



Evolution of Mammography Quality under MQSA, Lessons Learned and Future Opportunities

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What We Will Cover Today

- What is MQSA?
- How did it come to be?
- What does it do?
- Key features
- Has MQSA been successful?
- Thoughts for future

What is MQSA?

- The Mammography Quality Standards Act
- Signed into law October 27, 1992
- Required all mammography facilities to be certified by October 1, 1994, in order to legally operate
- Delegated to FDA to administer
- Gets reauthorized approximately every five years – new requirements can be added

How did it come to be?

- 1985-FDA's Nationwide Evaluation of X-Ray Trends surveyed U.S. mammography facilities and found wide variations in radiation dose and image quality
- 1987-American College of Radiology established voluntary accreditation program
 - by 1992 only 66% of facilities applied
 - 38% failed accreditation
 - did not provide for on-site evaluation of facilities

How did it come to be? (Continued)

- 1992 - Congressional Comments
 - “Patchwork of Federal, State, and private standards”
- 1992 - Political climate - Presidential election platforms emphasized women’s health issues
- Vigorous lobbying of Congress by consumer groups

What does it do?

- Requires all mammography facilities to meet baseline minimum quality standards
- Requires a facility to be ACCREDITED by an FDA-approved body and CERTIFIED by FDA (or SAC) to legally operate
- Requires that all facilities undergo an annual on-site inspection
- If standards are not met, allows for actions to be taken, both corrective and punitive

Key Features of MQSA

- Quality Standards
- Accreditation
- Certification
- Inspections
- Compliance and Enforcement
- Information Management
- Education

Quality Standards

- Quality Assurance standards
- Equipment standards
- Annual Physics survey +Mammographic Equipment Evaluations (MEE).
- Consumer complaint mechanism

Quality Standards

- Personnel qualifications - Interpreting physicians, Radiologic technologists, Medical physicists
- Reporting Standards for reports to referring physicians and patients
- Records Retention
- Medical Outcomes Audit

Patient/Provider – Centered Requirements

- Facility must display MQSA certificate
- A summary of results in lay language must be provided to patient (in addition to medical report to provider)
- Must have consumer complaint process
- Use of assessment categories to facilitate provider communication/follow-up

Accreditation

- Current Accreditation bodies
 - National - American College of Radiology
 - States - Iowa, Arkansas, Texas
- Perform review of clinical and phantom images from each of its facilities at least once every three years and perform Additional Mammography Reviews in cases where there is reason to suspect there is a risk to the public health

Certification

- Current Certification bodies
 - National - Food and Drug Administration
 - States – Iowa, Illinois, South Carolina, Texas
- Issue MQSA certificates granting status to facilities to legally provide mammography services
- Perform annual inspections and compliance/enforcement

Inspections

- Facilities inspected annually against quality standards – all facilities every year. Approx. 8,700 facilities
- Facilities pay an inspection fee
- Inspections performed under contract with States or by FDA (90% by States)
- Inspectors trained by DMQS (approx. 200 active inspectors)
- State performance assessed by annual audit of state inspectors by FDA auditors

Inspections

- Review of QC tests, dose, phantom image, Image Output Monitor QC
- Medical Audit and Outcome Analysis
- Review of procedure for sending lay summaries to patients
- Personnel qualifications, consumer complaints
- Random review of medical reports for proper use of assessment categories

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 Tools

- Directed Plan of Correction
- Patient and Provider Notification
- Follow-Up Inspection (fee based)
- Certificate Revocation, Suspension, or No Longer in Effect
- Civil Money Penalty



Information Management

The Mammography Program Reporting and Information System (MPRIS)

- Designed and developed to support MQSA
- Client-server and web-based applications

Each year:

- Processes 19,000 inspection transactions
- Processes 18,000 accreditation and certification transactions
- Processes 9,600 billing transactions
- Is accessed approximately 29,000 times
- Users run 1,700 reports

