

# Digital Mammography Inspections

## *A New Age & A Can of Worms!*

Tim F. Gibson, R.T.(R)

M.Q.S.A. Inspector

Texas Dept. of State Health Services

# Disclaimer

Some of the statements made in this presentation may not necessarily represent those of the Department of State Health Services. Some comments may be simply opinions formulated from a rogue inspector's personal experiences.



# A Can of Worms?

A situation that presents difficulty, uncertainty, or perplexity.

# Digital Mammography Statistics

U.S. Department of Health & Human Services [www.hhs.gov](http://www.hhs.gov)

**FDA U.S. Food and Drug Administration** [A-Z Index](#) Search  [go](#)

[Home](#) | [Food](#) | [Drugs](#) | [Medical Devices](#) | [Vaccines, Blood & Biologics](#) | [Animal & Veterinary](#) | [Cosmetics](#) | [Radiation-Emitting Products](#) | [Tobacco Products](#)

**Radiation-Emitting Products** [Share](#) [Email this Page](#) [Print this page](#) [Change Font Size](#)

[Home](#) > [Radiation-Emitting Products](#) > [Mammography Quality Standards Act and Program](#) > [National Statistics \(MQSA\)](#)

**Mammography Quality Standards Act and Program**

**National Statistics (MQSA)**

[Scorecard Articles](#)

[MQSA National Statistics](#)

## MQSA National Statistics

In this section of the MQSA Scorecard, we present the most commonly requested national statistics regarding the MQSA program. These statistics are updated on the first of each month.

|   |                |
|---|----------------|
| Certified facilities, as of October 1, 2009                                     | 8,713          |
| Certification statistics, as of August 1, 2010                                  |                |
| Total certified facilities / Total accredited units                             | 8,651 / 12,432 |
| Certified facilities with FFDM <sup>2</sup> units / Accredited FFDM units       | 5,826 / 8,514  |
| FY 2010 inspection statistics, as of August 1, 2010                             |                |
| Facilities inspected  | 6,844          |
| Total units at inspected facilities   | 9,602          |
| Percent of inspections where the highest noncompliance was a:                   |                |
| Level 1 violation   | 0.9%           |
| Level 2 violation   | 14.5%          |
| Level 3 violation   | 3.5%           |
| Percent of inspections with no violation  | 81.1%          |
| Total annual mammography procedures reported, as of August 1, 2010 <sup>1</sup> | 38,823,849     |

<sup>1</sup> This number is an aggregate of the total number of procedures performed annually as reported by facilities to their accreditation bodies. Facilities are asked to disclose this information at their initial accreditation, and then at the time of their re-accreditation, which takes place once every three years. FDA began collecting these data in 1998. The aggregate does not reflect the current number of procedures performed at these facilities, but only the numbers reported by them during the three-year period prior to the current date. We have aggregated only the numbers reported by certified, non-Veterans Administration facilities.

<sup>2</sup> FFDM - Full Field Digital Mammography unit.

2009 54%

2008 40%

67%

Page Last Updated: 08/02/2010

# What's Different? (Film Screen vs. Digital)

- No more wet processors.
  - Laser printers.
- QC tests are different.
  - Determined by the manufacturer.
- Image receptor
  - Digital detector or CR plate
- Viewing Stations/Monitors
  - Might be a different manufacturer than mammo unit.
  - Might reside in different location than mammo unit.



# Records Review

- QC—Quality control
  - Follow the manufacturer's QC manual (FDA)
    - Must be most recent version (with a few exceptions)
  - SNR, CNR, MTF, Flat Field, Artifacts, SMPTE, Compression force/accuracy, monitors, laser printers, repeat analysis.
  - Corrective action documentation.
  - All other record requirements still apply.
    - Medical outcomes audit, policy/procedures, mammogram result communication.

# Quality Control Records

- Different manufacturers equipment.
  - Monitors or Viewing Stations.
  - Laser printers.
- Refer to Mammography QC manual first.
  - Does it require separate testing or is it included?
  - If required, then you must follow the manufacturers QC requirements for that piece of equipment.
  - If the manufacturer does not have a specific QC protocol—then the medical physicist will need to create one that is appropriate.

# Facility Personnel Records

## ■ Physicians

### ■ Digital training—8 hours.

- Does not have to be CEU's (does not have to be Cat. I), it is not manufacturer specific.
- Can be “on the job” training with another physician that has satisfied the digital training requirement.
- No time requirement—training does not expire.
- Starting to see this documented in newer radiologists residency programs.

### ■ Physician CEU's—15 hours (36 month period)

- Must be AMA Category I (Category A is not equivalent)
- Majority must be in breast related topics.
  - Can allow in other topics if it is beneficial to improving the quality of mammography. (ethics, legal, patient care, billing)
    - Cannot be the majority of CEU's
- International CEU's—must have a reciprocal agreement with the American Medical Association.
  - Upon return to United States—the certificate must be sent to the A.M.A. to be converted to Category I certificate.

