

Film-Screen Mammography QA: What You Need to Know

Beth Schueler
Mayo Clinic Rochester

Objectives

- For those new to mammography:
 - Overview of what you need to do as a medical physicist
 - Specific details of how to perform tests will not be reviewed here – best learned in a hands-on environment
- For those who are experienced:
 - tips for improving efficiency
 - focusing the testing process on items that are most likely to fail

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Medical Physicist Responsibilities

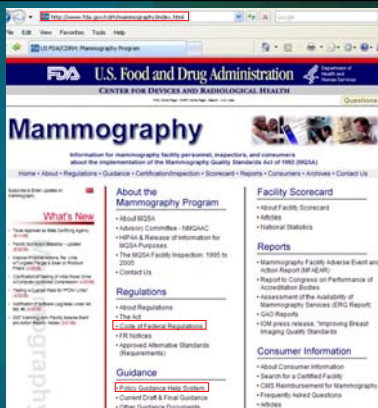
- Annual physics survey
- Equipment Performance Evaluation
 - Required for
 - New mammography units or processors
 - Disassembled and reassembled mammography units and processors
 - After mammography units or processors have undergone a major repair
 - Includes annual QC tests and Medical Physicist's Checklist

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Annual Physics Survey

- CFR Part 900 Quality Mammography Standards
 - 900.12(e)(5) Annual quality control tests
 - 900.12(e)(2) Image quality evaluation
- Can be found at the FDA website
 - <http://www.fda.gov/cdrh/mammography/index.html>
 - Includes rules and guidance documents

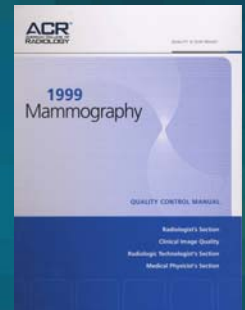
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Annual Physics Survey

- ACR Mammography QC Manual 1999 provides recommendations for performance testing that complies with MQSA
 - ACR and MQSA tests and action limits differ in some cases



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ACR QC Manual	
1. Unit Assembly	
2. Collimation	
3. System Resolution	
4. AEC Performance	
5. Uniformity Screen Speed	
6. Artifact Evaluation	
7. Image Quality Evaluation	
8. kVp Accuracy/Reprod.	
9. Beam Quality (HVL)	
10. Breast Dosimetry	
11. Viewbox Luminance	

ACR QC Manual	MQSA 900.12(e)
1. Unit Assembly	(5)(i) AEC Performance
2. Collimation	(5)(ii) kVp Accuracy/Reprod.
3. System Resolution	(5)(iii) Focal Spot Condition
4. AEC Performance	(5)(iv) Beam Quality (HVL)
5. Uniformity Screen Speed	(5)(v) Entrance Air Kerma/Reprod.
6. Artifact Evaluation	(5)(vi) Dosimetry
7. Image Quality Evaluation	(5)(vii) Collimation
8. kVp Accuracy/Reprod.	(5)(viii) Uniformity Screen Speed
9. Beam Quality (HVL)	(5)(ix) Artifact Evaluation
10. Breast Dosimetry	(5)(x) Radiation Output
11. Viewbox Luminance	(5)(xi) Decompression
	(2) Image Quality Evaluation

ACR QC Manual	MQSA 900.12(e)
1. Unit Assembly	(5)(xi) Decompression
2. Collimation	(5)(vii) Collimation
3. System Resolution	(5)(iii) Focal Spot Condition
4. AEC Performance	(5)(i) AEC Performance
5. Uniformity Screen Speed	(5)(viii) Uniformity Screen Speed
6. Artifact Evaluation	(5)(ix) Artifact Evaluation
7. Image Quality Evaluation	(2) Image Quality Evaluation
8. kVp Accuracy/Reprod.	(5)(ii) kVp Accuracy/Reprod.
9. Beam Quality (HVL)	(5)(iv) Beam Quality (HVL)
10. Breast Dosimetry	(5)(vi) Dosimetry, (5)(v) Entrance Air Kerma/Reprod., (5)(x) Radiation Output
11. Viewbox Luminance	