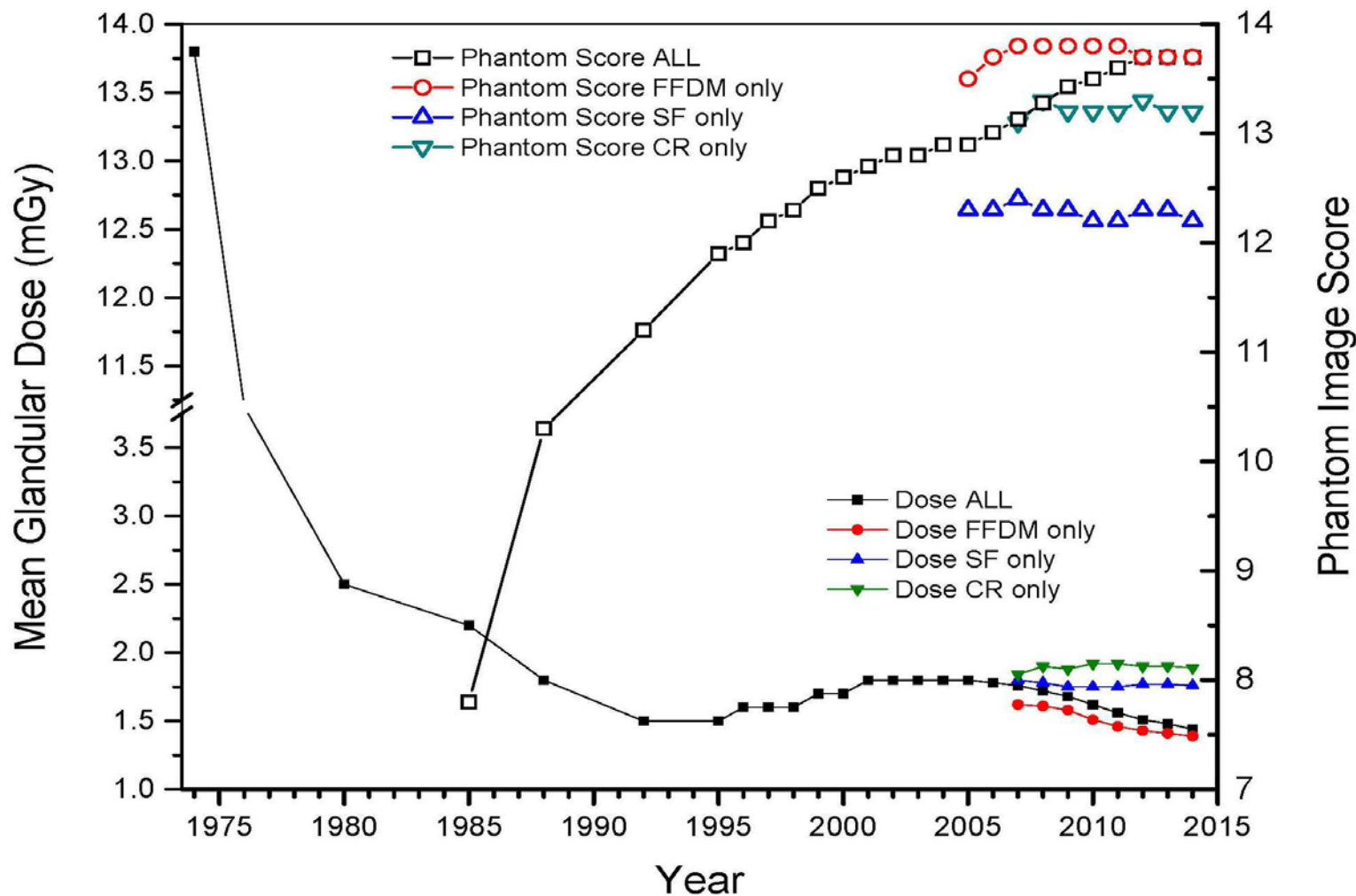
What does it cost to run?

- MQSA is both an appropriated and a user fee supported program – the facilities pay for the pleasure of us coming in to inspect once a year
- Total yearly operating costs approx. 20 million
- Breakdown is approx. $\frac{3}{4}$ user fee; $\frac{1}{4}$ appropriated

Has MQSA Been Successful?

