Appendix A

Technical Specifications

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1 Introduction

Association of Friends of the Tel Aviv Sourasky Medical Center ("ASSOCIATION") intends to develop and operate Israel's National Proton Therapy Institute, a state-of-the art facility for the delivery of proton radiotherapy for children and all other appropriate indications for proton radiotherapy in the Tel Aviv Sourasky Medical Center.
The facility will include:

- One (1) proton accelerator, either cyclotron or synchrotron, and two (2) 360 degree rotating gantries, capable of Pencil Beam Scanning (PBS) and Intensity Modulated Proton Therapy (IMPT).
- All vaults will be designed to accommodate advanced image-guided therapy.
- Imaging and treatment planning capability with dedicated space for CT Simulator, MRI Simulator, and future technological and clinical treatment opportunities
- Dosimetry and treatment planning area
- Reception, waiting, consultation and exam rooms
- Specialized Pediatric facility for anesthesia, preparation, recovery
- Technical Support facility
- Offices, storage, meeting rooms, etc.
- Optional two (2) additional treatment vaults will be constructed for phased installation of two (2) additional 360 degree gantries with identical PBS and IMPT capabilities ("Optional Facility").
- Heavy load cranes, rigging, and all internally installed cranes, required to ensure vendor's equipment may be installed into subterranean levels, and for subsequent use in phased build-out, as clinical operations expand to include additional treatment facility. See architectural schematic in Illustration 1 (end of this document).
- All other facilities necessary for operation

2 Scope of Work

Without derogating from the Agreement, Scope of Work shall include:

- in conjunction with Hospital's advisors, planners, construction company to be chosen by association, the design and construction of the facility housing the proton therapy equipment, including appropriate radiation shielding
- schedule and coordinate the design, delivery, installation, assurance of successful acceptance testing and commissioning of a clinical proton therapy system, including accelerator, beam line, gantries, nozzles, patient positioning and image guidance systems, treatment planning systems and oncology information system (R/V, EMR, etc.), through final acceptance.
- the continuing maintenance of and upgrades to the hardware system, including ancillary software and new features as they become clinically available.
- assistance with the acquisition of all regulatory clearances required for clinical operation

- the management of and responsibility for all subcontracts necessary to accomplish this work
- initial training and credentialing, as applicable, for medical and technical staff of the proton facility
- Support for start-up and commissioning

3 Phases of Planned Development

Development of the IPTI will occur in three phases, which we anticipate will be as follows:

Phase 1
• Construction of four treatment vaults designed to accommodate rotating gantries, facility for one cyclotron or synchrotron, and all ancillary facilities • Installation of cyclotron or synchrotron and two gantries with all advanced imaging and patient positioning systems in each vault • Acceptance, commissioning and clinical operation of the gantry treatment rooms • Commissioning of treatment planning system and all electronic medical record systems • Clinical Operation
Phase 2 (Optional)
• Installation of third rotating gantry, patient positioning system, etc. • Acceptance and commissioning, clinical operation
Phase 3 (Optional)
• Installation of fourth rotating gantry, patient positioning system, etc. • Acceptance and commissioning, clinical operation

4 Technical Specifications

For each specification that follows, please affirm that the equipment and systems proposed meet or exceed the specification stated. For technical inquires without stated performance specification, state your systems specification and provide as much supporting detail and/or documentation as required. For any specifications that the proposed system does not meet, please state the relevant specification achievable with the proposed system and briefly explain how the system still meets our overall technical, clinical, and safety goals.

4.1 Clinical Specifications

4.1.1 **Range in patient:** State the range of clinical treatment depth possible with the proposed system.

4.1.2 **Range adjustment:** Please describe your system for range shifting. Specify details such as size and weight of equipment, patient clearance distance, etc. Also, please describe the process for adding range shifter(s) to treatment beam path and any reduction in useful clinical field size. Describe manual and automatic features for insertion and extraction of range shifters.

4.1.3 **Average dose rates:** Sufficient to produce > 2 Gy/liter/30 seconds over full range and field size. Examples of time required to deliver various volumes at varying depths will be useful (ie, in phantom and clinical treatments).

