**P R O F O R M A**

**Request for Market Information (“RFI”) for
Supply of Mobile X-ray Machine**

**for the Chinese Medicine Hospital of Hong Kong (“CMHHK”)**

**(CMHPO Ref. : HHB/H/24/17/3/3/2 )**

To : Project Director (CMHPO)

 (Attn. Ms Ruth LEUNG)

[by fax: 2127 4795 or email: rhwleung@healthbureau.gov.hk]

Your ref: HHB/H/24/17/3/3/2

In response to the RFI of the CMHHK, my/our company, with contact details provided in Part 1 below, would like to provide the information and relevant supporting documents in Parts 2 to 9 of this Proforma.

**Part 1 – Supplier’s Contact Details**

From:

(Name of the Supplier): \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

(please fill in)

Name and Post of Contact person: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

(please fill in)

Email:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Telephone no.:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

(please fill in) (please fill in)

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*This document does not constitute any offer or invitation / solicitation of any offer in connection with the exercise described herein. Neither this document nor any activities in connection therewith shall create any legal obligations or liabilities in any way on the part of the Health Bureau (HHB) or the Government of Hong Kong Special Administrative Region. Neither this document nor anything contained herein shall form the basis of any contract or commitment whatsoever. In responding to the RFI, a respondent shall be deemed to have agreed to all the terms of this Request for Market Information.*

RFI (CE)

**Purpose and Background Information of the RFI**

1. Purpose

Chinese Medicine Hospital Project Office (“**CMHPO**”) of the Health Bureau (“**HHB**”) of the Government intends to invite a tender for the supply and installation of mobile x-ray machine (hereinafter refers as the “**System**”) for the Chinese Medicine Hospital of Hong Kong (“**opCMHHK**”) located at Pak Shing Kok in Tseung Kwan O. The CMHPO therefore wishes to collect market information on Mobile X-ray Machine.

1. Background of the CMH Project

The Chief Executive announced in the 2014 Policy Address that the Government had decided to reserve a site in Tseung Kwan O for setting up a CMH. The 2017 Policy Address stated that the Government decided to finance the construction of the CMH and identify by way of tender a suitable non-profit-making organisation (“NPMO”) to operate the CMH. CMH will be owned by the Government and the selected NPMO will operate the CMH. The CMH would be positioned as a flagship Chinese Medicine (“CM”) institution leading the development of CM services and Chinese medicines in Hong Kong. It will be a change driver, promoting service development, education and training, innovation and research, and facilitating collaboration with both local and international parties.

The CMH with provision of 400 beds will provide a comprehensive range of CM services. Service types include pure CM services, services with CM playing the predominant role in collaboration with Western Medicine (“WM”) and Integrated Chinese-Western Medicine (“ICWM”) services. The scope of service to be provided in the CMH covers inpatient, day-patient, outpatient and community outreach services.

To take forward the planning and development of the project on CMH, a designated office i.e. CMHPO, was established under the Health Bureau (the former Food and Health Bureau) on 2 May 2018. Hong Kong Baptist University (HKBU) was selected as the Contractor for the CMH operation. HKBU, as the Contractor, has incorporated a company limited by guarantee, namely HKBU Chinese Medicine Hospital Company Limited as the Operator to manage, operate and maintain the CMH. The CMH project has proceeded to the commissioning stage in 2021. It is targeted to commence hospital services by phases from 2025.

More information on the services provision and design of the CMH can be found in the following link:

<https://www.healthbureau.gov.hk/en/press_and_publications/otherinfo/200900_cmhp/index.html>

**Note to Suppliers**

1. If your company have more than one **mobile x-ray machine** that may meet the requirements of the System stated in this Proforma, **please complete and return, together with relevant supporting documents, one set of Proforma for each different mobile x-ray machine**.

**Part 2 – General Information of the System**

|  |  |
| --- | --- |
| 1. Place of origin
 |  |
| 1. Name of manufacturer
 |  |
| 1. Address of the manufacturer’s factory or plant (“Manufacturing Plant”)
 |  |
| 1. Product name of the System
 |  |
| 1. Model number/ name/ version number of the System
 |  |
| 1. Authorised agent or distributor of the manufacturer in Hong Kong
 |  |
| 1. Packing (if applicable)
 |  |
| 1. Delivery method and route (where the place of origin is outside Hong Kong)
 |  |
| 1. Warranty period of the System

