Mammography Regulations and Standards in the U.S.:

The Basics of the Mammography Quality Standards Act

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MQSA

- The Mammography Quality Standards Act was signed into law October 27, 1992
- It required all mammography facilities to be certified by October 1, 1994, in order to legally operate
- Is administered by the U.S. Food and Drug Administration (FDA)

Key Features of MQSA

- Implementing regulations set BASELINE QUALITY STANDARDS that all mammography facilities must meet
- Requires facilities undergo ANNUAL INSPECTION against those standards
- Requires mammography units at facilities be ACCREDITED by an FDA-approved body

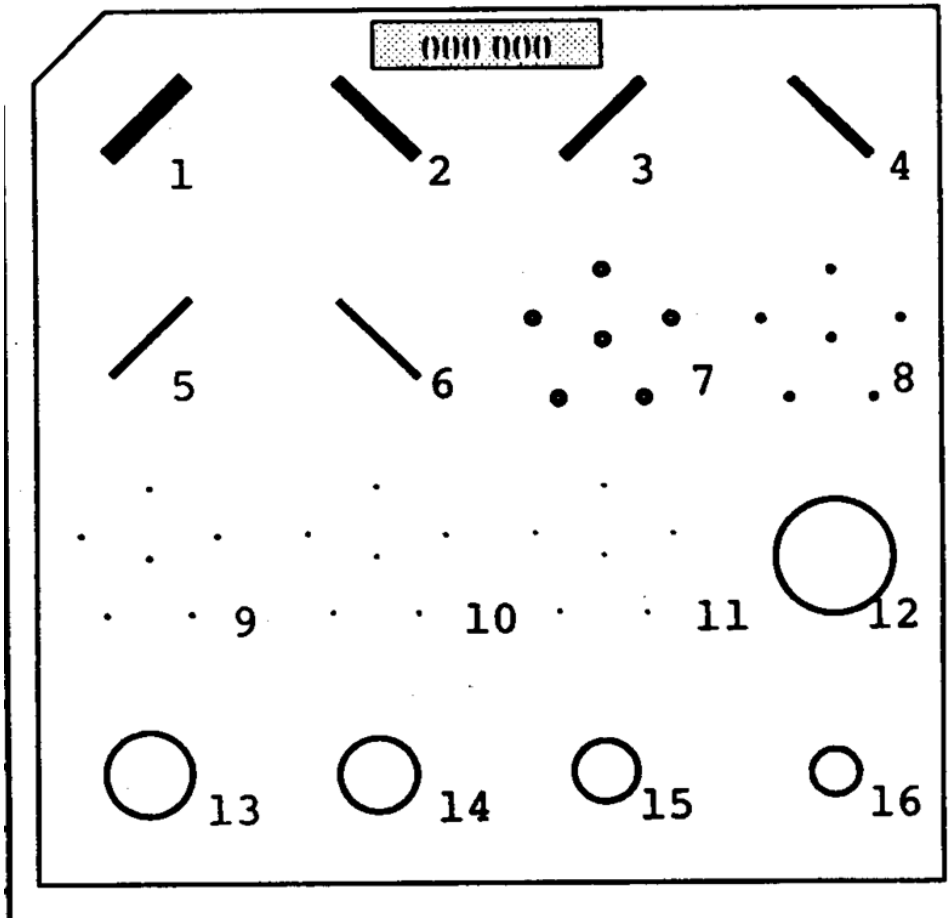
Key Features of MQSA

- Once accredited, a facility is CERTIFIED by FDA (or FDA-approved state), allowing it to legally perform mammography
- If standards are not met, MQSA allows for COMPLIANCE AND ENFORCEMNT ACTIONS, both corrective and punitive

Accreditation

- Each facility undergoes accreditation initially and every 3 years
- Clinical and phantom images are reviewed by experts
- Other QC and personnel documentation is reviewed

Phantom Image



Inspection

- Each facility is inspected annually
- Approximately 8,700 mammography facilities
- Facilities pay an inspection fee
- Inspections performed under contract with States or by FDA (90% by States)
- Inspectors trained by FDA (approx. 200 active inspectors)

Inspection Finding Levels

- **Level 3** - Facility performance generally satisfactory with a minor deviation from MQSA standards (next inspection)
- **Level 2** - Facility performance generally acceptable with a deviation that may compromise quality (30 days)
- **Level 1** - Deviation that may seriously compromise quality (15 days)

