MQSA : Beginning the Next Quarter Century with a Spotlight on Image Quality

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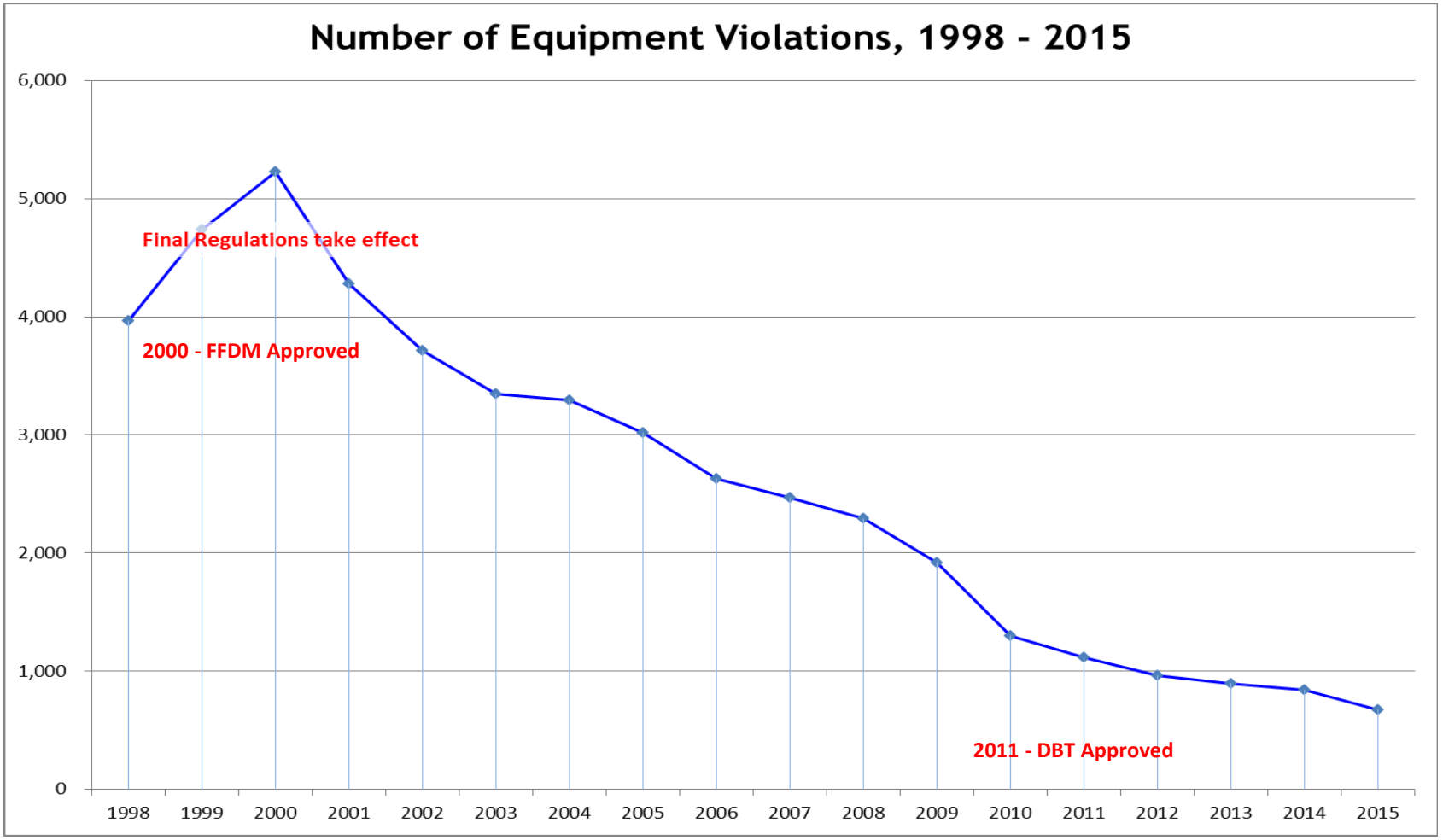
The Mammography Quality Standards Act (MQSA) of 1992

- October 27, 2016 begins the 25th year since the MQSA was signed into law by President George H.W. Bush
- What have we seen?
- What have we learned?
- How does what we have seen and learned inform the next steps?

