SFDA Screening
Mammography Quality Standards Program

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Radiological Health Executive Department

Medical Devices Sector

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## Acronyms & Definitions

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<th><strong>Acronym</strong></th>
<th><strong>Definition</strong></th>
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<tbody>
<tr>
<td>ALARA</td>
<td>As Low As Reasonably Achievable.</td>
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<tr>
<td>Ionizing &amp; Non-Ionizing Radiation</td>
<td>radiation that has energy that can move atoms in a molecule around or cause them to vibrate but is not enough to remove electrons is referred to as non-ionizing radiation. Any radiation that falls within the ionizing radiation range has enough energy to remove tightly bound electrons from atoms thus creating ions.</td>
</tr>
<tr>
<td>KERMA</td>
<td>Kinetic Energy Released in Matter (Air).</td>
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<tr>
<td>Mammography</td>
<td>means radiography of the breast.</td>
</tr>
<tr>
<td>Mammography equipment evaluation’</td>
<td>means an on-site assessment of the performance of a mammography unit or image processor by a medical physicist as a preliminary investigation of whether the equipment meets all of the applicable standards.</td>
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<tr>
<td>MDMA</td>
<td>Medical Devices Marketing Authorization.</td>
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<tr>
<td>MRSO</td>
<td>Medical Radiation Safety Officer.</td>
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<tr>
<td>mSv</td>
<td>means milliSievert, a derived unit of ionizing radiation dose in the International System of Units.</td>
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<tr>
<td>OSL</td>
<td>means Optically Stimulated Luminescence, a type of personal radiation dosimeter.</td>
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<tr>
<td>QA</td>
<td>Quality Assurance.</td>
</tr>
<tr>
<td>QC</td>
<td>Quality Control.</td>
</tr>
<tr>
<td>Screen-certified body</td>
<td>means a facility approved by SFDA to provide mammography-screening services.</td>
</tr>
<tr>
<td>SFDA</td>
<td>Saudi Food and Drug Authority.</td>
</tr>
<tr>
<td>TLDs</td>
<td>means thermoluminescent dosimeter, a type of personal radiation dosimeter</td>
</tr>
</tbody>
</table>
1. Introduction

Mammography is an effective method for screening breast cancer. However, there are safety implications of mammography equipment as they utilize X-rays, which are potentially dangerous, to produce images. Screening mammography services can be provided indoor clinics and mobile sites. The Saudi Food and Drug Authority law, according to the royal decree (M/6) on 25/01/1428, ensures the certification of mammography screening facilities including clinics and charities. The importance of the certification of mammography screening center is highlighted below.

- To increase the radiation protection of mammography x-ray facilities.
- To increase public awareness of mammography screening benefits.
- To minimize the number of women referred unnecessarily for further tests and dose.
- To minimize the number of false negative results in screened women.
- To ensure accurate detection of breast cancer.
- To minimize the number of unnecessary invasive procedures.

2. SFDA’s Mammography Certification Programs

SFDA has established mammography programs as follow:

a. SFDA schedules On-site visits.

b. SFDA provides a Mammography Certification for any facility or body which aims to provide breast cancer screening services.

c. SFDA carries out Mammography equipment evaluation.

d. SFDA conducts a Mammography Awareness to educate women about the importance of the early detection of breast cancer through mammography.
2.1 On-site visits Program

SFDA ensures that QA and safety standards are met by carrying out on-site visits in the Kingdom of Saudi Arabia. To evaluate the current status of mammography facilities. Therefore, guaranteed that SFDA requirements are met and radiation protection integrated into the screening room design.

