

# MINISTRY OF HEALTH STATE DEPARTMENT FOR MEDICAL SERVICES

# SUPPLY, DELIVERY, INSTALLATION, COMMISSIONING, TESTING AND TRAINING, ON USE AND MAINTENANCE OF BIOMEDICAL EQUIPMENT

#### **TENDER NO. MOH/EAKIP/ICB/001/2023-2024**

#### **TENDER CLARIFICATIONS**

#### Clarification 1

Need to give clarity on specifications whether a fluoroscopy with radiography system or a digital radiography system is required. As it is, the tender has not provided specifications for fluoroscopy.

Response; Specifications for fluoroscopy

# DIGITAL FLUOROSCOPY

**SYSTEM** 

## DIGITAL FLUOROSCOPY SYSTEM

Should be a digital Radiography system with flat panel detector and fluoroscopy system, Capable of taking digital images in horizontal, vertical positions of all skeletal body including spine and chest and should be capable for various fluoroscopic applications.

#### **Generator**

- 1. Generator should be of high-frequency inverter technology for constant output.
- 2. Should have at least 80KW power or better
- 3. The KV range from 40 to 150 KV or better
- 4. Should have 1000mA at 80 KV or better.
- 5. Should have an automatic exposure control device
- 6. Should have anatomical programming for radiography
- 7. Should have an load protection feature

- 8. Should have a digital display for KV and mAs
- 9. Should have pulsed fluoroscopy
- 10. Should have a minimum exposure time of at least 1ms or better.

# X-Ray tube and collimator:

- 1. Should be a high-speed rotating anode dual-focus tube compatible with the generator
- 2. Focal spot sizes shall be as per OEM
- 3. Should have a multi-leaf collimator a light source with auto shut provision for the light, auto collimation and remote control.
- 4. Should have overload protection.
- 5. Should have an anode heat capacity of 800 KHU or more -
- 6. It should be a carbon fibre/equivalent motorized / hydraulic movement floating table having a weight-carrying capacity of 200kgs or more.
- 7. It should have automatic exposure control with at least 3 fields
- 8. Vertical tilt +90 -90 / equivalent or better
- 9. At least 6-way movements shall be available either in the table or in combination with the imaging system
- 10. Should have integrated bucky unit for flat panel general radiography and fluoroscopy
- 11. Variable SID as per recommended by OEM according to different scan type.
- 12. Possibility to control the table movement from inside the control room.
- 13. Compression cone: 80 N or more
- 14. Head-side hand grips shall be available

## **Digital detector**

- 1. The detector should be a flat panel detector of latest direct digital technology / Amorphous silicon with Cesium Iodide Scintillator.
- 2. The size of the detector should be 43x43cm or more
- 3. Should have spatial resolution of 3.4 lines pair / millimeter or better
- 4. Detector Quantum Efficiency (DQE) should be 60% or more.
- 5. The active matrix size should be 2.8k x2.8k or more
- 6. Pixel Size: 150 um or better
- 7. 14 bits and 16 bits, both modes shall be available

# **Display and other features**

- 1. One System monitor: 21" or more
- 2. Display:  $1600 \times 1200$  pixels or more
- 3. (color/monochrome Playback images, processed images, multi-images, etc.)
- 4. 2 Nos. of Live monitors: 19" or more
- 5. Display: 1280 × 1024 pixels or more, monochrome Digital fluoroscopic images, fluorographic images, playback images, etc.

Note: Both should be provided by manufacturer. No local monitors will be accepted)

# **Image processing/equivalent processing**

- 1. Recursive filter with motion detection
- 2. Last image hold
- 3. Image flipping
- 4. Spatial filter (edge enhancement, smoothing)
- 5. DCF

# Recording

Fluoroscopic image and last-image-hold image can be stored to hard disk.

## Fluoroscopic image acquisition

• Frame rate: 0.5 to 15 fps

# **Pulsed fluoroscopy**

• Pulse rate: 1, 2.14, 3.75, 7.5, 15 fps

## Fluorographic function

• Images should be recorded to hard disk and displayed on the monitor. Real-time image processing: DCF (Digital Compensation Filter)

# **Digital One-Shot**

• Fluorography:  $1024 \times 1024$ , 16 bits

 $1536 \times 1536$ , 16 bits  $2048 \times 2048$ , 16 bits

 $2560 \times 2560$ , 16 bits

 $3072 \times 3072$ , 16 bits

## **Digital serial fluorography**

• Preset Sequence parameters:  $1024 \times 1024$ , 16 bits, max. 15 fps

 $1536 \times 1536$ , 16 bits, max. 10 fps

 $2048 \times 2048$ , 16 bits, max. 3.75 fps

Real-time image processing: DCF (Digital Compensation Filter).

