

## **Guidance on Requirement of Dual Energy X-ray Absorptiometry (DEXA)**

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## Introduction

Dual-energy X-ray absorptiometry (DEXA) clinically verified, precise, and effective method of measuring bone mineral density (BMD) in the spine, femur or total body of the human by using X-ray. It is used mainly in the diagnosis and management of osteoporosis and other disease states characterized by abnormal BMD, as well as to monitor response to therapy for these conditions.

This document is intended to clarify Saudi Food & Drug Authority (SFDA) requirements for the safe-use of DEXA in medical applications. To ensure and promote the efficiency of the radiation protection program, and to minimize the radiation risks by reducing the amount of radiation doses used in diagnosis while maintaining the image quality and its diagnostic information. This is to protect patients from unjustified excessive radiation doses during examination. Protecting and maintaining the public health within the Kingdom of Saudi Arabia (KSA) by implementing provisions to ensure a high level of safety and health protection to users, patients and public in health care facilities from ionizing and/or nonionizing radiation. This requirement applies to healthcare providers, radiation protection & safety service providers and users of DEXA in medical applications.

Healthcare providers and users of the ionizing radiation emitting medical devices shall apply and comply with these requirements to their own practices as appropriate.

## Requirements

### 1. General

- The healthcare provider shall implement the basics International Commission on Radiological Protection (ICRP) principles of radiation protections and safety (justification, optimization and dose limitation) while using a radiation medical device.

#### **a. Justification**

DEXA justification requires an assessment of the information quality produced by DEXA systems as well as the patient dose.

#### **b. Optimization**

DEXA optimization requires minimization of unnecessary radiation exposure. An important tool for optimization is the establishment of reference dose records.

#### **c. Dose limitation**

This requires an assessment of doses from DEXA systems, so that it can be determined whether or not dose limits to the operator or the general public might be breached.

- SFDA has the right to audit medical facilities in order to ensure quality, efficiency and safety of radiation emitting medical devices and the surrounding areas.
- Healthcare providers shall obtain designated practice license for radiation services by formal reference in KSA.
- SFDA will review and update these guidelines periodically.

## 2. License

- DEXA that offered for marketing and/or use within the Kingdom shall obtain a medical device & product marketing authorization (MDMA).
- DEXA shall only be used according to the approved intended purposes.

## 3. Quality Control (QC)

- Medical physicist is responsible for design and document a QC program to ensure the safe device operation.
- QC procedures should perform as per the manufacturer recommendations utilizing proper phantom.
- QC results shall be recorded, and kept in the radiology department at least for the last two years.
- QC tests shall be conducted on a daily base before scanning the first patient.
- If any radiation QC test fails, biomedical engineering department or vendor shall be noticed.
- DEXA must not be used until the problem fixed and pass all the QC tests.
- User of DEXA shall check and calibrate radiation quality, absorption coefficient, tissue equivalent and mechanical malfunction.
- At the installation process, the precision error and least significant change (LSC) values should be determined.
- If any radiation QC test fails, the SFDA must be notified and detailed copy of the report shall be sent within three working days, via email to: [rh.md@sfda.gov.sa](mailto:rh.md@sfda.gov.sa) .
- For failed radiation QC test, the healthcare provider shall send a corrective action plan within 30 days to: [rh.md@sfda.gov.sa](mailto:rh.md@sfda.gov.sa) .

#### 4. Planned preventive maintenance (PPM)

- PPM shall be done as per the manufacturer requirements by qualified and trained party.
- PPM and detailed manufacturer recommendation checklist reports shall be available.
- Records shall be kept the radiology department for at least 2 years.
- Shall tag the PPM date and the next due date clearly on the device.

#### 5. End user

- All DEXA users shall wear personal dosimeter badges.
- Records shall be kept in the radiology department for at least 5 years.
- Working periods for new employees are exempt.
- All DEXA users shall have appropriate qualifications and continuous trainings. Copies of training certificates shall be kept in the radiology department.

#### 6. Room

- DEXA will require lead shielding in many cases, if located beside a fully occupied area.
- Lead acrylic barrier shall be installed if:
  - a. Distance between the operator and the edge of the scanning table is less than 1 meter, or
  - b. Distance between the operator and the center of the scanning table is less than 2 meters.
- Examination room design shall satisfy the manufacturer requirements.
- Examination room should have a proper design to ensure adequate room size as device manufacturer requirements and radiation levels in the adjoining rooms within the

acceptable levels for public members and personnel. Accordingly, no additional radiation shielding in the walls is required.

- Dose estimation based on measurements shall be done during the installation process by radiation protection experts.
- Additional radiation shielding is required if the distance between the adjacent wall and the table axis is less than 1m.
- Radiation warning lights shall be installed above the door of the examination room .
- Radiation warning and pregnancy, caution signs (Hard Material) in both Arabic and English shall be posted on the door of the examination room.
- Last 2 years records of the radiation surveys for the examination room shall be kept in the radiology department.
- Radiation survey reports should not exceed the maximum limits set by local and/or international legislators.
- For failed radiation survey tests, the healthcare provider shall send a detailed report to the SFDA within 3 working days to: [rh.md@sfda.gov.sa](mailto:rh.md@sfda.gov.sa) .
- For failed radiation survey test, the healthcare provider shall send a corrective action plan within 30 days to: [rh.md@sfda.gov.sa](mailto:rh.md@sfda.gov.sa) .

## Annexes



## Annex (1): Definitions & Abbreviations

BMD	Bone Mineral Density
Device/s	Dual Energy X-Ray Absorptiometry
DEXA	Dual Energy X-Ray Absorptiometry
Examination Room	Dual Energy X-Ray Absorptiometry Room
ICRP	International Commission on Radiological Protection
KSA	Kingdom of Saudi Arabia
LSC	Least significant change
MDMA	Medical Devices Marketing Authorization
MDS	Medical Devices Sector
Medical device	<p>Means any instrument, apparatus, implement, machine, appliance, implant, in vitro reagent or calibrator, software, material or other similar or related article:</p> <p>A) Intended by the manufacturer to be used, alone or in combination, for human beings for one or more of the specific purpose(s) of:</p> <ul style="list-style-type: none"> <li>- Diagnosis, prevention, monitoring, treatment or alleviation of disease,</li> <li>- Diagnosis, monitoring, treatment, alleviation of or compensation for an injury or handicap,</li> <li>- Investigation, replacement, modification, or support of the anatomy or of a physiological process,</li> <li>- Supporting or sustaining life,</li> <li>- Control of conception,</li> <li>- Disinfection of medical devices,</li> <li>- Providing information for medical or diagnostic purposes by means of in vitro examination of specimens derived from the human body;</li> </ul> <p>and</p> <p>B) Which does not achieve its primary intended action in or on the human body by pharmacological, immunological or metabolic means, but which may be assisted in its intended function by such means.</p>
PPM	Planned preventive maintenance
QC	Quality control
SFDA	Saudi Food and Drug Authority