2D Digital Mammography-
An update on vendor-recommended QC tests

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We will consider:

1. Benefit of screening mammography
2. Importance of good image quality in mammography
3. Value of QC in mammography
4. Current QC program requirements for FFDM
5. Potential changes for the future
Age-adjusted Cancer Death Rates for Females in the US, 1930-2009

Approximately 38 million mammography procedures were performed in 2013

Age-adjusted Cancer Death Rates for Females in the US, 1930-2009

1986 ACS establishes Breast Cancer Awareness Screening Program

1990 ACR Standards for the Performance of Screening Mammography

1992 MQSA
Survival is very good if the cancer is found early

5-year survival rates (%):
- 98 if cancer is local
- 84 if regional
- 24 if metastasized

Why do we do mammography? What is the purpose of mammography?

*early and accurate detection of breast cancer with the minimum required radiation dose*
What is mammography image quality?

How is breast cancer detected in a mammogram?
How is breast cancer detected in a mammogram?

What is mammography image quality?
What is the benefit of QC in mammography?

How does it assure good image quality?

How does it improve breast cancer detection?
Quality control should not be thought of as an end in itself
What is mammography image quality?

Pathology to be seen:

high density mass

shape and margin
are important
What is mammography image quality?

Pathology to be seen:

micro-calcifications

morphology and distribution are important
What is mammography image quality?

Pathology to be seen:

architectural distortion
deviation from normal parenchymal pattern
How is breast cancer detected in a mammogram?

- 64% stellate and circular malignant tumors* without calcifications
- 17% stellate and circular malignant tumors* with calcifications
- 19% calcifications only

* 65% stellate, 35% circular

5 year retrospective study of 866 cancers

Tabar L, Tot T, Dean PB. Breast cancer: the art and science of early detection with mammography. Stuttgart, Germany, Thieme Verlag, 2005
How is breast cancer detected in a mammogram?

“…perception of the stellate lesion—while they are small [is] the number one task of mammography” L. Tabar

Tabar L, Tot T, Dean PB. Breast cancer: the art and science of early detection with mammography. Stuttgart, Germany, Thieme Verlag, 2005
Mammography QC- a little history:

- 1985 NEXT (FDA)  
  Wide variability in image quality and radiation dose in radiography

- 1986 Galkin et al

- 1986 ACS establishes Breast Cancer Awareness Screening Program
  ACS-ACR collaboration sets standard for quality mammography

- 1987- ACR launches voluntary accreditation program including mandatory QC testing
A little more history ....

1987: ACR initiates voluntary accreditation
1990: 1st ACR QC manuals
10/27/92: President Bush signs MQSA bill to take effect 10/1/94 (21CFR Part 900)
1992: 2nd ACR manual published
10/23/93: Interim MQSA regulations published
10/28/97: Final MQSA regulations published to take effect 4/28/99 (a few effective 10/28/02)
1999: New ACR manual to work with MQSA
The ACR QC program
• FDA certification and ACR accreditation
Mammography Quality Standards Act, 1992

Sec. 900.11
Requirements for certification.

(a) General. After October 1, 1994, a certificate issued by FDA is required for lawful operation of all mammography facilities subject to the provisions of this subpart. To obtain a certificate from FDA, facilities are required to meet the quality standards in Sec. 900.12 and to be accredited by an approved accreditation body or other entity as designated by FDA.
21CFR 900.12(e)(6):

Quality Control tests — other modalities.

For systems with image receptor modalities other than screen-film, the quality assurance program shall be substantially the same as the quality assurance program recommended by the image receptor manufacturer, except that the maximum allowable dose shall not exceed the maximum allowable dose for screen-film systems in paragraph (e)(5)(vi) of this section.
21CFR 900.12(e)(5)(vi):

Dosimetry.

The average glandular dose delivered during a single cranio-caudal 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.

Standard breast is defined as 4.2 cm compressed breast consisting of 50% glandular and 50% adipose tissue.
Other modalities (as of August 2013) are:

- **Full field digital mammography (FFDM)**
  - General Electric 2000D was first – 01/28/00
  - Currently 26 different models are approved

- **Digital Breast Tomosynthesis (DBT)**
  - Hologic Selenia Dimensions DBT – 02/11/11
Generic description of selected mammographic QC tests
Medical physicist QC tests for Screen-Film Systems: ACR and MQSA