1. Unit Assembly

- Unit is mechanically stable
- Cassettes do not slip when gantry is angled
- Compressed breast thickness scale is accurate to within 5 mm
 - Test with a phantom at 2, 4, and 6 cm thickness
- MQSA (5)(xi) Decompression:
 - Automatic decompression can be overridden
 - Status is displayed
 - Compression can be released manually if power fails

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2. Collimation

- X-ray to light field alignment
- X-ray to image receptor alignment
- Compression paddle chest wall alignment to image receptor



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2. Collimation

- Repeat for all routinely used collimator / bucky / paddle / target material combinations
 - MQSA: Only those combinations used for producing full-field clinical images in the contact mode
- Recommend that magnification mode collimation testing be included

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2. Collimation

- Action Limits:
 - X-ray to light:
 - L + R or anterior + chest deviations > 2% SID
 - X-ray to IR:
 - clipping is visible at chest wall
 - clipping R or L > 2% SID (ACR only)
 - clipping anterior > 4% SID (ACR only)
 - x-ray extends beyond IR > 2% SID on any side
 - Compression paddle:
 - edge visible in image
 - projects beyond chest wall > 1% SID

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3. System Resolution

- Evaluated with a high contrast resolution pattern
 - within 1 cm of chest wall
 - centered L-R
 - 4.5 cm above breast support surface
- Technique: AEC with kVp used for standard breast



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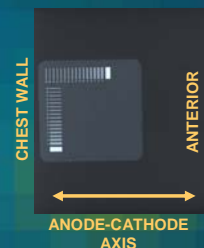
Clinical Technique for a Standard Breast

- Target, filter and kVp used for 4.2 cm thick 50% glandular breast
 - Same as used for Image Quality Evaluation
- What if this is not known for sure for a new installation?
 - Use best guess
 - MQSA guidance recognize it could change

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3. System Resolution

- Repeat for all target materials, focal spots, film-screen combinations
- View pattern on the film with a 7-10X magnifier
- Action limits:
 - < 11 lp/mm perpendicular to the A-C axis
 - < 13 lp/mm parallel to the A-C axis



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4. AEC System Performance

- Thickness / kVp tracking
 - Homogeneous phantom 2, 4, 6, 8 cm thick representative of typical breast size
 - Appropriate kVp for each thickness
- Image mode tracking
 - 4 cm thickness for small bucky, large bucky, magnification stand
- Density control function

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4. AEC System Performance

- Action limit:
 - Thickness / kVp tracking:
 - 2-6 cm thickness film OD > ± 0.15 OD of the mean
 - Image mode tracking:
 - Overall film OD > ± 0.3 OD of the mean
 - includes image modes and 8 cm thickness
 - MQSA: required for Equipment Performance Evaluation only
 - Recommend testing all image modes annually
 - Film optical density < 1.20 OD

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Multiple AEC Detectors

- If the system has a different AEC detector for each bucky:
 - Test thickness / kVp tracking on each one
- If the system has multiple AEC detectors in a single bucky that are individually selectable
 - Test thickness / kVp tracking on one detector and 4 cm thickness on all others
 - Must be within ± 0.3 OD of the mean

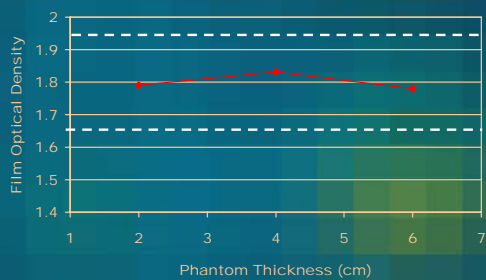
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AEC Calibration Methods

- Some systems have a separate AEC calibration for each kVp
- Automatic kVp selection may result in variable results
- Recommend testing all kVp values in the clinically used range for these specific systems

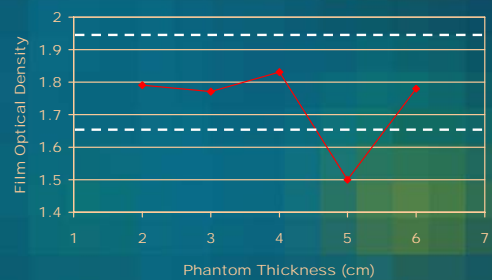
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Example 1: Thickness/kVp Tracking



