TECHNICAL SPECIFICATIONS

X ray unit for Dual Energy X Ray Absorptiometry

1. Scope

This specification describes the requirements for X ray unit for Dual Energy X Ray Absorptiometry (DXA) and associated equipment and services (hereinafter referred as “the System”) to be used in National Children's Specialized Hospital "OHMATDYT", Kyiv, Ukraine, hereinafter referred as “the End-User”). The procurement is carried out under a framework for the IAEA Technical Cooperation (TC) project UKR6013 “Enhancing Cancer Diagnostics and Treatment”.

The scope of the Specification also includes warranty, maintenance services, spare parts and training, as defined below.

2. Applicable Documents

The following documents shall be applicable for this Specification to the extent specified hereinafter:

2.1. EUROPEAN COMMISSION, FOOD AND AGRICULTURE ORGANIZATION OF THE UNITED NATIONS, INTERNATIONAL ATOMIC ENERGY AGENCY, INTERNATIONAL LABOUR ORGANIZATION, OECD NUCLEAR ENERGY AGENCY, PAN AMERICAN HEALTH ORGANIZATION, UNITED NATIONS ENVIRONMENT PROGRAMME, WORLD HEALTH ORGANIZATION, Radiation Protection and Safety of Radiation Sources: International Basic Safety Standards, IAEA Safety Standards Series No. GSR Part 3, IAEA, Vienna (2014).

2.2. International Electrotechnical Commission, Medical electrical equipment - Part 1-3: General requirements for basic safety and essential performance - Collateral Standard: Radiation protection in diagnostic X-ray equipment. IEC 60601-1-3:2008+AMD1:2013+AMD2:2021 CSV)

2.3. INTERNATIONAL ATOMIC ENERGY AGENCY , Dual energy X ray absorptiometry for bone mineral density and body composition assessment, IAEA, Vienna (2010).

2.4. All other applicable International Electrotechnical Commission Standards and International Atomic Energy Agency Safety Standards.

The X ray unit for DXA shall be certified and registered in Ukraine. The Contractor shall comply with national radiation protection regulators, for sale, transportation, installation and maintained of X ray units. The list of regulation is provided in the Annex.

In the event of conflict between the documents listed above and the content of this Specification, the content of this Specification shall take precedence.

3. Definitions, Acronyms, and Abbreviations

The following definitions, acronyms, and abbreviations shall apply throughout this Specification unless defined otherwise hereinafter:

IEC	International Electrotechnical Commission
System	The entire mammography equipment to be provided under the Contract including all units and accessories, unless mentioned separately
BSS	International Atomic Energy Agency Safety Standards, General Safety Requirements Part 3 No. GSR Part 3, Radiation Protection and Safety of radiation sources: International Basic Safety Standards, IAEA, Vienna (2014).
DICOM	Digital Imaging and Communications in Medicine
PACS	Picture Archiving and Communication System
DXA	Dual Energy X Ray Absorptiometry
BMC	Bone Mineral Content
BMD	Bone Mineral Density
QC	Quality Control
BMAD	Bone Mineral Apparent Density
aBMD	Areal Bone Mineral Density
WBMAD	Whole Body Bone Mineral Apparent Density
ROI	Region of Interest

4. Requirements

4.1. Functional and performance requirements

The System shall meet the following functional and performance requirements:

4.1.1. Shall be intended for measuring bone mineral content (BMC) and bone mineral density (BMD) in adult and paediatric patients;

4.1.2. Shall be capable of whole body and segmental scans of the following sites: lumbar spine, femur and hip in horizontal position; in the case of these sites rendering inaccurate results (e.g. scoliosis and prior bilateral hip prostheses), evaluation of other sites may be necessary (e.g., the radius).

4.1.3. Being able to acquire planar image that is the combination of low and high energy attenuations;

4.1.4. Being able to quantify the bone density as a mass per unit area.

4.2. Technical Requirements

The System shall meet the following technical requirements:

4.3. System shall consist of the following components:

4.3.1. X ray generator;
4.3.2. X ray tube;
4.3.3. High-resolution and high-efficiently detector;
4.3.4. Patient table ;
4.3.5. Calibration system;
4.3.6. Software for data analysis;
4.3.7. Auxiliary equipment;
4.3.8. Uninterruptible Power Supply (UPS).