(*Please refer to section G in Part 3 for details of the warranty service requirements*) | \_\_\_\_\_\_\_\_\_\_\_\_ months from Acceptance of the System(*Should not be less than 12 months*) |
| 1. Expected serviceable life (*Please specify any components of the System that cannot meet the serviceable life*)
 | The System shall have a serviceable life of \_\_\_\_\_\_\_ years from its date of acceptance except the following components: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_(*Please also provide the expected life of these excluded components*) |
| 1. Total weight of the proposed System
 | \_\_\_\_\_\_\_\_\_\_\_\_kg |

**Part 3 – Indicative Technical Requirements**

*Notes to Suppliers for Completion of Part 3*

1. *Unless specified otherwise, the “****System****” in this Part 3* ***refers to section A1.1 below****.*
2. *The indicative technical requirements are for the purpose of collecting market information only. They are subject to changes and do not represent the final technical requirements of the intended tender.*
3. *Please indicate, as a point by point compliance statement, whether your proposed System “****Comply****” or “****Not Comply****” with an indicative technical requirement stated in Column II by ticking (🗸) in the appropriate box under* ***Column III*** *and* ***Column IV*** *respectively.*
4. ***Where applicable****, please quote the value of your proposed System in either Column III (if “****Comply****”) or Column IV (if “****Not Comply****”) respectively against corresponding indicative technical requirement (use additional sheet(s) if space is insufficient*
5. *Please provide supporting documents (such as catalogues, user manual and/or operation manual, DICOM conformance statement, etc.) to illustrate the features of your proposed mobile x-ray machine against the corresponding indicative technical requirements.*

