SFDA Screening Mammography Quality Standards Program

Radiological Health Executive Department

Medical Devices Sector

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Acronyms & Definitions

(AEC) Automatic exposure control

ALARA As Low As Reasonably Achievable.

Ionizing & Non-Ionizing Radiation

Ionizing Radiation with energy that can move atoms in a molecule around or cause them to vibrate but is not enough to remove electrons 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.

KERMA Kinetic Energy Released in Matter (Air).

Mammography Radiography of the breast.

Mammography equipment evaluation 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.

MDMA Medical Devices Marketing Authorization.

MRSO Medical Radiation Safety Officer.

mSv MilliSievert, a derived unit of ionizing radiation dose in the International System of Units.

OSL Optically Stimulated Luminescence, a type of personal radiation dosimeter.

PPM Periodic Preventive Maintenance.

QA Quality Assurance.

QC Quality Control.

Screen-certified body Facility\Personal approved by SFDA to provide mammography-screening services.

SFDA Saudi Food and Drug Authority.

TLDs Thermoluminescent dosimeter, a type of personal radiation dosimeter.
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 for indoor clinics and mobile sites. The Saudi Food and Drug Authority (SFDA) law, according to the royal decree (M/6) on 25/01/1428, ensures the certification of mammography screening facilities including clinics and charities.

Reasons why the certification of the mammography-screening center is important are:
- 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.
SFDA Mammography Quality Standards Program

A. On-site visits Program

SFDA ensures that quality assurance (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.

1. General SFDA Requirements:

- Availability of radiation protective aprons and devices.
- Radiation shielded while exposures.
- Have a clear view during examination.
- Personal dosimeters availability with lifetime records.
- Locked entrance during examination.
- Audit of QA Program in the facility.
- Review the clinical images quality and phantom images.
- Review of the facility’s documentation.
- Confirmation of the medical audit method at facilities.
- Review of the staff qualifications.
- Review of the medical equipment used by the facility.
- Acceptance of the phantom image test.
- Compliance with SFDA audit reports.
- Annual evaluation of the radiation protection.
2. Room Design

Facility

- Each room has a mammography device should have a proper shielding as international radiation limits (20 mSv per year in controlled areas and 1 mSv per year in uncontrolled areas).

Equipment

- All medical devices utilized within the mammography facilities should have a valid SFDA’ Medical Devices Marketing Authorization (MDMA) Certificate.
- All medical devices utilized within the mammography facilities should have Periodic Preventive Maintenance (PPM).

3. Availability of Records

The following records should kept for references:

- The QA program.
- Documentation of construction justifying the installed shielding.
- Shielding survey tests.
- Information on changes.
- Subsequent survey reports after changes.
- Personnel dosimetry readings.
- Service manuals.
- Operating instructions.
- In-service training offered.
- PPM reports.
- Quality Control (QC) Performance Tests.
- Emergency maintenance reports and corrective maintenance reports.
- Electrical safety reports.
- Lead apron tests for shield integrity.
4. Quality Control (QC)

The QC tests (daily, weekly, monthly and annually) shall be performed as per the manufacturer recommendations and shall be documented in detailed information about the tests.

QC test ensure dose assessment including mammography mechanical integrity and stability, image performance of imaging processors and display units, X-ray performance and diagnostic performance.

5. 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.
B. mammography certification plan

Mammography certification will be provided by the SFDA for all facilities and body whom providing the breast cancer screening services.

1. Approval Application

Applicants looking for SFDA mammography screen certification shall contact the Executive Department of Radiological Health at SFDA via email: rh.md@sfda.gov.sa with the following information:

• Name, address, and phone number of the applicant.

• A list of staff members with their duties and responsibilities.

• Policies for minimizing occupational radiation exposures (pregnant workers, holding patients, training programs, medical device maintenance & tests, personnel radiation dosimetry monitoring, protective devices, radiation protection equipment and written emergency plan).

• Policies for minimizing radiation exposure to patients (examinations, pregnant patients, protective clothes, positioning manual and quality acceptance/reject of images).

• Guidelines for equipment quality control testing (listing of all X-ray equipment, performance parameters & limits of expecting QC tests, patient dose measurements, calibration and maintenance reports of X-ray equipment).