4.4. The gantry of the DXA unit shall consist of: X ray tube, filtration, pre-patient aperture, examination table or surface, pre-detector aperture and detector in a C-arm configuration;

X ray tube and generator

4.5. X ray tube shall have a tungsten anode with focal spot size smaller then 1 mm;

4.6. The System shall be able to produce a fan-shaped X ray beam for fast collection of low and high images;

4.7. X ray tube and X ray generator shall be able to produce low and high energy images. The contractor shall specify X ray tube voltage and method used for acquiring low and high energy images, respectively;

Digital detector

4.8. The System shall incorporate dose-efficient digital detector technology capable of detecting low and high energy photons. The Contractor shall specify the detector technology;

4.9. The System shall include a motorised patient table with integrated motorized C-arm high density multi-detector array assembly;

Patient table

4.10. The patient table shall be of minimal size 260 cm x 100 cm, and minimal height of 65 cm. The table shall be height adjustable and support patient weight up to at least 150 kg;
4.11. The table shall incorporate washable overlay;
4.12. The table shall be made of low attenuation material. The contractor shall specify the table attenuation in mm Al;

4.13. The System shall be capable of performing whole body scans in the minimal area of 190 cm x 65 cm;

4.14. The System shall have incorporated laser position indicators;

Acquisition workspace and software

4.15. The acquisition workspace shall be composed of a computer complaining with the following minimal specifications:

4.15.1. Operating system: Windows 10 Pro (64-bit version) or equivalent;
4.15.2. Processor: Intel® Core™ i5 Processor, or equivalent, 4 GB RAM;
4.15.3. Hard drive: 1 TB;
4.15.4. Monitor: 22'' thin-film transistor liquid-crystal display (TFT LCD or equivalent or better technologies) colour monitor;
4.15.5. Periphery: Windows compatible printer, keyboard and mouse;
4.15.6. Line voltage: 100–240V AC; Frequency: 50Hz to 60Hz, single phase.

4.16. The System shall include a software platform with:

4.16.1. Graphical interface:
4.16.2. Composition reporting tools;
4.16.3. Specific DXA scan protocols for adults and children;
4.16.4. Automatic scan mode selection;
4.16.5. Assessment of body composition and to define T-score and Z-score based on BMD measurement;
4.16.6. DXA scan analysis including the following features: automated placement of the ROI for adult patients, calculation of relevant parameters, e.g. aBMD, BMC, BMADS, WBMAD, etc, comparison with patient's previous examinations;
4.16.7. The system shall incorporate the following protocols for paediatric patients: spine measurement and analysis; total body measurement and analysis; femur measurement and analysis; assessments of growth and development including height for age, BMC for bone area, bone area for height, lean body mass for height, and BMC for lean".

4.17. The System shall be fully DICOM compliant. The DICOM shall support at least the following: DICOM 3.0 print, storage, send/receive, and query/retrieve. DICOM compliance statement shall be provided.

Auxiliary devices

4.18. The System shall include necessary patient positioning devices, cushions and accessories needed for scans of adult and children indicted in section 4.1.2;

Quality Control

4.19. The Contractor shall provide quality control (QC) protocol and procedures for monitoring scanner performance throughout the course of a study or during general use;

4.20. Phantoms necessary to perform QC test shall be included, e.g. spine phantom, hip/femur phantom and step phantom. The phantom shall be able to

mimic paediatric whole body scan. Alternatively, a dedicated paediatric phantom shall be included;

Power supply

4.21. Power input to be approximately 220 V, 50/60 Hz, triphasic electrical source;

4.22. The Contractor shall supply direct electric connection to the three-phase power supply network and the connection will be effectuated directly to the network with thermomagnetic disconnecting switch;

4.23. Protectors against power surge (over-voltage and over-current) line conditions shall be included;.

4.24. An uninterruptible power supply (UPS) with maintenance-free batteries for the backup of the entire system for at least 30 minutes shall be included.

Adequate details shall be provided to verify compliance with each specification, as well as an itemized response to the specification requirements.

In case of non-compliance with one of the required specifications due to different technology, justification and scientific evidence shall be provided for evaluation.

5. Site Preparation and Readiness

The Contractor shall communicate with the End-User's coordinator and verify the appropriateness of the designated area for the installation of the System. Furthermore, the Contractor shall inform on time the End-User for any additional requirement (structural, electrical, IT) necessary for the installation of the system.

The completion date of the Site preparation will be communicated to the IAEA to the Contractor in due time to start the execution of the Contract activities.

Notwithstanding any authorisation given by IAEA, the Contractor shall visit, inspect and ascertain that all necessary conditions are met at the End-User location before starting any activities. Any comments or suggestion as regards the conditions of the Site shall be made at least four (4) weeks before initiating the installation activities.

6. Compliance to applicable international safety standards
The Contractor shall provide evidence of compliance to international standards specified in paragraph 2. hereinabove.

7. Marking

The System shall have all safety markings in English language.

8. Packing

The System, for the shipment by air to the End-User, shall be packed in accordance with international standards that are applicable for the shipment by air of this kind of equipment.

9. Quality Requirements

9.1. The System shall be manufactured, shipped and installed in accordance with the Contractor's ISO quality assurance system or an equivalent quality assurance system.