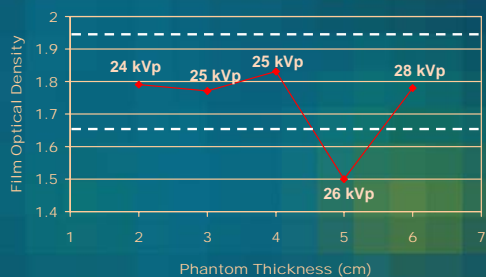
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Example 1: Thickness/kVp Tracking



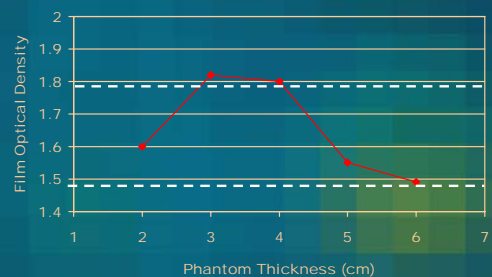
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Example 1: Thickness/kVp Tracking



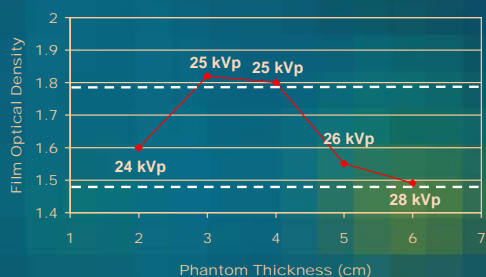
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Example 2: Thickness/kVp Tracking



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Example 2: Thickness/kVp Tracking



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4. AEC System Performance

- Density control function (ACR only)
 - 4 cm thickness at clinically-used density settings (typically -2 to +2)
- Action limit:
 - Steps should be approximately 0.15 OD change (12%-15% mAs change)

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Mammographic DCF Test Tool

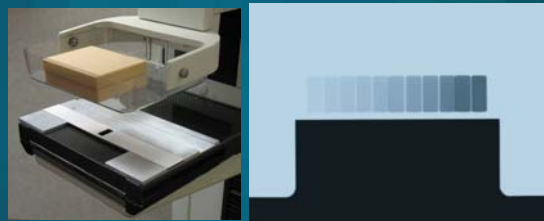
- Allows measurement of multiple AEC exposure ODs on a single film
 - Eliminates variations in film emulsion and processing



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Mammographic DCF Test Tool

- Available from Gammex-RMI
 - <http://www.gammex.com/>



5. Uniformity of Screen Speed

- Expose all cassettes using AEC
- Phantom: uniform 4 cm thick PMMA that covers the entire image receptor
- Image a control cassette multiple times to ensure repeatability of AEC and processor
- Review all images for presence of screen artifacts

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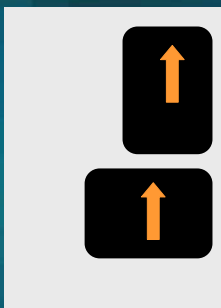
5. Uniformity of Screen Speed

- Action limit:
 - Difference between maximum and minimum film OD > 0.3 OD
- If groups of cassettes with different size or speed class are outside this range:
 - Appropriate compensation should be specified on the technique chart
 - Groups can be evaluated separately

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6. Artifact Evaluation

- Phantom: uniform 4-cm thick PMMA that covers the entire image receptor
- Make 2 identical exposures on the same cassette and process lengthwise and widthwise



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6. Artifact Evaluation

- Repeat for
 - Both image receptor sizes
 - Magnification stand and small focal spot
 - Each filter
 - Use large bucky for filter evaluations
- Review films for artifacts

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6. Artifact Evaluation

- Processor artifacts will be oriented on both films in the same direction relative to the direction of film feed



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6. Artifact Evaluation

- X-ray unit artifacts will be oriented on both films in the same direction relative to the long axis of the film



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Artifact Problem-solving

- To isolate filter or processor artifacts
 - Eliminate grid/bucky cover artifacts by placing cassette and phantom on top of the breast support tray



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Artifact Problem-solving

- To isolate grid artifacts
 - Image the grid in a stationary position
 - Imaging method will vary depending on the system design
 - Some options include:
 - If system allows exposure without a bucky, detach bucky from the gantry and image the grid with a cassette in the bucky
 - If system requires a bucky to be in place, install one and place the other on top of it and image the grid with a cassette inside