<table>
<thead>
<tr>
<th>Test Description</th>
<th>Pass/Fail</th>
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</thead>
<tbody>
<tr>
<td>1. Mammographic Unit Assembly Evaluation</td>
<td></td>
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<tr>
<td>2. Collimation Assessment</td>
<td></td>
</tr>
<tr>
<td>Deviation between X-ray field and light field ≤2% of SID</td>
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<tr>
<td>X-ray field does not extend beyond any side of the IR by more than 2% of SID</td>
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<tr>
<td>Chest wall edge of compression paddle doesn't extend beyond IR by more than 1% of SID</td>
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</tr>
<tr>
<td>3. Evaluation of Focal Spot Performance</td>
<td></td>
</tr>
<tr>
<td>Measured performance within acceptable limits for large focal spot</td>
<td></td>
</tr>
<tr>
<td>Measured performance within acceptable limits for small focal spot</td>
<td></td>
</tr>
<tr>
<td>4. Automatic Exposure Control (AEC) System Performance</td>
<td></td>
</tr>
<tr>
<td>Exposure reproducibility is within acceptable limits</td>
<td></td>
</tr>
<tr>
<td>AEC compensation for kVp, breast thickness and image mode is adequate</td>
<td></td>
</tr>
<tr>
<td>AEC density control function is adequate</td>
<td></td>
</tr>
<tr>
<td>5. Uniformity of Screen Speed</td>
<td>Pass/Fail</td>
</tr>
<tr>
<td>Optical density range is ≤0.30</td>
<td></td>
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<tr>
<td>6. Artifact Evaluation</td>
<td></td>
</tr>
<tr>
<td>Artifacts were not apparent or not significant</td>
<td></td>
</tr>
<tr>
<td>7. Phantom Image Quality Evaluation</td>
<td></td>
</tr>
<tr>
<td>4 largest fibers, 3 largest speck groups and 3 largest masses are visible</td>
<td></td>
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<tr>
<td>Phantom image quality scores:</td>
<td></td>
</tr>
<tr>
<td>Fibers</td>
<td></td>
</tr>
<tr>
<td>Specks</td>
<td></td>
</tr>
<tr>
<td>Masses</td>
<td></td>
</tr>
<tr>
<td>8. kVp Accuracy and Reproducibility</td>
<td></td>
</tr>
<tr>
<td>Measured average kVp within ±5% of indicated kVp</td>
<td></td>
</tr>
<tr>
<td>kVp coefficient of variation ≤0.02</td>
<td></td>
</tr>
<tr>
<td>9. Beam Quality (Half-Value Layer) Assessment</td>
<td></td>
</tr>
<tr>
<td>Half-value layer is within acceptable lower and upper limits at all kVp values tested</td>
<td></td>
</tr>
<tr>
<td>10. Breast Entrance Exposure, Average Glandular Dose and Radiation Output Rate</td>
<td></td>
</tr>
<tr>
<td>Average glandular dose for average breast is below 3 mGy (300 mrad)</td>
<td></td>
</tr>
<tr>
<td>Average glandular dose to a 4.2-cm-thick breast on your unit is</td>
<td></td>
</tr>
<tr>
<td>Radiation output rate is ≥800 mR/sec (7.0 mGy/sec) at 28 kVp with Mo/Mo</td>
<td></td>
</tr>
<tr>
<td>11. Viewbox Luminance and Room Illuminance</td>
<td></td>
</tr>
<tr>
<td>Mammographic viewbox is capable of a luminance of at least 3000 nit</td>
<td></td>
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<tr>
<td>Room illuminance (viewbox surface &amp; seen by observer) is 50 lux or less</td>
<td></td>
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</tbody>
</table>
Unit Evaluation – flat and parallel compression
Unit Evaluation – flat and parallel compression

$\Delta \leq 1 \text{ cm}$
Non-flat and non-parallel compression designs
Light field – x-ray field – detector alignment
light to x-ray: \( X \) and \( Y \) sum \( \Delta \leq 2\% \) SID

X-ray to detector: \( \Delta \leq 2\% \) along any side
Compression paddle to detector alignment

Paddle at ~ 4.5 cm

Paddle cannot extend beyond detector by > 1% SID
Focal Spot Performance (System Resolution)
AEC performance – thickness compensation – density control

Δ O.D. 2-6 cm ≤ +/- 0.15
Screen uniformity and artifacts

Artifacts are not apparent or significant
Phantom image quality – MAPP – 4/3/3
kVp accuracy and repeatability
accuracy 5%
CV ≤ 0.02
Beam quality (HVL)

$HVL \geq \frac{kVp}{100}$
Entrance exposure, average glandular dose, radiation output rate

Air kerma and mAs  CV ≤ 0.05
Output rate ≥ 7.0 mGy/sec (800 mR/sec)
Dg ≤ 3.0 mGy (300 mrad)
Viewbox luminance and viewing conditions (optional under MQSA)

Viewbox luminance $\geq 3000 \text{ cd/m}^2$
Luminance $\leq 50 \text{ lux}$
Masking and “hot light” are required (from *equipment requirements*)
Currently approved FFDM systems
## FFDM and DBT Systems

FDA approved, cleared, or accepted the following FFDM and DBT units for use as indicated by date:

<table>
<thead>
<tr>
<th>Konica-Minolta</th>
<th>Siemens Mammomat Inspiration Prime Edition cleared on 6/27/13</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Konica Minolta Xpress Digital Mammography Computed Radiography (CR) System on 12/23/11</td>
</tr>
<tr>
<td></td>
<td>Agfa Computed Radiography (CR) Mammography System on 12/22/11</td>
</tr>
<tr>
<td></td>
<td>Fuji Aspire Computed Radiography for Mammography (CRM) System on 12/8/11</td>
</tr>
<tr>
<td>Giotto</td>
<td>Giotto Image 3D-3DL Full-Field Digital Mammography (FFDM) System on 10/27/11</td>
</tr>
<tr>
<td>Fuji-DR</td>
<td>Fuji Aspire HD Full-Field Digital Mammography (FFDM) System on 9/1/11</td>
</tr>
<tr>
<td></td>
<td>GE Senographe Care Full-Field Digital Mammography (FFDM) System on 10/7/11</td>
</tr>
<tr>
<td>Planmed</td>
<td>Planmed Nuance Excel Full-Field Digital Mammography (FFDM) System on 9/23/11</td>
</tr>
<tr>
<td></td>
<td>Planmed Nuance Full-Field Digital Mammography (FFDM) System on 9/23/11</td>
</tr>
<tr>
<td></td>
<td>Siemens Mammomat Inspiration Pure Full-Field Digital Mammography (FFDM) System on 8/16/11</td>
</tr>
<tr>
<td>Philips</td>
<td>Hologic Selenia Encore Full-Field Digital Mammography (FFDM) System on 6/15/11</td>
</tr>
<tr>
<td></td>
<td>Philips (Sectra) MicroDose L30 Full-Field Digital Mammography (FFDM) System on 4/28/11</td>
</tr>
<tr>
<td></td>
<td>Hologic Selenia Dimensions Digital Breast Tomosynthesis (DBT) System on 2/11/11</td>
</tr>
<tr>
<td>Carestream</td>
<td>Siemens Mammomat Inspiration Full-Field Digital Mammography (FFDM) System on 2/11/11</td>
</tr>
<tr>
<td></td>
<td>Carestream Directview Computed Radiography (CR) Mammography System on 11/3/10</td>
</tr>
<tr>
<td></td>
<td>Hologic Selenia Dimensions 2D Full Field Digital Mammography (FFDM) System on 2/11/09</td>
</tr>
<tr>
<td></td>
<td>Hologic Selenia S Full Field Digital Mammography (FFDM) System on 2/11/09</td>
</tr>
<tr>
<td></td>
<td>Siemens Mammomat Novation S Full Field Digital Mammography (FFDM) System on 2/11/09</td>
</tr>
<tr>
<td></td>
<td>Hologic Selenia Full Field Digital Mammography (FFDM) System with a Tungsten target in 11/2007</td>
</tr>
<tr>
<td>Fuji-CR</td>
<td>Fuji Computed Radiography Mammography Suite (FCRMS) on 07/10/06</td>
</tr>
<tr>
<td></td>
<td>GE Senographe Essential Full Field Digital Mammography (FFDM) System on 04/11/06</td>
</tr>
<tr>
<td>Siemens</td>
<td>Siemens Mammomat Novation DR Full Field Digital Mammography (FFDM) System on 08/20/04</td>
</tr>
<tr>
<td></td>
<td>GE Senographe DS Full Field Digital Mammography (FFDM) System on 02/19/04</td>
</tr>
<tr>
<td>Lorad</td>
<td>Lorad/Hologic Selenia Full Field Digital Mammography (FFDM) System on 10/2/02</td>
</tr>
<tr>
<td>Fischer</td>
<td>Lorad Digital Breast Imager Full Field Digital Mammography (FFDM) System on 03/15/02</td>
</tr>
<tr>
<td>GE</td>
<td>Fischer Imaging SenoScan Full Field Digital Mammography (FFDM) System on 09/25/01</td>
</tr>
<tr>
<td></td>
<td>GE Senographe 2000D Full Field Digital Mammography (FFDM) System on 01/28/00</td>
</tr>
</tbody>
</table>
Common QC tests for FFDM