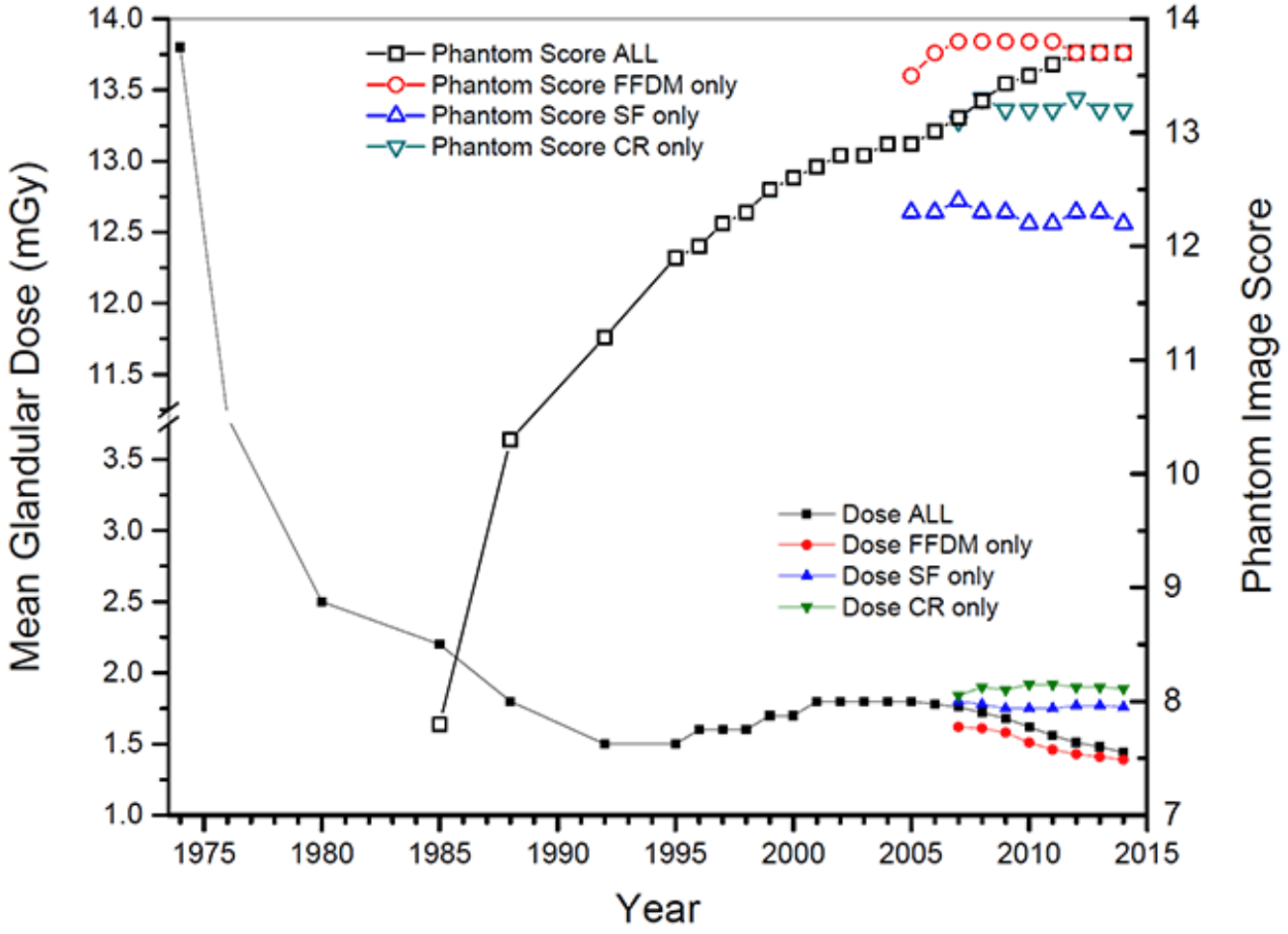
The First Quarter Century: What We Have Seen

- A sharp decline in equipment issues
- A decrease in dose and a rise in phantom images scores
- A relative decrease in breast cancer mortality
- Screen/film mammography head towards extinction in the U.S. – only 266 units remain

