MDS – G015

Guidance on SFDA Requirements for Quality Assurance Programs for Radiation Emitting and Imaging Devices Part 1: Mammography

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Introduction

Radiation emitting and imaging devices are one of the most effective methods for examining and diagnosing different health conditions. Since radiation emitting and imaging devices depend entirely on the X-rays production, there are potential health risks associated with using such devices. In order to maintain a high-quality image and keep the radiation dose to the minimum, healthcare providers are required to obligate to national and international requirements for quality assurance programs for radiation emitting and imaging devices.

Purpose

The purpose of this document is to specify and clarify the requirements for quality assurance programs for radiation emitting and imaging devices including mammography.

Scope

This document applies to all for radiation emitting and imaging devices including mammography used inside healthcare facilities located in KSA.

Background

SFDA has issued this document in reference to the following:

- Article (26) of the "Medical Devices Law" issued by the Royal Decree No. (M/54), dated 6/7/1442 H, stipulates that "The SFDA shall monitor the compliance of healthcare providers with technical regulations within healthcare facilities in order to ensure the safety and efficacy of medical devices in diagnosis and treatment".

- Royal Decree No. (60057) dated 9/11/1441 H, approving Saudi Health Council Resolution No. (3/88), stipulates that “healthcare providers shall comply with the national diagnostic reference level issued by the SFDA”.

- Requirements for Safe Use of Medical Device inside Healthcare Facilities (MDS REQ3) published on the SFDA website.

Qualifications and Responsibilities of Staff

Radiologists, radiologic technologists, medical physicists, and all supervising physicians are responsible for ensuring the safety of workplace by maintaining radiation exposure of staff and public using the "As Low As Reasonably Achievable" (ALARA) principle, taking into consideration the potential risk from exposure to radiation alongside the diagnostic image quality needed to accomplish the clinical diagnostic objective.

A. Radiologist

Radiologist shall be qualified to interpret mammograms. Radiologist shall actively participate in the quality assurance (QA) program by:

1. Interpreting mammograms and using examination results to direct appropriate medical care, in addition to recommending additional examinations when needed.
2. Notifying staff about any changes that affected image quality, whether they are a result of improper placement, or related to images loading or processing.

B. Mammography Technologist

Mammography technologist shall be able to conduct all types of mammograms (2D and 3D mammograms). Technologist shall actively participate in in the QA program by:

1. Maintaining the optimum image quality for diagnostic purposes.
2. Conducting daily and periodic quality control (QC) tests on mammography, image processors and associated equipment, and documenting these tests.
3. Notifying staff about any changes that affected the image quality.

C. Medical Physicist

Medical physicist undertaking the responsibility of performing essential surveys of mammography facilities and supervising the QA program by:

1. Conducting essential tests to ensure the safety and proper performance of mammography, including but not limited to, acceptance, commissioning and periodic QC tests.
2. Conducting continuous assessments of safety protocols, steering the required adjustments to maintain safety of patient and staff, as well as instructing staff toward using suitable radiation protection techniques.
3. Ensuring that the QA program implemented and managed correctly.

All staff involved in mammography are considered initially qualified in case they licensed by the Saudi Commission for Health Specialties (SCFHS). Those who fail to meet the licensing criteria shall be requalified before being allowed to conduct or assess mammography, interpret mammograms or perform facilities surveys.

Mammogram

All mammograms and accessories shall satisfy the following conditions:

1. They designed specifically for mammography and obtained MDMA certification.
2. Healthcare compliance with the National Diagnostic Reference Levels (NDRLs). The mammography doses data shall be collected either automatically or manually and sent periodically to the SFDA via email (NDRL@sfda.gov.sa), using the Mammography Dose Data Collection Sheet.

Mammography Facilities Setup

Radiation safety and protection necessitates the proper setup of mammography facilities and other surrounding facilities. It shall be verified that those in the facilities surroundings will not be exposed to radiation levels that exceed the established regulatory exposure (not more than 20 mSv per year for radiology staff, and less than 1 mSv per year for the public). The following measures shall be taken to ensure radiation safety and protection in mammography facilities:

1. Shielding the rooms that contain mammography and testing the shielding at least once every two years.
2. Conducting radiation survey tests after any modifications made on mammography or their rooms that may affect the efficiency of shielding.
3. Conducting radiation survey tests by qualified and trained specialists inside the healthcare facility or through a licensed service provider.
4. Immediately stop using mammography which failed in passing the radiation survey test and report the case to the National Center for Medical Devices Reporting (NCMDR).