# Post processing

- Grayscale: Adjustment of contrast and brightness
- Automatic adjustment of gray scale
- Spatial Filter: Edge enhancement and smoothing
- Neg. / Positive
- Zoom and pan
- ROI Zoom
- Rotation: 0°/ 90°/ 180°/ 270°

- Image inversion / reversal: Top-bottom and / or left-right reversal
- Multiple Display: not less than 64 images
- Electric shutter: to hide un necessary parts of an image
- Annotation: Text, Arrow, ROI
- Scale
- Measurement function: Length/angle
- Filming:
- Laser imager interface: DICOM Print connection
- Print preview

## **Network connectivity**

DICOM Storage DVD Ram Kit.

DICOM MWM DICOM MPPS

Media Storage (CD-R. DVD-R) DICOM 3.0 fully active

DAP interface: to add dose data to be added to DICOM data to be transmitted to the server

## **Basic Angiography Package**

with the following functions should be available to the image processor to support angiography.

- i. Real-time subtraction
- ii. Fluoroscopy roadmap
- iii. Pixel shift
- iv. Real-time edge enhancement
- v. Reference image display function

#### **Last Fluoro Hold**

LFH function with not less than 512 frames recording in the memory

# Accessories

- 1. An Online UPS to support the entire system.
- 2. Lead glass of size 80cms x 120cms or more
- 3. Light weight Radiation protection Apron of 0.5 mm lead equivalence, 5 No.
- 4. Four 2 ton split AC for X-Ray and work station room
- 5. Thyroid shield -5 No.
- 6. Lead goggles 5 No.

# **Ray Table Accessories**

- Mattress (Secured) with extra set mattress set
- Grip Bar
- Side Rail
- Hand Grip
- Footstep

### **Software**

Full set of software to enable the system fully operate to achieve both fluoroscopy and radiography procedure including but not limited to;

- DSA Software optional
- Stitching Software
- Long Bone stitching
- Statistical tool software
- Protocol analysis
- Repeat/Reject Analysis software.
- Dose reduction software

## **Consumables**

All necessary consumables and disposables for starting-up.

Test equipment for QC & performance verification

### **Integration Requirements:**

Recommended that all the medical devices, should support HL7 standard especially. Querry, retrieve and Archive should be possible

# **Approvals**

- The equipment should have US FDA or European CE with four digit notified body number certificate and certificate to be submitted.
- The system should be IAEA and KeNRA type approved.
- Regular QA according to KeNRA norms will be responsibility of bidder during warranty and CMC period.

## **Power supply:**

- Suitable Power input to be 220 240VAC, 50Hz OR 3 PHASE of appropriate rating Standards and safety and training.
- Electrical safety conforms to standards for electrical safety
- Safety aspects of Radiation dosage leakage should be spelt out
- Certificate for calibration should be provided

## **Documentation**

- The supplier must provide User manual/Technical Manuals in English both in soft and hard copies.
- Attach original manufacturer's product catalogue and specification sheet.

#### Warranty

• Minimum 2 years warranty and 5 years CMC

Comprehensive maintenance - please expound on comprehensive maintenance for three years and what entails.

# Response:

Comprehensive maintenance entails the supplier taking full responsibility for the equipment, thus both preventive and curative, to ensure that the equipment is readily available as and when required by the users.

#### Clarification 3

Currency - we are kindly requesting that we offer our prices in US dollars due to the constant change of dollar rate against the Kenyan shilling.

### Response:

The Tenderers are allowed to quote in US Dollars.

#### Clarification 4

CT Scan specifications -800 images per second is not achievable, so kindly clarify whether it was typing error.

#### Response

Reference is made to the reconstruction time of the spiral scan. Please respond as per the tender.

#### Clarification 5

Does the tender attract Taxes and Levies

### Response:

The tender is exempt from all taxes. The bidder should quote prices exclusive of all Taxes and Levies.

#### Clarification 6

Most tenders have considered the immediate last three years for submission. Would it be the case for this tender? Are certified audited financial statements for the last 3 years (2022, 2021 and 2020) permitted?

#### Response:

Provide Audited Accounts for the last Three (3) years (2022, 2021 and 2020) and not 2018, 2019 and 2020 as earlier indicated.

#### Clarification 7

Proposed delivery timelines <= 3 months is not realistic for most of the deliveries. Will the procuring entity be open to delivery timelines greater than 6 months?

#### Response

Kindly respond as per the tender requirements.

What is the lead equivalent for the 4 lead aprons with hangers to be quoted together with item number LOT1-8 digital X-ray system with Fluoroscopy?

# Response:

The Lead Equivalent is provided in the Specifications for the system above.