# Facility Personnel Records

- Technologist
  - Digital training—8 hours.
    - Does not have to be CEU's, not manufacturer specific.
    - Can be “on the job” training with another technologist that has satisfied the digital training requirement.
    - No time requirement—training does not expire.
  - Technologist CEU's—15 hours (36 month period)
    - Can be any category
    - Majority must be in breast related topics.
      - Can allow in other topics if it is beneficial to improving the quality of mammography. (ethics, legal, patient care, billing)
        - Cannot be the majority of CEU's

# Facility Personnel Records

## ■ Medical Physicist

### ■ Digital training—8 hours.

- Does not have to be CEU's
- Can be “on the job” training with another physicist that has satisfied the digital training requirement.
- No time requirement—training does not expire.

### ■ Physicist CEU's—15 hours (36 month period)

- Can be any category—does not have to be mammography related.
- Majority must be in breast related topics.
  - Can allow in other topics if it is beneficial to improving the quality of mammography. (ethics, legal, patient care, billing)
    - Cannot be the majority of CEU's

# Physicist Survey-Annual

- Must perform tests that are required by the mammography manufacturers QC manual.
  - Machine
  - Viewing station/Monitors
  - Laser printers
- Other manufacturers equipment
  - Viewing station/Monitors
  - Laser printers
  - Follow procedures for that piece of equipment.
- Report must be delivered within 30 days of survey.

# Physicist Survey

## Medical Equipment Evaluation

- Must be conducted whenever a new unit is installed, a unit is disassembled & reassembled, or major components of a mammography unit are changed or repaired.
- Does the physicist have to perform a MEE in person?
  - It depends on the nature of the repair/replacement component.
  - Some can be performed by physicist oversight.

# Physicist Survery

## Medical Equipment Evaluation

- In person: (source-FDA Policy Guidance Help System)
  - AEC replacement, AEC sensor replacement.
  - FFDM detector replacement or repair
  - Collimator replacement or blade replacement.
  - X-ray tube replacement
  - Generator replacement
  - Filter replacement
  - Software modifications (alternative standard)

# Physicist Survey

## Medical Equipment Evaluation

- Oversight: (source-FDA Policy Guidance Help System)
  - Bucky replacement-FFDM detector not replaced
    - AEC sensor not replaced
  - Density control-internal adjustment
  - Collimator adjustment
  - New compression paddle
  - kVp, mA, or time internal adjustments
  - Compression thickness scale accuracy adjustment

# Physicist Presence or Oversight

- A list of common repairs, changes, or adjustments can be found on the F.D.A.'s M.Q.S.A. website in the Policy Guidance Help System.
- If you don't find a repair listed in the table, it is best to consult your medical physicist and follow their recommendations.

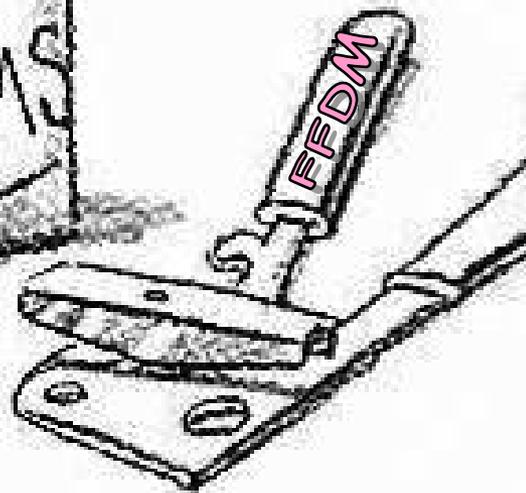
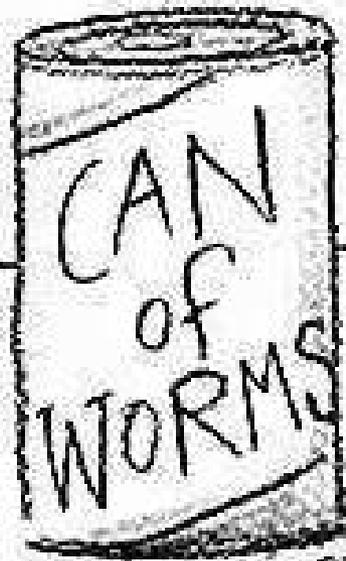
# Remote Locations

- Images interpreted or printed at another site.
  - Monitor QC records
  - Laser QC records

# QC Images/State Requirements

- QC Images-Digital or Hardcopy
  - Must be kept for 1 year.
- State Requirements
  - Quarterly review of QC records by Lead Interpreting Physician.
  - Densitometer calibration or verification.
    - Built into laser printer.
    - External

LOOKING FOR TROUBLE



# *Digital-The New Age*

- Has opened the biggest can of worms so far!
  - Images interpreted off-site.
    - Same city, different city, different state, radiologists's home, multiple sites.
    - T1 line, CD, PACS, Flashdrive, Hardcopy.
  - Images printed off-site.
    - Same city, different city, different state.

