الهيئة العامة للغذاء والدواء
Saudi Food & Drug Authority

Requirements for Safe Use of Mammography

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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.

HCP shall comply with SFDA requirements to:

- Increase the radiation protection of mammography X-ray facilities.
- Increase public awareness of mammography screening benefits.
- Minimize the number of patients referred unnecessarily for further tests and dose.
- Ensure accurate detection of breast cancer.
- Minimize the number of unnecessary invasive procedures.
- Help keeps occupational exposures from radiation within applicable limits and as low as reasonably achievable (ALARA)
- Limit the use of ionizing radiation and the use of non-ionizing radiation instead.

To ensure compliance with SFDA requirements. This document is intended to clarify the general requirement of safe use of mammography in healthcare Provider (HCP).

Requirements of Mammography-screening in healthcare facilities:

1. General requirements:

- Availablity 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 Quality Assurance (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. Requirements of room design

a. Facility

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

b. Equipment

- All medical devices utilized within the mammography facilities shall have a valid SFDA Medical Devices Marketing Authorization (MDMA) Certificate.
- All medical devices utilized within the mammography facilities shall have Periodic Preventive Maintenance (PPM).
- Mammography equipment evaluation.
- Provide suitable protection aprons for every mammography room.

3. Availability of Records

The following records shall be kept for references:

- The radiation protection program.
- Documentation of construction justifying the installed shielding.
- Shielding survey tests.
- Information on changes.
- Subsequent survey reports after changes.
- Personnel dosimetry readings (e.g. TLD, OSL)
- 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.
- MDMA certificate.

4. Quality Control (QC)

- 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.
- 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.

5. Emergency Plans

- A written emergency strategy within the department rooms.
- The written emergency strategy shall be reviewed and updated periodically.
- Adverse cases should be reported to the SFDA at: rh@sfda.gov.sa
- Actions of preventing future adverse cases.

6. 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

Mammography Quality Standards		
EU	ISO 3534-1977 (Quality control)	ISO 6215-1980 (Quality assurance)
USA	The Mammography Quality Standards Act (MQSA)	21 CFR part 900 (Regulation)

Annexes

Annex (1): Definitions & Abbreviations

ALARA	As Low As Reasonably Achievable.
HCP	Health care providers, mammography-screening facilities, clinics and charities that use mammography as screening.
Ionizing & Non-Ionizing Radiation	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.
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.
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.
SFDA	Saudi Food and Drug Authority.
TLDs	Thermoluminescent dosimeter, a type of personal radiation dosimeter.