**Terms of reference and technical Specifications**

1. **General information**

|  |  |
| --- | --- |
| Assignment name | **Provision of 1.5T Magnetic resonance imaging (MRI)** |
| Beneficiary | **Medical Research and Care Center (MRCC)** |
| Country | **Mosul, Iraq** |
| Total estimated number of days | **160 days** |

The project “Support to Medical Care and Research Centre (MRCC)” of the University of Mosul aims to improve the health conditions of the population of NinevehGovernorate, by providing a range of health care and strengthening medical training with a view to national excellence. The mail objective is to ensure the rehabilitation of the Centre’s building and equipment so as to enable rapid start-up of diagnostic and external consultation activities in Mosul while guaranteeing international standards are followed.

Focuses on the continuity of oncology healthcare services at MRCC's by integrating rehabilitation activity and ensuring the on time provision of essential medical equipment required for patient care and recovery. This includes the development of laboratory activities, radiography, cardiology, neurophysiology, endoscopy, urology, (~~and on)~~ radiotherapy and chemotherapy services.

MRCC requires medical equipment tailored to the specific needs and decided jointly based on current and future functional diagnostics of the various services. This includes the provision of Magnetic Resonance Imaging (MRI) as a non-invasive imaging technology that produces three dimensional detailed anatomical images, supporting clinical radiologists and radiation oncologists.

The use of MRI poses significant safety considerations for patients and staff and requires those working in MRI to have knowledge and understanding relating to the risks posed by static magnetic fields, time varying electromagnetic fields, body metal movement or metal projectiles and biological effects. Project will ensure setting standards, professional training, assessment and accreditation, and advocating access to quality care in both professions to create healthier communities.

MRI safety guidelines are to be established and applied to all clinical and research MRI systems operated at MRCC. Safety policies and procedures are evaluated on regular basis and updated for reference.

1. **Context and justification of the need**

Following a preliminary feasibility study conducted between May and September 2021 to assess and define the rehabilitation and development needs of the Medical Research and Care Center (MRCC) of the university of Mosul, to support the Ministry of Health (MoH) / Department of Health of Nineveh and the Ministry of Higher Education and Scientific Research (MoHESR) / University of Mosul (UOM) to prepare a detailed plan for the operationalization of the MRCC .

MRCC, a 150-bed research and therapeutic hospital located at the University of Mosul in Mosul-Ninawa Governorate, Iraq. MRCC is seeking MRI equipment services to replace a non-working MRI magnet and provide a new 1.5 Tesla MRI. This endeavour aims to support and enhance the capacity of medical imaging and support services for different medical specialties in MRCC.

1. **Objectives and desired results**
   1. **General objective**

The objective of those supplies is part of reopening and providing optimum Radiology services in the Medical Research and Care Centre MRCC. The requirements for medical equipment **1.5 T MRI (magnetic resonance imaging)** covered by this document will be a new, modern design with materials of the best quality.

* 1. **Specific objectives**

In one full package of service to:

* **Provision one new 1.5T MRI (Control and acquisition console, workstations and software), installation, commissioning (including regulatory checks), warranty, updates, maintenance, and training.**
* **Disassembly and removal of an existing non-working MRI device GE brand model Signa.**
* **Infrastructure and site readiness works, including MEP (mechanical, electrical plumbing) technical constraints and architectural finishes. Handling of wall modifications, electrical installations, and necessary all finishes of the service (including cooling / heating devices for all MR rooms of service, with no metallic part inside the MR room itself). Also, Medical gas outlet (O2, CA).**
* **Faraday Cage: old one to be removed and new one installed and RF leakage controlled (from 60 MHz up to 130 MHz (for 3T possible future upgrade).**
* **MRI chiller and UPS function and tests.**
* **Metal detector gate for the service main door**
* **Contrast injector**
* **Film printer**
* **Internet interface**
* **MR compatible Emergency trolly (with Oxygen cylinder) with Anaesthesia machine and non-magnetic (MR compatible) intensive care artificial ventilator as an option.**

**The proposal shall include the services below:**

The services include:

* De-installation of the current non-working MRI.
* Pre-installation preparations of the site and checks.
* Supply, delivery, and installation of the new 1.5T MRI, including workstation and software.
* Restoration of any damage caused during delivery and assembly.
* Provision and commissioning of a chiller unit of the new 1.5T MRI.
* Provision and commissioning of UPS units of the new 1.5T MRI.
* Completion of administrative procedures, on-site inspections, and necessary tests for regulatory compliance, commissioning and calibrations. This includes the provision of consumables required for these tests.
* Minmium two years Warranty coverage (labour, work and spare-parts replacement), including preventive and corrective maintenance. ,
* Financial offer for maintenance contract (validity 3 years) that will be addressed to MRCC direction for Three-years maintenance as an independent contract from Expertise France to be considered after the 2 years warranty.
* Clinical (MRCC medical and operational staff) and technical (MRCC technicians and engineering staff) training, including optimal use of sequences and patient throughput, security considerations, and technical first maintenance and quality control. The modalities must include any required travel and accommodation. Upon completion of training, engineers and technicians will be authorized to handle and commissioning the equipment within the limits specified by their authorization. They will also receive training materials.
* User documentation (Manuals and datasheets) and certification in English. If available, documentation in Arabic should also be provided.
* image1.pngOPTIONAL separate pricing for Emergency trolly (with Oxygen cylinder) with Anaesthesia machine and non-magnetic (MR compatible) intensive care artificial ventilator.
* OPTIONAL with separate pricing : spectroscopy sequences, specific neuro

1. Description of the assignment
   1. **Planned activities.**

* Disassembly and removal of existing non-working MRI device from GE model Signa.
* Implementation of new MRI

The implementation of the 1.5 Tesla MRI requires transformations/arrangements of the premises.

These will **be completely covered by the successful bidder**. The latter carries out an installation study of its equipment in order to verify its compatibility with the premises and existing technical infrastructures.

* Infrastructure works, including MEP and architectural finishes to have this radiology room available for patients’ services.
* Identify old device extraction points and new device entry points, in agreement with contracting agency and end users.

For all aspect biomed, Infra and MEP subjects:

* Feasibilities and assessment on site,
* Supply, delivery and installation,
* Maintenance and warranty
* All required tests from local authorities to handover the machine.

Assignment preparation

This contract is a public supply contract, aimed at the acquisition, delivery, installation (including necessary work), commissioning, warranty, maintenance, and training for a 1.5 Tesla MRI.

* Post-assignment follow-up: Follow up the implementation of the project according to the technical specifications
  1. **Anticipated deliverables**

|  |  |
| --- | --- |
| **Deliverables** | **End date** |
| Site visit report / assessments |  |
| Technical documentation and plan for selecting the best equipment per site assessment. |  |
| Methodology, layout, for new MRI installation |  |
| Methodology for dismantling and removing old equipment |  |
| Technical details, layout and methodology for infra and MEP works of the specific room |  |
| Submit the delivery plan for or MRI system including the (Shipping, delivery to the site, installation, commissioning, warranty, maintenance and training). | mentioning the delivery date |
| Service job report |  |
| Methodology for the taking-over of the equipment and the list of required tests to be done |  |
| Installation report |  |
| Taking-over documents for all biomed, infra and MEP subjects |  |
| Maintenance plan |  |
| Maintenance and warranty report at the end of the project |  |

**As part of the contract, each of the Bidders must:**

1. Define an activity schedule and the commissioning of the various equipment proposed, with deadlines for delivery, installation and training.
2. Specify for each piece of equipment:

* Environment conditions: evacuation, air-conditioning of the premises (temperature and hygrometry conditions, heat release of the equipment) and necessary extraction required per unit.
* Necessary power supply.
* Voltage (values, tolerance).
* Frequency (values, tolerance).
* Maximum power consumption.
* The equipment suitable for working in the climate conditions of Iraq in terms of temperature & humidity.
* Safety and fire equipment.
  1. **Coordination**

The service provider shall designate a single contact person for project implementation purposes.

A technical kick-off meeting shall be held 15 days max after the contract is duly signed. Close collaboration must take place with personnel from assignment preparation right up to completion. Furthermore, regular exchanges must take place with contracting agency on assignment progress and any difficulties that may be encountered.