4.1.4 **Beam time structure:** Ratio of instantaneous to average dose rate low enough to ensure safe operation and radiobiological response consistent with existing proton experience.

4.1.5 **Scanned Field size:** Please specify the maximum clinical treatment field size for pencil beam scanning. Please specify technical limitations on the stated field size for specific applications/features if any exist.

4.1.6 **Dose uniformity**: ±2.0% over treatment volume

4.1.7 **Dose accuracy:** ±1% absolute dose

4.1.8 **Dose reproducibility:** ±1.5%

4.1.9 **Distal dose falloff:** 0.1 g/cm^2 (80% -> 20%) above range straggling

4.1.10 **Lateral penumbra:** 2 mm greater than penumbra caused by interactions intrinsic to patient.

4.1.11 **Robotic tables:** Capable of ±185° rotation about vertical axis; ±5° pitch and yaw; and > 50 cm translation in all three axes. Minimum 180 kg capacity.

4.1.12 **Gantry room:** Gantry rotation ≥ 360°

4.2 General specifications

4.2.1 The installation will be designed and constructed in such a way as to allow operation of the accelerator for beam production to each room independent of all other rooms.

4.2.2 **Facility availability:** >98% of the time, with clinical beam available for treatment or quality assurance between 6:00 AM and 10:00 PM, Sunday through Thursday; 6:00 AM and 12:00 PM on Friday.

4.2.3 **Treatment control**

- 4.2.3.1 Startup from standby < 60 min
- 4.2.3.2 Startup from shutdown < 120 min
- 4.2.3.3 Shutdown to standby at day's end < 15 min
- 4.2.3.4 Manual setting of beam parameters (excepting patient/gantry positioning and beam modifiers) < 1 min
- 4.2.3.5 Automatic setting of all beam parameters from record and verify system < 0.5 min
- 4.2.3.6 Beam emergency stop (hard stop): < 10 μs
- 4.2.3.7 Beam stop (soft stop): < 1 sec or 0.2 Gy
- 4.2.3.8 Beam start: < 2 sec from pressing "beam on" button to start of beam delivery, given beam available to treatment room
- 4.2.3.9 Room-to-room beam switching time (beam-off to beam-on): < 10 sec

4.2.4 **Treatment Beam(s):** Each gantry will have the capability to deliver pencil beam spot scanning.

4.2.5 **Treatment room ceiling height:** Sufficient to accommodate current and future ceiling mounted imaging devices, ≥ 12 feet.

4.2.6 **Patient viewing and communication:** All treatment rooms will have patient viewing and communication equipment. This will consist of a minimum of 2 cameras mounted so that at least one camera is capable of meaningful observation of the patient at any gantry or table position. Two-way audio communication will be provided.

4.2.7 **Radiation monitoring:** All appropriate and regulatory required proton, photon and neutron monitoring equipment, warning signs and access control will be provided for appropriate areas of the facility.

4.2.8 **Accelerator** will consist of either: isochronous cyclotron, superconducting cyclotron or a synchrotron.

4.2.9 The accelerator will be **installed in the manufacturer's bunker** and adjusted for peak performance prior to delivery.

4.2.10 The **life expectancy** of the primary hardware components of the accelerator will be 30 years or greater.

4.2.11 The **beam production and control system** will be sufficient to deliver matched proton beams in up to 4 treatment vaults.

4.2.12 if **superconducting magnets** are employed, appropriate controls will be in place to minimize the likelihood and consequence of superconducting malfunction.

4.2.13 If **superconducting magnets** are employed, the time between helium fills will be greater than one year, and liquid nitrogen will not be used.

4.2.14 **Beam availability:** The system shall be designed such that the maximum anticipated wait time from beam completion in one room to start of beam in another room is less than or equal to 10 seconds.

4.2.15 **Neutron production:** The system shall be designed with minimal materials intersecting the beam line to minimize the production of neutrons in the proton delivery system. The Bidder will provide an estimate of neutron activity (both dose and half-life) upon beam stop after 8 hours of full operation.

4.2.16 **Residual radioactivity:** The Bidder shall provide an estimate of residual radioactivity of all system and building components assuming a 30 year operational lifetime of the facility.

4.3 Accelerator specifications

4.3.1 **Energy range:** Specify the range of energies available, measured at treatment nozzle exit that will be available in all treatment rooms.