2.1.1 SFDA Requirements:

• Assessment of overall clinical image-QA activities of the facility.
• Evaluation of the quality of review clinical images, phantom images, or any other information relevant to applicable standards as well as SFDA standards.
• Review of the facility’s documentation to determine if appropriate mammography reports are sent to patients and physicians.
• Verification of the medical audit system at facilities to ascertain if it correlates films and pathology reports for positive cases.
• Verification of the qualifications of the personnel that perform specific duties confirming that they are as specified by the facility.
• Verification of the equipment used by the facility for specific functions confirming that they are as specified.
• Inspection and observation of phantom image testing.
• Inspection and observation to interpret the physician’s qualifications
• Evaluation of evidence or information obtained from a facility’s certified body or from physician, patient, or technologist’s complaints regarding a quality problem at the facility
• Annual evaluation of the performance of mammography
• Compliance with SFDA audit reports.
2.1.2 Room Design:

Safety and protection are integrated into the design of mammography facilities, from the X-ray rooms to other rooms. Shielding and dose are also regulated according to the SFDA regulation for dose reduction. Safety measures incorporated into mammography facilities are as follows:

a. All medical devices utilized within the mammography facilities should have the SFDA MDMA.

b. The room design should be isolated to prevent the X-ray beam from unprotected areas; e.g., waiting area and corridor.

c. The X-ray room should to be designed to prevent the direct incident of the X-ray beam on access doors. The doors should be designed as protective barriers for dispersed radiation and closed when the X-ray beam is ON.

d. The operator should have a clear observation of the patient during the X-ray diagnostic procedure.

e. The patients’ waiting area should be at an appropriate distance from the operational room.

2.1.3 Quality Control (QC)

The QC of the physical and technical aspects must guarantee that the following objectives are met:

- The radiologist is provided with images that have the best possible diagnostic information obtainable when the appropriate radiographic technique is employed. The images should at least contain the defined acceptable level of information.

- The image quality is stable with respect to information content and optical density and consistent with that obtained by other participating screening centers.
- The breast dose is As Low As Reasonably Achievable (ALARA) for the diagnostic information required.

A. Daily Quality Control Tests

Film processors used to develop mammograms shall be adjusted and maintained to meet the technical development specifications for the mammography film in use. A processor performance test shall be performed every day before any clinical films are processed. The test shall include an assessment of base plus fog density, mid-density, and density difference, using the mammography film used clinically at the facility.

(i) The base plus fog density shall be within + 0.03 of the established operating level.

(ii) The mid-density shall be within +/- 0.15 of the established operating level.

(iii) The density difference shall be within +/- 0.15 of the established operating level.

B. Weekly Quality Control Tests

Facilities with screen-film systems shall perform an image quality evaluation test using an SFDA-approved phantom at least weekly.

(i) The optical density of the film at the center of an image of a standard SFDA-accepted phantom shall be at least 1.20 when exposed under a typical clinical condition.

(ii) The optical density of the film at the center of the phantom image shall not change by more than +/- 0.20 from the established operating level.

(iii) The density difference between the background of the phantom and the test object shall be measured and shall not vary by more than +/- 0.05 from the established operating level.
C. **Quarterly Quality Control Tests**

Facilities with screen-film systems shall perform the following quality control tests at least quarterly:

(i) *Fixer retention in film.* The residual fixer shall be no more than 5 micrograms per square cm.

(ii) *Repeat analysis.* If the total repeat or reject rate changes from the previously determined rate by more than 2.0 percent of the total films included in the analysis, the reason(s) for the change shall be determined. Any corrective actions shall be recorded, and the results of these corrective actions shall be assessed.

D. **Semiannual Quality Control Tests**

Facilities with screen-film systems shall perform the following quality control tests at least semiannually:

(i) *Darkroom fog.* The optical density of darkroom fog shall not exceed 0.05 when the mammography film used in the facility, with a mid-density of no less than 1.2 OD, is exposed to typical darkroom conditions for 2 minutes on a countertop with the emulsion side up. If the darkroom has a safelight used for mammography film, it shall be on during this test.

(ii) *Screen-film contact.* Testing for screen-film contact shall be conducted using 40 mesh copper screen. All cassettes used in the facility for mammography shall be tested.