#### Clarification 9

In this case, we request for a tender extension of fourteen (14) days to liaise with our principals.

### Response:

The Tender Opening /Closing date is now extended to 25<sup>th</sup> January, 2024 at 10.00Am Kenyan Time.

## The MRI system should include: -

- 1. 1 No. Metal detectors for MRI (Both walk through and Handheld)
- 2. 1 No. MRI Compatible laryngoscope and batteries
- 3. 1 No. MRI Compatible Emergency Trolley
- 4. 4 No. MRI Compliant sandbags/Positioners

### The CT-Scanner should include: -

- 1. 2 Pairs Head and footrests for the CT
- 2. 2 No. Paediatric Immobilization for CT
- 3. 2 No. Paediatric Immobilization for X-Ray

Section VII -Schedule of Requirements

LOT 1-1. MRI (1.5T) complete with injector pump.

Under Accessories Item 3 you require "Portable metal detector with battery loader? entry metal detector vs handheld metal detector."

Kindly clarify whether the "entry metal detector refers to a walk-through metal detector and if so would you like a quote for both or one?

#### Response:

This was clarified in the earlier clarification where 1 No. Metal detectors for MRI (Both walk through and Handheld).

#### Clarification 13

LOT 1-10 Premium Ultrasound System (With Cardiac Echo).

Title 3.25 is titled Color Printer but below it states as follows: -

- a. Accessories to be supplied along with
- i. Online UPS of appropriate KVA with 2 hr. Backup

#### While

Title 3.26. Power Supply states;

Should be provided with online UPS for power back up of minimum 30 minutes.

Please clarify whether the two UPS for the ultrasound and printer?

### Response:

The system should be supplied with appropriate UPS with backup of 2hours and to support the entire system in the event of power failure including the Printer.

## Clarification 13

LOT 1-12. Portable Ultrasound

Title 3.19. "CMC rates for 5 years after expiry of warranty period including labor cost and cost of spare parts for whole equipment including all probe. other accessories should be quoted separately.

However, in another clause it states that; "Comprehensive preventive and repair service "Provision for a comprehensive preventive and repair maintenance service contract including parts and material for a period of 10 years from commissioning date"

Please clarify if you need CMC for 5 years or CMC for 10 years.

#### Response:

The Comprehensive Maintenance Contract (CMC) is for a period of 5 years post-warranty and it includes labour costs and spare parts for the whole equipment including probes.

We had sought for clarifications on the same tender yesterday for which we are hopeful to receive a response and in view of this so as to allow time to align with the manufacturers after we receive the clarifications and being cognizance of the current holiday period during which information flow has slowed, we are requesting for a 15 days extension on the advertised tender closing date to 22nd January 2024.

## Response:

The Tender Opening /Closing date is now extended to 25<sup>th</sup> January, 2024 at 10.00Am Kenyan Time.

#### Clarification 15

#### Workstation and documentation

- The additional 5 workstations in number with parallel licences for concurrent use by more than one radiologist and also for academic use by students. The workstations should be vendor neutral to integrate with any modality with preferably the same user interface as of the main console with the availability of MPR, MIP etc. It should have 18-inch LCD monitor, with hard disk of at least 50 GB for at least 95000 image storage in 256 x 256 matrix, and 2 GB RAM.
- Image documentation should be possible from the main as well as the workstation(s).
  - 10. Projections & Server: A multimodality client (vendor neutral server) server architecture based solution with minimum concurrent 24,000 slices rendering capacity, with 128GB RAM with storage of minimum 2TB and Additional storage of at least 10 TB on the server. Client hardware specification- 2No. Projecation with license: Dual quad core processor, at least 16 GB RAM, 1TB hard drive, DVD Writing with medical grade monitor of minimum 2 MP resolution & 3 button mouse.

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From above we have noted request for 5 workstations independent for MRI (with its own software hardware) and 2 workstations independent for CT scanner. The best way always would be to consider bringing this architecture to one solution for CT and MRI, so as to allow the Radiologists to be able to report both MRI and CT from each of the station. The total number of workstations can be retained to be a total of 7 (5+2). This will improve efficiency and quick reference whenever a Doctor wants to refer to a study from either Modality. This also allows reduction of cost in most cases.

#### Response:

The stated systems are coming with the respective Equipment but that doesn't mean that they will be located in the respective equipment rooms, they will be installed in the reporting room where the radiologists will centrally manage all the modalities.

We would also wish to seek further clarifications on: On quantities required for items highlighted on Pg 109 of Tender Document.

Please advise if the quantities for MRI Compatible Monitor and Patient Monitor should be as is.

## Response:

The quantities should be as per the tender document.