Mammography
FDA and MQSA
Unit 6

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MQSA and ACR

- Department Organization
- Indicators & Treatment
- Breast Anatomy & Physiology
- Positioning
- Equipment
- Technical Applications
- Breast Variability & Pathology
- Quality Assurance & Quality Control
- Interventional Procedures
- Clinical Practicum
Department Organization

Mammography facilities include:

- Hospitals
- Outpatient departments
- Clinics
- Radiology Practices
- Mobile units
Ancillary Personnel

• **Interpreting Physicians:**
  – have to have special training in mammography.
  – have to hold a license to practice medicine.
  – have to have read 1000 mammograms, according to MQSA (Mammography Quality Standards Act) guidelines.

• Fellowships done in mammography need to be for a minimum of six months, but 1 year is ideal.
Ancillary Personnel

• **Interpreting physicians:**
  – have to have certification by FDA-approved bodies.
  – have to have continuing education specialized in mammography.

• **Continuing education is heavily regulated, and has strict requirements.**
Ancillary Personnel

- **Mammographers:**
  - have to have at least 40 hours of instruction.
  - 25 exams performed on patients, with direct supervision.
  - 75 exams performed on patients, with indirect supervision. These can be screening or diagnostic exams.
  - Q.C., interventional and special exam experience requirements performed.
Ancillary Personnel

• **Mammographers:**
  – have to be licensed by the ARRT (American Radiology of Radiologic Technologists), in mammography.
  – Some states require a state certificate, like California for example.
  – A license examination might be required.
Ancillary Personnel

• Continuing education requirements for mammographers:
  – is heavily regulated, and needs to be strictly adhered to
  – The ARRT requires a mammographer to complete at least 12 continuing education units (CEU’s) each biennium in mammography
  – California requires a mammographer to complete 5 units of continuing education per year. Other states may vary this rule
Ancillary Personnel

• A medical physicist:
  – is trained and licensed in mammography
  – His license has to be approved by the state in which they work
  – have to have experience in mammography physics
  – have strict requirements for continuing education that they need to adhere to

• MQSA heavily regulates these requirements
Patient Services

- Screening mammography
- Diagnostic mammography
- Localization procedures
- Biopsy procedures
- Other procedures
Patient Services

• **Screening Mammography** is performed on patients that are asymptomatic. (No lumps, pain or discharge from their nipples)

• These patients come in to a mammography center to have their annual screening mammogram.
Patient Services

• **Diagnostic mammography** is technically a consultative mammogram.

• These patients are coming in to a mammography center with a complaint of lumps, pain in a specific area, and/or discharge from the nipples.
Patient Services

• Diagnostic mammography is also performed, when a patient has already had a screening mammogram, and the radiologist needs to have a specific area looked at closer.

• These are magnification views and/or ultrasonography of the breast.
Patient Services

• **Diagnostic mammography** can also be performed on patients with a history of breast cancer.

• Patients with implants are sometimes confused with being diagnostic exams. These patients need a screening mammogram, unless they have a complaint of lumps, pain and/or discharge from their nipples.
Patient Services

• **Localization procedures** are done for patients who have had a mammogram, and there is an area of question, on it.

• These patients may have had a biopsy done already, giving the surgeon a positive result for breast cancer.
• Localization procedures are done sometimes, without a biopsy done before hand.
• Some patients and their surgeons may decide to forego the biopsy, and go straight to surgery to have a more invasive biopsy done.
• This requires anesthesia, and has more recovery time.
Patient Services

• The localization procedure requires a wire being placed inside the patient’s breast.

• The patient is then sent off to surgery, where the surgeon follows the wire down to the lesion in question, and excises it.
Patient Services

• **Biopsy procedures** can be performed on the breast in many ways.

  • The least invasive ways are either by ultrasound guidance, or by using stereotactic mammography.

  • These methods allow the radiologist to sample breast tissue with very little local anesthesia used.
Patient Services

• **Biopsies of the breast** can also be performed in surgery.
• This is a more invasive approach performed by surgeons.
• Patients take longer to recover from this procedure.
Other procedures in mammography include:

- **Galactograms/ductograms**: the radiologist injects dye into the patient’s mammary gland, to see if there is an abnormality.

