SPECIFICATION

Immobilisation Device Solution for radiation therapy patient simulation and treatment

1. Scope

This specification describes the requirements for **a complete solution** for immobilisation devices for **3-Dimensional Conformal Radiation Therapy** (3DCRT) for pelvis, thorax and head and neck regions, hereinafter referred as "The System", to be delivered to, hereinafter referred as "the End User".

The System is defined as the sum of all components and sub-components that when utilised or assembled together will serve to immobilise the patient securely, precisely and reproducibly for the safe and accurate delivery of high precision external beam treatments.

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

The System is to be operated in conjunction with infrastructure that consists of a CT simulator used for patient simulation and the Linac on site (see separate specification).

1.1. 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. "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)

2.2. All the applicable International Atomic Energy Agency Safety Standards.

2.3. International Standards Organisation: ISO 9001 Quality management 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:

3.1. 3DCRT - 3-Dimensional Conformal Radiation Therapy

3.2. CT - Computed Tomography

3.3. Linac - Linear Accelerator

3.4. MP - Medical Physicist

3.5. QC - Quality Control

3.6. RO - Radiation Oncologist

3.7. RTT - Therapy Radiographers

3.8. Units - X units include an appropriate number or quantity of items required for the use with X patients

3.9. VMAT - Volumetric Intensity Modulated Arc Therapy

4. Requirements

4.1. Functional and Performance Requirements:

4.1.1. Quantity of three (3) complete immobilisation sets for 3DCRT/VMAT to be used at the CT scanner, and treatment machines with the potential to be used concurrently at any one time;

4.1.2. The **immobilisation set for 3DCRT/VMAT** patients shall be capable to be used for pelvis, abdomen and thoracic sites including lung, liver, prostate and spine amongst others and

4.1.2.1. shall be based on the use of vacuum bags

4.1.2.2. provide specific components

4.1.2.2.1. **Three** compressors for vacuum bags capable of both inflate and deflate cycles, including connector valve

4.1.2.2.2. **Six** locking bars (indexing bars) compatible with the indexing system of the treatment couches of the Linac , the CT and simulator at the centre

4.1.2.2.3. **Three** sets of base plates for the vacuum bags compatible with the treatment and CT simulator couches.

4.1.2.3. Vacuum bags of small size (70x70 cm) and large size (70x100 cm) that will adequately provide general purpose use for pelvis, abdomen and thoracic sites. (**50 vacuum bags of each size).**

4.1.2.4. provide other available accessories as part of the solution, such as

4.1.2.4.1. **Three** sets of contoured knee support

4.1.2.4.2. **Three** sets of contoured feet support

4.1.2.4.3. **Three** sets of wing boards with handgrips CT compatible, that allows for the treatment of supine breast and thoracic tumours with the possibility of gradual inclination, capable of angling up to 25 degrees, including all accessories.

4.1.2.4.4. **Three** sets of prone breast boards compatible with treatment and CT simulation coaches
4.1.2.4.5. **Three** sets of prone pelvic boards (belly board) compatible with treatment and CT simulator coaches

4.1.3. **Thermoplastic immobilisation**
4.1.3.1. **One** Dry-heat oven for heating thermoplastic material (thermoplastic sheets) with two shelves allowing multiple thermoplastic devices to be prepared simultaneously. Allowing head and shoulder masks to fit in the oven.
4.1.3.2. Thermoplastic sheets for head, and head and neck immobilization, the sheets shall have a thickness of approximately 3 mm,
4.1.3.2.1. Head only, quantity **100** units
4.1.3.2.2. Head & Shoulder, **50** units
4.1.3.2.3. Paediatric open face 3-point head, **30** units
4.1.3.2.4. Paediatric open face 5-point head and shoulder, **30** units
4.1.3.3. Frames for Thermoplastic sheets, **quantity six (6**) of each compatible with the provided thermoplastic sheets (please note that alternative solution is acceptable)
4.1.3.3.1. Standard U-Frame, size approximately 10” x 10”
4.1.3.3.2. Standard S-Frame for Head & Shoulder
4.1.3.3.3. Paediatric U-frame size
4.1.3.3.4. Paediatric S-frame size
4.1.3.4. Head rest (head base) sets with different heights, compatible with treatment and CT simulator coaches, providing:
4.1.3.4.1. **Three** Sets of Head rest (head base) of low-density material for supine position (sizes A to F)
4.1.3.4.2. **Three** sets of Head rest (head base) of polyurethane-foam for supine position (sizes A to F)
4.1.3.4.3. **Three** sets of head rest or head base of low-density material for prone position with accessories
4.1.3.4.4. **Three** sets of Paediatric head rest or head base of low-density material for supine position
4.1.3.4.5. **Three** sets of Paediatric head rest or head base of low-density material for prone position
4.1.3.4.6. **Two** Head and neck overlays baseplates compatible with treatment and CT simulator coaches.

4.2. Technical Requirements

The system shall meet the following technical requirements:

4.2.1. The system shall be **compatible with**, fixed and indexed to the
4.2.1.1. linac with the Couchtop (see technical specification for the Linac),
4.2.1.2. CT Simulator (to be confirmed at the time or ordering)

5. Marking

The systems shall have all safety markings in the English language and must be CE marked.

6. Packing

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

7. Quality Requirements

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

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

   7.3. The Contractor shall provide a list of consumables and disposables for the system and identify items with a short shelf life.

8. Testing and Acceptance

   The system, prior to shipment, shall be tested for conformance of the systems with manufacturer's performance specifications and the minimum requirements specified herein.

   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.

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

9. Deliverable Data Items

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