| **Column****I** | **Column** **II** | **Column** **III** | **Column****IV** |
| --- | --- | --- | --- |
| **Section** | **Technical Specification** | **Tick (🗸) the Appropriate Box***(For aspects “Not Comply”, please also provide alternative proposal, if any)* |
| **Comply** | **Not Comply** |
| **A** | **Technical Requirements** |
|  | **Overall Requirements** |
|  | Two (2) sets of mobile x-ray machines capable of providing mobile digital radiography for diagnostic purpose (“System”) shall be provided. |  |  |
| 1.2 | Each System shall have the following components: |  |  |
| 1. One (1) set of x-ray generator as detailed in Section A2.1 below;
 |  |  |
| 1. One (1) set of x-ray tube unit as detailed in Section A2.2 below;
 |  |  |
| 1. One (1) set of x-ray collimator or beam limiting device as detailed in Section A2.3 below;
 |  |  |
| 1. One (1) set of integrated tube support assembly and carriage mechanics as detailed in Section A2.4 below;
 |  |  |
| 1. One (1) set of integrated acquisition and image processing console as detailed in Section A2.5 below; and
 |  |  |
|  | 1. One (1) set of large wireless detector as detailed in A2.6.
 |  |  |
|  | One (1) lot of accessories as detailed in Section A3 below (“Accessories”) shall be provided. |  |  |
|  | The System shall have a serviceable life of not less than eight (8) years from its Final Acceptance Date (“**Serviceable Life**”). |  |  |
|  | The total weight of each set of the System shall not exceed 500 kg. |  |  |
|  | The dimension of the System shall not be larger than 1,300 mm in length and 600 mm in width. |  |  |
|  | Quality Management System of the ManufacturerThe Manufacturer of the System shall have valid ISO 13485 certification (or equivalent) relevant to the System. |  |  |
|  | Marketing AuthorizationThe System shall have valid approval, clearance, or exemption of the Food and Drug Administration (FDA) of the United States, or valid relevant CE marking signifying its compliance with applicable legislation, technical and performance requirements of the European Union, or equivalent international standards.  |  |  |
|  | Power Supply RequirementThe System shall be designed for optimal operation with local power supply of 220 V ± 6%, 50Hz ± 2%, 13A or below, single-phase AC supply. |  |  |
|  | Equipment Safety Requirements The System and its accessories shall comply with the **latest version** of the following standards or equivalent: |  |  |
|  | The System shall comply with the safety requirement of IEC 60601-1-1 Medical Electrical Equipment - Part 1: General requirements for basic safety and essential performance, or equivalent. |  |  |
|  | The System shall comply with the safety requirement of IEC 60601-1-2 Electromagnetic Compatibility (EMC), or equivalent. |  |  |
|  | The System shall comply with the safety requirement of IEC 60601-1-3: Medical Electrical Equipment - Part 1-3: General requirements for basic safety and essential performance - Collateral Standard: Radiation protection in diagnostic X-ray equipment, or equivalent. |  |  |
|  | The System shall comply with the safety requirement of IEC 60601-2-28: Medical Electrical Equipment - Part 2-28: Particular requirements for the basic safety and essential performance of X-ray tube assemblies for medical diagnosis, or equivalent. |  |  |
|  | The radiation safety of the System shall comply with the latest requirements of ICRP and the statutory requirements of the Hong Kong Radiation Ordinance. |  |  |
|  | The potential supplier shall be responsible for the provision of the implementation services for the System as stipulated in Section B below. |  |  |
|  | The potential supplier shall be responsible for the provision of the Training as stipulated in Section Cbelow. |  |  |
|  | The potential supplier shall be responsible for the supply of the Documentation for the System as stipulated in Section D below. |  |  |
|  | The potential supplier shall be responsible for the performance of acceptance tests as stipulated in Section E below.  |  |  |
|  | **Performance requirements** |
|  | X-ray GeneratorThe x-ray generator of the System shall comply with the following features and requirements: |  |  |
|  | High frequency or constant DC output. |  |  |
|  | Microprocessor controlled. |  |  |
|  | Output power: 30 kW or higher. |  |  |
|  | kVp range: from 40 to 125 kVp or higher. |  |  |
|  | Maximum tube current: not less than 300 mA. |  |  |
|  | Exposure time range: from 4 ms or shorter to 2000 ms or wider range. |  |  |
|  | mAs range: 1 mAs or lower to 200 mAs or higher |  |  |
|  | There shall be automatic line voltage compensation. |  |  |
|  | Repeated exposures shall be made within 1 minute unless the system has been switched off. |  |  |
|  | X-ray Tube UnitThe x-ray tube unit of the System shall comply with the following features and requirements: |  |  |
|  | Dual focus design. The smallest focal spot shall not be larger than 0.8 mm.  |  |  |
|  | Anode heat storage capacity shall not be less than 120,000 HU. |  |  |
|  | Tube assembly heat storage capacity shall not be less than 600,000 HU. |  |  |
|  | Safety circuitry shall be incorporated to prevent overheating with indication on control console. |  |  |
|  | The radiation leakage of the tube housing shall comply with the latest requirement of ICRP and the statutory requirements of the Radiation Ordinance (Chapter 303B of the Laws of Hong Kong). |  |  |
|  | X-ray Collimator or Beam Limiting DeviceThe x-ray collimator or beam limiting device of the System shall comply with the following features and requirements: |  |  |
|  | Manually adjustable multi-diaphragms or shutters with an alignment light beam. |  |  |
|  | The light beam projected from the collimator shall be tallying with the X-ray field. |  |  |
|  | The intensity of the light beam at 100 cm SID shall not be less than 160 lux. |  |  |
|  | Automatic light beam power-off with timer. |  |  |
|  | The collimator shall be rotatable with at least ± 45° around the central X-ray beam axis. |  |  |
|  | Built-in measuring tape or electronic device for measuring FOD and SID. |  |  |
|  | Total filtration of the X-ray tube and collimator shall be not less than 2.5mm aluminium equivalent at 70 kVp or higher. |  |  |
|  | DAP measuring device shall either be built-in or incorporated for measuring the incident air kerma. |  |  |
|  | Integrated tube support carriage |  |  |
|  | The integrated tube support carriage of the System shall comply with the following features and requirements: |  |  |
|  | The integrated tube support carriage shall be fully counter-balanced.  |  |  |
|  | The integrated tube support carriage shall be mobile. All movements shall be stable.  |  |  |
|  | The design of the integrated tube support carriage shall be of articulated swivel-arm or column-arm. |  |  |