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6. Artifact Evaluation

- For units with multiple targets:
 - All focal spot / target / filter combinations used clinically must be tested for Equipment Performance Evaluation
 - e.g. Mo/Mo/LFS, Mo/Rh/LFS, Rh/Rh/LFS, Mo/Mo/SFS, Mo/Rh/SFS, Rh/Rh/SFS – 6 combos
 - An alternative standard allows for testing each focal spot, target and filter (not each combination) for annual physics survey only
 - e.g. Mo/Mo/LFS, Mo/Rh/LFS, Rh/Rh/LFS, Mo/Mo/SFS, Mo/Rh/SFS, Rh/Rh/SFS – 3 combos

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7. Image Quality Evaluation

- ACR Mammography Accreditation Phantom with contrast disc
- AEC exposure using clinical technique factors for a 4.2-cm thick breast
 - Verify with technologist (kVp, target, filter, density control setting, AEC cell location)



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7. Image Quality Evaluation

- Action limit:
 - Background density < 1.4 OD
 - (MQSA < 1.2 OD)
 - Change by > 0.20 OD
 - Density difference < 0.40
 - Change by > 0.05



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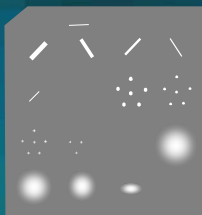
7. Image Quality Evaluation

- Additional recommendations:
 - Background density
 - 1.8 OD or higher
 - within 0.20 OD of facility's target
 - Density difference
 - 0.55 or higher
 - within 0.05 of facility's target
 - All units producing films that are read at a specific location should have the same target values

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Phantom Scoring: Fibers

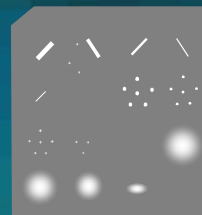
- Use optimal viewing conditions and a magnifying lens
- Count from thickest to thinnest
- Count as 0.5 if not all but more than half is visible
- Deduct for a fiber-like artifacts
 - from the last whole or half fiber counted only



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Phantom Scoring: Specks

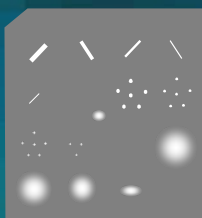
- Count from largest to smallest group
- Count as 1
 - if 4 or more specks in the group are visible
- Count as 0.5
 - if 2 or 3 specks visible
- Deduct for a speck-like artifacts 1 for 1 speck
 - from the last whole or half group counted only



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Phantom Scoring: Masses

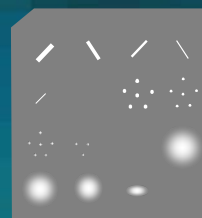
- Count from largest to smallest
- Count as 1
 - if > 75% perimeter is visible and generally circular
- Count as 0.5
 - if visible and not generally circular
- Deduct for a mass-like artifacts
 - from the last whole or half mass counted only



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7. Image Quality Evaluation

- Action limit:
 - < 4 fibers, < 3 speck groups, < 3 masses visible
 - Change in score of > 0.5 from previous measurement



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8. kVp Accuracy and Reproducibility

- kVp accuracy
 - Measure at these settings:
 - Lowest clinical kVp that the test device can measure
 - Most commonly used kVp (typically the same as the phantom kVp)
 - Highest available clinical kVp
- kVp reproducibility
 - Make 4 exposures at the most commonly used kVp

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8. kVp Accuracy and Reproducibility

- Action limits:
 - Measured kVp > 5% from set kVp
 - Coefficient of variation (standard deviation / mean) > 0.02

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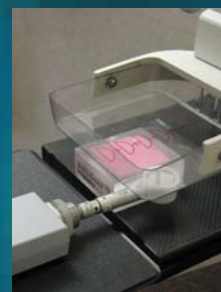
9. Beam Quality Assessment (HVL Measurement)

- Include compression paddle
 - Use type 1145 aluminum sheets (99.9% purity)
 - Repeat for all target / filter combinations
- Action limit:
 - MQSA: $HVL < kVp/100$ (mm Al)
 - ACR: $HVL < kVp/100 + 0.3$ (mm Al) or
 - $HVL > kVp/100 + 0.12$ (Mo/Mo),
 - $HVL > kVp/100 + 0.19$ (Mo/Rh),
 - $HVL > kVp/100 + 0.22$ (Rh/Rh)