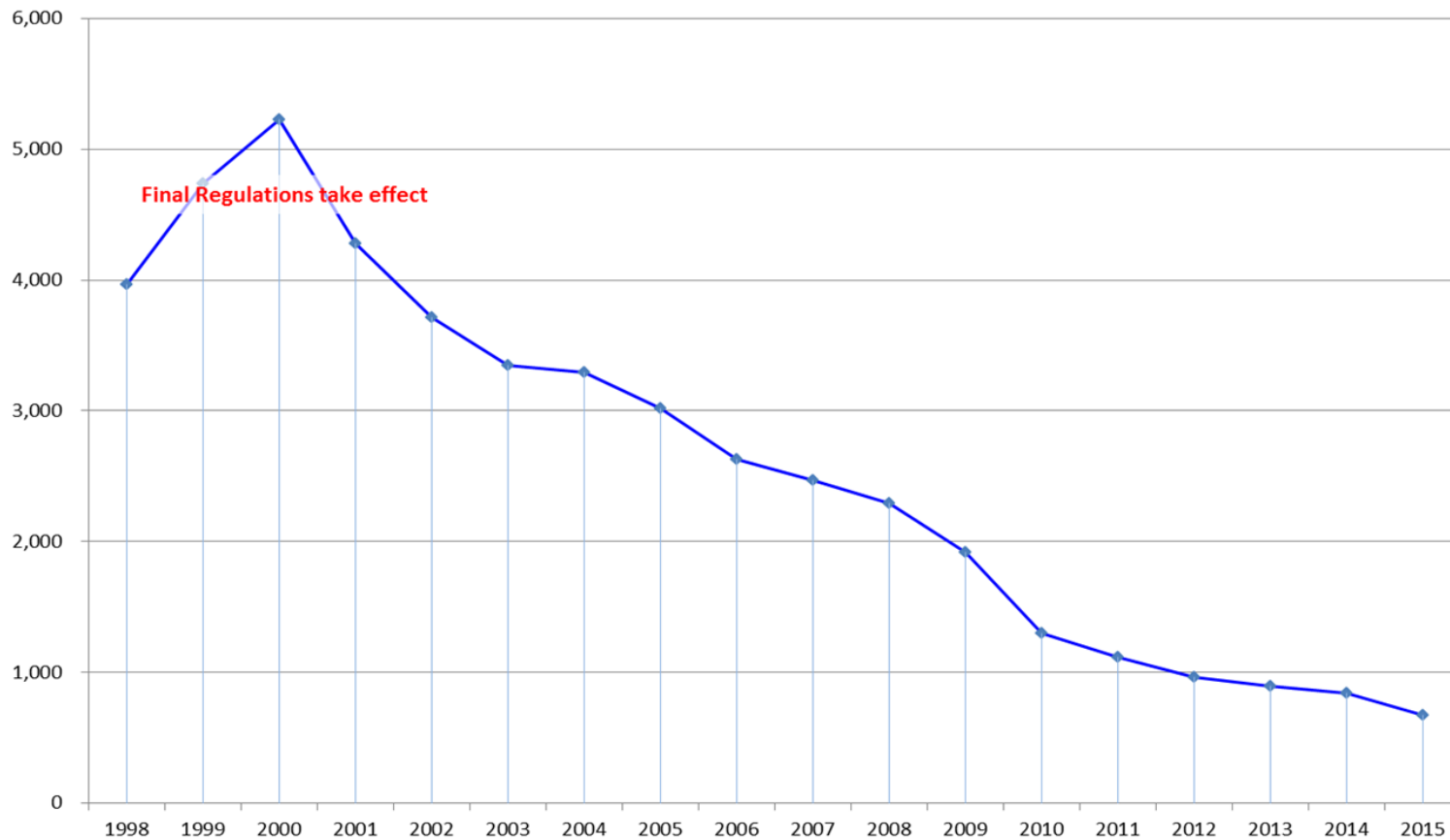
- Since the passage of MQSA, the morbidity and mortality rates of breast cancer have been decreasing about 2% per year (new treatments, increased awareness)
- In 1975 the five-year survival rate was 75.5%. In 2003 it was 89.9%

