What is FFDM QC and why is it important?

What to know before you start

Overview and compare QC tests

Key take home points

Introduction

MQSA
- Mammography Quality Standards Act

ACR
- American College of Radiology

Certified Statistics – Past Year

<table>
<thead>
<tr>
<th></th>
<th>July 1, 2007</th>
<th>July 1, 2008</th>
<th>Difference</th>
</tr>
</thead>
<tbody>
<tr>
<td>Total Certified Mammography Facilities</td>
<td>8,837</td>
<td>8,714</td>
<td>-123</td>
</tr>
</tbody>
</table>

In FFDM, the manufacturer designs and mandates their own QC program and action limits.

In FFDM, you must the manufacturers’ QC program.
Quality Control: Why?

- Reduce exposure to patients and personnel
- Consistent image quality
- Detect and correct for potential problems, before they impact image quality

What is Quality Control?

- Determination of what is “Normal”
- Detection of what is “Abnormal”
- Understanding of how to return to “Normal” from “Abnormal”
- In particular, in FFDM, how do you know what you are seeing is what it is supposed to be?

Before You Begin QC

- **Golden Rules for FFDM QC**
  - Must use manufacturer’s QC procedures
    - Mandate action limits
  - Manufacturers’ QC may refer to Monitor & Printer
  - Multimodality Workstations have own separate QC
  - Printers may have their own QC
  - Most failures result in stopping clinical imaging until failure can be corrected

Before You Begin

- Obtain proper training & CE credits (8 hours)
  - Hands-on training on actual unit:
    - Mechanics
    - Software
    - Artifacts
  - Learn vendor specific tests and tricks
Before You Begin

- Must have proper continuing experience:
  - 2 facilities
  - 6 units
  - Within last 2 years

Before You Begin

- Note:
  - For new unit: Must use most current version
  - For renewal unit: Can use older version (version used when tested previously)

Before You Begin

- ACR Accreditation - www.acr.org
  - Physics forms
  - GE Senographe 2000D, DS, and Essential
  - Fischer Senoscan
  - Lorad Selenia
  - Siemens Novation
  - Fuji FCRm
    - Note: if using unit for both screen-film & CR, you must accredit for both

- FDA Accreditation
  - www.fda.gov/cdrh/mammography/
  - Other vendors when approved

Before You Begin

Before You Begin

Before You Begin

Before You Begin

Before You Begin

Before You Begin
Before You Begin

MEDICAL PHYSICIST’S MAMMOGRAPHY QC TEST SUMMARY
Full-Field Digital – General Electric

1. Plot Trend
2. Quantitative Image Quality analysis (Di Top on each
3. Chest Wall Missed Tissue (Light Field) or Full Coverage of Receptor
4. MTF measurement (2000D or DS) in diameter
5. Evaluation of Image Spot/Filters
6. Check Image MTF

Collimation

- **Screen-Film Mammo**
  - X-ray field aligns with the light field
  - Collimator allows full coverage of receptor
  - Chest wall edge of compression paddle aligns with chest wall of receptor

- **FFDM**
  - Same
  - Multiple target/filters and/or multiple paddle positions
  - Chest Wall Missed Tissue
  - Compression Plate Overlap on the Chest Wall Side

Limiting Spatial Resolution

- **Screen-Film Mammo**
  - Line-pair test tool
  - Focal spot

- **FFDM**
  - Line-pair test tool
  - Focal spot
  - Detector & imaging chain

Spatial Resolution

<table>
<thead>
<tr>
<th></th>
<th>Fuji FCRn</th>
<th>GE 2000D, DS, Essential</th>
<th>Fascher Seimens</th>
<th>Lorad Senoscan</th>
<th>Siemens Novation</th>
</tr>
</thead>
<tbody>
<tr>
<td>Same as Screen-Film (Focal Spot)</td>
<td>X</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Measure using LP phantom on top of acrylic</td>
<td>X</td>
<td>X</td>
<td></td>
<td></td>
<td></td>
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<tr>
<td>MTF</td>
<td>X</td>
<td>X</td>
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</tbody>
</table>

AEC Performance

- **Screen-Film Mammo**
  - Measure optical densities
    - Different thicknesses using clinical modes
    - Different density settings (-2, -1, 0, +1, +2, etc.)