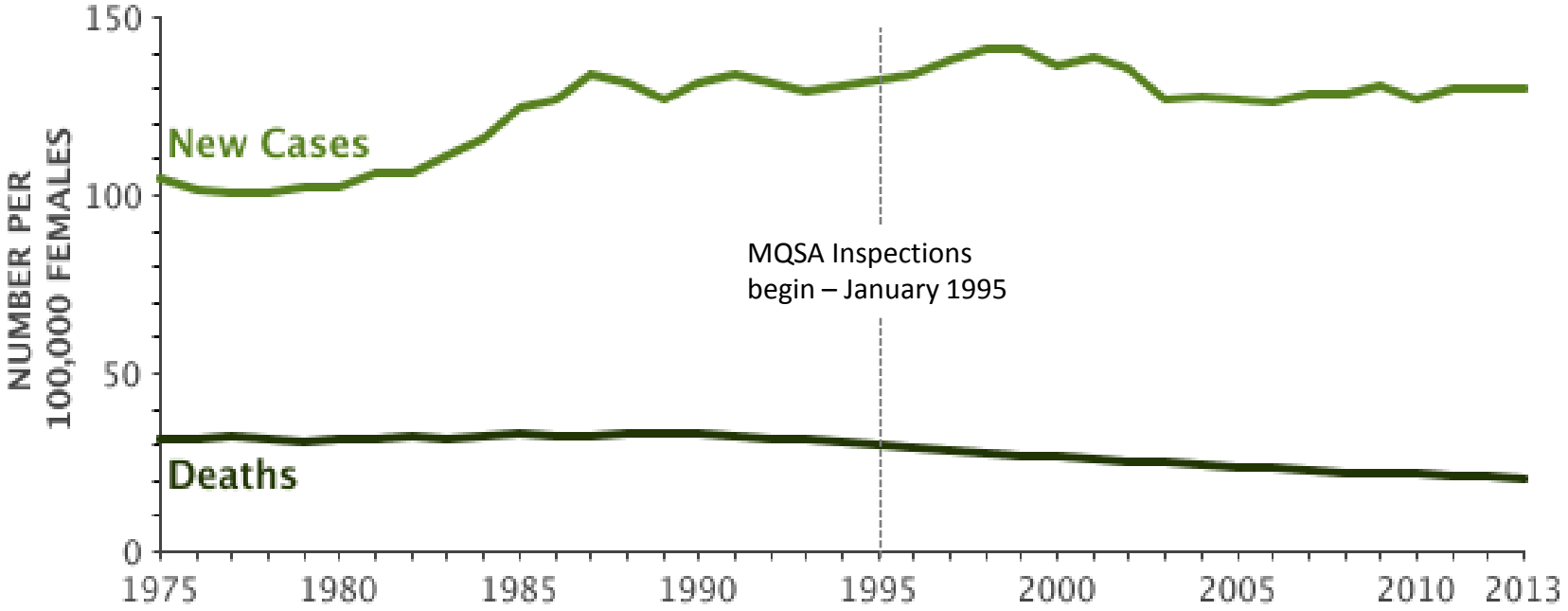
Equipment Violations History



Trends in Mammography Dose and Image Quality 1974-2014



New Cases, Deaths and 5-Year Relative Survival[1]



Year	1975	1980	1985	1990	1995	2000	2004	2008
5-Year Relative Survival	75.2%	74.9%	78.4%	84.6%	86.8%	90.2%	89.9%	90.6%

[1] NCI SEER 9 Incidence & U.S. Mortality 1975-2013, All Races, Females. Rates are Age-Adjusted.

The First Quarter Century: What We Have Seen

- New technologies for detecting breast cancer – Digital Breast Tomosynthesis; Automated Breast Ultrasound; Breast CT
- What we have seen means image quality has improved, BUT can it be improved even more?
- We continue to see problems with the “human factors” of image quality

Image Quality: The Human Factor Problems

- QC tests not performed at required frequencies
- Appropriate corrective actions not taken
- Effectiveness of corrective actions not assessed
- Poor patient positioning
- Inadequate compression

Image Quality: The Human Factor Problems

- Acceptance of suboptimal images for interpretation
- Lack of feedback and corrective action for poor image quality
- Lack of oversight/lack of knowledge about oversight responsibilities

What Have We Learned?

- More compliance cases come from image review than from inspection findings
- Equipment and dose are not the problem
- Poor image quality (positioning; compression) is the Achilles' Heel

In General:

- Image quality is the purview of accreditation bodies
- Equipment (dose, Q/C, etc.), personnel requirements is the purview of the inspection

What is Available to Us?

- Current method of image quality review through accreditation bodies: Limitations
  1. images looked at every 3 years
  2. random image checks cover only a small portion of facilities
- Inspection program – we are in every facility every year

Some “Aha!” Moments

- We find during inspections that QC data is missing – why? Where is the oversight?
- We have existing regulations that address maintaining image quality and personnel responsibilities for image quality
- Current inspection questions focus on technologist and physicist responsibilities

Some “Aha!” Moments

- Where are the interpreting physicians’ (IPs), in particular the lead interpreting physicians’ (LIPs) responsibilities in the inspection program (other than Medical Audit)?
- Can we use the inspection program to improve image quality?
- Can we use the required Medical Outcomes Audit as a model?

How Should We Use the Inspection Program to Improve Image Quality?

Different scenarios discussed:

- Adding a positioning measurement component to inspection
- Having FDA radiologists review images collected at inspection

How Should We Use the Inspection Program to Improve Image Quality?