Dose and Image Quality





Number of Equipment Violations, 1998 - 2015

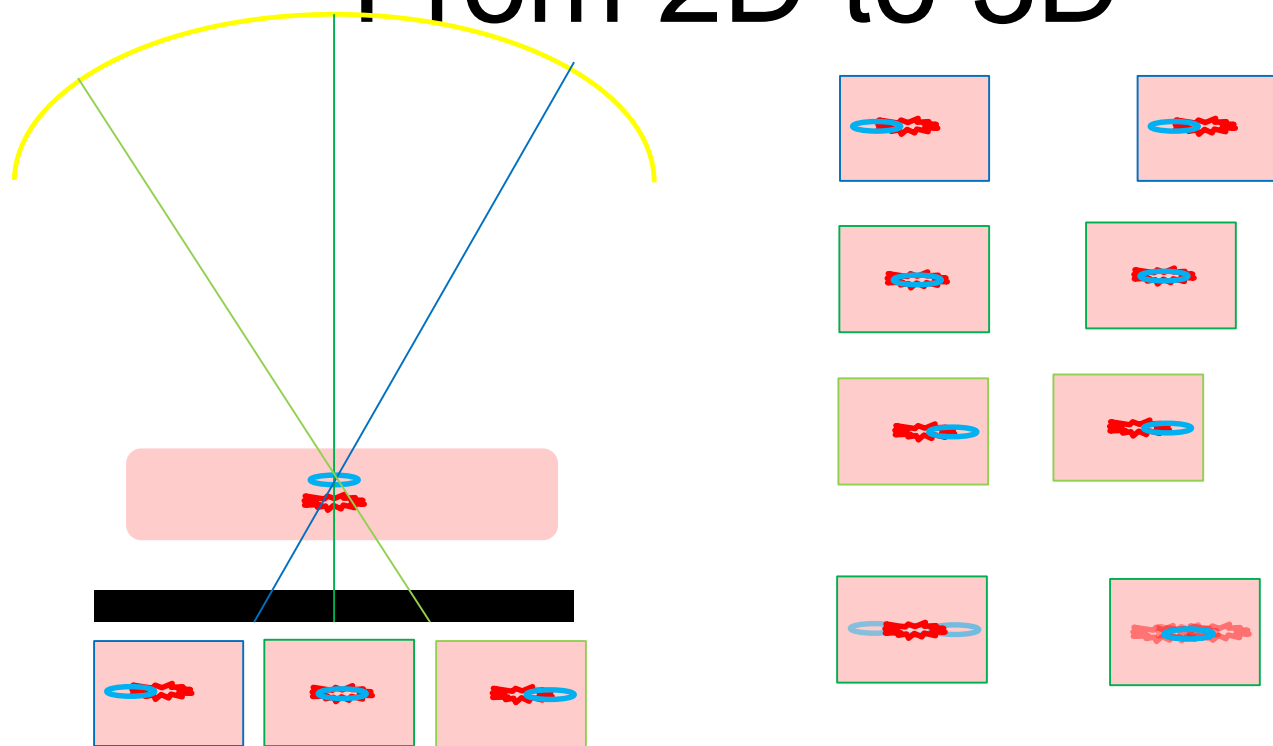


Screen film to digital

- Average number of mammography units per facility - 1.8
- % of facilities that are all digital - 97%
- % of units that are digital – 98%
- Facilities in 15 jurisdictions are 100% digital
- In 37 other jurisdictions, 90% or more of the facilities are all digital
- There are less than 300 screen-film units left in use in the US
- Approximately 39 million mammograms are performed yearly in MQSA certified facilities

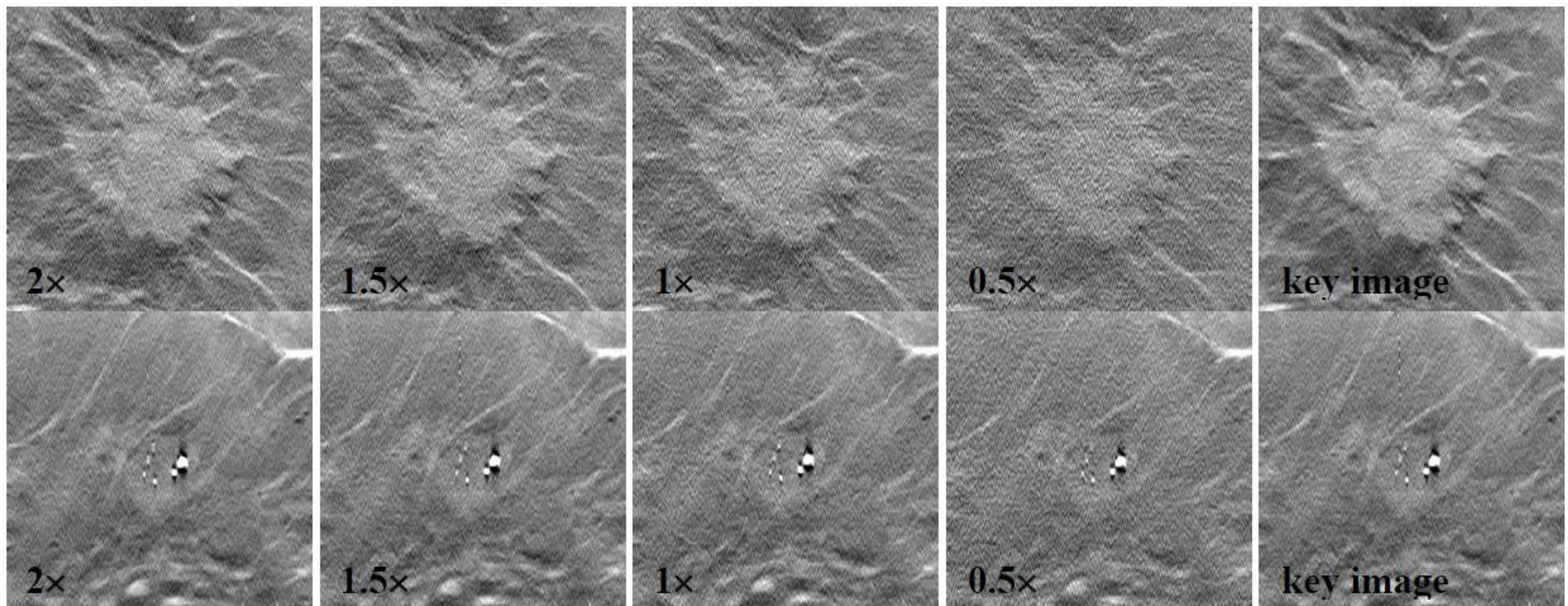
Source: *MQSA National Statistics* web page (data from MPRIS)