Mechanical/safety checks
Acquisition monitor checks
X-ray beam collimation and alignment (dead space)
Compression paddle position, flat and parallel
Spatial resolution (detector and system: GE)
AEC: thickness response, exposure compensation
Artifacts/uniformity (flat-field uniformity)
Image quality: 4/3/3 or 5/4/4
kVp accuracy and repeatability
HVL
Radiation dose
Radiation output rate
SNR/CNR

Reading workstation
Film printer
Common QC tests for FFDM – same as S/F

Mechanical/safety checks

Acquisition monitor checks

X-ray beam collimation and alignment (dead space)
Compression paddle position, flat and parallel
Spatial resolution (detector and system: GE)
AEC: thickness response, exposure compensation

Artifacts/uniformity (flat-field uniformity)
Image quality: 4/3/3 or 5/4/4

kVp accuracy and repeatability
HVL
Radiation dose
Radiation output rate

SNR/CNR

Reading workstation
Film printer
Acquisition Monitor IQ check - SMPTE pattern
Flat field calibration and test
video ~ 1 sec

take snapshot from video
Set to “true size”
Dead space
Collimation – sliding paddle
System Spatial Resolution
Image quality is still assessed with the MAP phantom

- Fibers = 4, 5
- Specks = 3, 4
- Masses = 3, 4

Radiation dose must be < 300 mrad (3 mGy)
SNR and CNR
Current Manufacturer-required QC tests for FFDM
GE
Senographe Essential
1. **Flat Field**

2. **Phantom Image Quality**
   - Phantom IQ Test on AWS
   - Phantom IQ Test on Printer

3. **CNR Measurement** *(NA for DS, Essential or Care if Sub-System MTF test done)*
   - CNR
   - Change in CNR ≤0.2 *(NA for Mammography Equipment Evaluations)*

4. **MTF Measurement** *(NA for 2000D, DS, Essential or Care if Sub-System MTF test done)*

5. **AOP Mode and SNR**

6. **Collimation Assessment**

7. **Evaluation of Focal Spot Performance** *(NA for 2000D, DS, Essential or Care if Sub-System MTF test done)*

8. **Sub-System MTF** *(NA for 2000D if MTF and Focal Spot Performance tests done; NA for DS, Essential or Care if CNR, MTF and Focal Spot Performance tests done)*

9. **Breast Entrance Exposure, Average Glandular Dose and Reproducibility**
   - Average glandular dose for average breast is ≤3 mGy (300 mrad)
   - Exposure reproducibility (CV) for air kerma (R) and mAs is ≤0.05

10. **Artifact Evaluation and Flat Field Uniformity**

11. **kVp Accuracy and Reproducibility**

12. **Beam Quality Assessment (Half-Value Layer Measurement)**

13. **Radiation Output**
   - Radiation output is ≥800 mR/s

14. **Mammographic Unit Assembly Evaluation**
   - Meets requirements for motion of tube-image receptor assembly
   - Meets requirements for compression paddle decompression

15. **Review Workstation (RWS) Tests** *(for all RWS, even if located offsite; NA if only hardcopy read)*
Contrast to Noise Ratio

• Contrast is difference between means of ROI 1 and 2.
• Noise is the SD of the ROI 2 (background)
• Contrast is measured between background and largest mass
MTF Measurement

