



CT SIMULATOR FOR RADIOTHERAPY

1. Scope

This specification describes the requirements for the supply, installation, training, and acceptance testing of a Computed Tomography for scanning radiotherapy patients and two (2) virtual simulation workstations (hereinafter referred to as “the System”) to facilitate treatment planning at the Radiotherapy Department, National Centre of Oncology, Baku, Azerbaijan.

The supply of the System shall be done after the review of the hospital layout room by the contractor to ensure compliance to specifications.

The delivery of this equipment is related to the IAEA-TC project AZB6013 “Improving Radiotherapy and Nuclear Medicine Services at the National Centre of Oncology”

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: General requirements for Safety, Rep. IEC 601-1, IEC, Geneva (2008)
- 2.2. International Electrotechnical Commission, Medical Electrical Equipment, Part 2-29: Particular requirements for the safety of radiotherapy simulators, Rep. IEC 601-2-29, IEC, Geneva (1999)
- 2.3. International Electrotechnical Commission, Radiotherapy simulators: Guidelines for functional performance characteristics, Rep. IEC 61170, IEC, Geneva (1993)
- 2.4. International Electrotechnical Commission, Medical Electrical Equipment: Requirements for the safety of radiotherapy treatment planning systems, Rep. IEC 62083, IEC, Geneva (2009)
- 2.5. “Setting up a Radiotherapy Programme: Clinical, Medical Physics, Radiation Protection and Safety Aspects”, IAEA, Vienna (2008) (http://www-pub.iaea.org/MTCD/publications/PDF/pub1296_web.pdf)
- 2.6. “Radiation Protection and Safety of Radiation Sources: International Basic Safety Standards”, IAEA, Vienna (2014) (http://www-pub.iaea.org/MTCD/Publications/PDF/Pub1578_web-57265295.pdf)
- 2.7. “Quality Assurance Programme for Computed Tomography: Diagnostic and Therapy Applications” IAEA Human Health Series 19, Vienna (2012) (<http://www-pub.iaea.org/books/IAEABooks/8751/Quality-Assurance-Programme-for-Computed-Tomography-Diagnostic-and-Therapy-Applications>)
- 2.8. All the applicable 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 to the extent of the conflict.

3. Definitions, Acronyms, and Abbreviations

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

BSS: “International Basic Safety Standards for Protection against Ionizing Radiation and for the Safety of Radiation Sources”, IAEA, Vienna (1996)

CCTV: Closed Circuit Television System

CT: Computed Tomography

OIS Oncology Information System

PACS: Picture Archiving and Communication System

RVS: Record and Verify System

SPR: scan projection Radiograph

UPS: Uninterrupted Power Supply

4. Requirements

4.1. Functional and Performance Requirements

The System shall meet the following functional and performance requirements:

- 4.1.1. Have a large bore of at least 80cm (large bore CT scanner) for radiotherapy treatment simulation;
- 4.1.2. Have a carbon fiber flat table-top with indexing facilities (for all kinds of immobilization systems used in radiotherapy) equivalent to the Exact IGRT carbon fiber flat 53 sm couch top with indexer hole on the existing Varian Linac Clinac iX;
- 4.1.3. Have conventional in-built lasers or light beams, which indicate the coincidence of the center of rotation and scan position;
- 4.1.4. Have a second set of external lasers (ceiling, lateral and sagittal) in order to mark and setup the patient on the table-top distant from the gantry structure;
- 4.1.5. The entire CT and virtual simulation workstation system shall be networked to the external beam record and verify system/ the oncology information system (OIS) Varian Aria system version 16.0, the treatment planning system and the laser system. DICOM (RT) format shall be used;
- 4.1.6. Be equipped with an Uninterrupted Power Supply (UPS);
- 4.1.7. Upgradable to 4D CT acquisition;
- 4.1.8. Upgradable to Fluoroscopic CT (FCT);
- 4.1.9. Optional: 4D CT acquisition; and
- 4.1.10. Optional: Fluoroscopic CT.

4.2. Technical Requirements

The System shall meet the following technical requirements:



4.2.1. **CT Scanner:**

The CT scanner shall be at least 16-slice (optional 64-slices and optional 128-slices) whole body spiral CT scanner.

4.2.2. **Gantry:**

4.2.2.1. Have a gantry aperture (large-bore) of at least 80 cm;

4.2.2.2. Have a scan field of view of at least 50 cm;

4.2.2.3. The couch positioning indicators in the gantry shall have a positioning accuracy of ± 1 mm or better.

4.2.3. **Couch:**

4.2.3.1. Have a couch top material made of carbon fiber, flat bed type, with minimum dimensions of 210 cm x 53 cm, having a longitudinal moving range of 170 cm or more and compatible to the carbon fiber flat tabletop *MTIL6520 from CIVCO* currently on the Toshiba CT with indexing (Varian linac couch top 215/53/7sm); and

4.2.3.2. Have a scannable range of at least 120 cm. It shall be able to take a maximum weight of 200 kg or more without any change in stated performance specifications.