(iii) *Compression device performance.*

(A) A compression force of at least 111 newtons (25 pounds) shall be provided.
(B) Effective October 28, 2002, the maximum compression force for the initial power drive shall be between 111 newtons (25 pounds) and 200 newtons (45 pounds).

E. Annual Quality Control Tests

Facilities with screen-film systems shall perform the following quality control tests at least annually:

(i) Automatic Exposure Control Performance

(A) The AEC should maintain a film optical density within +/- 0.30 of the mean optical density when the thickness of a homogeneous material is varied over a range of 2 to 6 cm and the kVp is varied appropriately over the kVp range used clinically in the facility. If this requirement cannot be met, a technique chart shall be developed showing appropriate techniques (kVp and density control settings) for different breast thicknesses and compositions that must be used so that optical densities within +/- 0.30 of the average under photo timed conditions can be produced.

(B) The AEC shall be capable of maintaining film optical density (OD) within +/- 0.15 of the mean optical density when thickness of a homogeneous material is varied over a range of 2 to 6 cm and the kVp is varied appropriately for such thicknesses over the kVp range used clinically in the facility.

(C) The optical density of the film at the center of the phantom image shall not be less than 1.20.

(ii) Kilovoltage Peak (kVp) Accuracy and Reproducibility

(A) The kVp shall be accurate within +/- 5 percent of the indicated or selected kVp at:

1) The lowest clinical kVp that can be measured by a kVp test device;
2) The most commonly used clinical kVp;
(3) The highest available clinical kVp, and

(B) At the most commonly used clinical settings of kVp, the coefficient of variation of reproducibility of the kVp shall be equal to or less than 0.02.

(iii) **System Resolution**

(1) Each X-ray system used for mammography, in combination with the mammography screen-film combination used in the facility, shall produce a minimum resolution of 11 Cycles/millimeters (mm) (line-pairs/mm) when a high contrast resolution bar test pattern is oriented with the bars perpendicular to the anode-cathode axis. When the bars are parallel to that axis, a minimum resolution of 13 line-pairs/mm shall be produced.

(2) The bar pattern shall be placed 4.5 cm above the breast support surface, centered with respect to the chest wall edge of the image receptor, with the edge of the pattern within 1 cm of the chest wall edge of the image receptor.

(3) Test kVp shall be set at the value used clinically by the facility for a standard breast and shall be performed in the AEC mode, if available. If necessary, a suitable absorber may be placed in the beam to increase exposure times. The screen-film cassette combination used by the facility shall be used to test for this requirement and shall be placed in the normal location used for clinical procedures.

(v) **Focal Spot Dimensions**

Measured values of the focal spot length (dimension parallel to the anode-cathode axis) and width (dimension perpendicular to the anode cathode axis) shall be within the tolerance limits specified in Table 1.
### Table 1: Focal Spot Tolerance Limit

<table>
<thead>
<tr>
<th>Nominal Focal Spot Size (mm)</th>
<th>Maximum Measured Dimensions</th>
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<tbody>
<tr>
<td></td>
<td>Width (mm)</td>
</tr>
<tr>
<td>0.10</td>
<td>0.15</td>
</tr>
<tr>
<td>0.15</td>
<td>0.23</td>
</tr>
<tr>
<td>0.20</td>
<td>0.30</td>
</tr>
<tr>
<td>0.30</td>
<td>0.45</td>
</tr>
<tr>
<td>0.40</td>
<td>0.60</td>
</tr>
<tr>
<td>0.60</td>
<td>0.90</td>
</tr>
</tbody>
</table>

(iv) **Beam Quality and Half-Value Layer (HVL)**

The HVL shall meet the specifications of Sec. 1020.30(m)(1) of this chapter for the minimum HVL. These values, extrapolated to the mammographic range, are shown in Table 2. Values not shown in Table 2 may be determined by linear interpolation or extrapolation.