1. **Duration and terms of performance**
   1. Implementation period: **160 days**
   2. Estimated start date: **January 2026**
   3. Estmated end date: **Third week of June 2026**
   4. Schedule/program: **to be provided by the bidder.**
2. **Required expertise and profile.**
3. **General professional experience**

* The eligibility for participation in this tender is limited to companies that possess both the "Manufacturer's Authorization" and certification as an official distributor. Additionally, it is desirable to be registered in the Ministry of Health (M.O.H) of either the Federal Government of Iraq or Kurdistan Region Authority.
* To be considered for this tender, companies must have technical teams capable of either traveling to or being based in Mosul. These teams will be responsible for the installation and training of medical staff in the MRCC.
* By submitting a proposal, the bidder agrees to fully and unconditionally accept the special and general conditions that govern this request for proposals and the proposed contract. The bidder acknowledges that these conditions, outlined in the contract, serve as the sole basis for this procurement process. Any other sales conditions are hereby waived by the bidder. Bidders are required to carefully review and adhere to all instructions, forms, contract provisions, and specifications provided in the tender dossier.
* It is strongly advised to thoroughly read and comprehend the tender rules document and its annexes. Failure to adhere to the procedures outlined therein may result in disqualification from the evaluation process

1. **Technical quality (70%)**

**1. Company’s capacity in Iraq (10 scores)**

* Iraq office = **2 scores**
* Staff number, composition and academic level qualification (at least 2 biomedical and 1 MEP engineers) = **2 scores**
* Similar Experience (Contracts) in supplying and installation of the MRI equipment (5 years MR experience suggested) = **4 scores**
* Number and location of similar installed MR systems in Iraq **2 scores**

**2. Technical specifications of proposed devices (40 scores)**

* **1.5T** MRI system (MANDATORY) = **20 scores**
* Chiller for cooling and Uninterruptible power supply (UPS) = **12 scores**
* Workstation specs, processing software, image link for the acquisition console and 2 workstations, DICOM system and version, and film printer = **8 scores**

**3. Site preparation, installation, commissioning and warranty (12 scores)**

* Proposition of an optimized layout of the MR service (including MR room, undress cubicle, control and 2 workstation interpretation room, technical room with gradients, RF, UPS added and chiller system) = **1 score**
* Disassembly and remove existing GE signa MR, Faraday Cage, MEP requirements, MRI chiller, UPS function and tests = **3 scores**
* Commissioning in real conditions of use and Phantoms for image quality tests. Including full documentation l certifications (English and Arabic) = **2 scores**
* Training of clinical staff and MR operating technicians and Local training of technicians and engineers of the hospital = **3 scores**
* Minimum Two years Warranty = **3 scores**

4. **Medium- and long-term management of the MRI: after-sales services (8 scores)**

* Three years maintenance conditions (Desirable)
* Continuous education and development of skills for clinical staff (prescription and radiologist) and MRI operating technicians = **4 scores**
* Upgrade after 3 years (Hardware, Software and sequences) = **4 scores**

1. **Price (Financial Proposal): 30%**

* Full and complete financial breakdown = **30 scores**

1. **General articles and requirements**

## ARTICLE 1: General requirements

* The bids must include all the equipment necessary for the correct operation of the device.
* All materials will be according to the international standards.
* The implementation will therefore be done at the optimum level to ensure the correct implementation of the installations, and the proper functioning from the start-up.

## ARTICLE 2: Authorization

The bidder must state whether it is a manufacturer, supplier, marketing company, or commercial agent in the authorization. If the company is a supplier, the following must be clarified:

1. The names and specialties of the manufacturing companies must have authorizations certified by the manufacturing companies.
2. If the marketing company is the supplier, a letter of authorization certified by the manufacturing companies is required.
3. Manufacturers must state and classify the company's specialties (information specific to a specific system).
4. A sole and exclusive representative to deal with for all its products must be stated. The company must also state the names of its factories and branches.
5. The authorization letter must be certified.
6. The authorization letter must be addressed to contracting agency.

## ARTICLE 3: Training (Application and Service training):

The offer must include full support: travel, accommodation, training costs, meals (lunch, accommodation) for the following personnel:

* End user (user training): The medical and paramedical team (day and night team).
* The Biomedical service (technical training): The biomedical engineer and/or the biomedical maintenance technicians (at least 3 persons)
* This will be sanctioned by a personal certificate, issued to each participant, stipulating that the level of skill required to ensure maintenance has been acquired by the technician.

During this training, all the necessary information must be provided:

* Complementary technical documentation.
* Set of computer access codes to the maintenance software, if applicable.
* List of the main spare parts to be kept in stock for MRCC
* The overall training offer must indicate the training schedule (periods, times) as well as the place and the planned training methods.