4.2.4. **X-ray System:**

4.2.4.1. Have a high frequency X-ray generator with power rating of at least 60 kW (broad focus). kVp shall be in the range of 80 kV to 130 kV;

4.2.4.2. Have a mA range from 30 mA to 400 mA, with step size of 5 mA or better. The peak anode heat dissipation rate shall be at least 1.1 MJ/min or better; and

4.2.4.3. Have a X-ray tube with dual focal spots.

4.2.5. **Detectors:**

4.2.5.1. Be a high performance, low noise, high data density, active response data acquisition system;

4.2.5.2. Be solid state or equivalent; and

4.2.5.3. Be free from repeated calibrations.

4.2.6. **Independent positioning laser system**

Consisting of

4.2.6.1. Additional moving lasers for Radiotherapy Patient positioning

4.2.6.2. Laser position control computer; and

4.2.6.3. The control computer shall be connected to the network to obtain isocentre and shift coordinates.

4.2.7. **Scan parameters:**

4.2.7.1. Slice thickness/spacing shall be selectable from at least 1 – 8 mm. Retrospective reconstruction shall be possible on raw data files with change in parameters such as FOV;

4.2.7.2. The following scanning modes shall be possible: SPR (scout views), axial and spiral. The SPR length shall be more than 1500 mm long and the width must be at least 500 mm. It shall be possible to obtain the SPR from AP or PA or lateral directions. The ability of the system to reproduce the scanning protocol from



- the SPR should be ± 3 mm or better. The accuracy of distance measurements in the SPR (taken at isocenter distance) shall be better than twice the pixel dimension;
- 4.2.7.3. Different selection of pitch shall be possible, from 0.5 to 1.5. State the pitch available;
- 4.2.7.4. The system shall have automatic mA control software that automatically adjusts mA for patient size, adjusts mA along the z-axis, and modulates mA during rotation;
- 4.2.7.5. Typical scan protocols for routine scanning (adult and paediatric) and quality control shall be available; and
- 4.2.7.6. Provision to create user protocol "a".
- 4.2.8. **Image Quality:**
- 4.2.8.1. The minimum reconstruction matrix shall be at least 256 x 256; and
- 4.2.8.2. High contrast spatial resolution: at least 15 lp/cm maximum at 0% modulation transfer function (MTF). Low contrast detectability: 5 mm or less @ 0.3% using a Catphan 600 phantom or similar (will be provided) on 10 mm slice thickness. The CT number accuracy shall be better than 0 ± 4 HU for water and -1000 ± 5 HU for air.
- 4.2.9. **Computer System for the CT scanner:** A high end computer system shall be provided.
- 4.2.9.1. Have two (2) at least 19" TFT flat screen LCD monitors at the console. One of these will be used for acquisition and the other will be used for image review/basic processing;
- 4.2.9.2. The local hard disk capacity of the main computer system shall be at least 1TB or more. The maximum possible hard disk capacity shall be provided;
- 4.2.9.3. For local copies of individual studies or software upgrade, a DVD reader/writer shall be provided;
- 4.2.9.4. The CT system shall be fully DICOM complaint. The DICOM shall support the following: DICOM 3.0 Print service class as a user, DICOM 3.0 Storage class as a user, DICOM 3.0 Storage class as a provider, DICOM 3.0 Send / Receive, DICOM 3.0 Query / Retrieve service class as a user and DICOM 3.0 Query / Retrieve service class as a provider. DICOM compliance statement shall be provided;
- 4.2.9.5. CT images shall be directly transferrable to the virtual simulation workstations, brachytherapy treatment planning system (Bebig Sagi Plan 2.2 TPS), external beam treatment planning system (Varian Eclipse version 15.6), and the record and verify system /oncology information system (Varian, Aria version 15.6);
- 4.2.9.6. A networked dry laser imager shall be provided (multiformat);
- 4.2.9.7. Two (2) separate virtual simulation workstations shall be provided for volume definition (contouring), isocentre localisation, field placement and field design (shielding blocks or MLC configuration) of the linac of external beam radiotherapy fields for 100 cm SADs (see Annexure 1 for installation configuration), including generation of digitally reconstructed



radiographs. It should be possible to seamlessly export patient administrative data, images, volumes and machine parameters to both of the linacs (Varian: Unique/VitalBeam/TrueBeam/Clinac iX), external beam treatment planning system (Varian, Eclipse version 16.1), laser imager and the record and verify oncology information system (Varian Aria system version 16.0).

