

TECHNICAL SPECIFICATIONS

X ray digital radiography/fluoroscopy unit

1. SCOPE

This specification describes the requirements for the digital radiography X ray and associated equipment and services (hereinafter referred as “the System”) capable to take digital images in horizontal, vertical and oblique positions of a wide range of anatomical regions. The System will be delivered and installed Kulob Oncological Hospital, Kulob, Tajikistan (hereinafter referred as “the End-User”). The procurement is carried out under a framework for the IAEA Technical Cooperation (TC) project TAD6009 “Upgrading the Diagnostic Capabilities of Kulob Oncology Hospital”.

2. Applicable Documents

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

- 2.1. 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 ed2.1.
- 2.2. International Electrotechnical Commission. Medical electrical equipment - Part 2-28: Particular requirements for the basic safety and essential performance of X-ray tube assemblies for medical diagnosis. IEC 60601-2-28.
- 2.3. International Electrotechnical Commission. Medical electrical equipment - Part 2-54: Particular requirements for the basic safety and essential performance of X-ray equipment for radiography and radioscopy. IEC 60601-2-54.
- 2.4. International Electrotechnical Commission, Electrical and loading characteristics of X-ray tube assemblies for medical diagnosis, IEC 60613 ed3.0.
- 2.5. International Atomic Energy Agency Safety Standards, General Safety Requirements Part 3 (GSR Part 3), Radiation Protection and Safety of radiation sources: International Basic Safety Standards, Vienna, 2014
- 2.6. Applicable International Electrotechnical Commission Standards and International Atomic Energy Agency Safety Standards.

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:

- (1) "Site": will mean the Kulob Oncological Hospital, Kulob, Tajikistan.
- (2) "The System" will mean the entire Stationary Digital X Ray (Radiography/Fluoroscopy) and the PACS. The System will be provided under the Contract including all units and accessories, unless mentioned separately.
- (3) 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)
- (4) DICOM = Digital Imaging and Communications in Medicine
- (5) KAP = Kerma Area Product
- (6) DAP = Dose Area Product
- (7) DQE = Detective quantum efficiency
- (8) PACS = Picture Archiving and Communication System

4. TECHNICAL REQUIREMENTS

4.1. The System will consist of:

4.1.1. X ray generator.

4.1.2. X ray tube.

4.1.3. X ray tube head.

4.1.4. Digital detector.

4.1.5. X ray Table.

4.1.6. Operation console / Acquisition workstation.

4.1.7. Associated accessories and Quality Control equipment.

4.1.8. Dedicated Uninterrupted Power Supply (UPS).

4.1.9. PACS



4.1.1 X ray Generator

X ray generator	Power	≥ 60.0 kW
	Input	3 phase // 400v +/-10%, 50 Hz
	Tube voltage range (radio)	40 – 150kVp
	Tube voltage range (fluoro)	50 – 120 kVp
	Tube current range (radio)	10 – 500 mA
	Tube current range (fluoro)	0.3 – 4 mA
	Tube load range (radio)	0.5 – 800 mAs
	Pulsed fluoroscopy	Pulse rate: 3.75, 7.5, 10, 15, 30 fps
	Automatic Exposure Control (AEC)	Manual and automated selection of exposure parameters

4.1.2 X ray tube

X ray tube	General	Integrated X ray tube
	Anode and Filter material	Materials shall be such to allow for low dose/high penetration spectra.
	Equivalent filtration	> 1.5 mm Al
	Focal spots	2 (appr. 0.6mm and 1.2mm), Both manual and automated selection of the focal spot shall be available.
	Anode heat capacity	At least 400.000 HU

4.1.3 X ray tube head

Gantry / tube head	Collimators	Both manual and fully automatic
	Source to image distance	110 – 160 cm
	Movements	Motorized movements
	Locking system	Electromechanical brakes or equivalent
	Arm moving system	Motorized

4.1.4 X ray Digital Detector



Digital detector	Detector type	Modern technology flat panel detector
	Effective field size	At least equivalent to 16 x 16 in
	Pixel size	< 150 µm
	Pixels	at least 7 million
	DQE	60 % (0.05 lp/mm) or more
	Image depth	At least 12 bits
	Last Image Hold	Required

4.1.5 X ray table

Table	Tabletop	Low attenuation material
	Tabletop elevation	65 – 95 cm
	Tilting angles	From -30° to +90°
	Lateral slide	> 20 cm
	Max patient load	> 150 kg

4.1.6 Operation console / Acquisition workstation

Operation console / Acquisition workstation	General	A separate operation console workstation for image positioning and patient demographic data
	Exposure parameters setting	Both manual and fully automatic
	Dose reduction tools	To be specified by the bidder
	Pre-set protocols	Anatomical protocols shall be described in detail
	Computer system	Processor generation/type/speed, RAM, hard disc, storage systems, etc) shall be described in detail
	Storage Capacity	Minimum 10.000 images
	Monitor (console)	2 x High resolution medical monitors (min 19')
	Monitor (in room)	2 × monitors (min 19')
	Patient dose display and record	Dose index shall be displayed for each exposure and recorded (e.g. KAP/DAP)
	External storage	CD-R/DVD-R, Multi Drive unit (DICOM Media Storage)
	DICOM functionality and connectivity	DICOM 3.0



4.1.7 Associated accessories and Quality Control equipment

Associated accessories and safety equipment	Shoulder rest	1 pair
	Hand grips	1 set
	Foot rest	1 set
	Phantoms	1 phantom for quality control. The Supplier shall provide an image quality phantom (spatial resolution and low contrast detectability) for image quality evaluation.