Compliance and Enforcement

- Directed Plan of Correction
- Patient and Provider Notification
- Follow-Up Inspection (fee based)
- Certificate Revocation/ Suspension
- Civil Money Penalty

Patient Focused Features MQSA

- Requires facilities to release ORIGINAL mammograms temporarily or permanently to patient, representative, or provider
- Requires patients to get WRITTEN results of mammogram in LAY LANGUAGE, in addition to health care providers' medical report
- Establishes TIME FRAMES for communicating results to patients and health care providers

Patient Focused Features MQSA

- Requires CERTIFICATE to be prominently displayed so that patients know facility has met quality standards
- Requires annual PUBLICALLY AVAILABLE REPORT on facility adverse events/compliance actions
- Requires special training for technologists who perform mammograms on patients with IMPLANTS

Quality Standards

- Quality Control testing and standards
- Quality Assurance standards
- Equipment standards
- Annual Physics Survey + Equipment Evaluation
- Consumer complaint mechanism
- Infection control procedures
- Records Retention and Release

Quality Standards

- Personnel qualifications - Interpreting physicians, Radiologic technologists, Medical physicists (licenses and certificates; initial and continuing education and experience)
- Standards for reports to referring healthcare providers and patients - assessment categories; time frames for reporting results
- Medical Outcomes Audit

Quality Control Testing Examples

Test	Frequency
Detector Flat Field	Weekly
CNR, SNR and Phantom Image Evaluation	Weekly
Review Work Station	Weekly
Compression Thickness	Weekly/Biweekly
Compression Force	Semi-annual
Repeat Analysis	Quarterly
Resolution/MTF	Annual
AEC Performance	Annual
Beam Quality	Annual
Radiation Dose	Annual
Radiation Output	Annual
X-ray field Alignment	Annual

Personnel Qualification Examples

Interpreting Physician: Initial

- Licensed to practice medicine in a State
- Specialty board certification or
- At least 3 months of formal training mammography interpretation under direct supervision of a qualified physician
- 60 hours of Category I CME
- Interpreted at least 240 mammograms

Interpreting Physician: Continuing

- From the date of the end of calendar year in which the initial qualifications are met, must read at least 960 mammographic examination within 24 months period, 15 category I continuing education within 36 months
- 8 hours of new mammographic modality related training before providing services

Technologist: Initial

- Licensed to perform general radiographic procedures in a State
- Certified by an appropriate specialty area by a body determined by FDA
- 40 contact hours training in mammography
- At least 25 examinations under the direct supervision of a qualified Rad Tech

Technologist: Continuing

- From the date of the end of calendar year in which the initial qualifications are met, 15 continuing education units within 36 months
- 8 hours of new mammographic modality related training before providing services in a new modality

Medical Physicist: Initial

- State approved or certified by FDA approved body
- Master's degree or higher in physical science with at least 20 hours in physics
- 20 contact hours in mammography
- At least 1 facility and 10 mammography units survey experience

Medical Physicist: Continuing

- From the date of the end of calendar year in which the initial qualifications are met, 15 continuing education units within 36 months, experience of surveying 2 mammographic facilities and total of 10 mammographic units
- 8 hours of new mammographic modality related training before providing services in a new modality