- 4.2.9.8. The workstation shall be equipped with an automatic overnight backup system to an external hard drive;
- 4.2.9.9. An external long-term image archive system shall be provided;
- 4.2.9.10. The system shall form part of the departmental intranet and shall not have access to the internet. Software installation and upgrades/updates shall be performed using CD/DVD and all other external data device inputs shall be disabled to enhance data protection and minimise virus infection;
- 4.2.9.11. A metal artefact reduction algorithm incorporated into image processing;
- 4.2.9.12. A dose reporting feature with dose display and the capacity to transfer dose information for recording purposes. DICOM structured dose report shall be available; and
- 4.2.9.13. Automatic mA control software that automatically adjusts mA for patient size, adjusts mA along the z-axis, and modulates mA during rotation.

4.2.10. Safety:

- 4.2.10.1. A bi-directional speaker communication shall be provided between the operator and the patient;
- 4.2.10.2. The console shall be positioned such that the operator has full view of the patient through the lead glass window (lead glass for the window to be supplied);
- 4.2.10.3. A CCTV system shall be available to view the patient from the back of the gantry; and
- 4.2.10.4. Radiation warning lights and a door interlock shall be installed.

4.3. Essential accessories to be included with the System

- 4.3.1. The CT scanner shall be equipped with an UPS solution due to unstable electrical power supply;
- 4.3.2. and On-line UPSs for the console and virtual simulation workstation (computers) for at least thirty minutes in order to allow shutdown in the event of a power failure;
- 4.3.3. Dose computation & display: The system shall display CTDIw and DLP;
- 4.3.4. Two lead aprons; and
- 4.3.5. Injector for contrast administration operated from the console.

5. Site readiness

- 5.1. 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.

5.2. The completion date of the Site preparation will be communicated by the IAEA's Technical Officer to the Contractor in due time to start the execution of the Contract activities.

5.3. Notwithstanding any authorization given by IAEA's Technical Officer, 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.

5.4. Annexure 1 provides the site layout and indicates the preferred positions of the equipment and workstations.

6. Marking

The System shall have all safety markings in English language.

7. Packing

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

8. Quality Requirements

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

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

9. Testing and Acceptance

9.1. 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. The System, in particular the CT scanner, UPS, laser imager and the virtual simulation workstation, after installation, shall be tested by the Contractor 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.

9.3. The results of the testing of the System shall be documented by the Contractor in an acceptance protocol that shall be signed by the End-User.



10. Installation and Training

- 10.1. The Contractor shall install the System at the End-User location.
- 10.2. No installation activities shall be initiated unless authorized by the IAEA and End-User.
- 10.3. Provided that the Site is ready, and IAEA has given proper authorization, 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).
- 10.4. The Contractor shall provide at least five (5) days training for up to six (6) staff 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.

11. Deliverable Data Items

The Contractor shall provide two (2) complete sets of operation and servicing manuals and technical drawings in the English language.

12. Warranty

- 12.1. The system shall be covered by one (1) year warranty offered by the contractor including parts and labour, starting as of the date of successful on-site acceptance, as per Section 9 above. 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 and Spare Parts

13.1. Maintenance

- 13.1.1. The Contract price includes on site full maintenance services during warranty period, for the proper functioning of the system.

Full maintenance services during the warranty period shall include:

- preventative maintenance
- on-call interventions
- any safety, software and hardware update and upgrade for the System that will be become available
- all necessary replacement and spare parts

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

- 13.1.3. 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.

- 13.1.4. The Contractor shall guarantee the response time (time from when the request is made to the time a technician is at site to assess the situation) on site within 35h.
- 13.1.5. The Contractor shall provide pricing per year for up to seven (7) additional years of full maintenance services (as defined in 13.1), following the initial one (1) year full warranty. The related costs shall be borne by the End-User.

13.2. Spare parts

- 13.2.1. Upon installation and without prejudice for warranty obligations of the Contractor, 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

- 14.1. The Contractor guarantees that the system shall have an up-time of at least 95% (excluding outages for scheduled maintenance or causes external to the System).
- 14.2. Uptime is calculated on a basis of 250 operating days per year (weekly working days).
- 14.3. Shall the down time exceed 2 working days cumulative on a six-month basis (i.e., summing up the hours), then the warranty and/or maintenance (as applicable) will be extended for a corresponding period.
- 14.4. The records of downtime of the system will be kept by a representative, at the Site. The Contractor shall have the right to request copies of such records.