From 2D to 3D



Dose

- MQSA limit for mammo + tomo = 300 mrad

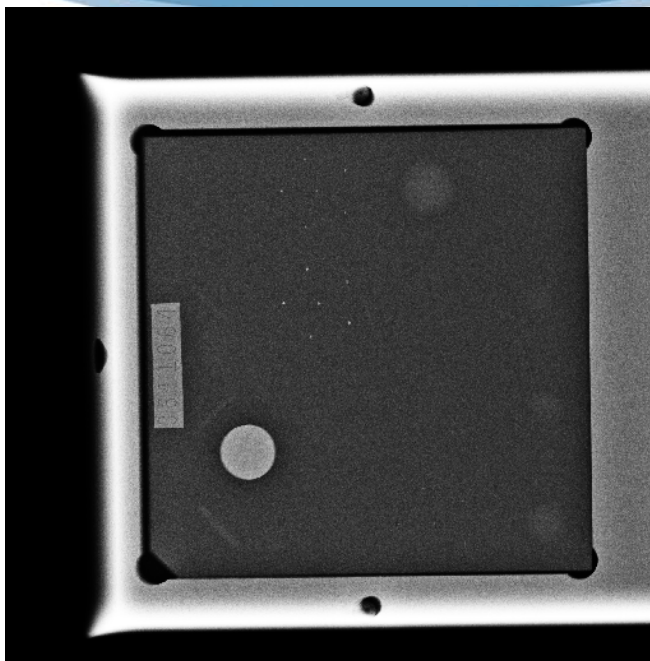


Key Quality Control Tests

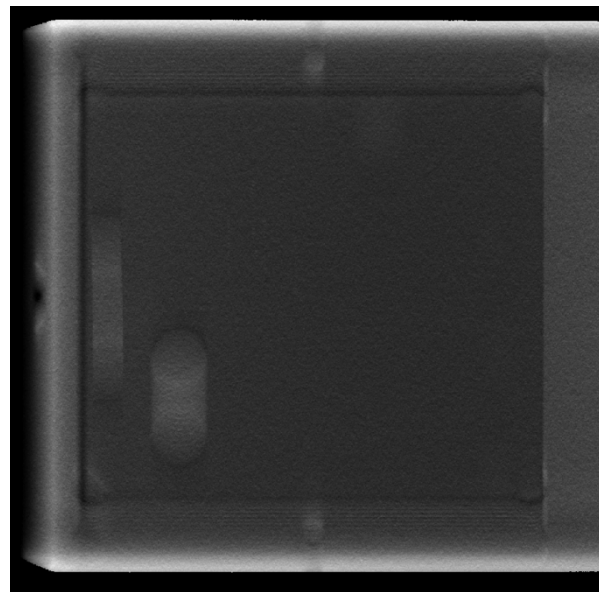
- Automatic Exposure Performance Test
- Spatial Resolution
- CNR and SNR Measurements
- Phantom Images
- Mean glandular dose