- **FFDM**
  - Measure resultant techniques
  - Measure signal, exposure, & SNR values
**AEC**

<table>
<thead>
<tr>
<th>Function</th>
<th>Fuji FCm</th>
<th>GE 2000D, DS, Essential</th>
<th>Fischler Senoscan</th>
<th>Lorad Selenia</th>
<th>Siemens Novation</th>
</tr>
</thead>
<tbody>
<tr>
<td>Same as Screen-Film</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Density Control Function</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td></td>
</tr>
<tr>
<td>ACR Reproducibility</td>
<td>X</td>
<td></td>
<td></td>
<td></td>
<td></td>
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<tr>
<td>Image Mode Tracking</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td></td>
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<tr>
<td>SNR</td>
<td>X</td>
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</table>

**GE 2000D**

- AOP Mode and SNR Check
  - Variable thicknesses of acrylic
  - Std, Auto
  - Evaluate:
    - Correct techniques?
    - Adequate SNR?

<table>
<thead>
<tr>
<th>Acrylic Thickness (cm)</th>
<th>kVp</th>
<th>mAs</th>
</tr>
</thead>
<tbody>
<tr>
<td>2.5</td>
<td>28</td>
<td>20-60</td>
</tr>
<tr>
<td>4.0</td>
<td>28</td>
<td>35-90</td>
</tr>
<tr>
<td>6.0</td>
<td>32</td>
<td>35-90</td>
</tr>
</tbody>
</table>

Each "raw" image must have a measured SNR of at least 50.

**GE DS & Essential**

- **DS specific QC tests**
  - AOP Mode and SNR Check
    - Use built-in software for image acquisition
    - AOP: STD/Auto

<table>
<thead>
<tr>
<th>Acrylic Thickness (cm)</th>
<th>Track/Filter</th>
<th>mAs</th>
<th>kVp</th>
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</thead>
<tbody>
<tr>
<td>25</td>
<td>Mo/Mo</td>
<td>20-60</td>
<td>28</td>
</tr>
<tr>
<td>60</td>
<td>Rh/Rh</td>
<td>45-60</td>
<td>35</td>
</tr>
</tbody>
</table>

SNR must be > 50

**Lorad Selenia**

- **Automatic Exposure Control**
  - AUTO-FILTER – 2, 4, 6, 8 cm
  - 4 cm (-5 thru +5, or -3 to +4)
  - Use ROI to measure mean pixel value inside virtual AEC detector

- **Performance Criteria**
  - Pixel value should not vary by more than 10% of mean
  - Exposure compensation steps shall meet requirements in pixel value table

**Siemens Novation**

- **AEC Image Stability and Reproducibility and SNR**
  - ACR Phantom
  - Mo/Mo, 28 kV, "H", sensor 1
  - Record mAs, SNR, Mean, Entrance Exposure (5 times)

- **Action Limits:**
  - Coef. of Var for mAs and X < 5%
  - SNR and Mean shall not vary by > 15% of Mean

**Siemens Novation DR**

- **AEC Thickness Tracking**
  - 2, 4, and 6 cm
  - "H" mode
  - Max deviation = (Max difference / mean value) * 100

<table>
<thead>
<tr>
<th>AEC testing</th>
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</tbody>
</table>
**Density Control Function**
- 4 cm acrylic, ACR phantom technique
- Repeat at -2, -1, 0, +1, +2 etc. density
- Record mAs
- mAs change should be 5 to 15% per step

**Reproducibility & Image Mode Tracking**
- 4 cm acrylic with clinical technique
- Position ion chamber in beam
- Record mAs and X
- Repeat 3 times
- Repeat in each mode (small, large, mag, no grid)
- **Action Limits**:
  - Coefficient of variation for Exposure or mAs must not exceed 0.05
  - No significant difference in exposure between small and large bucky when using similar grids

**CNR Per Object Thickness**
- CNR using clinical technique for 2 cm
- Repeat for 4 and 6 cm
- **Action Limits**:
  - CNR of 2 cm relative to 4 cm must be ≥ 100%
  - CNR of 6 cm relative to 4 cm must be ≥ 75%