4.3.2 **Energy selection time:** Please describe the time requirements for energy switching during beam delivery.

4.3.3 **Energy precision:** $\pm$0.4 MeV over entire energy range

4.3.4 **Energy variability:** $\pm$0.4 MeV over entire range, or sufficient to allow steps of 0.1 gm/cm^2 (0.05 gm/cm^2 for depths < 5 g/cm^2)

4.3.5 **Energy spread:** $\leq \pm$0.1% FWHM at nozzle exit for energy > 100MeV

4.3.6 **Energy variation of extraction:** $\leq \pm$0.1%

4.3.7 **Beam intensity:** Sufficient to deliver 2 Gy/liter/30 seconds in all treatment rooms

4.3.8 **Position and angle stability:** $\pm$1 mm and $\pm$1 mrad at accelerator exit

4.3.9 **Overall beam extraction efficiency:** > 90%

4.4 Beam transport, control and delivery specifications

4.4.1 **Can dose rate be varied dynamically on a spot by spot basis? Are multiple spot sizes available?**

4.4.2 **Beam parameters at isocenter:**

4.4.2.1 **List spot sizes in air at isocenter for multiple energies (g/cm^2):**
4.4.2.2 **Specify spot symmetry (mm):**
4.4.2.3 **Spot centroid positional accuracy:** < 1mm in x, y
4.4.2.4 **Specify deviation of spot size with varying gantry angle**
4.4.2.5 **Specify any other variations in spot specifications due to gantry angle**

4.4.3 **Beam switch time:** Room-to-room beam switch time; beam-off to beam-on ≤ 10 sec

4.4.4 **Layer switching time:** < 1 sec for adjacent layers

4.4.5 **Dosimetric equivalence of all treatment rooms:** Specify variation of dose output, depth dose curve width and range, spot size at isocenter.

4.4.6 **Specify Monitor Unit reproducibility:**
4.4.6.1 Minimum and Maximum spot MUs
4.4.6.2 Limitations due to gantry angle or field size

4.4.7 **Gantry angle vs MU Linearity**
Please provide linearity variations to deliver 2Gy/litre at gantry angles 0, 90, 180, 270 degrees for 3 energies (min, mid, max).

4.4.8 **Beam tuning:** All beam tuning will be automatic between gantry angles, energies, and rooms. No manual tuning of beam required after initial daily setup. There should be retractable beam monitors after each section of the accelerator to aid beam tuning.

4.4.9 **Gantry specifications**
Gantry equipment will be identical in each of the treatment rooms, with a nozzle offering spot scanning capability upon initial installation.

4.4.9.1 **Rotation angle:** ≥ 360°
4.4.9.2 **Rotation accuracy:** ±0.3°
4.4.9.3 **Rotation step size:** ±0.1°
4.4.9.4 **Rotation speed:** 1 RPM
4.4.9.5 **Braking:** 1° from full speed to complete stop in 1 sec
4.4.9.6 **Mechanical isocentricity:** <1 mm over full rotation
4.4.9.7 **Is gantry rotation speed variable (potential for proton arc IMPT)?**

4.4.10 **Gating interface:** All treatment rooms shall have a standard interface for motion control gating. Beam on/off signal to actual beam on/off lag time < 50 msec.

4.4.11 **Safety:** System will have sufficient systems and interlocks to ensure safe movement and beam delivery. System shall monitor beam continuously, with at least one dose monitoring chamber incapable of saturation at the maximum conceivable beam current and minimum beam size. Beam position, energy, uniformity and intensity should be continuously monitored and automatically tuned at accelerator exit, along beam line, and at nozzle exit. Beam trip time for out-of-tolerance parameters shall be 10 μsec. There should be a system for beam dump in each section of the beam line.

4.4.11.1 **Emergency off buttons** will be placed in each treatment room and at the console in order to inhibit extraction and delivery of the beam.

4.4.11.2 Please describe and document, as applicable, **safety records** for your proton therapy delivery systems in clinical operation at the time of this RFP response.

4.5 Scanning nozzle specifications

4.5.1 **Dose compliance:** The dose compliance must be such that at each point inside and outside the target volume, the dose is within $\pm$ 2.0% of the intended value.