# Remote Facility-QC Sharing

- QC sharing between facilities.
  - Routine QC tests, and annual physicist surveys, MEE's, for these devices.
  - The facility that is sending their images to another facility has to be able to verify that the other facility is operating in compliance.

# QC Sharing

- If images are being interpreted or printed off-site.
  - QC records of viewing station/monitors from the reading site must be shared with the other facility.
  - QC records for the laser printer from the printing site must be shared with the other facility.
- How often? Negotiable?

# Remote QC Question

- Does the interpreting site have to score my image quality phantom before I can start performing my mammograms?
  - No. You can score the image quality phantom on your acquisition monitor or hardcopy. If passing then you can proceed with your mammograms.
  - **HOWEVER...**An image quality phantom will still need to be scored by the interpreting/printing facility to verify that the images that come from your facility are of like quality.

# PACS

- Long term storage solution for digital images.
- Must be stored in final interpretive quality.
  - May only use lossless data compression.
- Mammogram clinical image retention is the same as with film.
  - Films and reports maintained for a minimum of 5 years.
  - If no additional mammograms are performed at the facility, then the films and reports are maintained for 10 years.

# PACS

- Printing directly from PACS.
  - Must be able to print in final interpretive quality.
    - Only lossless compression; true size.
  - You may not be able to do this at your facility.
    - or may not know how.
  - Access problems.
    - May not be able to access the correct printer.
    - May not be able to access the correct film size.
  - Formatting problems.
    - Image data overlies breast tissue.
    - Image data too small.
    - Not all of required image data is present.
- Usually is correctable.

# PACS-Image Requests

- Do I have to send a hardcopy image to a requesting facility? I would rather send it on a CD.
  - It is up to the receiving facility.
- If sent on a CD, it must still be in final interpretive quality.

**A can of worms won't open itself.**

**Lucky Numbers 09, F9, 11, 02, 9D, 74, E3,  
5B, D8, 41, 56, C5, 63, 56, 88, C0**

# Machine Inspection

- Similar but different.
  - Hold to same machine standards as film/screen.
  - FFDM vs. CR
  - Digital image receptor.
  - No film to compare (coins)
- DSHS has had to rethink and retool for the inspection process.
  - New meters—Unfors XI
    - HVL, kVp, direct measurement capability
    - AGD, AEC Reproducibility
    - Waveform graph

# Unfors XI



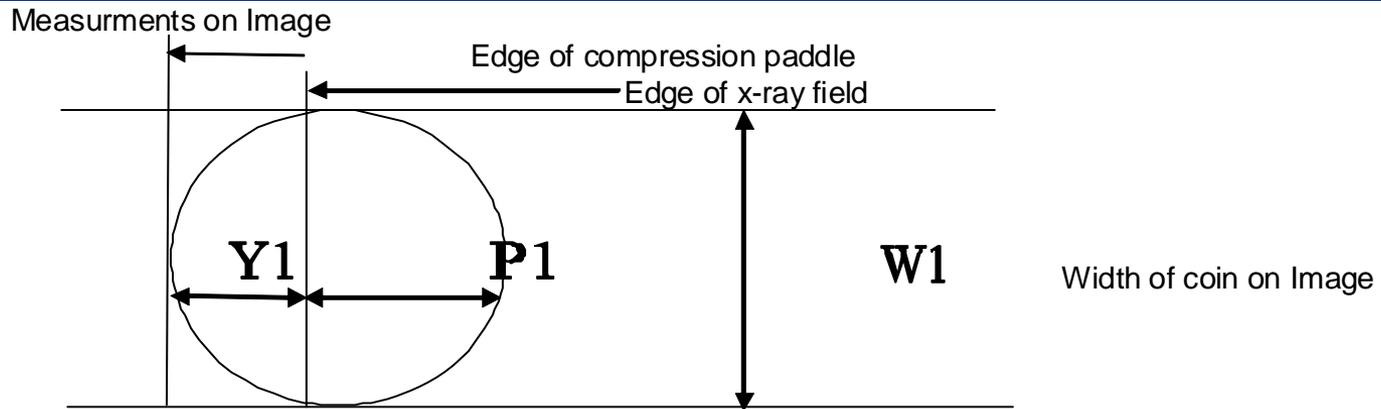
# Compression Paddle Overlap

- Still use the coin test for this.
- Print hardcopy (can be softcopy)
  - Measure the full coin
  - Measure the coin from the back edge to the chest wall edge
  - Input these values into a formula that calculates the overlap.
  - The formula calculates the magnification factor and applies this correction to the final value.

# Compression Paddle Overlap



# Compression Paddle Overlap



Source to Image Receptor Distance 66 cm.

W1 2.7 cm.

P1 2.3 cm.

Y1 0.4 cm.

W = 2.4 cm.

Y= 0.355556 cm.