Information Management: MPRIS

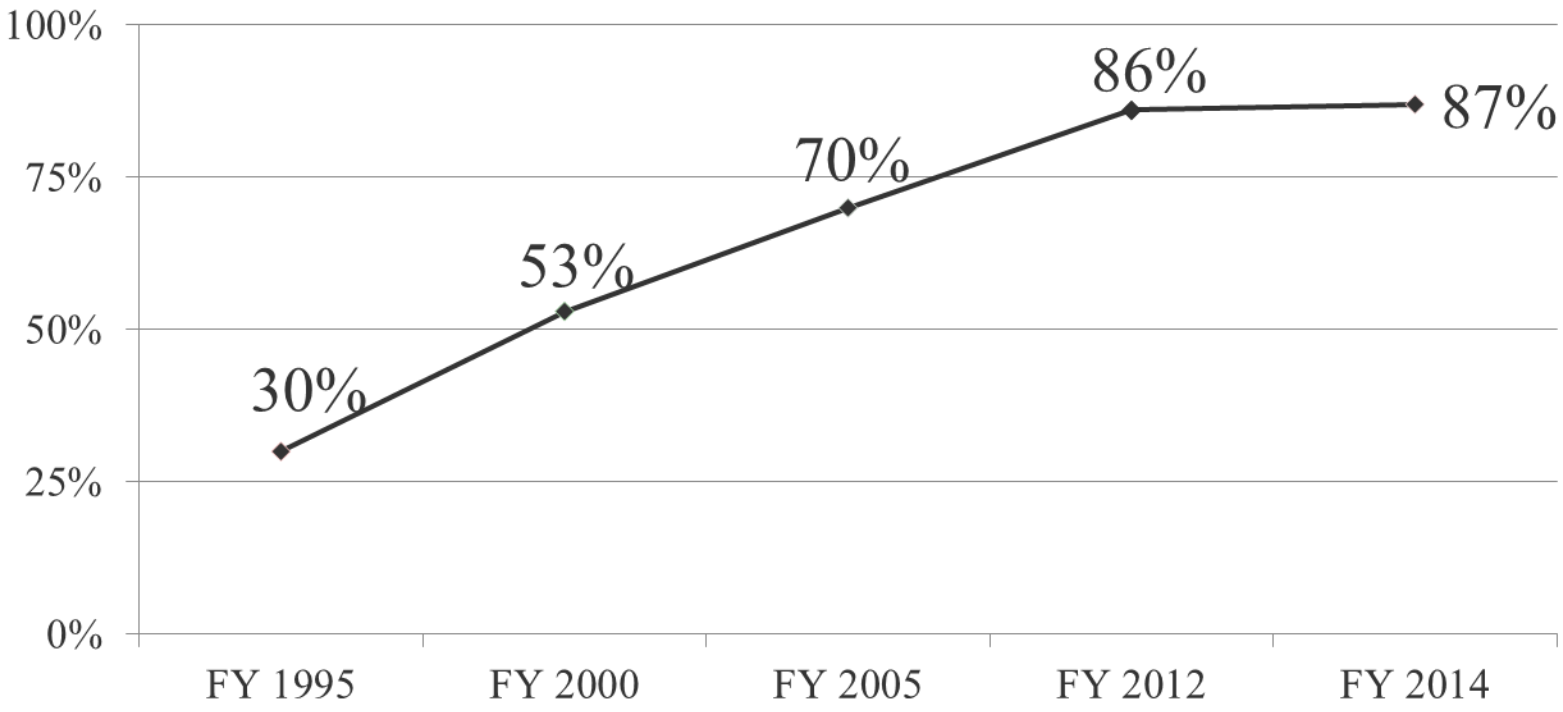
- Insures the quality, reliability, integrity, and accessibility of accreditation, certification, inspection, compliance, and billing data
- Inspection reports uploaded from inspector laptops to database
- Receives info from accreditation bodies and state certifiers
- Sends certification data to CMS
- Allows certified facility search by zip code

Has MQSA Been Successful?

- Since MQSA, the morbidity and mortality rates of breast cancer have been decreasing about 2% per year from 2002 to 2011 (new treatments, increased awareness)
- In 1975 the five-year survival rate was 75.5%. In 1990 it was 84.6%. In 2006 it was 90.6%
- Between 1994 and 1996, only 76% of mammography units passed accreditation on first full attempt – currently 99%