**Screen-Film Mammo**
- Measure if OD’s are consistent
- Check for artifacts

**FFDM**
- Flat-field uniformity
- Detector calibration
- Pixel correction test
- CR Reader Scanner Performance

**Detector Performance**

<table>
<thead>
<tr>
<th>Detector Performance</th>
<th>Fuji FCRm</th>
<th>2000D Essential</th>
<th>Fischer Sensiscan</th>
<th>Lorad Selenia</th>
<th>Siemens Novation</th>
</tr>
</thead>
<tbody>
<tr>
<td>Same as Screen-Film Screen Uniformity</td>
<td></td>
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<tr>
<td>Flat-Field Uniformity</td>
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<td>Detector Calibration</td>
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<td>CR Reader Scanner Performance</td>
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<td>Dynamic Range</td>
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<td>Primary Exposure</td>
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<tr>
<td>Film Base Consistency</td>
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<tr>
<td>Geometric Distortion</td>
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<tr>
<td>Pixel Correction</td>
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<td></td>
<td>X</td>
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<tr>
<td>Ghosting</td>
<td></td>
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<td></td>
<td></td>
<td>X</td>
</tr>
</tbody>
</table>

**Image Quality**

**Screen-Film Mammo**
- ACR Phantom Scores
- Optical Density & Contrast

**FFDM**
- ACR Phantom Scores
  - Pass/fail requirements differ by vendor
  - Signal-to-Noise Ratio (SNR)
  - Contrast-to-Noise Ratio (CNR)
**Image Quality**

<table>
<thead>
<tr>
<th></th>
<th>Fuji FCRm</th>
<th>GE 2000D, DAT Essential</th>
<th>Fischer Senoscan</th>
<th>Lorad Selenia</th>
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</thead>
<tbody>
<tr>
<td>Same as Screen-Film</td>
<td></td>
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<tr>
<td>Manual Techniques</td>
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<td>Clinical Technique</td>
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<td>Partial</td>
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<tr>
<td>CNR</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
</tr>
</tbody>
</table>

**ACR Phantom Imaging**

- **Manual technique** (Mo/Mo, 26 kVp, 125 mAs)
- Score the *processed* image
- Acquisition workstation
- Each monitor of the RWS
- Laser imager

**GE 2000D**

- **ACR Phantom Imaging**
  - Manual technique: Rh/Rh, 29 kVp, 56 mAs
  - Score the *processed* image
  - Acquisition workstation
  - Each monitor of the RWS
  - Laser imager

- **Contrast-to-Noise Test (CNR)**
  - To examine consistency of CNR ratio measured over time
  - Use the raw image
  - + 20% of baseline

**GE DS**

- **DS specific QC tests**
  - Phantom Image Quality
    - Manual technique: Rh/Rh, 29 kVp, 56 mAs
  - MTF and CNR Measurement
    - Use IQST test tool
    - Use built-in software for image acquisition
    - Manual technique: Rh/Rh 30 kVp, 56 mAs
    - Results are automatically displayed (pass/fail)
    - Same action limits as 2000D

**Lorad Selenia**

- **Phantom Image Quality**
  - Select clinical exposure mode (i.e. AUTO-FILTER)
  - Print film
  - Measure background OD and density difference –
    - Plot on tech worksheets
      - Background must be $\geq 1.20$ OD $\pm 0.20$
      - DD must be $\geq 0.40 \pm 0.05$
  - Score on each Soft Copy Workstation
    - 5 fibers
    - 4 speck groups
    - 4 masses
**Siemens Novation DR**

- **Phantom Image Quality**
  - Position phantom 1 cm over chest wall edge
  - Select: 28 kV, AEC-Auto, Mo/Mo
  - Score on RWS or Film
    - Fiber > 5
    - Specks > 4
    - Masses > 4

**Lorad & Siemens**

- **SNR and CNR Measurements**
  - SNR at least > 40
  - CNR should stay within ±15% of baseline
    - Obtained during acceptance testing

**Fuji FCRm**

- **Contrast-to-Noise Test (CNR)**
  - To examine consistency of CNR ratio measured over time
  - Use 4 cm acrylic & 0.2 mm Al
  - Manual technique (Mo/Mo, 26 kVp, 125 mAs)
  - Calculate CNR using software
    - ±20% of baseline

**Dose**

- **Screen-Film Mammo**
  - Dose for single CC view of ACR phantom shall not exceed 3.0 mGy per exposure per FDA
- **FFDM**
  - Same

**Film Processing**

- **Screen-Film Mammo**
  - Measure optical densities
    - Density difference, mid-density, base+fog
    - Measures consistency
- **FFDM**
  - Manufacturers’ recommendations
    - Some refer to printer manufacturers’ recommendations
    - Typically identical to ACR SFM Manual