MTF @ 2 lp/mm > 0.58
MTF @ 4 lp/mm > 0.25
Sub-System MTF Test

Measure Signal and Noise in ROIs

Contact

Magnification

2.09 and 3.93 lp/mm

5 and 8 lp/mm
Fisher Senoscan

- Generator
- Gantry
- Acquisition Station/Technologist Shield
- Review Station
1. X-Ray Field, Chest Wall Missed Tissue and Light Field Checks
2. Compression Paddle Alignment
3. kVp Accuracy Test
4. Linearity, Reproducibility and Accuracy
5. Half-Value Layer and Output
6. Dosimetry – Average Glandular Dose and Output
   Average glandular dose for average breast is ≤3 mGy (300 mrad) mrad
7. Phantom Image Acquisition Test *(values required for all tests)*
   No obvious artifacts
   Background StDev within +50/-0 ADU counts of baseline *(NA for Equipment Evaluations)*
   Background mean within ±100 ADU counts of baseline *(NA for Equipment Evaluations)*
   ADU level difference within ±300 ADU counts of baseline *(NA for Equipment Evaluations)*
8. Image Quality
   Largest 4 fibers, 3 speck groups and 3 masses
   Phantom IQ Test on Review Work Station
9. System Resolution/Scan Speed Uniformity
10. Flat Field Test
11. Geometric Distortion and Resolution Uniformity
12. Automatic Decompression Control
13. System Artifacts
14. Image Viewing Room Illuminance Test *(≤50 lux)*
15. Review Workstation (RWS) Tests *(for all RWS, even if located onsite; NA if only hardcopy read)*
Hologic/Lorad Selenia
Hologic Selenia Dimensions 2D (3D)
1. **Mammographic Unit Assembly Evaluation**
2. **Collimation Assessment**
3. **Artifact Evaluation**
4. **kVp Accuracy and Reproducibility**
5. **Beam Quality Assessment - HVL Measurement**
6. **Evaluation of System Resolution**
7. **Automatic Exposure Control (AEC) Function Performance** *(NA for systems without AEC)*
8. **Breast Entrance Exposure, AEC Reproducibility and Average Glandular Dose**
   Average glandular dose for average breast is \( \leq 3 \text{ mGy (300 mrad)} \)
9. **Radiation Output Rate**
10. **Phantom Image Quality Evaluation**
    Phantom image scores:
    - Fibers
    - Specks
    - Masses
11. **Signal-To-Noise Ratio and Contrast-To-Noise Ratio Measurements** *(values required for all tests)*
    - **SNR** *(value)*
    - **CNR** *(value)* *(Required for both new unit Mammography Equipment Evaluations and Annual Surveys)*
    - CNR should not vary by more than \( \pm 15\% \) *(NA for Equipment Evaluation)*
12. **Diagnostic Review Workstation (RWS) QC** *(for all RWS, even if located offsite; NA if only hardcopy read)*
13. **DICOM Printer QC** *(Mammography Equipment Evaluations only)*
14. **Detector Flat Field Calibration** *(Mammography Equipment Evaluations only)*
15. **Compression Thickness Indicator** *(Mammography Equipment Evaluations only)*
16. **Compression** *(Mammography Equipment Evaluations only)*
Image quality is still assessed with the MAP phantom

Fibers = 5

Specks = 4

Masses = 4
Siemens Mammomat Novation
1. Site Audit/Evaluation of Technologist QC Program
2. Mechanical Inspection
3. Acquisition Workstation Monitor Check
4. Detector Uniformity
5. Artifact Detection
6. Collimation, Dead Space & Compression Paddle Position
7. AEC Thickness Tracking
8. Spatial Resolution
9. SNR, CNR and AEC Repeatability
   Measured values: SNR [ ]  CNR [ ]
   CV for mAs and entrance air kerma ≤5%
   Max deviation of mean pixel values and SNR within ±15% of mean for measurements
10. Image Quality
    Largest 5 fibers, 4 speck groups and 4 masses visible*
    (*largest 4 fibers, 3 speck groups and 3 masses acceptable if spatial resolution and CNR pass)
    Phantom image scores: Fibers [ ]  Specks [ ]  Masses [ ]
11. Radiation Dose
    Average glandular dose for average breast is ≤3 mGy (300 mrad)
12. HVL and Radiation Output
13. Tube Voltage Measurement & Reproducibility
14. Film Printer Check
15. Review Workstation (RWS) Tests (for all RWS, even if located offsite; NA if only hardcopy read)
Contrast to noise ratio

- Contrast is difference between means of ROI 1 and 2.
- Noise is the SD of the ROI 2 (background)
Image quality is still assessed with the MAP phantom

Fibers = 5

Specks = 4

Masses = 4
Radiation dose must not exceed 3 mGy
Radiation dose should not exceed 2 mGy
Pre-requisites to calculate the mean glandular dose

Use formulae:

\[ D = K g c s \]  
[Dance et al 2000]

- \( D \) Mean glandular dose
- \( K \) Entrance air kerma
- \( g \) g-factor for breasts simulated with PMMA
- \( c \) c-factor for breasts simulated with PMMA
- \( s \) s-factor for clinically used spectra

Where \( K \) is the incident air kerma (without backscatter) calculated at the upper surface of the PMMA. The factor \( g \), corresponds to a glandularity of 50%, and is derived from the values calculated by Dance et al 2000 and is shown below for a range of HVL. The c-factor corrects for the difference in composition of typical breasts from 50% glandularity [Dance et al 2000] and is given here for typical breasts in the age range 50 to 64. Note that the \( c \) and \( g \)-factors applied are those for the corresponding thickness of typical breast rather than the thickness of PMMA block used. Where necessary interpolation may be made for different values of HVL. The factor \( s \) shown in the second table corrects for any difference due to the choice of X-ray spectrum (Dance et al 2000).