### Table 2: X-ray Tube Voltage (kilovolt peak) and Minimum HVL

<table>
<thead>
<tr>
<th>Designed Operating Range (kV)</th>
<th>Measured Operating Voltage (kV)</th>
<th>Minimum HVL (millimeters of aluminum)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Below 50</td>
<td>20</td>
<td>0.20</td>
</tr>
<tr>
<td></td>
<td>25</td>
<td>0.25</td>
</tr>
<tr>
<td></td>
<td>30</td>
<td>0.30</td>
</tr>
</tbody>
</table>

(v) **Breast Entrance Air KERMA and AEC Reproducibility**

The coefficient of variation for both air KERMA and mA's shall not exceed 0.05.
(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.

(vii) **X-ray Field/Light Field/Image Receptor/Compression Paddle Alignment**

(A) All systems shall have beam-limiting devices that allow the entire chest wall edge of the x-ray field to extend to the chest wall edge of the image receptor and provide means to assure that the x-ray field does not extend beyond any edge of the image receptor by more than 2 percent of the SID.

(B) If a light field that passes through the X-ray beam limitation device is provided, it shall be aligned with the X-ray field so that the total of misalignment of the edges of the light field and the X-ray field along the length or width of the visually defined field at the plane of the breast support surface shall not exceed 2 percent of the SID.

(C) The chest wall edge of the compression paddle shall not extend beyond the chest wall edge of the image receptor by more than one percent of the SID when tested with the compression paddle placed above the breast support surface at a distance equivalent to the standard breast thickness. The shadow of the vertical edge of the compression paddle shall not be visible on the image.

(viii) **Uniformity of Screen Speed**

The uniformity of the screen speed of all the cassettes in the facility shall be tested, and the difference between the maximum and minimum optical densities shall not exceed 0.30. Screen artifacts shall also be evaluated during this test.

(ix) **System Artifacts**

System artifacts shall be evaluated with a high-grade, defect-free sheet of homogeneous material large enough to cover the mammography cassette and shall
be performed for all cassette sizes used in the facility using a grid appropriate for the cassette size being tested. System artifacts shall also be evaluated for all available focal spot sizes and target filter combinations used clinically.

(x) Radiation Output

(A) The system shall be capable of producing a minimum output of 4.5 mGy air KERMA per second (513 milliRoentgen (mR) per second) when operating at 28 kVp in the standard mammography (moly/moly) mode at any SID where the system is designed to operate and when measured by a detector with its center located 4.5 cm above the breast support surface with the compression paddle in place between the source and the detector. The system shall be capable of producing a minimum output of 7.0 mGy air KERMA per second (800 mR per second) when operating at 28 kVp in the standard (moly/moly) mammography mode at any SID it is designed to operate.

(B) The system shall be capable of maintaining the required minimum radiation output averaged over a 3.0 second period.

(xi) Decompression

If the system has provision for automatic decompression after completion of an exposure or interruption of power, the system shall be tested to confirm that it provides:

(A) An override capability that allows maintenance of compression;

(B) A continuous display of the override status; and

(C) A manual emergency compression release that can be activated in the event of power or automatic release failure.
(iv) **Quality Assurance Equipment**

(1) 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 that recommended by the image receptor manufacturer, except that the maximum allowable dose shall not exceed the maximum allowable dose for screen-film systems.

(2) Mobile Units. The facility shall verify that mammography units used to produce mammograms at more than one location meet the requirements. Also, at each examination location, before any examinations are conducted, the facility shall verify satisfactory performance of such units using a test method that establishes the adequacy of the image quality produced by the unit.

(v) **Surveys**

1) At least once a year, each facility shall undergo a survey by a medical physicist or an individual under the direct supervision of a medical physicist. At a minimum, this survey shall include the performance of tests to ensure that the facility meets the quality assurance requirements of the annual tests and the weekly phantom image quality test described.