- **Fine needle cyst aspirations** (FNA’s): a needle is inserted into the patient’s lump, to try to withdraw fluid.
National Quality Standards

• **FDA** (Food and Drug Administration) is an approved accrediting body for mammography centers.
  – oversee private, nonprofit organizations
  – also regulate state agencies
National Quality Standards

• **FDA** is responsible for accrediting bodies.
• They have to make sure facilities are adhering to the standards made for mammography practice.
• The list of standards includes: standards for physicians, mammographers, medical physicists, X-ray equipment, quality assurance, quality control, phantom image quality testing, radiation dose limits, information update provisions, medical records, patient notification requirements, and clinical image review.
National Quality Standards

- MQSA requirements are:
  - accreditation of mammography facilities is approved by accrediting bodies
  - annual mammography facility physics survey, consultation and evaluation is performed
  - annual inspection of mammography facilities is performed by federally certified or state-certified inspectors
  - qualification standards for interpreting physicians, mammographers, medical physicists and mammography facility inspectors
  - specification of boards or organizations eligible to certify the training and experience of mammography personnel
  - establishment of quality standards for mammography equipment and practices, including quality assurance and quality control programs
  - establishment of a National Mammography Quality Assurance Advisory Committee
  - establishment of standards governing record keeping for patient notification by physicians
MQSA For Digital Mammography
Accrediting FFDM

1. Facility Completes Entry Application
   - ACR Reviews Entry Application; Sends Facility Full Application
     - New facilities only
     - ACR Notifies FDA
     - FDA Sends Facility a 6-mo Provisional Certificate (facility may do mammography)

2. Facility Completes Full Application & Returns to ACR
   - ACR Reviews Full Application
     - Clinical Image Review
     - Phantom Image Review
     - ACR Writes Final Report

3. Facility/Unit Deficiency (1st)
   - Facility Repeats, Appeals or Withdraws
     - Facility Repeats, Appeals or Withdraws
     - ACR Notifies FDA
     - FDA Sends Facility 3-yr Certificate (facility may continue mammography)

   - Facility/Unit Passes
     - Facility Renews Accreditation in 3 Years
Extension of Certification of FFDM Uses

• Initially the facility has to be SFM certified (new application, if not).
• Facility has to provide a list of all personnel who will be working in the facility with the FFDM modality
  – interpreting
  – performing
  – surveying
Approval Items

• Facility status information
• FFDM unit identification
• Digital image receptor identification
• ID of printers for hard copy output
• Monitor identification
• Phantom identification and image
• Signature of lead interpreting physician
• Personnel ID and qualification
• Report of mammography equipment evaluation
• Manufacturer’s QC program in accordance with 900.12(e)((6)
MQSA Final Regulations

- 21 CFR 900.12(e)(6)
- For systems with image receptor modalities other than screen-film, the quality assurance program shall be substantially the same as the quality assurance program recommended by the image receptor manufacturer, except that the maximum allowable dose shall not exceed the maximum allowable dose for screen-film systems in paragraph (2)(5)(vi) of this section.
New mammographic Modality Training

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

• Hands-on training is strongly recommended
New Mammographic Modality Training

• Interpreting physicians 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 technologist at a facility using an FFDM unit must be a qualified radiologic technologist who also meets the training requirement for performing FFDM examinations.
Documentation

- Attestation (if experience prior to 10/1/94)
- Mammography modality – specific CME/CEU certificates
- CME/CEU certificates plus agenda, course outline or syllabus
- Confirming letters from CME/CEU granting organization
- Letters, certificates, or other documents from manufacturers or other formal training courses
Oversight of FFDM Accreditation

- Quarterly reviews for the first year and yearly reviews thereafter which will include reviews of MEE reports and phantoms images obtained the ACR.

- Same oversight procedures will apply to all future FDA approved accreditation bodies.
Dual Accreditation

• Dual Accreditation – Multiple units located at the same site accredited by different accreditation bodies.

• Facilities have the option to choose the same AB for both FFDM and SFM units. Dual accreditation may increase cost and paperwork associated with dealing with two accreditation bodies.
MQSA Inspections

• FFDM Personnel inspection question:
  – Q1 – New modality training (8 hours)

• FFDM QA/QC inspection questions:
  – Q1 – Manufacturer recommended QC procedures followed?
  – Q2 – Monitor QC done per manufacturer’s recommendation?

• If hard copy display is used for image interpretations
  – Q3 – Manufacturer recommended procedures for printer used?
Compliance

• Facilities are cited for any “No” answer.
ACR Hardcopy Requirements

- **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
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
  - Subtract for artifacts
Clinical Image Quality Evaluation

- Positioning
  - Major reason for failure
- Compression
- Exposure level
- Contrast
- Sharpness
- Noise
- Artifacts
- Exam ID
  - Must be present
  - OK under HIPAA
Accreditation Testing Must Pass

• Clinical image review (fatty and dense breast)
• Phantom image review
• Dose (<300 mrads)
• Processor QC or
• Laser QC for FFDM
  – Follow mfr QC manual
• Criteria the same for digital as with screen-film
# Mfc Manuals are Very Different

## Frequencies

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<th>Test</th>
<th>Soft Copy Display</th>
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<tr>
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• Follow latest version of mfr’s QC manual procedures for unit tested
• Meet mfr’s performance standards
• Failures must be fixed before use on patients (no more 30 days)