<table>
<thead>
<tr>
<th>PMMA thickness (mm)</th>
<th>Equivalent breast thickness (mm)</th>
<th>HVL (mm Al)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>0.25</td>
</tr>
<tr>
<td>( g )-factor</td>
<td>45</td>
<td>53</td>
</tr>
<tr>
<td>( c )-factor</td>
<td>45</td>
<td>53</td>
</tr>
<tr>
<td>( g )-factor</td>
<td>50</td>
<td>60</td>
</tr>
<tr>
<td>( c )-factor</td>
<td>50</td>
<td>60</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th></th>
<th>Mo/Mo</th>
<th>Mo/Rh</th>
<th>W/Rh</th>
</tr>
</thead>
<tbody>
<tr>
<td>( s )-factor</td>
<td>1.000</td>
<td>1.017</td>
<td>1.042</td>
</tr>
</tbody>
</table>
Fuji ClearView CRm
1. S Value Confirmation \( (\leq 120 \pm 20\% \ [96 \leq \text{corrected S value} \leq 144]) \)
2. System Resolution \( (8 \text{ lp/mm} \pm 2 \text{ lp/mm in both directions}) \)
3. CR Reader Scanner Performance
4. Mammography Unit Assembly Evaluation
5. Collimation Assessment
   - Chest wall edge of X-ray field extends to edge of IR
   - Deviation between X-ray field and light field \( \leq 2\% \) of SID
   - X-ray field does not extend beyond any side of the IR by more than \( 2\% \) of SID
   - Paddle chest wall edge not beyond IR by more than \( 1\% \) of SID or appear on the image
6. Automatic Exposure Control (AEC) System Performance Assessment
   - AEC density control function meets Fuji performance criteria
   - Reproducibility (CV) for either exposure or mAs is \( \leq 0.05 \)
   - Image mode tracking meets Fuji performance criteria
   - CNR per object thickness meets Fuji performance criteria
7. System Artifact Evaluation
8. Phantom Image Quality Evaluation
   - Phantom IQ (printed images)
   - Phantom IQ (softcopy)
   - Other tests meet Fuji performance criteria \( (\text{mAs, OD & DD for hardcopy, S value for soft copy}) \)
9. Dynamic Range
10. Primary Erasure (Additive and Multiplicative Lag Effects)
11. Inter-Plate Consistency \( (\text{variation of mAs within } \pm 10\%; \text{ SNR within } \pm 15\%) \)
12. kVp Accuracy and Reproducibility
   - Measured average kVp within \( \pm 5\% \) of indicated kVp
   - kVp coefficient of variation \( \leq 0.02 \)
13. Dose \( (\text{average glandular dose for average breast is } \leq 3 \text{ mGy} \ [300 \text{ mrad}]) \)
14. Beam Quality Assessment & HVL Measurement
   - HVL \( \geq \text{kVp}/100 \text{ mm Al} \)
15. Radiation Output
   - Radiation output rate is \( \geq 800 \text{ mR/sec} \) \( (7.0 \text{ mGy/sec}) \) at 28 kVp with Mo/Mo
16. Viewing and Viewing Conditions
   - Room illuminance \( \leq 20 \text{ lux} \) or as recommended by the monitor manufacturer
17. Review Workstation (RWS) Tests \( (\text{for all RWS, even if located offsite; NA if only hardcopy read}) \)
18. Film Printer Tests \( (\text{for all printers used for mammography, even if located offsite}) \)
At 20 mR, for 25 kVp and Mo/Mo:

\[ S = 120 \pm 20\% \ (96-144) \]

Expose – read should be 5-10 minutes
Carestream DirectView
ROI target = $1000 \times \log_{10}(\text{mR}) + 1000$
QC Manual – Important Points

Calibration = 5 minutes
TQT = 5 minutes
QC testing = 5 minutes
Sectra MicroDose Mammography
Calibration phantom

Daily QC phantom
System uses scanning multi-slot geometry

X-ray exposure is pulsed:
  10-50 msec, 5-30 pulses/sec.

mAs ≈ 1% conventional mAs

Assure that exposure and kVp meters will work with this system

Place Pb aperture on paddle for HVL
1. X-ray Tube Output (air kerma)
2. Air Kerma Reproducibility
3. Half Value Layer
4. AEC System: Breast Thickness and Exposure
5. AEC System: Density Compensation
6. Image Quality Evaluation
   - Phantom image scores: Fibers Specks Masses
   - Average glandular dose for average breast is ≤1 mGy (100 mrad)
7. Contrast-to-Noise Ratio Reference Level
   - CNR (value)
8. Tube Voltage
9. Image Field and X-Ray Field Agreement
10. Missed Tissue at Chest Wall
11. Viewing Conditions
The average glandular dose (AGD) is calculated by

\[ AGD = ESAK \cdot g \cdot c \cdot s , \]

where \( g \) and \( c \) are functions of the breast thickness and HVL and \( s \) is a function of breast or PMMA thickness. The \( g \)-, \( c \)- and \( s \)-tables can be interpolated. The entrance surface air kerma (ESAK) should be calculated at the entrance surface of the breast.

Table 11  g-factor as a function of breast thickness and HVL [10].
Table 12  c-factors for average breasts for women 50 to 64 [10].
Table 13  s-factors

\[ D_g \leq 1 \text{ mGy (100mrad)} \]
Contrast-to-noise ratio measured using the Daily QC Phantom
1. Monitor Cleaning (AWS and RWS) (Mammography Equipment Evaluation only)
2. Monitor Quality (AWS) - TG-18 QC test phantom (Mammography Equipment Evaluation only)
3. Phantom Image Quality (AWS and RWS) (Mammography Equipment Evaluation only)
   
<table>
<thead>
<tr>
<th>Phantom IQ Test on AWS</th>
<th>Fibers</th>
<th>Specks</th>
<th>Masses</th>
</tr>
</thead>
</table>

4. Viewbox and Viewing Conditions (Mammography Equipment Evaluation only)
5. Signal Homogeneity (Mammography Equipment Evaluation only)
6. Uncorrected Defective Elements (DEL) (Mammography Equipment Evaluation only)
7. Large Focus Calibration (Mammography Equipment Evaluation only)
8. Small Focus Calibration (for mags only) (Mammography Equipment Evaluation only)
9. Signal-to-Noise (SNR) (Mammography Equipment Evaluation only)
10. Contrast-to-Noise Ratio (CNR) (Mammography Equipment Evaluation only)
11. Visual Checklist (Mammography Equipment Evaluation only)
12. Repeat Analysis (Mammography Equipment Evaluation only)
13. Defect Acceptance Test (Mammography Equipment Evaluation only)
15. Review Workstation QC-Overall (Mammography Equipment Evaluation only)
16. Film Printer QC (Mammography Equipment Evaluation only)
17. Ghosting
18. Modulation Transfer Function (MTF)
19. Linearity/Noise Linearity
20. AEC
21. Compression Force
22. Mammographic Unit Assembly
23. Beam Quality Assessment - HVL Measurement
24. Breast Entrance Exposure and Average Glandular Dose
   
