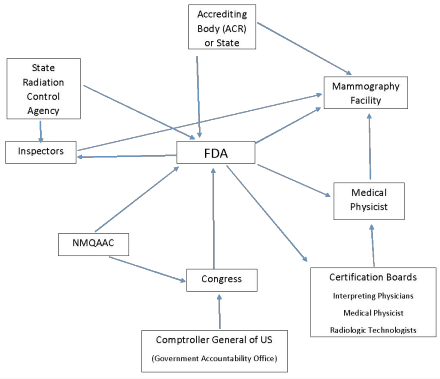
MAMMOGRAPHY EDUCATORS

MQSA

- Be certified to perform mammography by the FDA. Certificate to be displayed where it is visible by mammography patients.
- Maintain facility certification by:
  - Maintaining accreditation
  - Annual physicist survey
  - Annual inspection by MQSA inspector
  - Paying applicable fees
  - Correcting any and all deficiencies

MAMMOGRAPHY EDUCATORS

Accreditation Structure



MAMMOGRAPHY EDUCATORS

Accrediting Body (AB)

- Currently 4 AB's
  - ACR
  - State of Arkansas
  - State of Iowa
  - State of California
  - State of Texas
- FDA approves AB's for 7-year period, then renewal is required

MAMMOGRAPHY EDUCATORS

MQSA - Facility Requirements

- Certificate display
- Equipment tests
- Records inspection
- Quality assurance and quality control records and program
- Medical physicist survey report

MQSA - Facility Requirements

- Mammography Equipment Evaluation
- Personnel qualifications
- Medical records
- Mammography medical audit and outcomes analysis

Certificate Display


U.S. DEPARTMENT OF HEALTH & HUMAN SERVICES
Public Health Service
Food and Drug Administration
CERTIFIED MAMMOGRAPHY FACILITY
FDA

MQSA – Education and Training Requirements

- Interpret/Inspect/Image a minimum number of mammograms and units per year
- Obtain minimum number of continuing education credits within a specific period

MQSA – Education and Training Requirements

- Must meet the MQSA licensing requirements
- Mammography Technologists
- Medical Physicist
- Interpreting Physicians

Mammography Technologists – Initial Qualifications

- Be State licensed to perform radiographic procedures.

OR

- Board Certified
  - American Registry of Radiologic Technologists (ARRT)
  - American Registry of Clinical Radiography Technologists (ARCRT)

Mammography Technologists – Initial Training

- 40 contact hours of mammography training
- Performance of 25 supervised mammography examinations
- 8 hours training in new mammography modality (eg. Digital, DBT, Stereotactic Biospy)

Mammography Technologist-Continuing Experience/Education

- Performed 200 mammography examinations in a 24-month period.
- Have taught or completed 15 continuing education units (CEU's) in a 36-month period.
- At least 6 CEU's in each modality used by the technologist.

Medical Physicist – Initial Qualifications

- Be licensed or approved by a State to perform mammography surveys.

OR

- Board Certified
  - American Board of Radiology (ABR)
  - American Board of Medical Physics (ABMP)

Medical Physicist – Education, Training, Experience

- Masters Degree or higher
- 20 graduate or undergrad hours of physics
- 20 contact hours of mammography facility survey training
- Conducted surveys for at least 1 facility and minimum of 10 mammography units.
- 8 hours in each new mammographic modality to be used

Medical Physicist – Continuing Education/Experience

- 2 facility surveys and 6 mammography unit surveys in 24-month period
- Taught or completed 15 continuing education in medical physics or mammography in 36-month period

Interpreting Physicians – Initial Training

- Be State licensed to practice medicine
- The American Board of Radiology (ABR)
- The American Osteopathic Board of Radiology (AOBR)
- The Royal College of Physicians and Surgeons of Canada (RCPSC)

Interpreting Physicians

OR….

- 3 months documented formal training in interpreting mammograms and topics related to the modality

Interpreting Physicians – Initial Education

- Documented minimum 60 hrs Category I medical education in mammography
- 15 of those must be acquired within 3 yrs prior to initial qualification

Interpreting Physician – Initial Experience

- Have interpreted or multi-read 240 mammographic examinations under direct supervision (within 6 month period prior to qualification date)
- Acquire 8 hours training in any new mammographic modality (i.e. DBT, Stereotactic Biopsy, etc.)

Interpreting Physician – Continuing Experience/Education

- Interpret or multi-read 960 mammogram examinations in 24-month period.
- Have taught or completed 15 Category I continuing medical education (CME) credits at minimum in 36-month period.