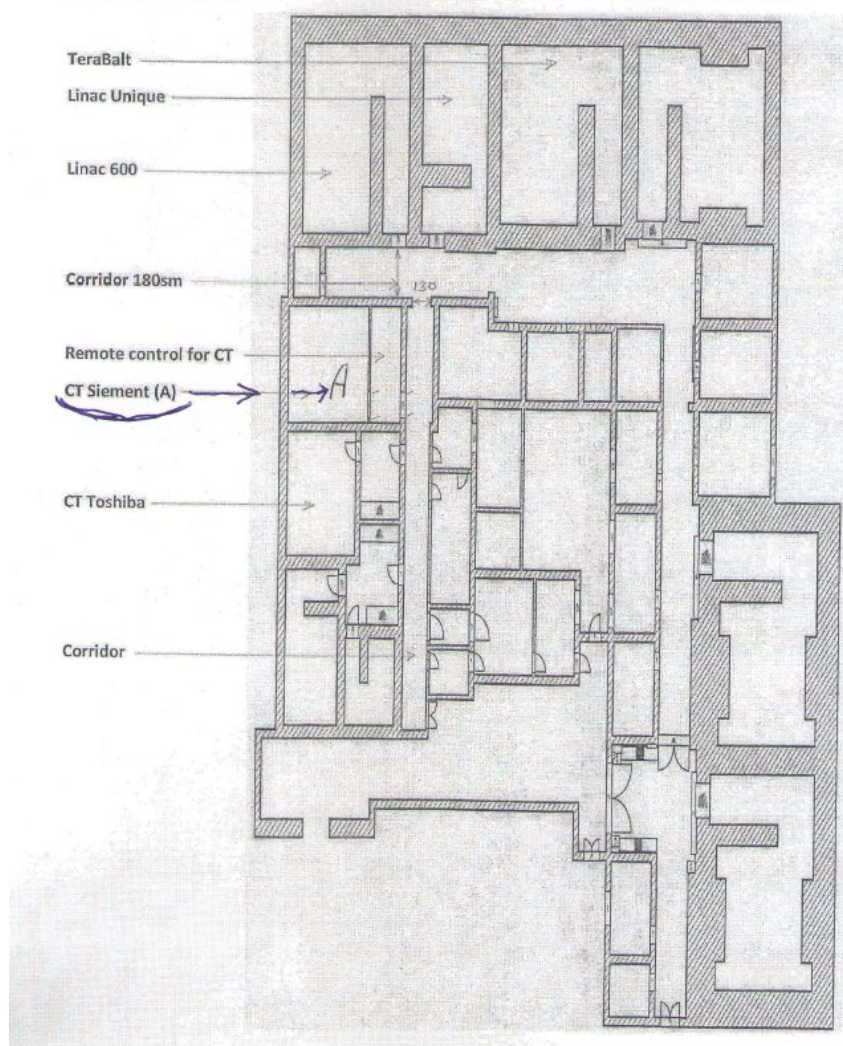


Annexure 1.1

Plan of the first floor of the Department of Medical Physics

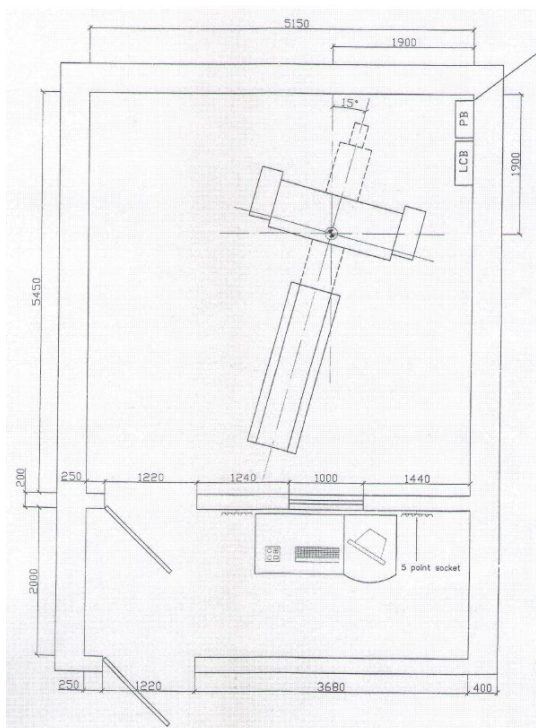
The walls of the bunker are reinforced with barite to improve radiation shielding. Using of the CT scanners in there is approved by the National Radiation Safety Service.

All radiotherapy equipment - Varian Medical Systems (for example, 2 VitalBeam accelerators)





Annexure 1.2 (old Siemens CT scanner to be dismantled)



Annexure 2.1 couch top Linac



Annexure 2.2 CIVCO couch top at CT Toshiba