**Film Processor QC**

<table>
<thead>
<tr>
<th></th>
<th>Fuji FCRm</th>
<th>GE 2000D, DS, Essential</th>
<th>Fischer Senoscan</th>
<th>Lorad Selea</th>
<th>Siemens Novation</th>
</tr>
</thead>
<tbody>
<tr>
<td>Follow Printer Manufacturers QC</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td></td>
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<tr>
<td>If Not, Use Theirs</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td></td>
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<tr>
<td>Follow FFDMs QC</td>
<td>X</td>
<td>X</td>
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<td></td>
<td></td>
</tr>
</tbody>
</table>
Artifacts

➢ Description:
GE Good Flat-field Image

Artifacts

➢ Description:
Hologic Good Flat Field

Artifacts

➢ Description: Acceptable
ACR Phantom image
➢ Raw image
➢ WW = 200

Artifacts

➢ Artifact evaluation – Contact Mode GE 2000D

Mo/Mo  Mo/Rh  Rh/Rh

Artifacts

➢ Artifact evaluation - windowing

Window width = 30  Window width = 200  Window width = 1000
Artifacts

- **Description:** Non-uniform background
- **Possible Cause:** Calibration file
- **Solution:** Recalibrate

Artifacts

- **Description:** Low contrast overall
- **Possible Cause:** Window width too wide (~750)
- **Solution:** Re-window

Artifacts

- **Description:** Poor contrast, fibers and masses failing
- **Possible Cause:** Ultra low dose – Mo/Mo, 29 kVp, 25 mAs, 0.58 mGy
- **Solution:** Increase techniques

Artifacts

- **Description:** Vertical and horizontal lines
- **Possible Cause:** Gridlines, grid artifacts in cal file
- **Solution:** Check grid mechanism, recalibrate

Artifacts

- **Description:** White vertical bands
- **Possible Cause:** Calibration file
- **Solution:** Recalibrate detector
Artifacts
➢ Description: Magnification image, several small flecks, grayscale gradation
➢ Possible Cause: Object calibrated into Cal file, grayscale gradation ~ normal
➢ Solution: Clean detector and tube head, recalibrate detector

Artifacts
➢ Description: White pixels
➢ Possible Cause: Detector going bad
➢ Solution: New Detector

Artifacts ➢ 2x

Artifacts ➢ 4x

Artifacts ➢ 6x

Artifacts ➢ 8x
Artifacts

- **Description:** Gridlines, black flecks
- **Possible Cause:** Grid failure, calibration file
- **Solution:** Grid repair, clean the imaging chain, and recalibrate

Artifacts

- **Description:** Image processing around wax insert
- **Possible Cause:** Image processing algorithm
- **Solution:** None

Artifacts

- **Description:** Washed out Image
- **Cause:** Phantom not at chest wall edge
- **Solution:** Re-position the phantom

Artifacts

- **Description:** Linear and rectangular banding
- **Possible Cause:** Calibration file
- **Solution:** Re-calibrate

Artifacts

- **Description:** Shadows just outside of breast skin line
- **Possible Cause:** Saturated detector due to overexposure from dense breast
- **Solution:** Siemens recommends to increase kVp to reduce exposure time

Artifacts

- **Description:** CR - Noisy Background, dark speck
- **Possible Cause:** Background somewhat normal
- **Solution:** Check screen and system to identify black speck
Artifacts

- **Description:**
  Horizontal, vertical, and curved lines multiple density differences – printed from "flat-field" menu on Lorad Selenia
- **Possible Cause:** Dirty spinner assembly in optics casting shadows
- **Solution:** Clean spinner assembly

Possible Cause: Dirty spinner assembly in optics casting shadows

Solution: Clean spinner assembly

Collimator needs adjustment at chest wall edge

Readout Line Artifact

Artifacts

- **Description:**
  Horizontal and curving lines
- **Possible Cause:**
  Readout error, ghosting
- **Solution:** Recalibrate, let detector sit idle, replace detector

Processing Steps for Digital Images

- Image Detection
- Image Correction
- Image Processing
- Image Display
Summary on Artifacts

- Most artifacts due to calibration file
- Window/level adjustments can appear as AEC and/or exposure problems
- Printers can cause fine, linear streaking artifacts - rare
- Look at technique factors, breast thickness, and breast density for clues
- Objects on bucky, mag stand, and up in tube head often make their way into the image – dust on accessories
- Detectors can, and do, fail

Key Take Home Points

- Obtain relevant hands-on training
- Must perform manufacturer specific QC tests
- Artifacts – most problems can be seen here
- Re-booting and/or re-calibrating fixes most problems
- Laser Printer
  - $D_{\text{max}}$ at least 3.5 OD
  - Mid-density about 1.5 OD

SAMs Questions

In digital mammography, who mandates the pass/fail criteria for site QC?