Pass

Actual width of coin... for a quarter it is 2.4 cm

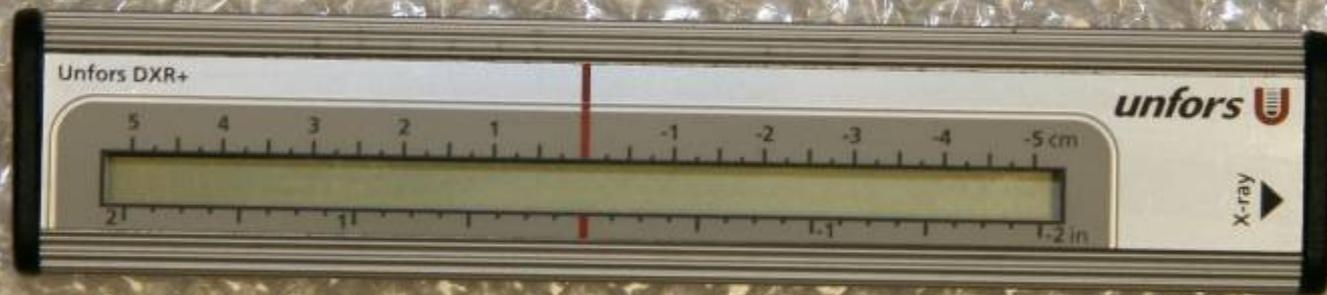
# Collimation Testing

- Fuji CR
  - Very similar to film/screen unit.
  - Able to use coins and compare hardcopy films.
    - X-ray/light field alignment, x-ray field overlap, paddle overlap.
  - Have to perform using “Physics Collimation” image processing mode.
  - All this is as described in the Fuji CR-QC manual.

# Collimation Testing

- FFDM—Had to rethink the process completely.
  - Don't have films to compare.
  - Multiple manufacturers of machines.
- DSHS needed a generic method to test equipment.
  - Unfors DXR+ digital ruler
    - Evaluates the x-ray/light field alignment.