   Average glandular dose for average breast is ≤3 mGy (300 mrad)
FUJI Aspire
1. 1Shot Phantom
   Missed Tissue on Chest Wall Edge
   CNR (Mammography Equipment Evaluation only)
   1 Shot Phantom Sensitivity Constancy (Mammography Equipment Evaluation only)
   Geometric Distortion (Mammography Equipment Evaluation only)
   System Artifact Evaluation (Mammography Equipment Evaluation only)
   Uniformity (Mammography Equipment Evaluation only)
   Dynamic Range (Mammography Equipment Evaluation only)
   Spatial Resolution (SR) (Mammography Equipment Evaluation only)
   Low Contrast Detectability (LCD) (Mammography Equipment Evaluation only)
   Linearity/Beam Quality Constancy (Mammography Equipment Evaluation only)

2. ACR Phantom (Mammography Equipment Evaluation only)
   Phantom IQ Test on AWS
   Phantom IQ Test on RWS

3. Image Basic Test
4. Compression Device Confirmation
5. Viewbox Maintenance
6. Monitor Quality Control (Secondary/AWS)
7. Additive Lag Effects
8. Multiplicative Lag Effects (Ghost)
9. Visual and Functional Test
10. Spatial Resolution (Magnification)
11. kVp Accuracy and Reproducibility
12. Half Value Layer (HVL)
13. Collimation Assessment
14. Radiation Output
15. AEC Reproducibility
16. CNR Mode 1
17. AGD Mode 1
18. AGD-ACR Phantom
   Average glandular dose for average breast is ≤3 mGy (300 mrad)
19. Review Workstation QC-Overall
20. Film Printer QC-Overall
1. Collimation Assessment
2. Artifact Evaluation
3. Automatic Exposure Control (AEC), Signal-To-Noise Ratio (SNR) & Contrast-To-Noise Ratio (CNR)
   - SNR (value) ≥ 60
   - CNR (value) (Required for both new unit Mammography Equipment Evaluations and Annual Surveys)
   - CNR should not vary by more than ±20% (NA for Equipment Evaluation)
4. AEC Reproducibility
5. ACR Phantom Image Quality
   - Phantom image scores:
     - Fibers
     - Specks
     - Masses
6. Ghost Factor
7. Inactive Border at Chest Wall Edge
8. Flat Field Homogeneity
9. Detector Response Function and Noise Evaluation
10. Spatial Resolution
11. kVp Accuracy and Reproducibility
12. Tube Output
13. Exposure Time
14. Beam Quality (HVL)
15. Mean Glandular Dose (MGD)
   - Average glandular dose for average breast is ≤3 mGy (300 mrad)
16. Viewbox Luminance
17. Diagnostic Review Workstation (RWS) QC (for all RWS, even if located offsite; NA if only hardcopy read)
18. Film Printer QC
Konica-Minolta

Xpress CR - Contact Mammography Upgrade
### Konica Minolta

<p>| | |</p>
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<thead>
<tr>
<th></th>
<th></th>
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<td>Physical Inspection</td>
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<td>2.</td>
<td>Tube Voltage Measurement and Reproducibility</td>
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<tr>
<td>3.</td>
<td>Beam Quality</td>
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<td>4.</td>
<td>Radiation Output Rate</td>
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<td>5.</td>
<td>Average Glandular Dose</td>
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<tr>
<td></td>
<td>Average glandular dose for average breast is $\leq 3$ mGy (300 mrad)</td>
</tr>
<tr>
<td>6.</td>
<td>View Boxes and Viewing Conditions</td>
</tr>
<tr>
<td>7.</td>
<td>Monitor QC (CR Console Monitor)</td>
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<td>8.</td>
<td>Dark Noise</td>
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<td>9.</td>
<td>Ghost Image Evaluation</td>
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<td>10.</td>
<td>S value Response Indicator</td>
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<td></td>
<td>S value variation: $\pm 20%$</td>
</tr>
<tr>
<td>11.</td>
<td>AEC Performance Checks</td>
</tr>
<tr>
<td></td>
<td>Stability and Reproducibility: mAs CV $\leq 5%$</td>
</tr>
<tr>
<td></td>
<td>Thickness Tracking: CNR (2cm) $&gt; 100%$, CNR (6cm) $&gt; 75%$, S value variation $\leq 20%$</td>
</tr>
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<td>12.</td>
<td>Collimation Assessment</td>
</tr>
<tr>
<td>13.</td>
<td>CR Reader Scanner Performance</td>
</tr>
<tr>
<td>14.</td>
<td>Spatial Resolution</td>
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<tr>
<td>15.</td>
<td>Artifact Evaluation</td>
</tr>
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<td>16.</td>
<td>Inter-Plate Consistency</td>
</tr>
<tr>
<td></td>
<td>SNR variation: $\pm 15%$</td>
</tr>
<tr>
<td></td>
<td>S value variation: $\pm 15%$</td>
</tr>
<tr>
<td>17.</td>
<td>Phantom Image Quality</td>
</tr>
<tr>
<td></td>
<td>Phantom image scores: Fibers [ ] Specks [ ] Masses [ ]</td>
</tr>
<tr>
<td></td>
<td>Density Check: S value variation $\pm 20%$; background density change $\pm 20$; density difference change $\pm 0.05$</td>
</tr>
<tr>
<td></td>
<td>Thickness Check: $\pm 0.5$ cm</td>
</tr>
<tr>
<td>18.</td>
<td>Review Workstation QC-Overall</td>
</tr>
<tr>
<td>19.</td>
<td>Film Printer QC-Overall</td>
</tr>
</tbody>
</table>
QC PHANTOMS AND AUTOMATED ANALYSIS PROGRAMS: GE

flat field test
AOP and SNR
IQST (Image Quality Signature Test) Phantom- MTF and CNR
1. Flat Field and Image Quality Checks (Weekly technologist test.)

a. Flat Field: 2.5 cm thick uniform PMMA; 26 kVp; 200 mAs; Mo/Mo. Phantom evaluated on AWS.