The Bidder also undertakes to train again, at his own expense, the user, medical and biomedical teams, in the event of changes to the devices supplied (hardware or software changes). The training may be postponed of several months after the installation and commissioning phases, if the biomedical and technical teams of the MRCC are not designated yet.

## ARTICLE 4: Organization of delivery, installation, and commissioning reception

The delivery of equipment to the service premises, assembly, installation and commissioning are the responsibility of the Bidders, they must explicitly show the conditions of ground load, electrical power supply, average power, peak power absorbed, the tolerable temperature in each room (in particular the maximum tolerable variation gradient).

The mandatory tests and inspections for the commissioning of the equipment and the verification of their performance will be carried out before receipt according to the manufacturer's recommendations and the regulations in force. The cost of these operations is the responsibility of the Bidder.

CONTRACTING AGENCY shall bear no responsibility over losses or damages of the procured products incurred during the performance period and before acceptance of said products. The bidder bears the responsibility to verify and certify that the goods they supply are in keeping with the conditions applicable to them.

Before each delivery, the bidder must submit a copy of the delivery note and all the shipping documents detailed, at least 15 days prior the arrival of the device to the site in order to get the formal agreement from end user to deliver the goods. For every consignment, the bidder shall always send a delivery note. Delivery slips shall necessarily bear the Contract Reference, batch numbers, serial numbers if any, the full designation and quantities of the delivery.

Added to the delivery note, the selected bidder will also have to provide with:

* a delivery notes and / or Packing List
* a commercial invoice
* a Certificate of Origin from the manufacturer.
* a Certificate of Conformity or Certificates of Analysis (if applicable)
* other documents.

The Bidder commits to inform Contracting agency any constraint or specific regulation linked to the goods or service supply or to the country of importation.

The Bidder will inform Contracting agency CONTRACTING AGENCY about all quality certifications, labels (NF, ISO, CE…) and internal quality process that may apply to its goods or services and will supply all official documents upon Contracting agency request.

###### Non-conformity of delivery

Should the quality or the condition of the products not satisfy CONTRACTING AGENCY requirements at the moment of the preliminary inspection or delivery inspection, CONTRACTING AGENCY reserves the right to demand:

* The delivery of products which conforms to the order. They will need to be replaced by the Bidder at his/her own expenses. The replacement will be executed as soon as possible, at latest within fifteen (15) calendar days from the discovery of the non-compliance (from the issuing of a certificate of non-conformity). The replaced products will again be subject to the rules laid down in this contract, including the twelve (24) month guarantee (IF APPLICABLE)
* Or the immediate reimbursement of the payment
* Or the cancellation of the order and of the corresponding price.

## ARTICLE 5: Upgrade

The homogeneous evolution of all the equipment is planned with this contract. This evolution concerns both the hardware part, software and accessories.

For each of the products and software offered, the Bidder will list the major hardware and/or software developments already implemented since the date of first commissioning. It will imperatively be indicated the version of the software provided. The Bidder will specify which hardware and/or software developments are planned, detailing:

* the nature of the expected change,
* the methods of implementation,
* the planned publication date or the planned periodicity,
* the approximate additional implementation cost.

The Bidder will also indicate which characteristics (technology, architecture, etc.) facilitate the subsequent development of the products offered. The Bidder will specify the terms of support for upgrades, hardware and software developments and undertake to do so contractually.

The Bidder will commit in particular to the tariffs and/or the minimum discount rates which will be practiced during the operation of the equipment. In the event of technological development of its products, during the period of execution of the contract, the selected bidder may propose to substitute a new product for the old one. This substitution can only be effective after written acceptance by the manager of the establishment and without change in the unit price.

## ARTICLE 6: Medical equipment fitting and Room layouts (loaded drawings)

The Bidder must provide the medical equipment that will be fitted according to room layout. In this tender, the specific room details will be provided later to recognize the equipment locations.

1. **Assignment reports**

A report following the model provided must be forwarded by e-mail on conclusion of the assignment: it must correspond with the deliverable summary analytical report.