4.5.2 **Beam spot size:** FWHM at highest specified energy
FWHM at 120 MeV
FWHM at lowest specified energy

4.5.3 **Scanning technique:** Describe techniques available (eg, layer by layer, volumetric repainting, etc). Describe beam position and profile at various distances from isocenter

4.5.4 **Automatic Volumetric Repainting:** Can beam scanning be automatically controlled to repeat volumetric scans multiple times in the course of a clinically relevant beam delivery to mitigate the effects of patient motion? Describe.

4.5.5 **Dosimetry:** Describe system of independent dosimetry for continuous monitoring of the dose delivered (eg, number of dosimeters, size, position, purpose, saturation limits, etc.)

4.5.6 **Beam energy modification:** The range of the protons must be capable of being changed during treatment to produce an effective spread out Bragg peak over a range from 1 g/cm^2 to 16 g/cm^2 in 0.5 g/cm^2 steps. Specify lag time for energy switching between layers.

4.5.7 Maximum Field size vs. Energy: Describe the dose limits specific to maximum field sizes at the highest and lowest energies.

4.5.8 **Safety:**

4.5.8.1 If a beam monitor is out of tolerance, the beam must be shut off immediately, before more than 0.5% of the total treatment dose is delivered anywhere in the treatment volume.

4.5.8.2 All physically moveable devices such as beam monitors, apertures, etc., must be interlocked and monitored for correct position.

4.5.9 **Beam modulation:** Is a collimation or beam control system available for precise and sharp field shape modulation?

4.5.10 **Spot scanning intensity:** Specify the range over which the number of protons per spot is intensity regulated.

4.5.11 **Beam Shaping Apertures:** A method to allow for the addition of adaptive field sharpening apertures that reduce field edge penumbra with spot scanning may be considered. Multi-leaf collimator (MLC) technology is preferred but alternatives offering comparable functionality will be considered. (If possible, the proposal should include a quotation for both MLC and an alternative). The adaptive aperture should ideally allow for initial loading of all field shapes specific to a patient, with rotation through the specific apertures being completed without the necessity to manually manipulate apertures between beams and would require no more than 15 seconds for each field shape. If an MLC is proposed, an analysis of induced radioactivity should be supplied.

4.6 Patient-Specific Quality Assurance

Please describe the secondary QA process resident in your system and the software for handling machine-patient-specific quality assurance data files (eg, log files, trajectory analysis files) that may eliminate or minimize the requirement for patient-specific QA.

4.7 Patient support system specifications

4.7.1 The patient support systems shall have **full 6D movements**, with < 0.1 mm and < 0.1° precision over a range of motion sufficient to employ in-room imaging and treatment delivery.

4.7.2 **Translation and rotation accuracy:** 0.1 mm, 0.1°

4.7.3 The support system shall be **capable of handling patients up to 180 kg.**

4.7.4 The patient support system must be **compatible with standard radiotherapy immobilization devices and the ancillary imaging equipment**.

4.7.5 **Attenuation of the treatment beam** through the support assembly at any angle shall be < 5%.

4.7.6 **Software control or hardware interlocks** will prevent patient support system/nozzle/floor collision.

4.7.7 **Patient Orientation** will allow for head-first and feet-first setups.

4.7.8 The patient support system shall be capable of accommodating **anesthesia equipment,** with mechanisms for attaching IV poles, cardiac monitors, CO_2 monitors, etc.

4.7.9 Anti-collision system between all devices will force all motion to stop. Describe sensor locations and method.

4.8 Patient alignment system specifications

4.8.1 The patient alignment system in each room shall consist of:

4.8.1.1 **Isocentric Cone-Beam CT (CBCT) Imaging** capable of real-time adaptive therapy from the CBCT

4.8.1.2 **Planar imaging –** orthogonal kV imaging

4.8.1.3 **Real-time patient position monitoring** via an infrared reflector system, optical surface matching system, or other solution

4.8.1.4 Capability of integrating with industry **standard respiratory management/gating systems.**

4.8.2 The **patient alignment system shall be well-integrated** such that image acquisition; automated fusion with planning images; movement of the patient; secondary image acquisition and fusion for confirmation can all take place without the necessity to enter the room. The entire process, from first image to final alignment, should take place in under three minutes.