# Unfors DXR+



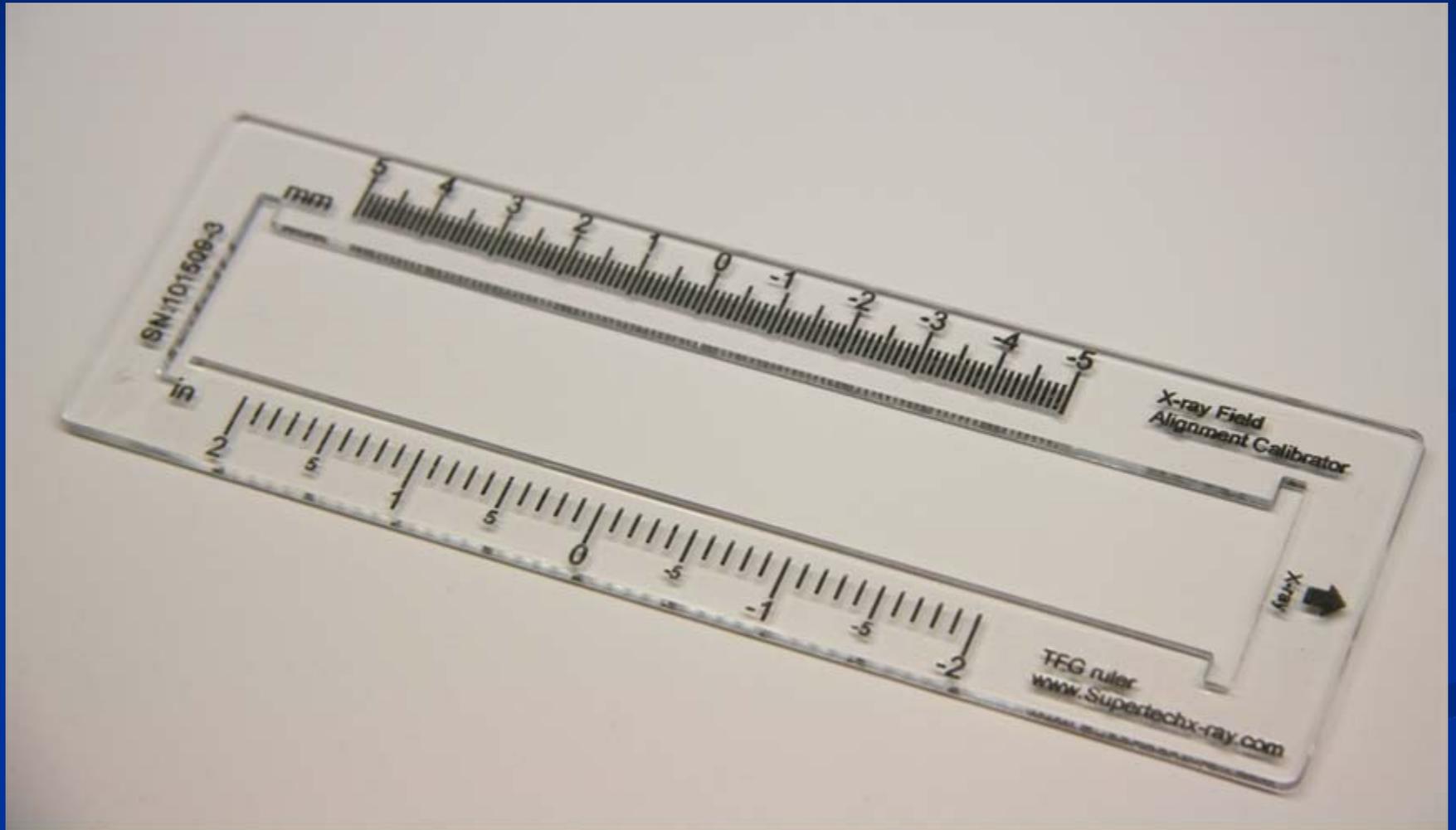
# Collimation Testing-FFDM

- X-ray Field Overlap
  - Where is the edge on a digital image receptor?
  - Where is the x-ray field edge?
  - What is the x-ray field overlap of these two?

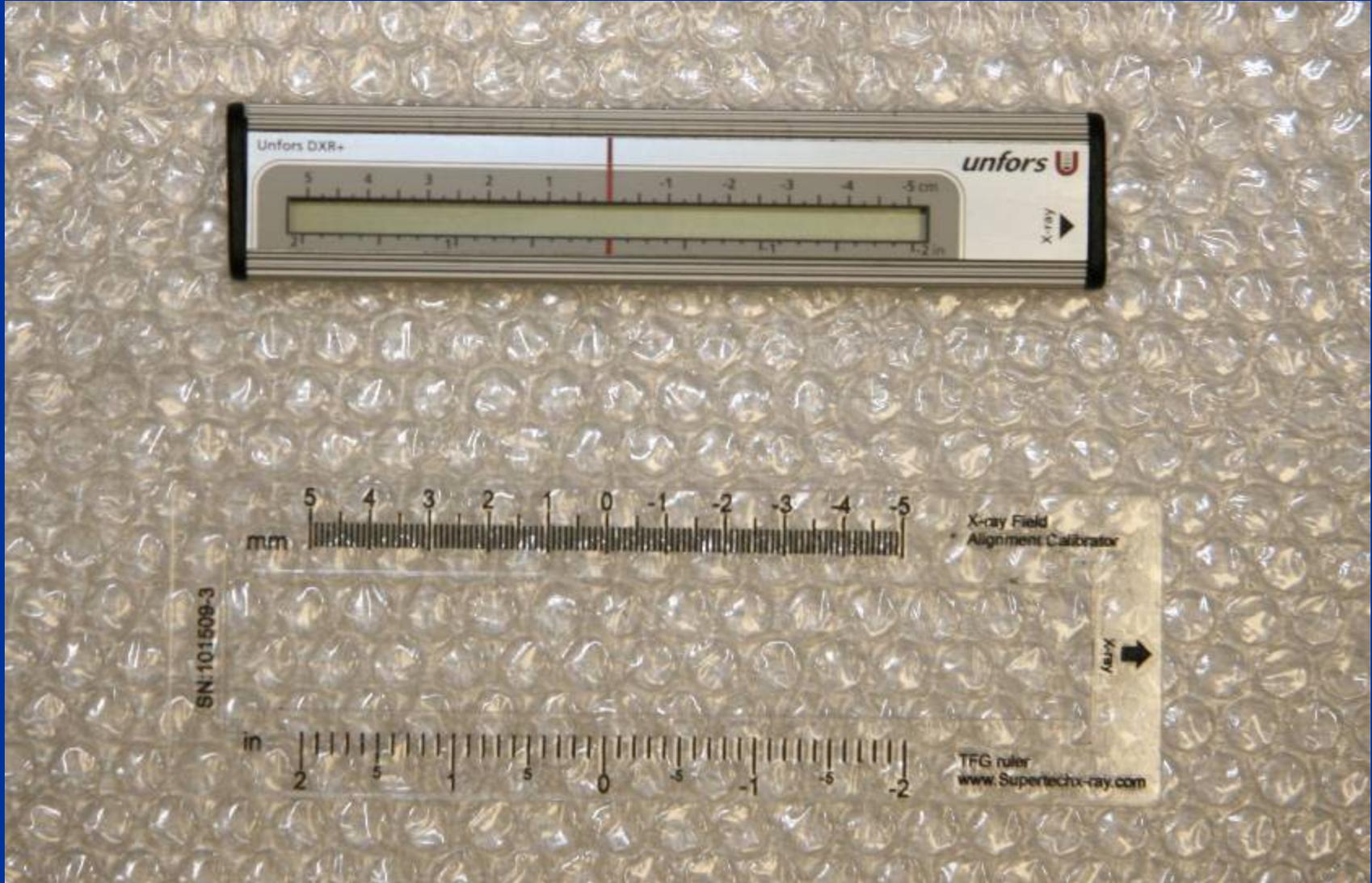
# TFG Ruler

- Works in tandem with the DXR+ ruler.
- TFG Ruler
  - Gives a visual reference of the digital image receptor edge.
- DXR+ Ruler
  - Gives us the position of the x-ray field edge.
- Then it becomes simply a comparison of the difference between the two.

