SPECIFICATION

Medical Linear Accelerator, Treatment Planning System and Oncology Information System (including the Record and Verify System)

1 Scope

1.1. This specification describes the requirements for a medical linear accelerator, treatment planning system, oncology information system (including record and verify system) and associated hardware and software (hereinafter referred to as “the System”) to be used to expand the capacity of the external-beam at the Bukovinian Clinical Oncology Center, Chernivtsi, Ukraine (hereinafter referred to as “the End-User”).

1.2. The supply and delivery of the System is related to the IAEA Technical Cooperation (TC) project number UKR6014 “to support Ukraine in strengthening radiation therapy and medical imaging”.

1.3. The System is to be operated in conjunction with the infrastructure that consists of a CT simulator (see separate specification) and dosimetry workstation, and shall be capable of future integration with a PACS system.

1.4. Alternatives

The Contractor may propose alternatives that differ from this Specification but are proven to produce the same or better results for this application. In such cases, the Contractor must clearly state the alternative, and provide enough technical information to assure compliance with this Specification

2. Applicable Documents

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

2.1. INTERNATIONAL ATOMIC ENERGY AGENCY "Radiation Protection and Safety of Radiation Sources: International Basic Safety Standards, General Safety Requirements Part 3", IAEA, Vienna (2014)

2.2. INTERNATIONAL ATOMIC ENERGY AGENCY, “Setting up a Radiotherapy Programme: clinical, medical physics, radiation protection & safety aspects”, IAEA, Vienna (2008)

2.3. INTERNATIONAL ELECTROTECHNICAL COMMISSION, Medical Electrical Equipment, Part 1: General requirements for Safety, Rep. IEC 60601-1:2005+AMD1:2012, IEC, Geneva (2012)

2.4. INTERNATIONAL ELECTROTECHNICAL COMMISSION, Medical Electrical Equipment, Part 60601-2-1: Particular Requirements for the Basic

Safety and Essential Performance of Electron Accelerators in the Range 1 MeV to 50 MeV, Rep. IEC 60601-2-1:2009+AMD1:2014, IEC, Geneva (2014)

2.5. INTERNATIONAL ELECTROTECHNICAL COMMISSION, Medical electrical equipment - Medical electron accelerators - Functional performance characteristics, IEC 60976, IEC, Geneva (2007)

2.6. INTERNATIONAL ELECTROTECHNICAL COMMISSION, Medical Electrical Equipment - IEC 60601-1-4 Part 1-4: General Requirements for Safety - Collateral Standard: Programmable Electrical Medical Systems 1.1 Edition, April 2000

2.7. INTERNATIONAL ELECTROTECHNICAL COMMISSION, Radiotherapy equipment - Coordinates, movements and scales, IEC 61217, IEC, Geneva (2011).

2.8. INTERNATIONAL ELECTROTECHNICAL COMMISSION, Medical Electrical Equipment: Requirements for the safety of radiotherapy treatment planning systems, Rep. IEC 62083:2009, IEC, Geneva (2009)

2.9. INTERNATIONAL ATOMIC ENERGY AGENCY, “Introduction of Image Guided Radiotherapy into Clinical Practice”, IAEA Human Health Reports Nº 16, Vienna (2019).

2.10. INTERNATIONAL ELECTROTECHNICAL COMMISSION (IEC) developed IEC 62274 ed.1.0, ‘Safety of Radiotherapy Record and Verify Systems’ (2005).

2.11. IAEA Human Health Report No. 7, ‘Record and Verify Systems for Radiation Treatment of Cancer: Acceptance Testing, Commissioning and Quality Control’ (2013).