1. **Monitoring-evaluation**

**Performance indicators**

|  |  |  |  |
| --- | --- | --- | --- |
| Deliverables | Immediate effects | Intermediate effects | Verification sources |
|  |  | officeArt object |  |

1. **Personal Protective Equipment (PPE) for Construction**

Required personnel protection equipment (PPE) must be always worn when on construction or renovation sites at Mosul University. At a minimum, each employee is required to wear a hard hat and safety glasses. High visibility safety vests with reflective striping are required when employees are exposed to vehicular traffic. In the absences of vehicular traffic, high visibility shirts should be always worn. All workers must wear shirts with sleeves, long work pants, and sturdy work shoes or boots when working on a construction or renovation site. Sleeveless or tank top shirts, short pants, sweatpants, sneakers, sandals, and high-heeled or open-toed shoes are not permitted. Depending on the circumstances and potential hazards present, additional PPE may be required:

Specific protective clothing such as welding leathers when welding or FR clothing when working with live electric.

1. **Technical Data Instructions**

For the submission of bids, each candidate will propose a plan layout of the proposed equipment. The layout will make it possible to check the ergonomics of the rooms by showing the effects of handling of the MRI installation requirements. **The implantation and installation layout will be required.**

### **I.1.1 Objective and Technical characteristics of 1,5 T Magnetic resonance imaging (MRI)**

Provision of 1.5T MRI (magnetic resonance imaging) to meet a need requiring cutting-edge technology (simultaneous multi-slice acquisition, iterative reconstruction, AI/deep learning, etc.). This acquisition will replace the GE Signa MRI, currently in place. The equipment covered by this contract will be new, of modern design with materials of the best quality. Used or reconditioned equipment is inappropriate and unacceptable.