Image ID and Proper Labeling

- Image should be labeled and include patient identification.
- Displayed in a permanent, legible, and unambiguous manner, not to obscure anatomic structure.

Image ID and Proper Labeling

- Name of patient and additional identifier
- Date of examination
- View and laterality (near axilla)
- Facility name, location (min. of City, State, zip code)
- Technologist identification
- Unit Identification

Maintenance of Images and Reports

- Maintain mammography images in a permanent record for a period of not less than 5 years or no less than 10 years if no prior images have been performed at the facility (or per State law).
- Transfer mammogram images and reports to medical institution, physician, or patient, at the request of the patient.

Quality Control

- "A process in which entities review the quality of all factors involved in production."

Source: Wikipedia

Quality Assurance

"Way of preventing mistakes and defects in products and avoiding problems when delivering products or services."

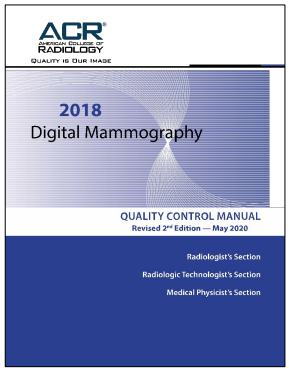
"Quality Control and Quality Assurance are often used interchangeably to refer to ways of ensuring the quality of a service or product."

Source: Wikipedia

Quality Control Program

- Helps maintain consistent, high quality mammographic images with the lowest radiation exposure to patients.
- Detects and fixes potential problems before quality is compromised.

Quality Control Manual



QC: Why?

- Assurance that all the physics involved are working properly.
- Determines standard operating levels for unit.
- **To maintain ACR accreditation!!**

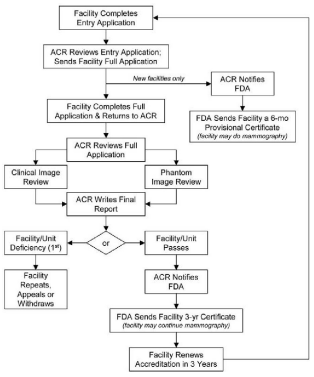
Role of QC Program in Facility Accreditation

- Part of the annual MQSA and State Inspection process.
- Inspector will review QC program and ensure compliance and documentation of all required testing.

Role of QC Program in Facility Accreditation

- Review has been completed by Physicist and Lead Interpreting Physician at the appropriate time intervals.
- Without an approved QC program, the accreditation/renewal will not be granted.

Facility Accreditation – ACR



(Judy M. Destouet, MD et. al, 2005)

Facility Accreditation – ACR

- All new facilities must register equipment with State
- Application process for ACR
- New units/replaced units
- Moved unit/new ownership

Facility Accreditation – ACR

- Units w/ Digital Breast Tomosynthesis (DBT) are considered 2 units, application needs to be submitted for both 2D and 3D.
- Units w/upright attachment for Stereotactic Biopsy also need separate application for that modality.

Facility Accreditation

ACR – Requires QC forms be included as part of the testing material packet at the time of initial application or renewal submission

- Technologist - daily, weekly, monthly, quarterly, semi-annual, annual checklist
- Annual Physicist survey report
- Physicist QC test checklist

Quality Assurance (QA) Team

- Lead Interpreting Physician
- Medical Physicist
- The QC Technologist/s
- Manager

Quality Assurance Team

- Supervisory Mammography Technologist
- Additional interpreting physicians
- Other support personnel like a nurse, medical secretary or desk attendant
- May also include surgeons, referring physician, RN navigator or anyone who provides breast care to patients

Quality Assurance Team

- Oversight of QA program
- Setting goals and direction
- Determining policies
- Accessing effectiveness of QA activities

Facility QC Review

- Lead mammography technologist, radiologist and facility manager are to review the QC test results at least quarterly or more frequently if problems are noted.