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:

3D-CRT – 3D conformal radiotherapy

4D CBCT- Four dimensional CBCT, Respiratory Gating imaging

CBCT – cone beam computed tomography

DRR – digitally reconstructed radiograph

EAEA – Egyptian Atomic Energy Authority

EPID – Electronic portal imaging device

FFF – Flattening filter free

IGRT – Image Guided Radiation Therapy

IMRT – Intensity modulated radiation therapy

Linac – Medical linear accelerator

MLC – Multi leaf collimator

MU – monitor unit

RVS – record and verify system (please note that these systems are sometimes referred to as Oncology Information Systems)

TBI – Total Body irradiation

TMR – Tissue maximum ratio

TPR – Tissue phantom ratio

TPS – treatment planning system-

TSEI - Total Skin Electron Irradiation

UPS – Uninterruptible power supply

VMAT – volumetric modulated arc therapy

HI – High Intensity

4 Requirements

4.1 Functional and Performance Requirements

The System shall meet the following functional and performance requirements:

4.1.2. **Medical linear accelerator** shall:

4.1.1.1. Generate a range of megavoltage photon beams of 6MV, , 10MV, (optional 12MV), 15MV and 6 MV FFF High dose rate for treating cancer patients with external beam radiotherapy;

4.1.1.2. Generate a range (at least 4) of most clinical used electron beams from 6MeV to 18MeV

4.1.1.3. Be equipped with an EPID, kV (planar and CBCT capable) imaging for patient setup verification and an MLC (at least 120 leaves);

4.1.1.4. Be capable of treating 40 – 60 patients per day using 3D-CRT and advanced IMRT techniques (VMAT);

4.1.1.5. Be fully integrated and compatible to RVS and to the TPS; and

4.1.1.6. Optional, the System shall be matched (beam/energy) to one of the existing nearby facility as back-up solution in case of machine down-time (TBC).

4.1.3. **Treatment Planning System** shall

4.1.1.7. Meet the requirements for 2D, 3D CRT, IMRT and VMAT planning of radiotherapy treatments from patient CT image data sets including those with field parameters and/or contours imported from virtual simulation; and

4.1.1.8. Be capable of transferring DRRs and treatment parameters directly to the Record and Verify System. Beam data input and commissioning shall be facilitated through direct input from the beam acquisition computer and/or dosimetry server.

4.1.4. **Oncology information system** shall be able to:

4.1.1.9. Manage the flow and storage of electronic information, including patient data, in the radiotherapy department; and

4.1.1.10. Establish a bilateral communication as a Record and Verify system with the TPS, Linac, and Brachytherapy (see separate Technical Specifications).

4.1.5. **Image Guided Radiation Therapy (IGRT): A solution** for 4D motion management and gating system including all necessary hardware and software licences to perform motion management on the Linac as well as licences for the client TPS;

4.2 Technical Requirements

The System shall meet the following technical requirements:

4.2.1 **Medical linear accelerator:**

4.2.1.1 Have photon energies of 6 MV, 10 MV, (12 MV optional) and 15MV with flattening filter;

4.2.1.2 Have one photon energy of 6MV FFF Hi, without flattening filter and high intensity;

4.2.1.3 Have at least 4 different electron energies between 6 and 18 MeV;

4.2.1.4 Have an IEC 61217 scale convention in clinical mode;

4.2.1.5 Have a motorized gantry with isocentric design, 100 cm source to axis distance and gantry rotation at least ± 180°;

4.2.1.6 The mechanical isocentre shall have a maximum diameter of ≤ 2 mm for all three rotation axes (collimator, gantry, EPID and kV imaging systems and treatment table);

4.2.1.7 Have a Collimator rotation at least ± 100° with motorized rotation;

4.2.1.8 Have Asymmetric jaw movements;

4.2.1.9 Have an optical distance indicator with range at least SAD ± 25 cm;

4.2.1.10 Have a universal hard and/or soft wedge providing wedge angles of up to 60° (in the direction of the MLC movement);

4.2.1.11 Have a maximum photon beam field size at the isocentric plane of 40 cm × 40 cm (50% isodose level);

4.2.1.12 Have a dose rate up to at least 500 MU/min for photons and

electrons;

4.2.1.13 Have a dose rate for 6MV FFF beam that reach at least 1400 MU/min;

4.2.1.14 Have a light field to indicate the radiation field aperture and a graticule to indicate the principal axes and collimator axis of rotation;

4.2.1.15 Have an optical or laser back-pointer;

4.2.1.16 Have an integrated multi-leaf collimator (MLC) with at least 120 leaves providing 5 mm leaf width at the isocentre, isocenter in, at least, the central 20cm of the field;