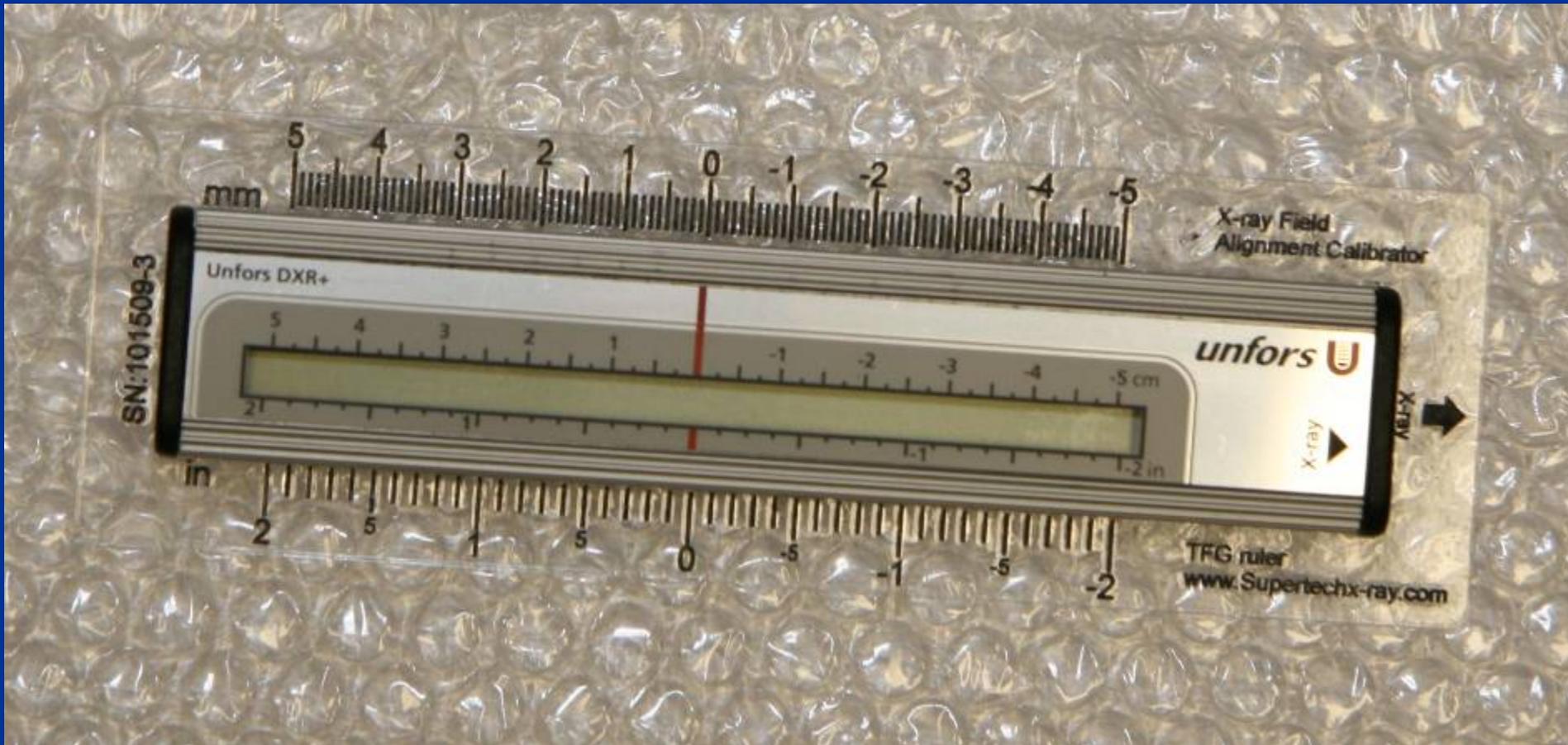
# TFG Ruler



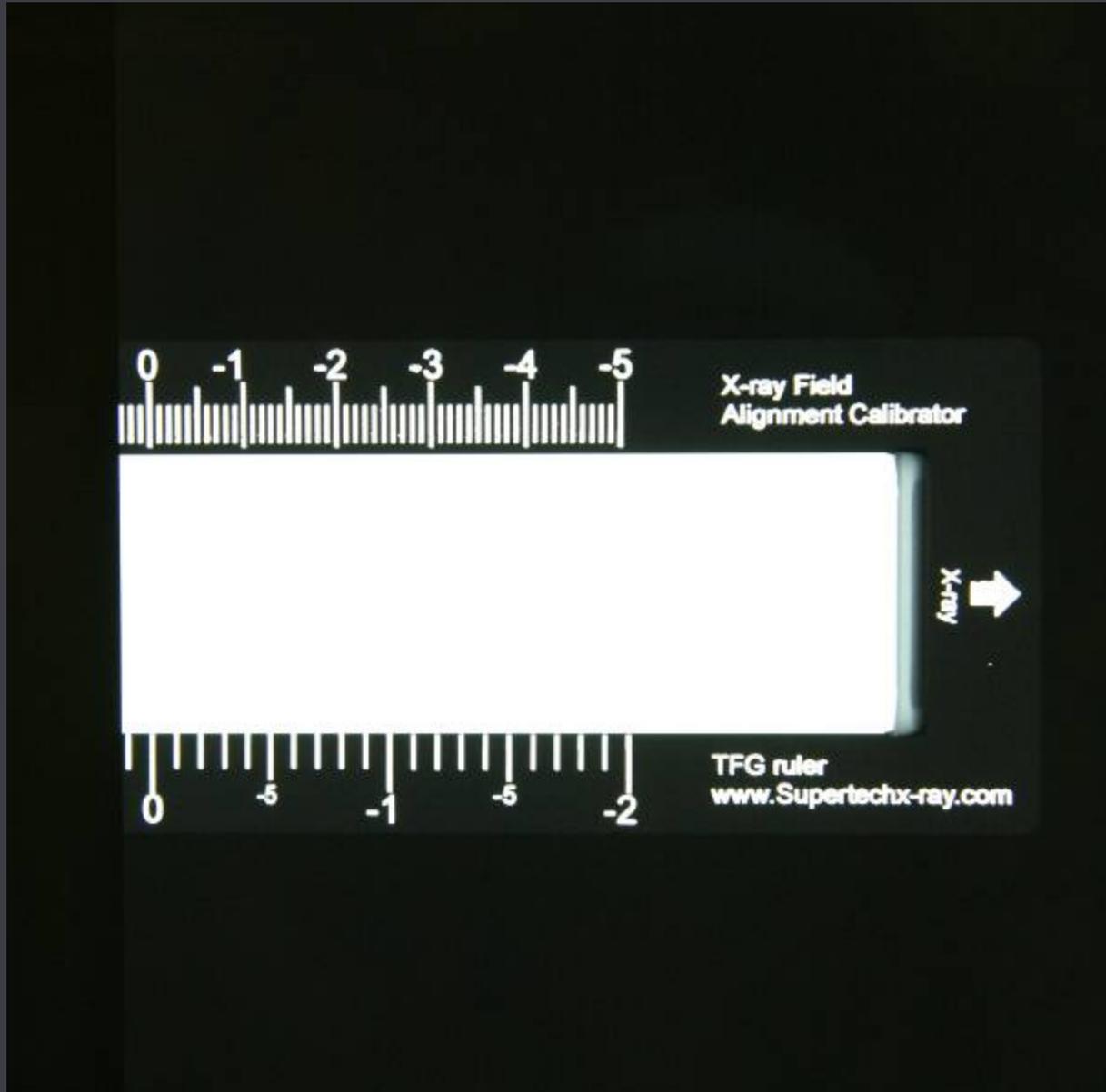
# TFG Ruler/DXR+ Ruler



# TFG Ruler/DXR+ Ruler Docked



# TFG Ruler-Image



# X-ray Field Overlap TFG Ruler Method

| <u>DXR+</u> | <u>TFG</u> | <u>X-ray Overlap</u> |
|-------------|------------|----------------------|
| +0.50 cm    | 0.0 cm     | 0.5 cm               |
| +0.50 cm    | -0.25 cm   | 0.75 cm              |
| +1.0 cm     | -0.5 cm    | 1.5 cm               |
| -0.2 cm     | -1.0 cm    | 0.8 cm               |

# Image Quality Phantom

- Review soft or hardcopy.
- Can only hold phantom to MQSA rule.
  - 4 fibers, 3 speck groups, 3 masses
- If your manufacturer holds you to a higher standard in your QC manual. You must hold yourself to this standard. (Hologic, Siemens)

# Protection of the Detector

- D.S.H.S. Inspectors utilize a sheet of aluminum to protect the detector from exposures during testing.
  - The “Cookie Sheet”



# Violations



# Violations-Severity Levels

- FDA—Levels 1, 2, 3 (Adverse Inspection Observations)
  - Level 1—Failure to meet key MQSA requirements that may compromise the quality of mammograms.
  - Level 2—Meets all key MQSA requirements but fails to meet a significant quality item.
  - Level 3—Meets all major MQSA requirements with only minor problems.
  - Repeat violations can also occur.

# Violations-Severity Levels

- State of Texas (DSHS)—Levels I, II, III, IV
- 25 TAC §289.205(k)(2)
  - Level I-Serious noncompliance that may adversely affect image quality or compromise the quality of mammography services.
  - Level II-key quality system requirements are being met, but a failure to meet one or more quality standards that may lead to a compromise of the quality of mammography services.
  - Level III-Quality system requirements are met, but minor corrective actions are required for compliance with quality standards.
  - Level IV-Quality system requirements and standards are met, but minor corrective actions are required for compliance.
  - Repeat violation can also occur—will escalate to the next severity level.