## **I.1.2 General technical description**

|  |  |  |  |
| --- | --- | --- | --- |
| **CLINICAL MR HARDWARE** | **High performance, whole body, general application MR system** | |  |
| ***MAGNET*** | | |  |
| Strength | | 1.5T |  |
| Guaranteed homogeneity, ppm, within 30cm DSV | |  |  |
| Guaranteed homogeneity, ppm, within 45cm or 40cm DSV | |  |  |
| Dimension of maximum useful FOV and homogeneity, (x,y,z), cm | |  |  |
| ***GANTRY*** | | |  |
| Bore diameter at isocentre, cm | | ≥ 70 cm OK |  |
| Total bore length with covers, cm | |  |  |
| ***TABLE*** | | |  |
| Maximum patient weight (including vertical and horizontal movement), kg | | ≥ 200 Kg |  |
| Elevating | | YES |  |
| Minimum table height from floor, cm | | ≤ 70 cm |  |
| ***ACOUSTIC NOISE*** | | |  |
| Maximum sound pressure level (SPL) at peak gradient  amplitude and slew rate, dB (A) | | Low preferably |  |
| Acrostic noise reduction | | High preferably |  |
| ***GRADIENT SYSTEM*** | |  |  |
| Max strengths (x, y, z) | |  |  |
| Max sew rate | |  |  |
| Gradient ECHO pulse sequences, minimum TR in 2D and 3D, msec | |  |  |
| Minimum slice thickness 2D mm | |  |  |
| Minimum slice thickness 3D mm | |  |  |
| ***RF TRANSMIT AND RECEIVE*** | |  |  |
| Power output, kW | | ≥ 15 kW |  |
| No. of independent receiver channels that can be used simultaneously in one single scan at one FOV each generating an independent partial image | | ≥ 32 or independent |  |
| Parallel imaging | | YES |  |
| ***COILS*** | | |  |
| Dedicated surfaces or adaptable multi-element matrix coils | | YES |  |
| Coils selection | | head and neck, spine, torse/body, breast, knee, shoulder, flexible (indicate the number of channels for each coil) |  |
| Other standard coils | |  |  |
| ***SCANNING APPLICATION TECHNIQUE*** | | |  |
| Standard pulse sequences | | All clarified in detail |  |
| ONCOLOGY per organ and bone metastasis analysis | | state of the art standards of best sequences per organ |  |
| WHOLE BODY | | 3D T1 FSE or TSE, 3D GRE, 3D T1 Dixon GRE, 3D DWI, 3D DWIBS, 3D STIR, … |  |
| NEURO (brain and spine) | | T1, T2, FLAIR, DWI, SWI, Injected T1, TOF (all 2D and 3D) |  |
| CARDIO | | morphology, perfusion, cine, late enhancement |  |
| OSTEOARTICULAR | | state of the art standards of best sequences for muscles, knee, hips, shoulder, wrist, …. ultra short TE appreciated |  |
| ANGIO | | TOF, PC, Injected enhanced |  |
| Other propositions /Options | |  |  |
|  | |  |  |
| ***Fast full exam protocols, series of sequences, optimization of throughput of patients*** | |  |  |
| ***Heart and breath gating synchronisation*** | |  |  |
| coils | | **At least : head and neck, spine, torse/body, breast, knee, shoulder, flexible (indicate the number of channels for each coil)** |  |
|  | | Other propositions |  |
| ***Channels*** | | > 32 |  |
| ***CONTROL CONSOLE*** | | |  |
| **Control console** | |  |  |
| Specifications | |  |  |
| **Reconstruction, postprocessing and interpretation workstation** | |  |  |
| Specifications | |  |  |
| List of treatment and processing software included in the package | |  |  |
| **Net** | |  |  |
| ~~I~~mage link for the acquisition console and 2 workstations | |  |  |
| DICOM system and version | |  |  |
| Distance MR performance and maintenance diagnostic | |  |  |
|  | |  |  |
| **Film printer and files digital storage** | |  |  |
| Specifications | |  |  |
| **Metal detector for MR entrance door** | | patients and staff safety control |  |
| MRI compliant stretcher | |  |  |
| MR compliant wheelchair and truly for transporting a patient into the examination room | |  |  |
| ***SITE PREPARATION*** | | |  |
| Initial visit, diagnostic and insight of the site  Proposition of an optimized layout of the MR service (including MR room, undress cubicle, control and 2 workstation interpretation room, technical room with gradients, RF,UPS added… and chiller system)  Installation  Disassembly and remove existing GE signa MR  Faraday Cage : old one to be removed and new one installed and RF leakage controlled (from 60 MHz up to 130 Mhz (for 3T possible future upgrade))  Handling of wall modifications, electrical installations, and necessary all finishes of the service (including cooling / heating devices for all MR rooms of service, with no metallic part inside the MR room itself  UPS function and tests  Fluids (O2, CA)  Inspection of close metallic mass present or in motion (car parking, for inst.) and correction if needed  Tuning of nominal RF and field and accurate shimming and calibration  Upgrade air conditioning central system for MR service | |  |  |
| ***Power supply*** | | | |
| Line voltage | | Medical approved 380 VAC, 50-60Hz | |
| Smart UPS for all system including chiller | | 160 KVA continues power suppling compatible with MRI | |
| ***COOLING SYSTEM*** | |  | |
| MRI chiller function and tests | | | |
| ***CONTRAST INJECTOR SYSTEM*** | |  | |
| Head injector (starting kit of disposable syringe sets for ≥ 100 patients) | | | |
| ***DRY RADIOGRAPHIC FILM PRINTER*** | | | |
| Standard specifications should be specified (starting kit ≥ 1000 film is supplier responsibility) | | | |
| ***TRAINING*** | | | |
| **Local training of clinical staff and MR operating technicians**: use of **sequences** and **patient flow optimisation** (installation, preparation of series of sequences, …)  **Local training of clinical staff and MR operating technicians**: **security conditions** of use  **Local training of technicians and engineers** of the hospital | | Local training during commissioning | |
|  | |  | |
|  | |  | |
| ***Warranty and maintenance*** | | | |
| Minimum 2-years Duration of the warranty  Conditions of warranty : intervention maximal time, penalties,  starting day  Desirable: 3-years commitment on the annual price of maintenance all included : spare parts, refill of He, work, travel, restart  Intervention delay  Distance performance and failure monitoring  Maintenance of air conditioning central system for MR service | |  | |
| ***ACCESSORIES*** | | | |
| 2.2 Instrumentation (OPTIONAL separate pricing)  Reconstruction, postprocessing and interpretation workstation  MR compatible Emergency trolly (with Oxygen cylinder)  laryngoscope  Ambu-bag (Adult and paediatric)  Biphasic defibrillator (with AED mode)  Portable suction unit  Patient transfer bed  oxygen and AC flowmeter  Anaesthesia machine  Nonmagnetic (MR compatible) intensive care artificial ventilator | |  | |

### **I.1.6 Completion of the premises:**

Regarding Infra, MEP and architectural works and Radio attenuation will be in accordance with the specifications of the proposed equipment:

* shielding of walls, ceiling and floor,
* adaptation of the cage to existing networks (medical fluids, electricity, chilled water network),
* the removable panels allowing the delivery of the magnet,
* the observation bay (minimum dimensions: 1m50 wide by 1m high),
* the armoured sliding door (leaded, RF standards, etc.), providing access to the MRI room,
* the technical penetrations through the cage and the necessary filters (radio frequencies for electrical penetrations, wave guide to the control room, passage of ventilation ducts),
* the Quench line if the existing one could not be used,
* A plan and section view of the installation will be sent with the offer. The bidder Will include the Iso Magnetic liens.