QC Technologist

- Perform QC daily, weekly, monthly, quarterly, semi-annual and annual tests
- Maintain QC book with all documented records of QC testing
- Run QA reports for all IP's
- Report substantial changes in images or imaging system

QA/QC Policy Manual

- Clearly assigned responsibilities and developed polices for QA/QC testing
- Records of the QC tests performed by the QC technologist and medical physicist
- Records of any corrective action as a result of the QA/QC testing

QA/QC
Policy Manual

- Document of defined roles and responsible staff
- Policies for proper use and maintenance of equipment

QA/QC
Policy Manual

- Records of routine and non-routine equipment service and maintenance
- Records of QAC meetings
- A description of the orientation program for operators of mammography equipment, including its duration and content

QA/QC
Policy Manual

- Mammographic techniques to be used including pertinent information on positioning, compression, appropriate image receptors, imaging modes, and kVp-target-filter combinations if applicable
- Technique charts

QA/QC
Policy Manual

- Radiation Safety Policy
- Assigned Radiation Safety officer
- Policies and employee responsibilities concerning personnel radiation monitoring
  - Dosimeter badges
  - Access to reports

MQSA Required Policies

- Imaging Patients with Implants
- Infection Control
- Medical Outcomes/Audit
- Consumer Complaint
- Medical Records
- Patient/Provider Notification of Results

MQSA Required Policies

- Patient Notification of Privacy Practices
- Quality Assurance Records
- Self-Requesting Patients/Self-Referred
- Quality Control/Quality Assurance

Imaging Patients with Implants

- Mammography procedure and technique for imaging patients with breast implants.
- Procedure to inquire whether the patient has implants prior to the actual exam.

Infection Control

- System/procedure for cleaning and disinfecting equipment.
- Blood borne pathogen/contact with blood or other infectious materials.
  - Spill Log
- Manufacturer recommended cleaning/disinfecting
- Vendor approved cleaners
- Material Safety Data Sheets (MSDS)

Medical Outcomes Audit

- Establish and maintain a tracking system for follow-up on positive mammographic findings, with biopsy/pathology results.
- Follow-up on abnormal results to ensure add'l imaging was completed.
- Manual or electronic
- Completed yearly and reviewed by Audit Interpreting Physician.

Consumer Complaint

- Written, documented system for collecting and resolving patient complaints.
- Maintain records of serious complaints for 3 yrs.
- Provide consumer adequate direction for contacting facility
- Posted instructions on how to file unresolved complaints to the AB.

Your Facility Here
Breast Imaging Division

Policy: Mammography Consumer Complaint **Location:** Your facility here
Effective Date:
Revise Date:_____ **Review Date:**_____
Approved By:_____
Personnel Responsible: Mammography Staff

Purpose: To provide guidelines and specific instruction to respond to both identifiable and anonymous consumer complaints.

Policy: In accordance with the Mammography Quality Standards Act Final Regulations, section 21 CFR 900.12(h) Consumer Complaint Mechanism, _____ shall:

- Receive consumer complaints via Mammography Staff.
- Complaints will be documented and will receive immediate attention.
- Attempt to resolve any complaint immediately to the patient's satisfaction.
- If the manager and/or lead tech cannot satisfy the complaint, the next line of supervision should be notified as soon as possible to resolve the issue. .
- After the complaint is resolved, the manager will document the steps taken to resolve the complaint in accordance with Fuji Medical policy.
- Maintain a record of each serious complaint received for at least 3 years from the date the complaint was received.
- Post a notice within the clinic providing the consumer with direction for filing any unresolved serious complaint with the ACR.
- Report any unresolved complaints to the ACR within 30 days.

Consumers may directly contact the ACR to report a serious complaint if they feel that their concerns have not been adequately addressed by the facility. All serious complaints must be submitted to the ACR in writing and include the:

- Consumer's name, address, and telephone number
- Consumer's signature (if reported by the consumer)
- Name and location of the ACR – accredited facility where the mammogram was performed
- Description of the complaint

Copies of any supporting documentation that would be helpful in addressing the complaint

- The ACR will:
- Acknowledge the receipt of the complaint by letter to the patient (or facility)
- Obtain a signed Serious Consumer Complaint Inquiry Release Authorization from the patient
- Request a response from the facility in writing
- Provide a summary of its resolution to the patient
- Forward unresolved complaints to the FDA as appropriate
-
- Consumer complaints may be faxed, e-mailed, or mailed to:
- Director, Breast Imaging Accreditation Programs
- American College of Radiology
- 1891 Preston White Drive
- Reston, VA 20191-4397
- Fax: (703) 648-9176
- Mamm-accred@acr.org
-
- **Definitions:** The following definitions are provided for reference:
- Consumer: a person who is receiving mammography services.
- Serious Complaint: a report of a serious adverse event, which means an event that significantly compromises clinical outcomes or one for which the facility fails to take appropriate corrective action in a timely manner.
- Serious Adverse Events:
  - The use of personnel that do not meet FDA qualifications
  - Missed cancer
  - Poor image quality
  - Failure to send mammography reports or lay summaries within 30 days