2) The results of all tests conducted by the facility as well as written documentation of any corrective actions taken and their results, shall be evaluated for adequacy by the medical physicist performing the survey.

3) The medical physicist shall prepare a survey report that includes a summary of this review and recommendations for necessary improvements.

4) The survey report shall be sent to the facility within 30 days of the date of the survey.

5) The survey report shall be dated and signed by the medical physicist performing or supervising the survey. If the survey was performed entirely or in part by another individual under the direct supervision of the medical physicist, that individual and the part of the survey that the individual performed shall also be identified in the survey report.
(vi) **Mammography Equipment Evaluations**

Additional evaluations of mammography units or image processors shall be conducted whenever a new unit or processor is installed. The evaluations are also carried out when a unit or processor is disassembled and reassembled at the same or a new location, or major components of a mammography unit or processor equipment are changed or repaired. These evaluations shall be used to determine whether the new or changed equipment meets the requirements. All problems shall be corrected before the new or changed equipment is put into service for examinations or film processing. The mammography equipment evaluation shall be performed by a medical physicist or by an individual under the direct supervision of a medical physicist.

(vii) **Facility Cleanliness**

1) The facility shall establish and implement adequate protocols for maintaining darkroom, screen, and view box cleanliness.

2) The facility shall document that all cleaning procedures are performed at the frequencies specified in the protocols.

(x) **Calibration of Air KERMA Measuring Instruments**

Instruments used by medical physicists to measure the air KERMA or the air KERMA rate from a mammography unit in annual surveys shall be calibrated at least once every 2 years and each time the instrument is repaired. The instrument calibration must be traceable to a national standard and calibrated with an accuracy of +/- 6 percent (95 percent confidence level) in the mammography energy range.

(ix) **QC Measurements and Frequencies**

Bodies certified by SFDA ensure that objectives are met with QC measurements which follow a written QC control adapted to specific requirements.
Elaborate measurements are carried out by professional medical physicists who specialize in mammography QC. Local staff also carry out several measurements.

The radiographic technique employed determines the image quality and breast dose.

QC monitors certain physical and technical parameters of the mammography system and its components; they include:

- X-ray generator and control system;
- Bucky and image receptor;
- Film processing;
- System properties (including dose);
- Viewing conditions.

(x) Staff and Equipment

The staff that carries out daily/weekly QC tests utilizes the following equipment at the screening site.

- Sensitometer
- Densitometer
- Thermometer
- PMMA plates
- Daily QC test object
- Reference cassette

The following additional equipment are utilized by the medical physicists for the specialized tests:

- Dosimeter
- Stopwatch
- kVp-meter
- Film/screen contact test device
- Exposure time meter
• Tape measure
• Light meter
• Compression force test device
• QC test objects
• Rubber foam
• Aluminum sheets
• Lead sheet
• Focal spot test device + stand - Aluminum step wedge.

(xi) Availability of Records

The following records should be kept for at least five years for future references:

• The drawing records and calculations of the accepted shielding
• Documentation of construction justifying the installed shielding.
• Survey reports
• Information on changes
• Subsequent survey reports after changes
• Personnel dosimetry
• Area survey outcome
• Rejected images and films
• Installation documents, including conditions of power as well as ventilation
• Service manuals
• Operating instructions
• In-service training offered
• Preventative maintenance reports
• Quality Control Performance
• Emergency maintenance reports
• Corrective maintenance reports
• Electrical safety reports
• Lead apron tests for shield integrity.
(xii) **Emergency Plans**

- A written emergency strategy within the department rooms.
- The written emergency strategy should be reviewed and updated periodically.
- Adverse cases should be reported to the SFDA.
- Actions of preventing future adverse cases.
2.2 Mammography Certification Program

SFDA provides a Mammography Certification for any facility or body which aims to provide breast cancer screening services.