9.2. The Contractor shall document the compliance with this quality assurance system.

10. Testing and Acceptance

10.1 Factory Acceptance Test (FAT)

The System, prior to shipment, shall be tested for conformance of the System with manufacturer's performance specifications and the minimum requirements specified herein. The results of the testing of the System shall be documented by the Contractor in a Factory Acceptance Test Report to be provided to the IAEA before shipment to the End-User location.

10.2 On site Acceptance Test (SAT)

The System, after installation, shall be tested by the Contractor together with the End-User's medical physicist to demonstrate that the performance meets the manufacturer's performance specifications and the minimum requirements specified herein as determined by the IAEA and the End-User.

A minimum of six (6) weeks prior to installation, the Contractor shall notify the IAEA, which retains the right to depute an IAEA representative to be present at the SAT.

The results of the testing of the System shall be documented by the Contractor in an Acceptance Document that shall be signed by the End-User's medical physicist and the Contractor's representative. This document shall be dated and accepted as the start of the System's warranty period. A copy of the Acceptance Document shall be sent to the IAEA.

11. Installation and Training

The System shall be delivered in installed in Ukraine, at End-User's premises. No installation activities shall be initiated unless authorised by the IAEA.

Provided that the Site is ready, and IAEA has given proper authorisation, the Contractor, in agreement with the End-User, shall install the System at the Site. The Contractor shall provide for this purpose all necessary tools and staff (including their travel, accommodation and subsistence as necessary).

The Contractor shall provide at least three (3) days training for up to four (4) staff of the End-User in the operation and application of the System and its components at the End-User location immediately after the installation has been completed.

The training shall be held in the English language.

The Contractor shall provide personnel and tools as necessary for a proper training.

12. Deliverable Data Items

The Contractor shall provide, before the start of the on-site training (paragraph 11. hereinabove), two (2) complete sets of Operation and Servicing Manuals and Technical Drawings as necessary to perform maintenance/repair, in hard copies and one (1) in electronic version in the English language.

13. Warranty, Maintenance and Spare Parts

13.1 Warranty

The System shall be covered by one (1) year warranty that includes parts and labour, starting as of the date of successful on-site acceptance, as per Section 10 above.

The warranty shall cover hardware and software upgrades and updates.

Warranty shall include all necessary spare parts, shipment to site, cost of replacement (work, personnel etc.) and disposal of faulty parts.

13.2 Maintenance

The Contractor shall also provide on-site full maintenance services for one (1) year during the warranty period, for the proper functioning of the System.

Full maintenance services shall include:

- preventative maintenance
- on-call interventions
- any software update/upgrade for the System that will become available
- all necessary replacement and spare parts, if not covered under warranty

As part of the On-Site acceptance, the Contractor shall provide to the local engineer and to the hospital medical physicist a plan for preventative maintenance and the name and contacts of a service representative/office for on-call maintenance intervention.

Intervention time shall be clearly defined and shall comply with the uptime requirements define in paragraph 15 below.

The Contractor shall provide evidence of the capability to adequately provide technical support for the System in the future, in a timely manner, stating the network of official representatives in the Country and/or in the Region.

13.3 Spare parts

Upon installation, an initial set of essential spare parts shall be provided to be stored at the Site. A list of available spare parts and prices shall subsequently be provided and updated as necessary.

14. Uptime and Penalties

The Contractor guarantees that the System will have an up-time of at least 98% (excluding outages for maintenance or causes external to the System).

Uptime is calculated on a basis of 250 operating days per year (weekly working days).

Should the down time exceed two (2) working days cumulative on a six (6) months basis (i.e. summing up the hours), then the warranty and/or maintenance (as applicable) will be extended for a corresponding period.

The records of downtime of the System will be kept by a representative of the End-User at the Site. The Contractor shall have the right to request copies of such records.

15. Optional

The Contractor shall provide five (5) additional years maintenance services, following the initial one (1) year full warranty, including parts and labour costs, to be considered by the End-User. This should not be included in the total price of the equipment but should be provided as a separate document.

Annex

List of applicable national regulations

Про затвердження Загаль... | on February 16, 2017 № 51/151 (rada.gov.ua)

Про використання ядерної ен... | від 08.02.1995 № 39/95-ВР (rada.gov.ua)

Про дозвільну діяльність у ... | від 11.01.2000 № 1370-XIV (rada.gov.ua)

Про затвердження Вимог та умов б... | від 28.12.2007 № 193 (rada.gov.ua)

Про затвердження Вимог та умов б... | від 02.12.2002 № 125 (rada.gov.ua)

Про затвердження Положення про п... | від 06.08.2012 № 153 (rada.gov.ua)