All tests are performed to assure machine performance

Measured with phantom as surrogates for patients



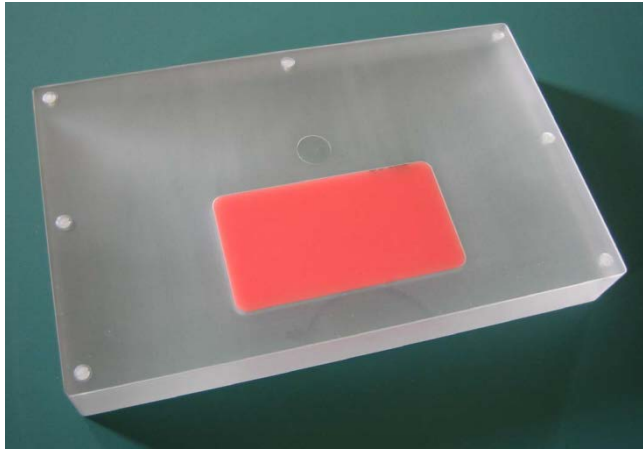
2D



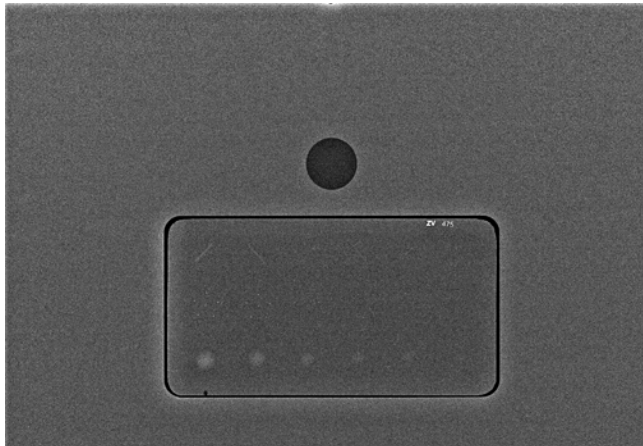
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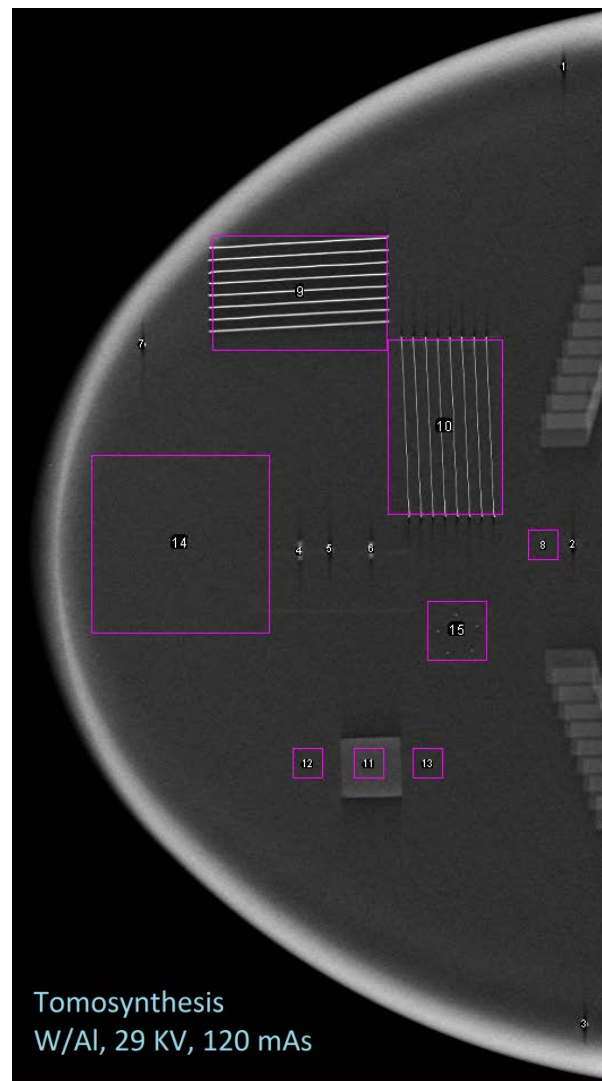
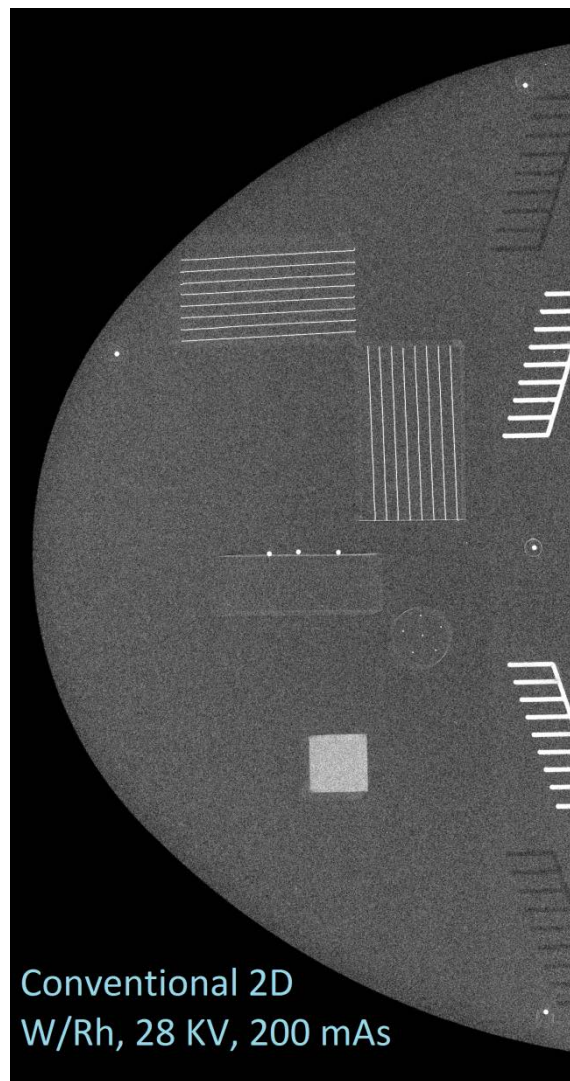
Phantom Image Quality Evaluation