- Sending images collected at inspection to accrediting bodies
- Adding inspection questions related to image quality responsibilities

EQUIP: Enhancing Quality Using the Inspection Program

- Goal is to equip facilities to address image quality on a continuing basis and emphasize LIP and IP responsibilities
- Images will not be looked at during inspections – rather the facility's processes for ensuring image quality will be inspected
- Adds questions to the quality assurance part of the inspection procedures
- Citations for inadequate or missing image quality processes

New EQUIP Questions

Supporting Regulations

- § 900.12 (d)(1)(ii)(A) All interpreting physicians shall follow the facility procedures for corrective action when the images they are asked to interpret are of poor quality.
- § 900.12(d)(2) *Quality assurance records*. The lead interpreting physician ... shall ensure that records concerning mammography technique and procedures, quality control (including monitoring data, problems detected by analysis of that data, corrective actions, and the effectiveness of the corrective actions), safety, protection and employee qualifications to meet assigned quality assurance tasks are properly maintained and updated.
- § 900.12(i) *Clinical image quality.* Clinical images produced by any certified facility must continue to comply with the standards for clinical image quality established by that facility's accreditation body.

New EQUIP Questions

Quality Assurance — Clinical Image Corrective Action

1. ***Does the facility have procedures for corrective action (CA) when clinical images are of poor quality?*** (Yes / No)

   (Cite § 900.12(d)(1)(ii)(A))

   (a) Do the procedures include a mechanism for providing ongoing IP feedback on image quality to RT's or other designated facility personnel? (Yes / No)

   (b) Do the procedures include a mechanism for documenting any needed corrective actions and documenting the effectiveness of any corrective actions taken? (Yes / No) (Cite § 900.12(d)(2)), § 900.12(d)(1)(i))

New EQUIP Questions

Clinical Image Quality

2. ***Does the facility have procedures to ensure that clinical images continue to comply with the clinical image quality standards established by its accreditation body?*** (Yes / No)) (Cite § 900.12(i))

   (a) Do the procedures include a mechanism for regular reviews of image quality attributes of a sample of mammograms performed by each active RT and a sample of mammograms accepted for interpretation by each active IP? (Yes / No)

   (b) Is there documentation of such review since the last inspection? (Yes / No) [Note: Documentation could include: a summary report; signed statement by the LIP that a review was performed; clinical image review records; memos to RTs and IPs, etc.] (Cite § 900.2(u), § 900.2(x), § 900.2(rr), § 900.12(d)(2))

New EQUIP Questions

Quality Control

3. ***Does the facility have a procedure for LIP oversight of QA/QC records and corrective actions?*** (Yes / No)) (Cite § 900.12(d)(2)) [Note: LIP Provides answers verbally, provides answers in an attestation, or an SOP signed by the LIP is presented at inspection]

   (a) Does the procedure include LIP oversight of QA/QC records, including review of the frequency of performance of all required tests? (Yes / No) *[Note: This includes tests performed by the QC technologist, medical physicist, and any other designated personnel.]*

   (b) Does the procedure include LIP review to determine whether appropriate corrective actions were performed when needed? (Yes / No)

Metrics of Success

- Fewer Additional Mammography Reviews (AMRs) resulting from:
  1. Images submitted for accreditation
  2. Random Image Checks
  3. Other types of image evaluation

- Fewer AMRs that fail, resulting in fewer compliance cases due to poor image quality which in turn means;
- Fewer number of Patient and Provider Notifications/Safety Notices needed

Possible Carrot?

- Can the clinical image review and the LIP oversight of QA/QC also meet Practice Quality Improvement (PQI) requirements for those IPs who are certified by the American Board of Radiology (ABR) and are subject to PQI requirements?

EQUIP Timeline

- October 27, 2016: New EQUIP questions in FISS
- Training the inspectors using FDA Regional Radiological Health Representatives (RRHRs)
- First inspections using new FISS questions will begin before the end of Calendar Year 2017.
- Phased in approach: No EQUIP violations for the first year
- FAQ's for facilities and MQSA inspectors

Compliance Strategy

- Year One : Grace Period, Education
- Year Two: Level 2 Citations for Clinical Image Quality violations (requires response to District and corrective action)
- Year Three and Beyond: Level 1 Citations - referral to the facility's AB for a clinical image review (requires response to District, corrective action, possible Warning Letter)
- District Warning Letter language regarding AB referral

Compliance Strategy

- ABs may use existing image review process or create a new one (can charge)
- Parameters for Image Review
  - Random
  - From images already obtained by facility
  - Sample of two images
- Can count towards required % random reviews

MQSA: The Future

- Focus on enhancing image quality
- Optimize inspections by including image quality assurance elements
- Increase attention paid to image quality standards of accreditation bodies
- Increase awareness of IP and LIP responsibilities
- ???????

Clarifying Questions?

Questions for the Committee

- Do you believe EQUIP has the potential to improve image quality?
- How do you think EQUIP will be perceived by the mammography community?