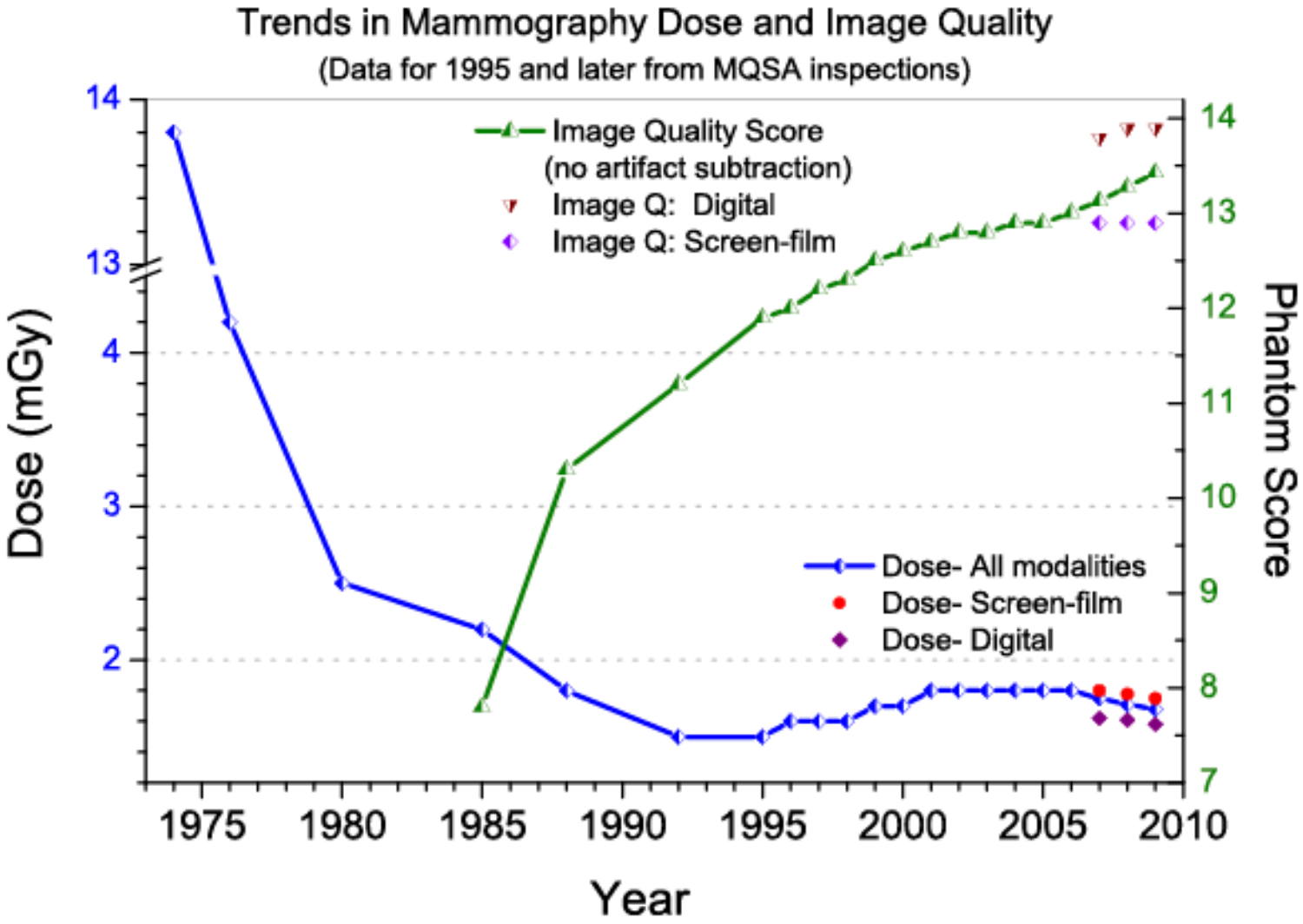
Has MQSA Been Successful?

Compliance: % Violation Free



Of facilities with violations, only 0.4% have Level 1 (the most serious) violations

Dose and Image Quality



Current Statistics

- Average number of mammography units per certified facility is 1.6
- 94% of certified facilities are now completely digital
- In ten States and the Armed Forces, 100% of certified facilities are all digital
- In 35 states, over 90% of certified facilities are all digital
- Approximately 39 million mammograms are performed yearly in U.S.

Source: ***MQSA National Statistics*** web page (data from MPRIS)

Take Home Point: Mammography Is a Team Sport

- Interpreting Physicians
- Mammography Technologists
- Medical Physicists
- Other imagers: breast ultrasound; MRI
- Surgeons; Pathologists
- Administrators/Purchasers
- Support Staff

More Information

- MQSA Internet home page

  www.fda.gov/Radiation-EmittingProducts/MammographyQualityStandardsActandProgram/default.htm

- Policy Guidance Help System (PGHS)

  www.fda.gov/Radiation-EmittingProducts/MammographyQualityStandardsActandProgram/Guidance/PolicyGuidanceHelpSystem/default.htm

- Certified facility search by ZIP Code

  www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMQSA/mqsa.cfm

- MQSA Facility Hotline: 1-800-838-7715