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10. Breast Dosimetry

- Breast entrance exposure
 - Measure for ACR mammography phantom using clinical technique factors
- AEC Reproducibility
 - Repeat 4 times
- Radiation output rate



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10. Breast Dosimetry

- Action limit:
 - Coefficient of variation > 0.05 for either exposure or mAs
- Multiple AEC Detectors
 - If different AEC detector for each bucky:
 - Test AEC reproducibility on each one
 - If multiple AEC detectors in a single bucky that are individually selectable
 - Test AEC reproducibility on one only

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Average Glandular Dose (D_g)

- $D_g = D_{gN} \times X_{ESE}$
 - where D_g = average glandular dose,
 D_{gN} = glandular dose to exposure factor,
and X_{ESE} = entrance skin exposure
 - D_{gN} is a function of filter/target, kVp and HVL
 - Tables 1-3 in ACR Quality Control Manual, 1999
- Action limit:
 - $D_g > 3$ mGy

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Radiation Output Rate

- Measure 4.5 cm above breast support tray
 - At 28 kVp, Mo target, Mo filter, > 3 sec manual exposure time
 - Maximum SID
 - With compression paddle in place
- Action limit:
 - Radiation output rate < 7.0 mGy/sec

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11. Viewbox Luminance and Room Illuminance

- Photometers
 - Vendors include:
 - UDT Instruments
 - Quantum Instruments
 - Various display monitor luminance measuring units (MSfit ACT, ...)
- 30 min warm-up time for viewboxes needed for stable measurements



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11. Viewbox Luminance and Room Illuminance

- Action limits:
 - Viewbox luminance < 3 kcd/m²
 - Illuminance on viewbox surface and seen by observer > 50 lux
- Most commercially available rollo-scopes for mammography can achieve > 6 kcd/m²
 - Change in luminance of 1-2 kcd/m² generally indicates a bulb or ballast needs to be replaced

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Report

- Preliminary report recommended
 - Let the facility know about any repairs needed at the time of the survey if possible
- Final report required
 - Returned within 30 days of the survey date
 - Dated with report date
 - Signed
- Include a review of technologist's QC tests

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Corrective Action

- For Equipment Performance Evaluation
 - All test failures must be corrected prior to patient use
- For annual QC survey
 - Image quality evaluation or Average glandular dose:
 - Failures must be corrected prior to patient use
 - All other tests:
 - Failures must be corrected within 30 days of survey date

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Test Equipment Calibration

- Air kerma measurement device must be calibrated at least once every 2 years and after a repair
 - NIST traceable calibration laboratory
- Record calibration date on survey report
- Keep letter or certification from calibration laboratory for possible review

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Practical Tips

- Talk with the technologist before you start
 - Phantom technique
 - kVp, typical mAs, AEC mode, AEC cell location, density control function setting, target OD and DD
 - Technique chart use
 - What techniques do they actually use?
 - Does the chart need changes?
 - What density function control settings do they use in practice?
 - Any specific equipment issues or problems?

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Practical Tips: QC Test Order

- kVp first
 - Must pass for most other test results to be valid
- Dosimeter tests
 - HVL, Output, Dose and Image Quality
 - Use last Dose image for IQ evaluation

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Practical Tips: QC Test Order

- Small bucky
 - Collimation, Resolution
 - AEC
 - Test compressed breast thickness scale readout with different phantom thicknesses
 - Screen Speed Uniformity, Artifact
 - Use repeat Screen Speed Uniformity images for Artifact Evaluation

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Practical Tips: QC Test Order

- Large bucky, magnification stand
 - Complete applicable tests
- Reading room
 - Score IQ phantom image
 - Viewbox luminance and room illuminance

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Common Test Failures

QC Test	# of Failures Found *
Artifact Evaluation:	35
Processor (27)	
X-ray unit (5)	
Cassette (3)	
Collimation:	34
Light to x-ray (12)	
X-ray to IR (10)	
Compression paddle chest (12)	

61 * Out of 110 surveys

Common Test Failures

QC Test	# of Failures Found *
Unit Assembly: Thickness readout	31
AEC: Thickness/kVp tracking	24
Uniformity Screen Speed	5
System Resolution	0
Image Quality Evaluation	0
kVp Accuracy/Reprod.	0
Beam Quality (HVL)	0
Breast Dosimetry	0

62 * Out of 110 surveys

Mammography Equipment Evaluation

- Required for
 - New mammography units or processors
 - Disassembled and reassembled mammography units and processors
 - After mammography units or processors have undergone a major repair
- What is considered a “major repair”?