4.2.1.17 Have a dual independent system of ionization chambers for monitoring dose, dose rate, beam symmetry and beam steering;

4.2.1.18 Have an independent backup system to indicate accumulated monitor units and setup parameters at the time of a power failure;

4.2.1.19 Have hand pendants in the treatment room to allow manual control of linac and treatment table movements;

4.2.1.20 Have a treatment table with motorized lateral, longitudinal and vertical movements and isocentric table rotation up to minimum ± 95°; and the lateral offset of the couch shall be less than +/-25 cm;

4.2.1.21 Have a table fitted with a system to enable manual removal of the patient in the event of a power failure;

4.2.1.22 Have a carbon fibre tabletop and indexed to allow reproducible placement of immobilization equipment. The tabletop shall be the same type and model as on the CT Simulator at the site and/or to the other department where patients are simulated to guarantee full compatibility (to be confirmed by the end-user after award);

4.2.1.23 Have a computerized control console with a slave display inside the treatment room with interface. All the functions and modes of the accelerator shall be controlled via software. The console shall have various modes including clinical, physics and service modes. The control console shall have an on/off removable key;

4.2.1.24 Access to physics and service mode shall only be possible by password or key control;

4.2.1.25 Include an integrated amorphous silicon EPID mounted on a motorized arm for planar portal imaging and include software at the treatment control for comparing/matching EPID images with TPS generated DRRs;

4.2.1.26 Have EPID software capable of image enhancement, overlay and matching tools, electronic image approval/rejection, editing and commenting. The software shall be capable of providing the user with suggested couch movements to achieve an improved setup;

4.2.1.27 The EPID shall be capable of imaging at least a set field size

of 25 cm x 25 cm with collision detection;

4.2.1.28 The EPID shall be capable of sending images directly to the dosimetry server for routine QC purposes;

4.2.1.29 Include a mounted 2D planar, 3D CBCT and (*optional* 4D CBCT kV, for respiratory gating) imaging system and include software at the treatment control for comparing/matching these images with TPS generated DRRs;

4.2.1.30 Have kV software capable of image enhancement, overlay and matching tools, electronic image approval/rejection, editing and commenting. The software shall be capable of providing the user with suggested couch movements to achieve an improved setup;

4.2.1.31 The kV imaging for patient setup verification shall be capable of imaging at least a set field size of 25 cm x 25 cm;

4.2.1.32 Have a voltage stabilizer/power conditioner;

4.2.1.33 Have a water chiller for linac cooling (closed system);

4.2.1.34 Have at least two-colour CCTV systems for viewing of the patient from the console in the control room, (one with pan, tilt and zoom) and a bidirectional audio intercom system;

4.2.1.35 Include emergency stop buttons located on the table, treatment console and around the treatment room; and

4.2.1.36 Have an external (wall-mounted) laser system indicating the position of the isocentre including 2 side lasers (vertical and longitudinal) and 1 sagittal laser.

4.2.2 **UPS solution** for all system relevant computers and control units in Radiothearpy.

4.2.3 The **Treatment planning system** shall include the following:

4.2.3.1 Two (2) treatment planning workstations, including dual 23-inch monitors, keyboard, mouse and network capability for each of the workstations;

4.2.3.2 Two additional (2) treatment planning workstations dedicated for contouring, including dual 23- inch monitors, keyboard, mouse and network capability for each of the workstations;

4.2.3.3 A module to allow import of patient data sets from various imaging modalities that are used to facilitate target definition, using the DICOM standard. Image import may be achieved through direct connectivity to the CT simulator and/or radiology picture archiving and communication system (PACS) system;

4.2.3.4 An image registration module using either rigid and/or deformable registration modes;

4.2.3.5 3D visualization capability for patient data display, beam display and dose distribution display;

4.2.3.6 Contouring tools that allow the definition in 3D of structures, including target, organs at risk and patient outline;

4.2.3.7 Automated tools to allow the expansion of the clinical target volume (CTV) to a planning target volume (PTV) with non-uniform margins in three dimensions;