Quality Assurance (QA) Program

Quality Assurance (QA) program aimed to producing high quality images along with lowering radiation dose exposed to patients and staff to the minimum.

All QA program policies and procedures shall be documented and made available. One of these essential procedures is the QC test, which is a series of technical measures that aim to assure safety and effectiveness of the device by providing high quality diagnostic imaging and maintaining the radiation dose to the minimum. Moreover, QA program includes, but not limited to, a list of staff and their responsibilities, a list of equipment used for QC tests, a specific policy for lowering radiation exposure for staff and patients including pregnant women, emergency procedures and records keeping policy.

General Requirements for the Quality Assurance (QA) Program

1. Conducting periodic internal audit on the QA program.
2. Annual evaluation of the performance of mammography.
3. Revision of the facility's documentation to determine if mammography reports are sent to patients and physicians.

4. Verification of the qualifications of the staff.
5. Verifying that the mammography used for intended purpose specified by the manufacturer.
6. Evaluation of complaints raised by physicians, patients, or mammography technologists regarding quality problems.
7. Revise the quality of clinical and phantom images, and ensuring that they are evaluated accurately and consistently.

Mammography Quality Control (QC) Test

Healthcare providers shall comply with the following requirements:

1. Conducting QC tests associated with mammography periodically and in accordance to the manufacturer's QC manual.

   Note: In case the manufacturer's QC manual is not available, the "ACR Digital Mammography QC Manual" may be used as a basis for conducting QC test. The international standards and references for quality assurance and quality control indicated in Annex (1) may be followed.
2. Conducting the mandatory QC teat specified in this guidance.
3. Conducting QC tests by trained and qualified specialists.
4. Calibration and verification of equipment used for QC tests in order to ensure the accuracy of measurements.
5. Any failure in passing QC tests shall be reported to the National Center for Medical Devices Reporting (NCMDR), and a corrective action plan shall be attached within (3 days) from receiving the QC test report.

Mobile mammography

For mobile mammography, the same quality assurance program requirements for fixed mammography that is mentioned in this document are applied. Additional QC tests (image quality check, compression thickness indicator check and radiologist workstation check) shall be conducted, and radiation survey tests shall be conducted prior to radiological examination to ensure the proper performance of the mobile mammography.

Keeping Records

Healthcare provider shall keep records of credentials for all staff including radiologists, mammography technologists and medical physicists, and shall archive records of staff who left the healthcare facility. These records shall be accessible by SFDA inspectors for evaluation.

The following records shall be kept for at least (5 years) for future references:

1. Drawings and calculations of the shielding acceptance.
2. Construction documents related to shielding installation.
3. Radiation survey reports.
4. Information on modifications made on the mammography or room setup.
5. Subsequent radiation survey reports after modifications.

6. Personnel dose records.
7. Rejected images.
8. Installation documents, including power and ventilation system.
9. Service manual.
10. Operating instructions.
11. In-service training documents.
12. Periodic Preventive Maintenance (PPM) reports.
13. Corrective Maintenance (CM) reports.
14. QC tests reports.
15. Lead apron tests.
16. Radiation protection program documents.
17. MDMA certificate for all devices.

Mammography Mandatory Quality Control (QC) Test

Performing QC tests on a regular basis, it helps facilities ensuring the Mammography devices are operating properly, and the produced images are good quality, which lead to accurate diagnosing services with acceptable dose limits to the patients.

The frequency may vary depending on the specific recommendations of the manufacturer or the facility's quality control program.

The following QC tests are the mandatory tests for Mammography devices:

1. Image Quality

1. This test performed to evaluate the quality of the images produced by device.
2. A phantom is used to perform the test, which is a device that contains a known amount of x-ray attenuating material.
3. The image quality test is performed daily to ensure that the device is functioning properly.
4. If the test results are outside of the acceptable range, the device may need to be repaired or replaced.

2. Dose

1. These tests ensures that the delivered radiation dose to the patient is lowest possible dose according to ALARA, while the image quality still maintaining.
2. It is performed monthly or quarterly.

A. Average Glandular Dose (AGD) Measurement

1. This test aims to measure the delivered dose radiation average to the breast glandular tissue.
2. This amount should keep as low as possible, while still maintaining image quality.

B. Exposure Reproducibility Test

1. This test measuring the consistency of the radiation dose delivered by mammography.
2. The amount of reproducibility should be within acceptable limits.