- 20% The American College of Radiology
- 20% The FDA
- 20% The FFDM unit manufacturer
- 20% NEMA
- 20% MQSA

Answer: 3 - The FFDM unit manufacturer

References

- MQSA Regulations 900.12(e)(6)
- http://www.fda.gov/CDRH/MAMMOGRAPHYfrmamcom2.html#s90012

Answer 3: The FFDM unit manufacturer

Explanation

“the quality assurance program shall be substantially the same as the quality assurance program recommended by the image receptor manufacturer, except that the minimum allowable dose for screen-film systems in this section”
How do you accredit a Fuji CR Mammography system which uses both CR and screen-film on the same x-ray system?

- 25% 1. As 1 mammography unit?
- 25% 2. As 2 mammography units?
- 25% 3. You cannot use CR and film on the same unit.
- 25% 4. CR is exempt from accreditation.

Answer: 2 – As 2 mammography units

Explanation

As of November 15, 2006 facilities using both screen-film and CR on the same mammography units must accredit these 2 systems as 2 separate units.

What are the minimum passing ACR phantom scores for the Siemens Novation DR for weekly QC?

- 20% 1. 5 Fibers, 4 Speck Groups, 3 Masses
- 20% 2. 4 Fibers, 3 Speck Groups, 3 Masses
- 20% 3. 5 Fibers, 4 Speck Groups, 4 Masses
- 20% 4. 4 Fibers, 4 Speck Groups, 3 Masses
- 20% 5. 4 Fibers, 4 Speck Groups, 4 Masses

Answer 3: 5 Fibers, 4 Speck Groups, 4 Masses

Explanation

The Siemens Novation DR QC manual states that the ACR Phantom minimum passing scores are as follows:

- 5 Fibers
- 4 Speck Groups
- 4 Masses

References

- Siemens. Siemens Quality Control Manual Version 05, Erlangen, Germany. 2007
For FFDM, the exposure for a single CC view of the ACR Phantom shall not exceed?

- 20% 1. 0.75 mGy/exposure
- 20% 2. 1.25 mGy/exposure
- 20% 3. 2.00 mGy/exposure
- 20% 4. 3.00 mGy/exposure
- 20% 5. 4.00 mGy/exposure

Answer 4: 3.00 mGy/exposure

References

- 900.12(e)(5)(vi): Dosimetry. The average glandular dose delivered during a single craniocaudal view of an FDA-accepted phantom simulating a standard breast shall not exceed 3.0 milligray (mGy) (0.3 rad) per exposure. The dose shall be determined with technique factors and conditions used clinically for a standard breast.

Answer 3: 2 Facilities and 6 Mammography Units

Explanation
The FDA requires:
- 3.00 mGy/exposure

References

- http://www.fda.gov/CDRH/MAMMOGRAPHY/robohelp/STAG/STAG.HTM
- 900.12(a)(3)(iii)(B): Continuing experience. Following the second anniversary date of the end of the calendar quarter in which the requirements of paragraphs (a)(3)(i) and (a)(3)(ii) of this section were completed or of April 28, 1999, whichever is later, the medical physicist shall have surveyed at least two mammography facilities and a total of at least six mammography units during the 24 months immediately preceding the date of the facility’s annual MQSA inspection or the last day of the calendar quarter preceding the inspection or any date in between the two. The facility shall choose one of these dates to determine the 24-month period. No more than one survey of a specific facility within a 10-month period or a specific unit within a period of 60 days can be counted towards this requirement.

To meet the FDA requirement for continuing experience, how many mammography facilities and mammography unit surveys must be performed within the previous 24 months?

- 20% 1. 6 Facilities and 2 mammography units
- 20% 2. 4 Facilities and 12 mammography units
- 20% 3. 2 Facilities and 6 mammography units
- 20% 4. 1 Facilities and 6 mammography units
- 20% 5. 2 Facilities and 12 mammography units

Answer 3: 2 Facilities and 6 Mammography Units

Explanation
The FDA requires:
- 2 Facilities
- 6 Mammography Units
- Within past 24 months
Thank You