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Major Repairs

- Defined in Policy Guidance Help System
 - Under Index: Medical Physics Survey: Medical Physics Annual Survey
- Major repairs require medical physicist conducts evaluation on-site
- For other repairs, FDA recommends
 - Medical physicist oversight (review of tests performed by the technologist or service engineer)
 - Medical physicist involvement optional

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Item	Major Repair	MP Involvement
AEC sensor replacement	Y	On-site testing
X-ray tube replacement	Y	On-site testing
Filter replacement	Y	On-site testing
Collimator/blade replacement	Y	On-site testing
Collimator adjustment	N	Oversight
Density control internal adjustment	N	Oversight
Bucky replacement (no AEC sensor)	N	Oversight
Processor roller replacement	N	Optional

Medical Physicist's Checklist

- Items found in 900.12(b)
- Includes items related to x-ray equipment:
 - Magnification between 1.4 and 2.0
 - Focal spot / target material displayed to user
 - Hands-free power-driven compression from both sides of the patient
- Items related to processing and viewing:
 - Hot light and film-masking devices available

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Medical Physicist's Checklist

- Can be downloaded as an Excel file from ACR website www.acr.org

MEDICAL PHYSICIST'S CHECKLIST MQSA REQUIREMENTS FOR MAMMOGRAPHY EQUIPMENT			
Facility Name:		Model:	
Unit Manufacturer:		Year Bld:	
Serial Number:		Name Bld:	
Medical Physicist:		Survey Date:	
Signature:			
Criteria	ASB Item Number	Requirement	Meets Requirement (If not, please explain)
Position of tube angle indicator	501	The indicator shall be visible in every field of view position when it is designed to operate. Once located, any field position it indicates shall be accurate within 1.0°.	3.0/4/5/6/7/8/9/10/11/12/13/14/15/16/17/18/19/20/21/22/23/24/25/26/27/28/29/30/31/32/33/34/35/36/37/38/39/40/41/42/43/44/45/46/47/48/49/50/51/52/53/54/55/56/57/58/59/60/61/62/63/64/65/66/67/68/69/70/71/72/73/74/75/76/77/78/79/80/81/82/83/84/85/86/87/88/89/90/91/92/93/94/95/96/97/98/99/100
	502	This mechanism shall not be in the field of view of patient.	3.0/4/5/6/7/8/9/10/11/12/13/14/15/16/17/18/19/20/21/22/23/24/25/26/27/28/29/30/31/32/33/34/35/36/37/38/39/40/41/42/43/44/45/46/47/48/49/50/51/52/53/54/55/56/57/58/59/60/61/62/63/64/65/66/67/68/69/70/71/72/73/74/75/76/77/78/79/80/81/82/83/84/85/86/87/88/89/90/91/92/93/94/95/96/97/98/99/100
	503	On devices using screen film image receptors shall provide, as a minimum, two parallel side image receptors of 18 x 24 cm and 24 x 30 cm.	3.0/4/5/6/7/8/9/10/11/12/13/14/15/16/17/18/19/20/21/22/23/24/25/26/27/28/29/30/31/32/33/34/35/36/37/38/39/40/41/42/43/44/45/46/47/48/49/50/51/52/53/54/55/56/57/58/59/60/61/62/63/64/65/66/67/68/69/70/71/72/73/74/75/76/77/78/79/80/81/82/83/84/85/86/87/88/89/90/91/92/93/94/95/96/97/98/99/100
Image receptor size	401	On devices using screen film image receptors shall be equipped with moving grid indicators to all image receptors.	3.0/4/5/6/7/8/9/10/11/12/13/14/15/16/17/18/19/20/21/22/23/24/25/26/27/28/29/30/31/32/33/34/35/36/37/38/39/40/41/42/43/44/45/46/47/48/49/50/51/52/53/54/55/56/57/58/59/60/61/62/63/64/65/66/67/68/69/70/71/72/73/74/75/76/77/78/79/80/81/82/83/84/85/86/87/88/89/90/91/92/93/94/95/96/97/98/99/100
	402	On devices using non-screen film image receptors shall be equipped with grid indicators to all image receptors.	3.0/4/5/6/7/8/9/10/11/12/13/14/15/16/17/18/19/20/21/22/23/24/25/26/27/28/29/30/31/32/33/34/35/36/37/38/39/40/41/42/43/44/45/46/47/48/49/50/51/52/53/54/55/56/57/58/59/60/61/62/63/64/65/66/67/68/69/70/71/72/73/74/75/76/77/78/79/80/81/82/83/84/85/86/87/88/89/90/91/92/93/94/95/96/97/98/99/100
	403	On devices using non-screen film image receptors shall be equipped with grid indicators to all image receptors.	3.0/4/5/6/7/8/9/10/11/12/13/14/15/16/17/18/19/20/21/22/23/24/25/26/27/28/29/30/31/32/33/34/35/36/37/38/39/40/41/42/43/44/45/46/47/48/49/50/51/52/53/54/55/56/57/58/59/60/61/62/63/64/65/66/67/68/69/70/71/72/73/74/75/76/77/78/79/80/81/82/83/84/85/86/87/88/89/90/91/92/93/94/95/96/97/98/99/100
Image receptor and grid ratio	504	On devices intended to be used with grid ratios shall be equipped with grid indicators to all image receptors.	3.0/4/5/6/7/8/9/10/11/12/13/14/15/16/17/18/19/20/21/22/23/24/25/26/27/28/29/30/31/32/33/34/35/36/37/38/39/40/41/42/43/44/45/46/47/48/49/50/51/52/53/54/55/56/57/58/59/60/61/62/63/64/65/66/67/68/69/70/71/72/73/74/75/76/77/78/79/80/81/82/83/84/85/86/87/88/89/90/91/92/93/94/95/96/97/98/99/100
	505	On devices intended to be used with grid ratios shall be equipped with grid indicators to all image receptors.	3.0/4/5/6/7/8/9/10/11/12/13/14/15/16/17/18/19/20/21/22/23/24/25/26/27/28/29/30/31/32/33/34/35/36/37/38/39/40/41/42/43/44/45/46/47/48/49/50/51/52/53/54/55/56/57/58/59/60/61/62/63/64/65/66/67/68/69/70/71/72/73/74/75/76/77/78/79/80/81/82/83/84/85/86/87/88/89/90/91/92/93/94/95/96/97/98/99/100