4.2.3.8 The ability to add bolus structures to the patient data set of various shape and density;

4.2.3.9 A comprehensive “forward planning” environment that allows the user to modify beam weights, beam positioning, jaw position, wedges and blocks, or MLC to optimize the treatment plan;

4.2.3.10 Photon beam and electron beam algorithms that calculate the dose to the patient considering the 3D nature and heterogeneity of the patient data set. The photon beam algorithm shall use advanced methods (e.g. convolution, Boltzmann transport, Monte Carlo). The electron beam algorithm shall be based on pencil beam or Monte Carlo methods. The dose matrix (calculation grid) should be user adjustable and the accuracy of the dose calculations shall be such that it is possible to meet the tolerance criteria in Table 4 of IAEA TECDOC 1540 (59);

4.2.3.11 The capability to calculate MU for all beam models;

4.2.3.12 The capability to allow dose prescription to a point, volume or isodose line;

4.2.3.13 Advanced plan review and evaluation tools, including dose volume histograms (DVHs), dose statistics, 2D and 3D dose visualization, and plan addition and plan comparison;

4.2.3.14 The capability to generate and view DRRs;

4.2.3.15 Display of all relevant treatment unit parameters in the IEC 61217 scale convention as at least one option;

4.2.3.16 A comprehensive beam modelling module that allows the configuration of complete geometric and dosimetric models for treatment unit photon and electron beams. The module shall have the following features:

4.2.3.16.1. Ability to use the measured beam profiles and output factors;

4.2.3.16.2. Ability to model dynamic, fixed and internal wedges;

4.2.3.16.3. Tools to allow the comparison of the beam model and measured data, and

4.2.3.16.4. Security features that protect beam data and beam models from modification.

4.2.3.17 A module to allow the creation of CT number to mass density or electron density data for various CT scanners for use by the photon and electron beam algorithms;

4.2.3.18 User and password security that allows approval/locking of treatment plans and different levels of access to the functionality of the TPS based on the user’s profile, e.g. administrator, planner, medical physicist, physician;

4.2.3.19 A printer for A3/A4 output of isodose distributions, beam shapes and treatment plan parameters;

4.2.3.20 A module to allow export of beam block shapes to a third-party block cutting device, and

4.2.3.21 A module to allow export of approved treatment plans and DRRs to an OIS.

4.2.4 **Oncology Information System (OIS)** shall include the following:

4.2.4.1 A secure, remote server with back-up solution and minimum five (5) workstations, at least 19-inch monitors, keyboard, mouse and network capability;

4.2.4.2 An UPS, including an automated daily back-up system to an external hard drive (or equivalent) with autodetect and auto-shutdown after 20 minutes in the event of a power failure;

4.2.4.3 A gateway that is HL7-compliant to a hospital information system (HIS) for patient administrative fields only (retrieve only). Mandatory fields shall be used to ensure and internally validate unique patient ID, e.g. first name, surname, gender, date of birth and national ID number;

4.2.4.4 Workstations located in the treatment planning room that shall be capable of:

4.2.4.4.1 Manual data entry of 2D cases, clinical markups and emergencies;

4.2.4.4.2 Approval and entry of prescriptions and free text setup instructions;

4.2.4.4.3 Upload of photographic images;

4.2.4.4.4 Electronic chart checks;

4.2.4.4.5 Image review of DRRs and treatment images (portal and setup);

4.2.4.4.6 Networking to the TPS to allow import of the patient administration data, beam delivery parameters and DRRs of graphically planned patients; the importation of data should be customized to correctly download and translate the TPS information to the scales and graduations of the department treatment units; and

4.2.4.4.7 A fully integrated workstation shall be provided for each of the treatment units, including all interfaces to fully operationalize the system for automated download and verification of the treatment parameters as well as capture and storage of portal and setup images. The workstations should include an in-room alternative monitor to facilitate patient identification and viewing of the setup instructions, including digital images. The system should be supported by a local UPS such that there is no loss

of data in the event of a power failure to the treatment unit.