2.2.1 Application for Approval as a Screen-Certified Body

(a) Charity organizations, private nonprofit organizations or clinics that can meet SFDA’s requirements may apply for approval as screen-certified bodies.

(b) Application for initial approval.

1. An applicant seeking initial SFDA approval as a screen-certified body shall inform the Executive Department of Radiological Health, Saudi Food and Drug Authority of its desire for approval and the requested scope of authority by email: rh.md@sfda.gov.sa

2. The applicant shall send the following information, materials, and support documentation:

   a. Name, address, and phone number of the applicant and, evidence if it is a nonprofit body.

   b. A detailed description of the screen-certified body. The applicant will require facilities that meet SFDA’s standards; a discussion substantiating their equivalence to SFDA standards is also required.

   c. A detailed description of the applicant's screen-certified review and decision-making process, including:

      i. Procedures for performing screen-certified and recertified clinical image review.

      ii. Procedures for performing the phantom image review.
iii. Procedures for assessing mammography equipment evaluations and surveys.
iv. Procedures for initiating and performing on-site visits to facilities.
v. Procedures for assessing the qualifications of facility personnel.
vi. Policies and procedures for notifying facilities of deficiencies.


viii. A description of the applicant’s appeal process for facilities contesting adverse screen-certified body status decisions.

d. Education, experience, and training requirements for the applicant's professional staff, including reviewers of clinical or phantom images.

e. Description of the applicant's electronic data management and analysis system with respect to screen-certified review and decision processes and the applicant's ability to provide electronic data in a format compatible with SFDA data systems.

f. Fee schedules with supporting cost data.

g. Statement of policies and procedures established to protect confidential information the applicant will collect or receive as a screen-certified body.

h. Disclosure of any specific brand of imaging system or component, measuring device, software package, or other commercial product used in mammography that the applicant develops, sells or distributes.

i. Any other information as may be required by SFDA.
2.2.2 Screen-Certified Bodies

(a) The screen-certified body shall inform SFDA as soon as possible but in no case longer than 2 business days after becoming aware of any adverse event.

(b) The screen-certified body shall establish and administer a quality assurance (QA) program that has been approved by SFDA. Such quality assurance program shall:

1. Include requirements for clinical image review and phantom image review;
2. Ensure that clinical and phantom images are evaluated consistently and accurately; and
3. Specify the methods and frequency of training and evaluation for clinical and phantom image reviewers and the bases and procedures for removal of such reviewers.

(c) The screen-certified body may require specific equipment performance and design characteristics approved by SFDA.

(d) The screen-certified body shall obtain SFDA authorization for any changes it proposes to make to the standards previously accepted by FDA.
2.3 Mammography Equipment Evaluation Programs

Equipment evaluation should be consulted for a complete understanding of the equipment performance requirements. SFDA conducts assessment of the performance of a mammography unit or image processor by a medical physicist as a preliminary investigation of whether the equipment meets all of the applicable standards.

1. **Prohibited Equipment**

   Radiographic equipment designed for general purposes or special non-mammography procedures shall not be used for mammography. This prohibition includes systems that have been modified or equipped with special attachments for mammography.

2. **General**

   All radiographic equipment shall be specifically designed for mammography and shall be certified under SFDA MDMA.

3. **Motion of Tube-Image Receptor Assembly**

   a. The assembly should be designed to be fixable in the position where it operates. Once fixed, it shall not undergo unintended motion.

   b. The mechanism shall not fail in the event of power interruption.

4. **Image Receptor Sizes**

   a. Systems using screen-film image receptors shall provide image receptors of at least 18 x 24 centimeters (cm) and 24 x 30 cm for operation.

   b. Systems using screen-film image receptors shall be equipped with moving grids matched to all image receptor sizes provided.

   c. Systems used for magnification procedures should be able to operate with no grid between the source and image receptor.
5. **Light fields**

For any mammography system with a light beam that passes through the X-ray-beam-limiting device, the light shall provide an average illumination of at least 160 lux (15-foot candles) at 100 cm or the maximum source-image receptor distance (SID), whichever is less.