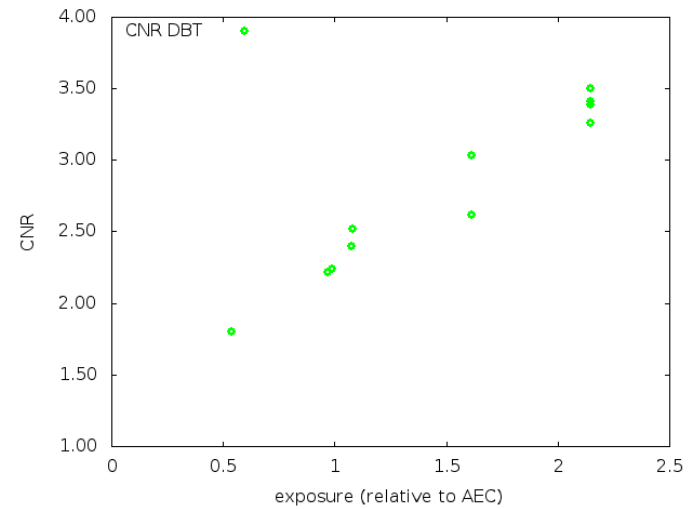
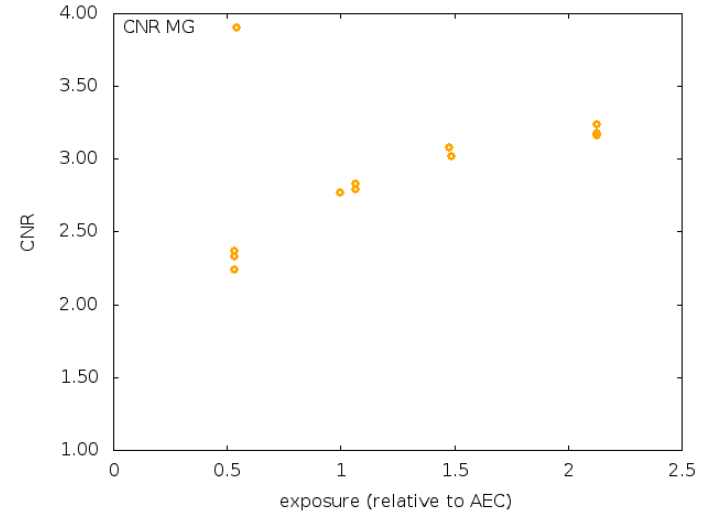
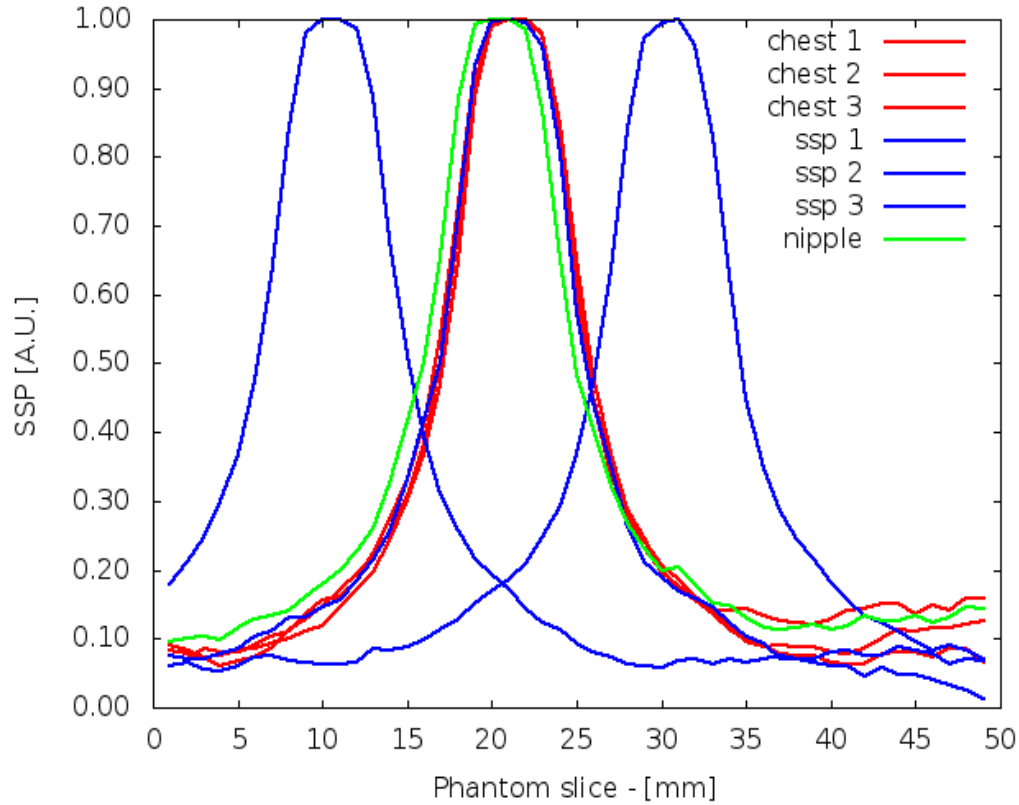
ACR Prototype FFDM Accreditation Phantom