• Any other information as may be requested by SFDA.
C. Mammography Equipment Evaluation Programs

Mammography equipment must meet all SFDA safe use requirements. The following table summarizes the SFDA equipment regulations that applies both FFDM and Screen-film (S-F) as indicated:

<table>
<thead>
<tr>
<th>Feature</th>
<th>Requirements</th>
<th>Mammography device type</th>
<th>Screen Film Mammography (S-F)</th>
<th>Full Filed Digital Mammography</th>
</tr>
</thead>
<tbody>
<tr>
<td>X-ray film</td>
<td>The used mammography film should be designed by film manufacturer and appropriate for mammography.</td>
<td></td>
<td>✓</td>
<td></td>
</tr>
<tr>
<td>X-ray tube</td>
<td>If the device provides multiple focal spots, the system shall indicate which focal spot selected before exposure.</td>
<td></td>
<td>✓</td>
<td>✓</td>
</tr>
<tr>
<td></td>
<td>If the device has multiple targets, the preselected material shall be indicated by the system prior exposure.</td>
<td></td>
<td>✓</td>
<td>✓</td>
</tr>
<tr>
<td></td>
<td>If the system algorithm selects a focal spot and/or target material based on exposure, after exposure the system shall display the used focal spot and/or target material during the exposure.</td>
<td></td>
<td>✓</td>
<td>✓</td>
</tr>
<tr>
<td>Tube image receptor assembly motion</td>
<td>The assembly shall: 1- Not undergo unintended motion, once fixed. 2- Have a capability of fixing in any operation location that design for screening. - This technique should not fail in the event of power interruption.</td>
<td></td>
<td>✓</td>
<td>✓</td>
</tr>
<tr>
<td>Film processing solutions</td>
<td>The chemical solutions that used to develop the films in the facility shall at least meet the film manufacturer minimum requirements.</td>
<td></td>
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</tr>
<tr>
<td>Size of the image receptor</td>
<td>Devices have screen-film image receptors shall have:  - Image receptors: 18x24 cm and 24x30 cm at minimum for operation. - Equipped with moving grids matched to all provided image receptors sizes.</td>
<td></td>
<td>✓</td>
<td></td>
</tr>
<tr>
<td>Lights fields</td>
<td>- If the mammography systems provided with a light beam that passes through the X-ray beam-limiting device, an average limitation at 100 cm or at the maximum source-image receptor distance whichever is less, should be more than 160 lux (15 ft.-candles).</td>
<td>✓</td>
<td>✓</td>
<td></td>
</tr>
<tr>
<td>Beam Limitation</td>
<td>All systems shall have beam-limiting devices. These devices used to extend the useful beam to the chest wall edge of the image receptor or beyond it.</td>
<td>✓</td>
<td>✓</td>
<td></td>
</tr>
</tbody>
</table>
| Compression Application | Each system shall:  
- Patient both side have operable excellent adjustment compression controls.  
- Provide an initial power driven compression activated by hands-free controls operated from both sides of the patients. | ✓ | ✓ |
| Compression paddle | - Different sizes of compression paddles should be provided for each system and match the sizes of all system full filed image receptors.  
- Flat compression paddle shall be parallel to the breast support table and the deflection from the parallel not more than 1 cm at any point on the compression paddle surface when applied the compression.  
The chest wall edge:  
- The edge of the image receptor shall be parallel to the chest wall.  
- Can be bent upward to allow for patient comfort but should not appear in the image.  
The manufacturer specifications and maintenance requirements shall met the equipment designed from the manufacturer to not be flat and parallel to the breast-supporting table during compression. | ✓ | ✓ |
### Automatic exposure control (AEC)
Each S-F system shall provide an AEC mode that operable in all combinations of equipment configuration provided.

<table>
<thead>
<tr>
<th>Film masking devices</th>
<th>The film masking devices shall limit the illuminated area to region $\leq$ exposed portion of the film is available to all physicians in the facility.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Lighting</td>
<td>Unique lights for film illumination shall be provided by the facility available to the interpreting physician.</td>
</tr>
</tbody>
</table>
| Magnification        | - Systems with magnification procedures should at a minimum provided at least one magnification value within the range of 1.4 to 2.  
- Non-interventional problem-solving systems procedures shall have radiographic magnification capability available for use by the operator. |
| Technical factor selection and display | - The manual factors of exposure components shall be available.  
- Before the exposure begins, the used exposure factor shall be specified.  
- No need to designate the exposure factor if the AEC is used. |

### Van or Portable Mammography

For the portable mammography, the same requirements shall be implemented for the regular mammography unit. Due to movement of the portable mammography, some additional QC and survey tests are needed to ensure that the unit movement does not affect the device performance. All QC and survey tests shall be performed as required by manufacturer’s recommendations.
Recommended International Standards

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

Reference