4.1.8 Dedicated Uninterrupted Power Supply (UPS)

Dedicated UPS (for the acquisition workstation) for a minimum backup time of 30 minutes.

4.1.9 PACS System

4.1.9.1 System description

A PACS system consisting of image management, post processing and storage system for advanced digital imaging to support diagnosis shall be provided. The image production system shall send studies to the PACS. The PACS shall be expandable to accommodate more equipment and have DICOM-storage functionality and user worklist. Be suitable for handling and storing of an average 50,000 studies per year with storage for five (5) years.

4.1.9.2 Technical requirements

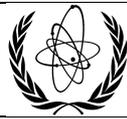
1	1 workstation
2	Three (3) high resolution viewing workstations with user licenses
3	Web-based architecture
4	Instant messaging solution
5	Access to information according to demand
6	Allow unlimited growth in storage size
7	Allow increase in the number of annual studies according to the production of End-User

5. MARKING AND COMPLIANCE TO THE APPLICABLE INTERNATIONAL SAFETY STANDARDS

5.1. The System shall have all safety markings in the English and Russian language.

5.2. The Contractor shall provide evidence of compliance to the International Basic Safety Standards (BSS) specified in Section 2 "Applicable documents"; BSS 3.49 (a) (iv), and 3.49 (c)

5.3. The Contractor shall provide evidence of compliance on the following:



- 5.3.1. Provides clear displays, gauges and instructions on operating consoles in the appropriate language understandable to users; and
- 5.3.2. Making information available, in the appropriate language understandable to users, on the proper installation and use of the radiation generator and on its associated radiation risks, including performance specifications, instructions for operating and maintenance, and instructions for protection and safety.

6. 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.

7. SITE READINESS

- 7.1. 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 of any additional requirement (structural, electrical, IT infrastructure) necessary for the installation of the System. Annex 1 provides the site layout.
- 7.2. The completion date of the Site preparation will be communicated by the IAEA and/or the End-user to the Contractor in due time to start the execution of the Contract activities.
- 7.3. Notwithstanding any authorisation given by IAEA, the Contractor shall visit, inspect and ascertain that all necessary conditions are met at the End-User Site before starting any activities. Any comments or suggestion as regard the conditions of the Site shall be made at least four (4) weeks before initiating the installation activities.

8. QUALITY REQUIREMENTS

- 8.1. The System shall be produced and installed in accordance with the Supplier's ISO quality assurance system or an equivalent quality assurance system.
- 8.2. The required software packages described in this Specification shall be registered as a medical device and shall comply with the requirements of the Medical Device Directive 93/42/ECC, or equivalent.
- 8.3. The Supplier shall document the compliance with this quality assurance system and CE marking.



9. TESTING AND ACCEPTANCE

- 9.1. 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.
- 9.2. Site Acceptance Test (SAT): The System, after installation, shall be tested by the Supplier together with the End-User 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, who retains the right to depute an IAEA representative to be present at the SAT at the Site.
- 9.3. The results of the SAT shall be documented in an acceptance test protocol that shall be signed by the End-User (after consultation with the medical physicist that will take part in the SAT) and the manufacturer. Formal handover of the System shall only be done after the successful completion of the SAT as defined above.

10. INSTALLATION AND TRAINING

- 10.1 The Supplier shall install the System on-site at a location designated by the End-User.
- 10.2 The Supplier shall provide at least five (5) days training for designated staff members of the End-User in the operation and maintenance of the System at the End-User's location immediately after the installation of the System. The training shall be in English (Russian is preferable).

11. DELIVERABLE DATA ITEMS

The Supplier shall provide two complete sets of operation and servicing manuals and technical drawings (if applicable) in the Russian and English language.

12. WARRANTY

- 12.1 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 9 above. The warranty shall also cover hardware and software upgrades and updates.
- 12.2. Warranty shall include all necessary spare parts, shipment to site, cost of replacement (work, personnel etc.) and disposal of faulty parts.



13. MAINTENANCE SERVICES

- 13.1. The Supplier shall provide on-site full maintenance services during the warranty period for the proper functioning of the System.
- 13.2. Full maintenance services during the warranty period shall include:
- (1) Preventive maintenance;
 - (2) On-call interventions;
 - (3) Any safety, software and hardware update and upgrade for the system that will become available; and
 - (4) All necessary replacement and spare parts.
- 13.3. As part of the on-site acceptance, the Supplier shall provide the End-User with a plan for preventive 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 defined in Section 14 below.

14. Intervention Time and Maintenance Response:

- 14.1 The Supplier 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 in the region.
- 14.2 The Contractor shall ensure that a suitable qualified person shall be onsite within forty-eight (48) hours following an unexpected breakdown and shall investigate the problem within the next twenty-four (24) hours during the warranty period.

15. UPTIME AND PENALTIES

- 15.1 The Contractor guarantees that the system shall have an uptime of at least ninety-five percent (95%) excluding outages for scheduled maintenance or causes external to the System.
- 15.2 Uptime is calculated on a basis of two hundred and fifty (250) operating days per year (weekly working days) cumulative on a six months basis (i.e. summing up the hours), then the warranty and/or maintenance (as applicable) shall 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.



16. OPTIONS

At the request of the End-User, the Contractor shall provide pricing per year for up to five (5) additional years of full maintenance services (as defined in art. 12 above), following the initial one (1) year full warranty. The related costs shall be borne by the End-User.