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Field Light Illumination

- 900.12(b)(5) Illumination of not less than 160 lux at the maximum SID
- Difference between readings with and without field light on
- Photometer



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Compression Paddle Deflection

- 900.12(b)(8)(ii)(B) The compression paddle shall be flat and parallel to the breast support table and shall not deflect from parallel by more than 1.0 cm at any point on the surface of the compression paddle when compression is applied.
 - Measurement procedure found in Policy Guidance Help System
 - Under Index: Compression Device: Compression paddle

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Compression Paddle Deflection

- Compress foam or tennis balls to 111 N (25 lbs)
- Measure the height of each corner of the paddle above the breast tray
- Maximum deviation < 1.0 cm



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Compression Paddle Deflection

- 900.12(b)(8)(ii)(C) Equipment intended by the manufacturer's design to **not be flat and parallel** to the breast support table during compression shall meet the manufacturer's design specifications and maintenance requirements.

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Compression Paddle Deflection

- Example: Hologic Fully Automatic Self-adjusting Tilt (FAST) Paddle
 - Designed to flex to conform to tissue
 - Manufacturer specification:
 - 18x24 cm: 1.5 cm deflection at 107 N (24 lbs)
 - 24x30 cm: 2.25 cm deflection at 138 N (31 lbs)

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Information Resources

- FDA Mammography website
 - <http://www.fda.gov/cdrh/mammography/index.html>
 - CFR Part 900.12 Quality Mammography Standards
 - Policy Guidance Help System
- ACR Mammography QC Manual (1999)
- ACR website
 - <http://www.acr.org/>
 - Test data forms in Excel

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Information Resources

- Physics QC Test data forms in Excel with formulas (Doug J. Simpkin, Ph.D.)
 - <http://www.geocities.com/djsimpkin/>

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