Reporting of Mammography Results

- All mammogram exams should have results reported using the appropriate BI-RADS assessment category and associated verbiage (Breast Imaging, Reporting, and Data System)

BIRAD Categories

- BIRAD 0: Incomplete, need additional imaging evaluation
- BIRAD 1: Negative
- BIRAD 2: Benign Findings
- BIRAD 3: Probably Benign
- BIRAD 4: Suspicious Abnormality
- BIRAD 5: Highly Suspicious of Malignancy
- BIRAD 6: Known biopsy with proven Malignancy

Medical Records

- Communicate results to patient and provider within 30 days of examination.
- Communicate findings that are "suspicious" or "highly suspicious" to provider as soon as possible.
- Established communication system in place that meets all requirements.

Medical Records

- Reports to Providers
- Lay Summary to Patients
- Breast Density Notification (Depending on State Law)

Personnel Records

- Maintain records documenting initial training/education, all qualifications.
- Employees no longer at facility maintain until the next annual inspection.

Record Keeping

- All QA/QC Records
- Written QC Records retained until the next MQSA Inspection or until the QC test has been performed two additional times.
  - Eg. Repeat Analysis (Quarterly)

Tests Performed by QC Technologist

- Phantom Image
  - Quality
  - Artifact
- Compression Thickness
- Visual Checklist
- Viewing Conditions

Tests Performed by QC Technologist

- Workstation Monitors (AWS and RWS)
  - Cleanliness
  - Calibration and test patterns (SMPTE,TG18)
- Repeat Analysis
- Compression Force
- Manufacturer Detector Calibration

Lead Interpreting Physician

- Ensuring optimal diagnostic quality mammograms by following EQUIP standards.
- Working with Lead Technologist, to provide feedback regarding image quality on a regular basis.

Lead Interpreting Physician

- Ensuring that feedback regarding quality of images is reviewed with technologists and documented annually at a minimum.

Lead Interpreting Physician

- Ultimately responsible for operating under MQSA regulations at all times
- Quarterly facility QC review
- Chair of the QA committee
- Yearly medical audit

Medical Physicist

- Review of QC program
  - Technologist test
  - Reports
  - QC book
  - Radiation assessments

Medical Physicist

- **ANNUAL** inspections on each unit and reading stations and whenever a major component is replaced (i.e. tube, detector)
- Advisor to the QC Technologist
- Member of the QA Team

Annual Physicist Testing

- Mammographic equipment evaluation
- Collimation assessment
- System resolution
  - Spatial
  - Modulation Transfer Function (MTF)
- Automatic Exposure Control (AEC) system performance

Annual Physicist Testing

- Artifact Evaluation
- Image Quality
- kVp accuracy
- Beam quality assessment
- Breast exposure and AEC reproducibility

Annual Physicist Testing

- Average glandular dose
- Radiation output rate
- Compression paddle alignment
- Viewbox luminance & Rm luminance (FILM)

Annual Physicist Testing

- System spatial resolution (CNR,SNR,MTF) (DIGITAL)
- Printer check (DIGITAL)
- Acquisition and Radiologist Review Workstation QC (DIGITAL)

References

- Berns, Eric PhD, FACR et al. *ACR 2018 Digital Mammography Quality Control Manual.* Revised 2nd edition – May 2020. American College of Radiology.
- Destouet, J., Bassett, L., Yaffe, M., Butler, P. and Wilcox, P., 2005. *The ACR'S Mammography Accreditation Program: Ten Years Of Experience Since MQSA.* Journal of American College of Radiology.

References

- U.S. Food and Drug Administration. 2020. *MQSA National Statistics.* [online] Available at: <https://www.fda.gov/radiation-emitting-products/mqsa-insights/mqsa-national-statistics> [Accessed 13 August 2020].
- U.S. Food and Drug Administration. 2020. *Policy Guidance Help System - PGHS Main.* [online] Available at: <https://www.accessdata.fda.gov/cdrh_docs/presentations/pghs/PGHS_Main.htm> [Accessed 13 August 2020].

MAMMOGRAPHY EDUCATORS

Thank you!

For questions or more information, contact us at:

www.mammographyeducators.com

619-663-8269

info@mammographyeducators.com

Services we offer include:

- Onsite Positioning Training
- Assistance with Accreditation & Inspection Processes
- Live Webinars
- Customized Continuing Education Programs

MAMMOGRAPHY EDUCATORS