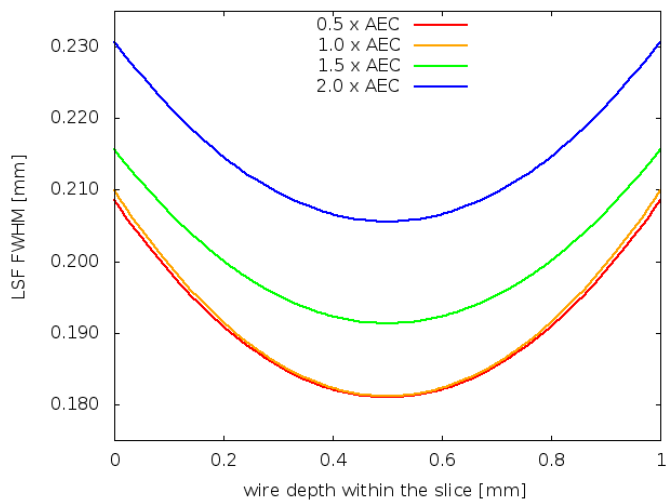
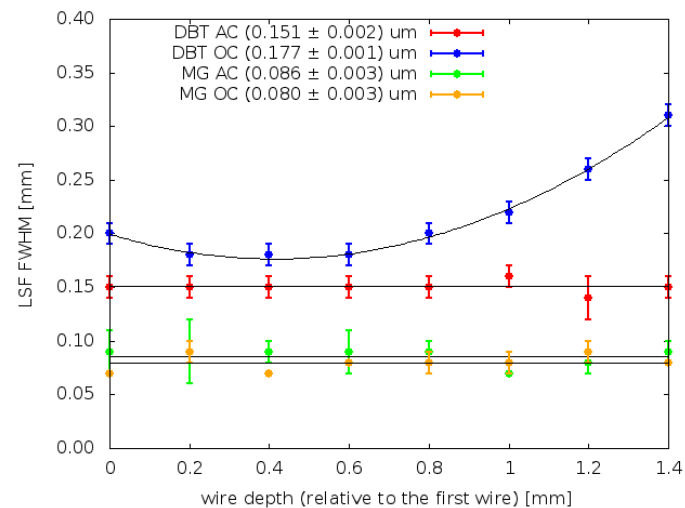
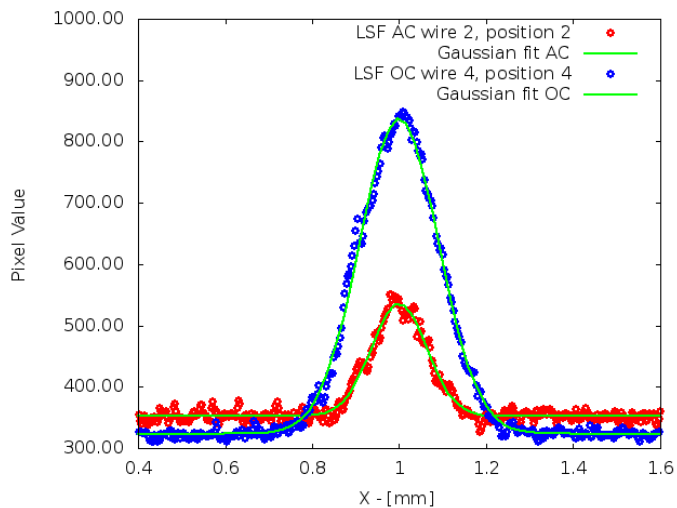


- Subjective and objective assessment of image quality
- Features:
 - 6 speck groups, 6 fibers and 6 masses
 - Cavity to calculate CNR
 - Homogeneous area to calculate noise
- Shortcomings:
 - Homogeneous background
 - Objects only in one height
 - All masses are always visible











Next Step

Qualitative TO more Quantitative Imaging

Continuous quality control

Cloud-based system to manage image files

Digital data from 9000 facilities

Data sharing

Multi read, multi modality PACS

AMR

Workflow

Ubiquitous pay for access

Across the board uniform ~~minimum~~ standards.



More Information

- MQSA Internet home page

www.fda.gov/Mammography

- Policy Guidance Help System (PGHS)
- Certified facility search by ZIP Code
- MQSA Facility Hotline: 1-800-838-7715