# How to Respond to a Violation Notice

## ■ FDA

- Level 1, repeat Level 1, or repeat Level 2.
  - All corrections should be made as soon as possible.
  - Written response of corrections within 15 days of receiving inspection report.
- Sent to DSHS Central Office-Mammography.
  - Mail, e-mail, or fax

# How to Respond to a Violation Notice

## ■ FDA

- Level 2, repeat Level 3.
  - All corrections should be made as soon as possible.
  - Written response of corrections within 30 days of receiving the inspection report.
- Sent to DSHS Central Office-Mammography.
  - Mail, e-mail, or fax

# How to Respond to a Violation Notice

- FDA

- Level 3.

- All corrections should be made as soon as possible.
    - No written response of corrections is required.

# How to Respond to a Violation Notice

- State of Texas—DSHS
  - A Notice of Violation will be sent by mail to you. Usually this will be sent to the R.S.O.
  - Corrective actions should be initiated as soon as possible.
  - A written response of corrections within 30 days of receipt of Notice of Violation.
  - A written response is required for all Severity Levels of violations.

# Certifying Body

- The State of Texas is a Certifying Body with the F.D.A.
  - Texas performs all of the duties under M.Q.S.A. and essentially becomes the F.D.A. for the state.
- Since you may have responded to a violation under the F.D.A., the Notice of Violation from the State may not require a response.

# Escalated Enforcement

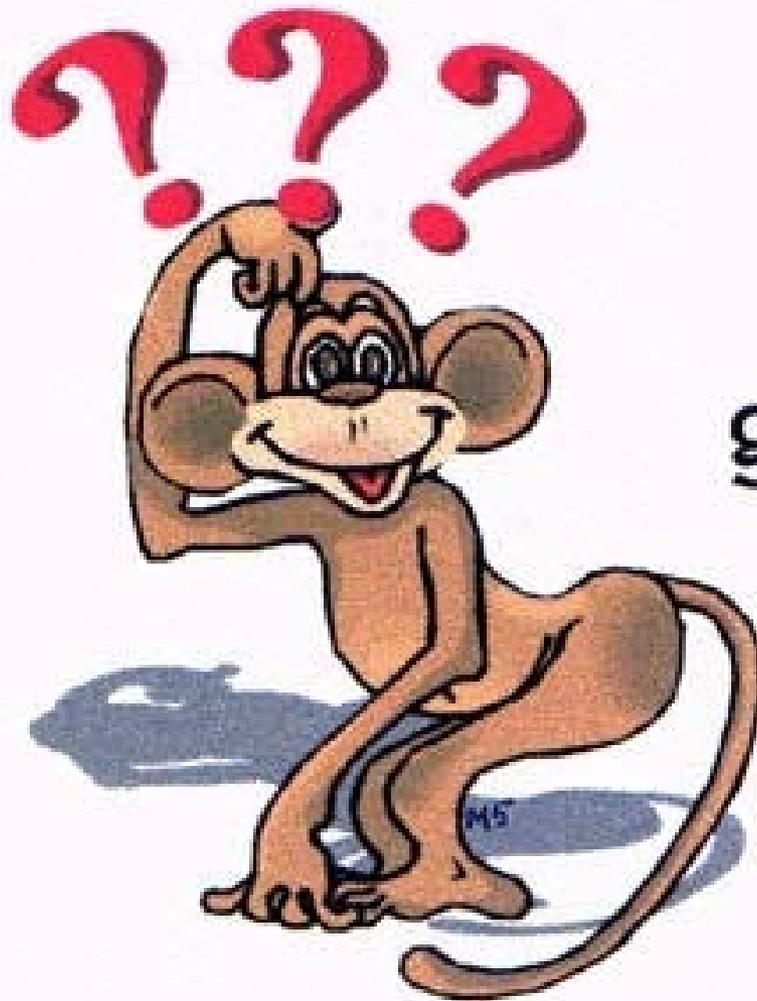
- If violations are severe enough, escalated enforcement review may occur.
  - All Level I violations
  - Two or more Level II violations.
  - Several other scenarios that could result in review.
- Enforcement Review Committee
  - Reviews each case and decides if escalated enforcement is warranted.
  - Assess administrative penalties.

# Other Actions

- Emergency Orders
- Impoundment Orders
- Additional Mammography Reviews
  - Conducted by the Accrediting Body (ACR or Texas)
    - Random
    - Targeted

# Conclusion

- We are all after the same thing.
  - Good quality mammograms that are performed in a safe manner.
- Inspection is just part of the quality process.
  - Medical physicists
  - QC technologists
  - MQSA Inspectors



Questions  
are  
guaranteed in  
life;  
Answers  
aren't.