4.2.4.5 Software features including:

4.2.4.5.1 Digital photos of patient (ID and/or setup photos);

4.2.4.5.2 Automated logging of cumulative dose;

4.2.4.5.3 Free text entry of setup instructions or alerts based on cumulative dose;

4.2.4.5.4 Hierarchical security features, including requirement for authorized approval of the dose prescription and field parameters prior to treatment;

4.2.4.5.5 Complete log of activities and users;

4.2.4.5.6 Generation of statistical data according to user-defined fields, e.g. diagnosis and managing consultant;

4.2.4.5.7 Library of diagnoses according to the WHO International classification of diseases, 11th revision (ICD-11);

4.2.4.5.8 Ability to correctly log cumulative dose in the event of a treatment interruption or termination, and

4.2.4.5.9 Patient appointment scheduling.

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 authorisation 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.

6 Marking

The System shall have all safety markings in English languages.

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 System.

8 Quality Requirements

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

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, 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's location;

10.2 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 in hard copies and one (1) set in electronic version of operation and servicing manuals and technical drawings in the English and preferable local languages;

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 hereinabove. Warranty shall also cover hardware and software upgrades and updates.

12.2 Warranty shall include all necessary spare parts, their 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 updates and upgrades 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. Intervention time shall be clearly defined and shall comply with the uptime requirements defined in section 14 below.

13.2 Spare parts

Upon installation and without prejudice for warranty obligations of the Contractor, an initial set of essential spare parts to guarantee the up-time of the linear accelerator 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.

13.3 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.

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).

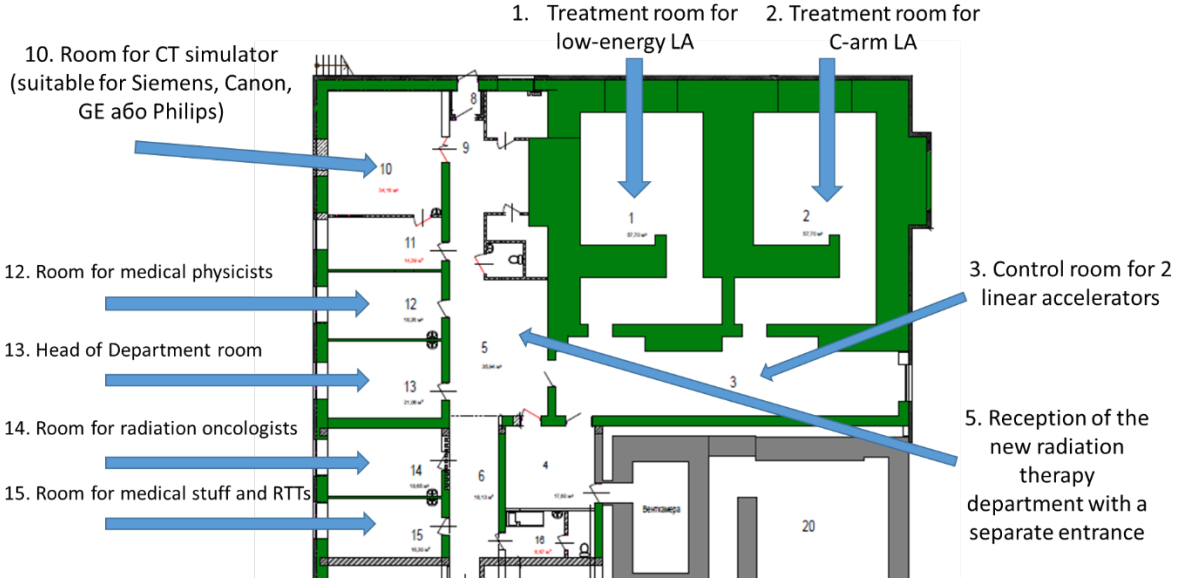
14.2 Uptime is calculated on a basis of 250 operating days per year (weekly working days).

14.3 Shall the down time exceed two (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 of the Radiation Unit, EAEA, at the Site. The Contractor shall have the right to request copies of such records.

Annex 1 – Radiotherapy facility overview

Bukovinian Clinical Oncology Center



Annex 2 – Radiotherapy facility layout (construction planned to be completed by September 2023