6. **Magnification**

   a. Systems used to perform noninterventional problem-solving procedures shall have radiographic magnification capability available for use by the operator.

   b. Systems used for magnification procedures shall provide at least one magnification value within the range of 1.4 to 2.0.

7. **Focal spot selection**

   a. When more than one focal spot is provided, the system shall indicate, before exposure, the preselected focal point.

   b. When more than one target material is provided, the system shall indicate the preselected target material.

   c. When the target material and/or focal spot is selected by a systematic algorithm that is based on the exposure or a test exposure, the system shall display, after the exposure, the target material and/or focal spot used during the exposure.

8. **Compression**

All mammography systems shall incorporate a compression device

   a. *Application of Compression*,

   each system shall provide:
i. An initial power-driven compression activated by hands-free controls operable from both sides of the patient; and

ii. Fine adjustment compression controls operable from both sides of the patient.

b. Compression Paddle

i. Systems shall be equipped with different sizes of compression paddles that match the sizes of all full-field image receptors provided for the system. Compression paddles for special purposes, including those smaller than the full size of the image receptor (for "spot compression") may be provided.

ii. The compression paddle shall be flat and parallel to the breast support table and shall not deflect by more than 1.0 cm at any point on the surface of the compression paddle when compression is applied.

iii. 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.

iv. The chest wall edge of the compression paddle shall be straight and parallel to the edge of the image receptor.

v. The chest wall edge may be bent upward to allow for patient comfort but shall not appear on the image.

9. Technique Factor Selection and Display

a. Manual selection of milliampere seconds (mA's) or at least one of its component parts (milliampere (mA) and/or time) shall be available.

b. The technique factors (peak tube potential in kilovolt (kV) and either tube current in mA and exposure time in seconds or the product of tube current and exposure time in mA's) to be used during an exposure shall be indicated before the exposure
begins, except when automatic exposure controls (AEC) are used. In the case of automatic selections, the technique factors set prior to the exposure shall be indicated.

10. Automatic Exposure Control  
   a. Each screen-film system shall provide an AEC mode that is operable in all combinations of equipment configuration provided, e.g., grid, non-grid; magnification, non-magnification; and various target-filter combinations.  
   b. The positioning or selection of the detector shall permit flexibility in the placement of the detector under the target tissue.  
      i. The size and available positions of the detector shall be clearly indicated at the X-ray input surface of the breast compression paddle.  
      ii. The selected position of the detector shall be clearly indicated.  
   c. The system shall provide means for the operator to vary the selected optical density from the normal (zero) setting.  
   d.  
11. X-ray Film  
The facility shall use only X-ray films that have been designated by the film manufacturer as appropriate for mammography.  

12. Intensifying Screens  
The facility shall use intensifying screens that have been designated by the screen manufacturer as appropriate for mammography. The film shall be matched to the screen's spectral output as specified by the manufacturer.  

13. Film Processing Solutions  
For processing mammography films, the facility shall use chemical solutions that can develop films equivalent to the minimum requirements specified by the film manufacturer.
14. Lighting
The facility shall make special lights for film illumination, i.e., hot-lights, that can produce light levels greater than that provided by the view box, available to the interpreting physicians.

15. Film Masking Devices
Facilities shall ensure that interpreting physicians make use of film masking devices that can limit the illuminated area to a region equal to or smaller than the exposed portion of the film.
3. International Standards

<table>
<thead>
<tr>
<th>Mammography Quality Standards Act (MQSA)</th>
<th>USA</th>
<th>21 CFR part 900 (Regulation)</th>
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<tbody>
<tr>
<td>ISO 3534-1977 (Quality control)</td>
<td>EU</td>
<td>ISO 6215-1980 (Quality assurance)</td>
</tr>
</tbody>
</table>
Reference