4.8.3 With a rigid body and feature rich images, the system shall be capable of **aligning a patient at isocenter** with < 0.5 mm accuracy.

4.8.4 The **image acquisition and fusion system** shall have the ability for the user to define on a patient specific basis the:

4.8.4.1 Image field of view: please describe

4.8.4.2 Fusion algorithm (manual, edge matching, maximization of mutual information, rigid, deformable, etc.)

4.8.4.3 The area of the image over which the fusion algorithm will perform its calculation, including manually defined non-rectangular areas.

4.8.4.4 Please describe the CBCT specifications (reproducibility, contrast resolutions, Hounsfeld Unit accuracy and uniformity, acquisition time, etc).

4.8.5 The system shall have **Real-Time Adaptive re-Planning** allowing for real-time adaptive treatments from the on-board CBCT image acquisition. If this feature is not currently available, Bidder should describe development plans (if any) for such for this functionality.

4.9 Motion management and beam triggering

Describe the Bidder's motion management system, respiratory gating and other sources of trigger input, as well as interfaces available from third party systems. If imaging techniques are available for assessing target movement and subsequent impact of movement on treatment, please describe.

4.10 Treatment Planning System specifications

4.10.1 Fifteen planning stations will be available with floating licenses for full treatment planning, contouring, dose calculation, plan review, etc.

4.10.2 Two planning stations, with sample beam data and full planning capabilities, shall be delivered within 60 days of ASSOCIATION's request. The balance shall be delivered at start of acceptance. The two systems delivered within 60 days of request will be upgraded to the latest version of hardware and software consistent with the remaining 13 planning systems/licenses delivered at the start of acceptance.

4.10.3 The treatment planning system shall provide the following capabilities:

4.10.3.1 Proton, photon and electron dose calculations

4.10.3.2 DICOM RT import and export capability for images, structures, isocenters, beams and doses

4.10.3.3 As applicable, capable of interfacing with Aria, the electronic medical record system in current use at TASMC

4.10.3.4 Capability to participate in all RTOG, NRG, COG and other trials

4.10.3.5 Use CT, MR and PET images with robust fusion algorithms

4.10.3.6 The ability to combine photon, electron and proton doses

4.10.3.7 Perform 3D dose calculations superposition/convolution/Monte Carlo algorithm.

4.10.3.8 Calculate dose on a variable spatial resolution from 1 mm cubic voxels to 5 mm cubic voxels
4.10.3.9 Perform and export dose volume histograms
4.10.3.10 Model the beam delivery system
4.10.3.11 Meet current AAPM recommendations for dose calculation accuracy
4.10.3.12 Provide for accurate heterogeneity corrections
4.10.3.13 Have the ability to override density information on the CT data set
4.10.3.14 Export alignment information to the image guidance systems
4.10.3.15 Optimization algorithms for VMAT and IMPT calculations
4.10.3.16 Allow for some control of radiobiological factors in the dose calculations, eg., proton Co-60 Gy equivalence
4.10.3.17 Have the capability to export all pertinent treatment data from the treatment planning system to the accelerator control system such that, in normal operation, no data need be entered manually in transferring a plan to treatment delivery
4.10.3.18 Include an automated archive and retrieval system
4.10.3.19 Include a mechanism to incorporate plan robustness optimization accounting at a minimum for range uncertainties and user specifiable patient positioning uncertainties.

4.11 **Record and verify system**

Sixty (60) floating licenses will be required that provide access to the Electronic Medical Records/Record and Verify modules of the software to be used for patient data entry, scheduling, billing, etc.

4.11.1 The record and verify system shall **accept parameters from the treatment planning system in standardized DICOM format**.

4.11.2 The system shall have a method to **correlate patient demographic information with prescriptions and treatment parameters**.

4.11.3 The system shall **monitor all treatment-related equipment parameters,** such as beam-on time, field size, beam modifiers, gantry position, table position, and patient-specific beam modifiers.