C. Radiation Output- Beam Quality Test – Half Value Layer (HVL)

1. The radiation output test is a way to measure the intensity of the x-ray beam at a specific point in the field of view.
2. The test typically performed twice a year to ensure that the x-ray beam is of the correct quality.

3. Automatic Exposure Control (AEC)

1. A routine test is performed to ensure that the AEC system is functioning properly.
2. The test involves exposing a phantom to a known amount of radiation and then measuring the resulting image quality.
3. The test performed once a week.
4. If the image quality is not within acceptable limits, then the AEC system may need to be adjusted or repaired.

4. Compression Paddle Uniformity

1. This test measures the evenness of the applied pressure by the compression paddle to the breast during the mammography scan.
2. It is important to ensure that the breast is compressed evenly, which helps to reduce the artifacts and improve image quality.
3. The test performed weekly, by exposing a phantom to a known amount of radiation and then measuring the resulting image quality.
4. If the image quality is not within acceptable limits, then the compression paddle may need to be adjusted or repaired.

5. Image Display Quality Control Test

1. It is performed in monthly basis to ensure that the images displayed correctly on the mammogram monitor.
2. The test involves displaying a phantom on the monitor and then evaluating the image quality.
3. If the image quality is not within acceptable limits, then the monitor may need to be adjusted or calibrated.

6. Artifacts

1. Artifacts can make it difficult to visualize the breast tissue and can lead to missed diagnoses.
2. This test performed quarterly.
3. Types of tests:
    A. Motion artifact.
    B. Spike artifact.
    C. Dead pixel artifact.
    D. Ghosting artifact.

7. Dark Field

1. This test achieved by blocking the direct beam of radiation and allowing only the scattered radiation to pass through.
2. This results in an image that shows the microcalcifications as bright spots against a dark background.
3. This test performed annually.

8. Focal Spot Size

1. This test is performed to ensure that the focal spot size of the x-ray tube is within the acceptable limits.
2. This test performed annually.

9. Collimation

1. It helps to reducing the amount of radiation to the patient by restricting the x-ray beam to the area of the breast that is being imaged.
2. This test performed annually.

Annexes

Annex (1): International Standards and references for Quality Assurance and Quality Control

1. **ISO 6215:1980** Nuclear power plants — Quality assurance
2. **21 CFR part 900** Mammography
3. **The Mammography Quality Standards Act (MQSA)**

Annex (2): Definitions & Abbreviations

KSA	Kingdom of Saudi Arabia.
SFDA	Saudi Food and Drug Authority.
Marketing Authorization	A document issued by the SFDA permitting the circulation of a medical device in the market.
MDMA	Medical Devices Marketing Authorization.
Healthcare Provider	Any government or private establishment that provides healthcare services.
Mammography	Radiography of the breast.
Quality Assurance	A set of technical tests, measurements and calibration approved by the SFDA, to ensure the safety of radiation emitting devices, as well as the accuracy and quality of images, in order to ensure the effectiveness and adequacy of diagnosis and treatment.
mSv	MilliSievert: a derived unit of ionizing radiation dose in the International System of Units (SI).
Corrective Action	An action taken to solve nonconformity reasons for the establishment, manufacture or medical device.
Corrective Maintenance (CM) / Repair	An unscheduled process or procedure to correct or repair malfunctions of medical device or its components, including repair, restore or replace used components or systems to restore safety and performance of a medical device.
Periodic Preventive Maintenance	A scheduled process or procedure at specific intervals includes specific maintenance processes such as lubrication, cleaning or replacing parts that are expected to wear or which have a finite life. The procedures and intervals are usually specified by the manufacturer

Annex (3): List of Changes on the Previous Version

Number & Date of the Previous Version	Changes Description
1 01/01/2021	○ Modifications on the clause “Background”. ○ Modifications and on some requirements based on the "Medical Devices Law", the "Implementing Regulation of Medical Devices Law" and the “Requirements for Safe Use of Medical Device inside Healthcare Facilities (MDS REQ3)”. ○ Addition of the link to the “Mammography Dose Data Collection Sheet”. ○ Addition of the “National Center for Medical Devices Reporting (NCMDR)” as the main contact channel for reporting any failure in passing the radiation survey test or failure in passing QC tests. ○ Mammography Mandatory Quality Control (QC) Test ○ Addition of the “Annex (1): International Standards and references for Quality Assurance and Quality Control”.