<table>
<thead>
<tr>
<th>Test</th>
<th>Results</th>
<th>Status</th>
<th>Objects</th>
<th>Observed</th>
<th>Status</th>
</tr>
</thead>
<tbody>
<tr>
<td>Brightness Uniformity &lt; 10%</td>
<td>1.82</td>
<td>Pass</td>
<td>Fibers</td>
<td>5.5</td>
<td>Pass</td>
</tr>
<tr>
<td>High Freq Modulation &lt; 0.8</td>
<td>0.49</td>
<td>Pass</td>
<td>Specks</td>
<td>4</td>
<td>Pass</td>
</tr>
<tr>
<td>Bad Pixel &lt; 100</td>
<td>0</td>
<td>Pass</td>
<td>Masses</td>
<td>4</td>
<td>Pass</td>
</tr>
<tr>
<td>Bad ROI = 0</td>
<td>0</td>
<td>Pass</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>SNR Uniformity &lt; 40%</td>
<td>23.03</td>
<td>Pass</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

b. Phantom Image Quality (Print, AWS and RWS).

RMI Model156 Phantom: 26 kVp; 125 mAs; Mo/Mo.
<table>
<thead>
<tr>
<th>Test</th>
<th>Measurement</th>
<th>LSL</th>
<th>USL</th>
<th>Status</th>
</tr>
</thead>
<tbody>
<tr>
<td>Brightness Non Uniformity</td>
<td>1.66</td>
<td>N/A</td>
<td>10.00</td>
<td>PASS</td>
</tr>
<tr>
<td>High Frequency Modulation</td>
<td>0.49</td>
<td>N/A</td>
<td>0.80</td>
<td>PASS</td>
</tr>
<tr>
<td>Bad Pixel</td>
<td>0.00</td>
<td>N/A</td>
<td>100.00</td>
<td>PASS</td>
</tr>
<tr>
<td>Bad ROI</td>
<td>0.00</td>
<td>N/A</td>
<td>0.00</td>
<td>PASS</td>
</tr>
<tr>
<td>SNR Non Uniformity</td>
<td>28.67</td>
<td>N/A</td>
<td>40.00</td>
<td>PASS</td>
</tr>
<tr>
<td>Test</td>
<td>Measurement</td>
<td>LSL</td>
<td>USL</td>
<td>Status</td>
</tr>
<tr>
<td>-------</td>
<td>-------------</td>
<td>------</td>
<td>------</td>
<td>--------</td>
</tr>
<tr>
<td>AOP 25mm</td>
<td>Mo/Mo/26kv</td>
<td>32.50</td>
<td>60.00</td>
<td>PASS</td>
</tr>
<tr>
<td>MAS 25mm</td>
<td>Mo/Mo/26kv</td>
<td>20.00</td>
<td></td>
<td></td>
</tr>
<tr>
<td>SNR 25mm</td>
<td></td>
<td>50.00</td>
<td>N/A</td>
<td>PASS</td>
</tr>
</tbody>
</table>
DS IQ Signature Test
automates SNR and MTF
### Image Quality Test Results

**Test** | **Measurement** | **LSL** | **USL** | **Status**
--- | --- | --- | --- | ---
TF Parallel at 2 lp/mm | 64.61 | 49.00 | N/A | PASS
TF Parallel at 4 lp/mm | 30.64 | 18.00 | N/A | PASS
TF Perpendicular at 2 lp/mm | 66.98 | 49.00 | N/A | PASS
TF Perpendicular at 4 lp/mm | 32.28 | 18.00 | N/A | PASS
SHL | 42.96 | N/A | N/A |

**Previous CNR values**
- 42.90, 45.57, 41.89

**Change in CNR**
- 0.01 | N/A | 0.40 | PASS

**QST device reference**
- 676

---

*Put 25mm acrylic plates on the bucky.*
*Align the longest side of the plates with the chestwall edge of the bucky.*
*Center the plates left-right.*
*Apply a compression force of 5 daN.*
*Perform 1 exposure.*
QC PHANTOMS AND AUTOMATED ANALYSIS PROGRAMS: Hologic

Auto SNR and CNR
Contrast to Noise Ratio
QC PHANTOMS AND AUTOMATED ANALYSIS PROGRAMS: Fuji CR

Auto SNR and CNR
ROI placement for automated CNR and SNR calculation
QC calculation tool - offline
QC PHANTOMS AND AUTOMATED ANALYSIS PROGRAMS: Fuji DR

Fuji One Shot phantom and auto QC program
Fuji 1 Shot Phantom M Plus weekly constancy test tool
## 9.1 Specification Outline of 1Shot Phantom M Plus