4.11.4 The system shall have a **fault recovery system** for completing interrupted treatments.

4.11.5 The system shall have an **automated backup system**.

4.11.6 The system shall be **compatible with standard photon beam systems,** as well as proton therapy systems.

4.11.7 The system shall be **HIPAA-compliant**.

4.11.8 The system shall be **DICOM-compliant.**

4.11.9 As applicable, the system shall interface with **Aria, Chameleon, Namer**, the electronic medical recording systems used by TASMC.

4.11.10 Describe possible limitations on the PT system functionality vis-à-vis the Oncology Information System, and if manual interactions are required.

5 Utility Requirements

The utility requirements will be specified and the design will accommodate those specifications, including power from the local utility. These specifications will include at a minimum:

5.1 Electrical power requirements and conditions

5.2 Back-up power requirements. Backup power shall be supplied to maintain accelerator operation in the event of a power outage.

5.3 HVAC requirements

5.4 Compressed air requirements

5.5 Chilled water requirements

5.6 State the annual power consumption of your system for the clinical stages defined in the Timetable (Section 3).

5.7 Are there features developed or in development to reduce the power consumption of the proton therapy system?

6 Power Conditions

6.1 Power-conditioning Equipment: ASSOCIATION cannot guarantee the quality of its electrical power system. Selected Bidder must provide power-conditioning equipment (if necessary) to protect against sags, surges, etc., as the specified equipment and installation equipment

requires. Selected Bidder must provide and install the power conditioning equipment, conduit, conductors, contractors, and other auxiliary equipment associated with the conditioned electrical supply. Selected Bidder will be responsible for compatibility of its equipment and the conditioned power supply. Selected Bidder must provide ASSOCIATION with the electrical load requirements.

6.2 Required power facilities: All quotations must explicitly state all electrical power facilities that must be provided by ASSOCIATION for the specified equipment. Specifically, for each power line the following must be specified: number of phases, voltage, voltage regulation required, recommended kVA rating of the distribution transformer, and the maximum current demand.

7 Physics and Quality Assurance Equipment

The Bidder will supply all the quality assurance equipment (QA phantoms, chambers, electrometers, etc.) required for acceptance, commissioning and ongoing clinical quality assurance of the proton therapy units. Please list equipment to be provided.

8 Radiation Safety

8.1 **Shielding design** shall be consistent with contemporary radiation safety standards for occupational radiation workers and general public, and consistent with the State of Israel's regulations and ALARA principles. In general, shielding will be sufficient such that public and occupational exposures will be significantly less than these figures. Calculations and simulations of shielding designs should be provided that meet these requirements.

8.2 Unfocused beam current will be minimized and beam dump will be designed such that residual radiation levels at the accelerator, energy selection system, and beam line will be low enough to allow occupancy in less than 15 minutes.

9 Training

Training prior to and at facility start-up for Phase I and Phase II (for additional staff) will be provided for radiation oncologists, physicists, dosimetrists, and therapists both on-site and off-site. Arrangements for on-going training (e.g., for new staff or related to upgrades in equipment or software) should be described.

9.1 **On-site training** for Radiation Oncologists, Medical Physicists, Dosimetrists, Therapists: Please describe fully the On-Site training provided by the Bidder. Include length of training and training syllabus defined per clinical job definition.

9.2 **Off-site training** for Radiation Oncologists, Medical Physicists, Dosimetrists, Therapists: Please describe fully the Off-Site training provided by the Bidder. Include length of training and training syllabus defined per clinical job definition.

9.3 **Commissioning assistance**: Describe Bidder's training, assistance and support during clinical commissioning.

10 Bidder Partners, Subcontractors, and Sub-Bidders

The Bidder shall specifically list all significant partners, subcontractors and/or sub-Bidders included in delivery and installation of the proton therapy system per the scope of work for this RFP (e.g., for the record and verify system, treatment planning system, patient support system, immobilization devices, image-guidance systems, etc.)

11 Research and Development Plans

11.1 The Bidder shall supply, subject to appropriate non-disclosure agreements, its 7-year timeline for development of improvements to existing capabilities and development of new capabilities. Specific attention shall be addressed to beam control and delivery improvements, including improved control of existing nozzles, potential new nozzles, spot-scanning improvements, arc therapy, and real-time adaptive planning and treatments.