Lighting: an LED type light strip, with variable intensity, will be placed around the perimeter of the room, as well as “backlit pattern” type lighting of approximately 180cm x 120cm above the table, also variable intensity.

The shielded door: it will be of the sliding type (leaded, RF standards, etc.), motorized, of sufficient width for the passage of non-magnetic stretchers.

Shielded glass: it will be in the same place as currently and of identical dimensions.

Internal signage: pictograms to place.

The successful bidder is required to carry out a check of the effectiveness of the attenuation of the FARADAY cage, before installing the equipment to allow any possible modifications. Upon commissioning, it will carry out a radiofrequency measurement test as well as an acoustic study in the premises adjacent to the MRI room. Any necessary adaptations following the completion of these studies are the responsibility of the successful bidder.

The documents attesting to the completion of these studies and their results will be an integral part of the file submitted to Expertise France.

### **I.1.7 Objective Standards and Regulations**

**Standards and regulations**

Medical devices, their components, and the services provided must comply with all applicable standards and regulations mentioned in this section on the date of contract signature, as well as those applicable at the time of final acceptance of equipment and services:

* ISO 13485:2003 Medical devices -- Quality management systems -- Requirements for regulatory purposes (Australia, Canada and EU)
* ISO/TS 10974
* IEC 60601-2-33

**CE marking**

All equipment, peripherals, accessories and consumables will comply with the regulations relating to Directive 93/42/EEC.

The installation must be in accordance with standards and all the regulations in force (hygiene, machine safety, electrical safety, etc.).

Each medical device and pressure device will be accompanied by CE declarations and CE type-examination certificates with the limit of validity and recurrence of controls.

**FDA clearance (Preferred) and ISO certificates**

The required certificates are to be provided.

**Out-of-warranty maintenance:**

The Bidder will specify in his offer the elements relating to the support of out-of-warranty maintenance with an offer including:

* Training of the technical team in curative and preventive maintenance of equipment.

The equipment and conditions of realization necessary for a support by the maintenance service of MRCC.

* labor, parts (excluding consumables) for support by the bidder's after-sales service, for maintenance from level 2.

The services are carried out in partnership with the technical staff of the Biomedical department of the **MRCC medical centers** according to their availability. However, MRCC reserves the right to involve the contracting party if necessary. The Bidders will indicate in his offer the amounts relating to this type of intervention.

**Annexes:**

1. **Annex 1 MRI 1.5 T scoring.**

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## **2.** Annex 2: Manufacturer’s Authorization Form

The authorization certificate must be attached to the Bidder's proposal includes the following format:

**MANUFACTURER’S AUTHORIZATION FORM**

(to be submitted by authorized manufacturers/importers in a **letterhead**)

No. Dated:

To: Expertise France

MRCC / Medical equipment tender n°1 committee

Dear Sir / Madam,

Equipment/Item Name:

1. We ……………………………….………………… (Name of the OEM) are the original manufacturers of the above equipment having a registered office at …………………………………………………………………………………. (Full address with telephone number/fax number & email ID and website), having factories at

\_\_\_\_\_\_\_\_\_\_\_\_\_\_ and \_\_\_\_\_\_\_\_\_\_\_\_\_\_, do hereby authorize M/s.\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_............... (Name and address of supplier) as submit bids, and subsequently negotiate, sign the contract and to supply, install & commission the above items with you against the above bid no……………………………….

2. We also hereby undertake to provide full guarantee/warranty /CMC/AMC as agreed by the supplier in the event the Bidder is changed as the dealers, or the supplier fails to provide satisfactory after sales and service during such period of Comprehensive warranty/CMC/AMC and to supply all the spares/reagents / consumables for 5 years.

3. We also hereby declare that we have the capacity to manufacture and supply, install, and commission the quantity of the equipment’s bided within the stipulated time.

(Name)

for and on behalf of M/s.\_\_\_\_\_\_\_\_\_\_\_\_

Date: (Name of manufacturers)

Place:

Seal