<table>
<thead>
<tr>
<th>Test Contents</th>
<th>Applicable Phantom</th>
<th>Outline of Calculation Method</th>
</tr>
</thead>
<tbody>
<tr>
<td>Missed tissue on chest wall edge</td>
<td>Bar patterns (1 mm spacing)</td>
<td>The amount of missed tissue on the chest wall-side edge is calculated by using coordinate information of the slit.</td>
</tr>
<tr>
<td>CNR</td>
<td>AI (0.2 mm)</td>
<td>CNR is calculated according to the definitional equation described in IEC 61223-3-2.</td>
</tr>
<tr>
<td>1Shot Phantom sensitivity constancy</td>
<td>Uniform exposure region at 60 mm from the chest wall-side edge</td>
<td>A calculation area (20 x 20 mm) is set at the lateral center and also at 60 mm from the chest wall-side edge. Based on the pixel value in this calculation area, the value inversely proportional to the air kerma is calculated. Note: Although this value is calculated in the same way as S value, this value and S value need to be discriminated.</td>
</tr>
<tr>
<td>Geometric distortion</td>
<td>Lines indicated with triangle markers (100 mm spacing)</td>
<td>The distance between the two lines is calculated.</td>
</tr>
<tr>
<td>System artifact evaluation</td>
<td>Uniform exposure region made of metal and plastic (The transmission factor becomes equivalent to 40-mm PMMA phantom at 28kVp, Mo/Mo.)</td>
<td>N/A</td>
</tr>
<tr>
<td>Uniformity (Uniform Exposure Region)</td>
<td>Uniform exposure region at 60 mm from the chest wall-side edge and uniform exposure regions at four corners of the phantom</td>
<td>A calculation area (10 x 10 mm) is set at the lateral center and also at 60 mm from the chest wall. Based on this calculation region, the pixel value and relative SNR value are calculated in the calculation regions (10 x 10 mm each) at four corners of the phantom.</td>
</tr>
<tr>
<td>Dynamic range</td>
<td>The lightest region of the step wedge</td>
<td>The pixel value in the highest density region of the step wedge is calculated. According to IEC 61223-3-2, calculation is executed only in the highest density region.</td>
</tr>
<tr>
<td>Spatial Resolution (SR)</td>
<td>Bar patterns slanted at 45 degrees (2, 4 and 8 cycles/mm)</td>
<td>SCTF is calculated according to the definitional equation described in IEC 61223-3-2.</td>
</tr>
<tr>
<td>Low Contrast Detectability (LCD)</td>
<td>PMMA phantom (¢2 mm, contrast 1.4%)</td>
<td>A cross-correlation factor is calculated based on the reference image (ideal image).</td>
</tr>
<tr>
<td>Linearity/Beam quality constancy</td>
<td>Five step-wedge patterns forming a density region in the range of the center density plus or minus about one digit</td>
<td>The pixel value is calculated in each step of the step wedge and then the difference between the adjacent steps is calculated.</td>
</tr>
<tr>
<td>ACR Phantom image confirmation</td>
<td>1Shot Phantom image confirmation</td>
<td></td>
</tr>
<tr>
<td>------------------------------------------------------------------</td>
<td>------------------------------------------------------</td>
<td></td>
</tr>
<tr>
<td>Density at center of Phantom</td>
<td>Geometric distortion</td>
<td></td>
</tr>
<tr>
<td>Density inside the disk</td>
<td>Fail</td>
<td></td>
</tr>
<tr>
<td>Density outside the disk</td>
<td>Pass</td>
<td></td>
</tr>
<tr>
<td>Fibers Score</td>
<td>Artifact</td>
<td></td>
</tr>
<tr>
<td>Specks Score</td>
<td>Fail</td>
<td></td>
</tr>
<tr>
<td>Masses Score</td>
<td>Pass</td>
<td></td>
</tr>
<tr>
<td>Step Phantom image confirmation</td>
<td>Good practice</td>
<td></td>
</tr>
<tr>
<td>Visible step wedge Step</td>
<td>X-ray equip. cleanliness</td>
<td></td>
</tr>
<tr>
<td>Specks Step</td>
<td>Fail</td>
<td></td>
</tr>
<tr>
<td>Masses Step</td>
<td>Pass</td>
<td></td>
</tr>
<tr>
<td>Good practice</td>
<td>IP / Cassette cleanliness</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Fail</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Pass</td>
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<tr>
<td></td>
<td>Screen cleanliness</td>
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<td></td>
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<td>Pass</td>
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<td>Viewing box cleanliness</td>
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</tr>
<tr>
<td></td>
<td>Fail</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Pass</td>
<td></td>
</tr>
</tbody>
</table>

**Cancel**

**OK**
QC PHANTOMS AND AUTOMATED ANALYSIS PROGRAMS: Carestream

CR Mammo TQT
Manual QC Procedure vs. CR Mammo TQT

The DIRECTVIEW Total Quality Tool (TQT) enables you to perform objective image tests and QC measurements with the same interface used for examinations.
Manual QC Procedure vs CR Mammo TQT

- Manual QC procedure satisfies 21 CFR 900, TQT does not
- TQT is a scanner test only
- Performed by Service upon install
- Recommended for sites to perform twice a year
- Some states make it a yearly requirement
- Does not change the QC testing that has to be performed
Potential future changes

- ACR FFDM QC program
- Universal phantom
- Alternative standard (MQSA)
New ACR accreditation phantom (proposed)
Who determines the QC requirements for a new mammography modality?

1. FDA
2. ACR
3. Imaging system manufacturer
4. On-site physicist
5. Image receptor manufacturer

21 C.F.R. 900.12(e)(6)
Which of the following are new modalities- requiring 8 hours of initial training before use?

1. Screen/film and stereo mammography
2. Full-field digital mammography and digital breast tomosynthesis
3. Stereotactic biopsy
4. Digital stereotactic biopsy
5. Automated breast ultrasound

www.fda.gov/Radiation-EmittingProducts/MammographyQualityStandardsActandProgram/Guidance/PolicyGuidanceHelpSystem/ucm136925.htm
www.fda.gov/Radiation-EmittingProducts/MammographyQualityStandardsActandProgram/FacilityCertificationandInspection/ucm243765.htm
The 5 year survival for a minimal breast cancer is

1. Less then 50%
2. 60-70%
3. 70-80%
4. 80-90%
5. Greater than 90%

The most reliable indication of breast cancer in a mammogram is

1. Architectural distortion
2. Clustered calcifications
3. Linear and branching calcifications
4. **Spiculated mass**
5. Skin thickening

Tabar L, Tot T, Dean PB. Breast cancer: the art and science of early detection with mammography. Stuttgart, Germany, Thieme Verlag, 2005
What performance parameter(s) does MQSA specify for FFDM quality assurance?

1. Phantom dose < 3.0 mGy for one CC view
2. Phantom dose < 2.0 mGy for one CC view Image
3. Image quality must exceed S/F IQ
4. Dose can’t exceed max. allowed S/F dose
5. Patient dose ≤ 3.0 mGy for one CC view

21 C.F.R. 900.12(e)(6); 21 C.F.R. 900.12(e)(5)(vi)