11.2 The Bidder shall describe any existing or planned relationships with other industry, academic, or public entities for the purposes of research and development of products related to proton therapy.

11.3 The Bidder will commit to support and promote the Israel National Proton Center as a beta-site for testing, and participating in research for PT related areas of interest, such as: Proton Arc Therapy, Flash Therapy, RBE, Real-Time Adaptive Therapy, Artificial Intelligence capabilities, etc. Describe the Bidder's vision for a strategic long-term relationship in terms of clinical, research, and educational missions.

12 Documentation

Within 14 days of ASSOCIATION's request, Bidder will provide documentation to include:

12.1 Schematics and engineering drawings for Full device (accelerator, beam transport system, gantry, etc.) must be provided by Selected Bidder for the life of the equipment. The documentation must be supplied in English, in metric units, including documentation of the "service mode" and "research mode" of the devices. Both electronic (.doc or pdf format) and paper versions of the documentation must be provided to ASSOCIATION. All upgrades to the system, both hardware and software, must be accompanied by the same type of documentation.

12.2 Documentation required:

12.2.1 Two (2) sets of operator instructions materials per treatment room.

12.2.2 Two (2) complete and detailed electrical and mechanical schematics per treatment room.

12.2.3 Two (2) complete and detailed equipment system theory of operations manuals per treatment room.

12.2.4 Two (2) complete and detailed preventative maintenance schedules and procedure materials per treatment room. All preventative maintenance materials must be contained in one volume for all subsystems of the equipment quoted.

12.2.5 Two (2) complete and detailed replacement parts lists per treatment room.

12.2.6 One (1) set of complete maintenance and preventative maintenance software routine with detailed utilization and analysis capability per treatment room.

12.2.7 All software, hardware, and firmware keys and passwords to access full and complete maintenance and preventative maintenance repair, and maintenance features in service modes must be provided to ASSOCIATION service personnel by Selected Bidder at the time of delivery. Any special terminals or diagnostic test equipment for normal routine maintenance must be provided by Selected Bidder.

12.3 Documentation updates: Updates to service manuals must be provided for the lifetime of the machine. These must be provided within three months of their release to Respondent's service organization.

13 Footprint and preliminary design drawing

The purpose of this information is to assess minimum site requirements and the feasibility of our phased construction plan. General architectural design falls outside the scope of this RFP. The minimum footprint and preliminary design drawings should include the required elements of the proton therapy system proposed in Bidder's response and do not need to include ancillary spaces (lobby, offices, additional imaging equipment). Please refer to Illustration 1 for rigging and heavy equipment access points.

13.1 Please provide an estimate of **minimum footprint** for the required elements of the proton therapy system, inclusive of shielding, for:

13.1.1 **Phase 1:**
Accelerator, beam line, and control room(s)
Two rotating gantry treatment rooms
Patient gowning and anesthesia induction and recovery areas
Any other space required for operation or maintenance of the system

13.1.2 **Phase 2**
Extension of beam line
One additional gantry treatment room

13.1.3 **Phase 3**
Extension of beam line
One additional gantry treatment room

13.2 Please provide a **preliminary design drawing** or drawings for Phases 1 through 3 showing the required elements of the proton therapy system. Please demonstrate in the design drawings how our phased construction plan could be accommodated.

14 Project Management

Please provide a narrative of how the Bidder will support ASSOCIATION during the design phase of the project.

14.1 Describe the roles and responsibilities of the project support team members during building planning, shielding design, coordination, construction, and commissioning.

14.2 Please describe the dedicated and committed project manager and team who serve as the primary interface with hospital management, physicists, and hospital approved subcontractors.

15 Summary of Competitive Advantages

Please summarize the competitive advantages offered by this system and the Bidder over other proton therapy systems and Bidders in terms of: technical specifications and/or performance (including currency of technology, research and development plans and resources, and upgradeability); clinical specifications and/or performance (including treatment modalities or applications, ease of operation, and patient throughput); cost of equipment, required facilities, and of ongoing operation; safety; Bidder's business relationship to ASSOCIATION (including Bidder stability and resources, track record of systems delivered on time, responsiveness to ASSOCIATION requests/concerns); and any other areas the Bidder feels are relevant.

Illustration 1