|  | The integrated tube support carriage shall allow tilting and safely fixing to cater for radiography of different heights and at different projection angles. |  |  |
|  | The integrated tube support carriage shall have a safety mechanism to prevent the x-ray tube of the System from falling in case of failure of lock, spring, cable etc.  |  |  |
|  | The integrated tube support carriage shall be motor-driven with forward and reverse drive. |  |  |
|  | The integrated tube support carriage shall be equipped with inch mover or equivalent feature which allows the System to be moved forward or backward for fine adjustment of position. Execution of such feature shall be done by pressing a button on collimator assembly or on tube arm.  |  |  |
|  | The integrated tube support carriage shall be equipped with wheel brakes.  |  |  |
|  | The integrated tube support carriage shall be equipped with a built-in locking system.  |  |  |
|  | The integrated tube support carriage shall be equipped with safety sensors or equivalent anti-collision feature, which stops the motion of the System to avoid collision. |  |  |
|  | The integrated tube support carriage shall have a storage compartment for detectors of the System.  |  |  |
|  | The integrated tube support carriage shall have a storage compartment for items such as gloves and lead markers.  |  |  |
|  | All cables, except the exposure and power cords, shall be hidden within the integrated tube support carriage for hygiene and durability purpose. |  |  |
|  | Integrated Acquisition and Image Processing ConsoleThe integrated acquisition and image processing console (“console”) of the System shall comply with the following features and requirements: |  |  |
|  | The console shall have an exposure control including but not limited to the following features:1. digital display of kV and mAs setting;
2. audible and visual indicator for x-ray exposure;
3. light beam control at collimator head and console;
4. tube overload indication and/or protection;
5. digital display of error codes with self-diagnostic functions;
6. there shall not be less than 20 steps between the lowest and highest mAs and kV setting; and
7. buzzer indication shall be provided during x-ray exposure and hall be accurately synchronized.
 |  |  |
|  | The console shall have the provision of **one (1) set of bar code reader** to achieve the following functions:1. recognize barcode labels (1D or 2D including QR) on image request form and over patient’s wrist band for ID verification; and
2. retrieve the corresponding patient worklist automatically.
 |  |  |
|  | The console shall be equipped a 15-inch (diagonal) or larger touch-screen colour LCD monitor shall be provided with image resolution of not less than 768 x 1,024 pixels. |  |  |
|  | The console shall be equipped with one (1) full set of operation and application software including but not limited to the following features:1. patient data management;
2. procedure mapping;
3. image windowing and levelling;
4. edge filtering;
5. noise filtering;
6. pan and zoom;
7. image flip and rotation;
8. image shutter and trimming;
9. advanced image processing software;
10. grid pattern removal software or equivalent mechanism;
11. free text annotation and at least 45 different image markers including L, R, ERECT, etc. The marker shall be user definable;
12. image reject reason analysis; and
13. preset image processing protocols for different body parts.
 |  |  |
|  | The console shall be equipped with one (1) full set of system administrative software including but not limited to the following features:1. create/modify output printer configuration;
2. create/modify radiographer comment;
3. manage image output queue;
4. re-send image output; and
5. manage local database: view or delete patient image file.
 |  |  |
|  | For security purpose, the console shall support log-in/log-off function. |  |  |
|  | The console shall be able to perform without limitation the following procedures and functions:1. supports real time DICOM worklist data directly retrieved from RIS of CMHHK. It shall be able to retrieve all patient and examination data including but not limitied to name, birth date, ID number, sex and accession number. etc. directly from the RIS. The successful tenderer shall be responsible for the cost of the broker licenses;
2. allows retrospective amendments of patient demographic and examination data;
3. supporst selection of examination menu, projection and position for automatic image processing;
4. adjusts all processing parameters in the examination menu according to the users’ preference;
5. Allows inappropriately selected anatomical region and/or examination menu be re-adjusted during or after the examination procedure; and
6. supports manual input of patient demographic data when the DICOM worklist is disabled or could not be retrieved from the network.
 |  |  |
|  | The System shall be DICOM 3.0 compatible, without limitation, in the following functions of printing, query and retrieve, storage and modality worklist with conformance statement:1. DICOM modality worklist SCU;
2. DICOM query / retrieve SCU;
3. DICOM print SCU;
4. DICOM storage commitment SCU; and
5. DICOM storage SCU and provider (DR class).
 |  |  |
|  | The System shall have image storage capacity of not less than 1500 images in native resolution. |  |  |
|  | The System shall contain one (1) set of wireless remote control for making exposure. |  |  |
|  | Large Wireless DetectorThe wireless detector of the System shall comply with the following features: |  |  |
|  | The imagine area shall be 35 cm x 43 cm (±5%).  |  |  |
|  | The number of pixels detector array shall be at least 2300 x 2800. |  |  |
|  | The effective pixel output to other DICOM device shall be at least 2300 x 2800 pixels. |  |  |
|  | The surface load of the detector, or together with one set of radiolucent protective cover, shall not be less than 150kg.  |  |  |
|  | The thickness shall be 20 mm or less. |  |  |
|  | The wireless detector shall be made of Cesium Iodide (CsI) on Amorphous Silicon receptor or better. |  |  |
|  | The limit spatial resolution shall be at least 3.3 lp/mm. |  |  |
|  | The pixel size shall not be more than 150 µm. |  |  |
|  | The data acquisition shall not be less than 16 bits per pixel. |  |  |
|  | The Detection Quantum Efficiency (DQE) shall be at least 50% at 1 lp/mm. |  |  |
|  | The Modulation Transfer Function (MTF) shall not be less than 59% at 1 lp/mm. |  |  |
|  | The applicable X-ray kV range of the wireless detector shall be 40 kV to 125 kV or wider. |  |  |
|  | The detector shall support image preview on the display console in 5 seconds or less. |  |  |
|  | The image capture cycle time shall be 20 seconds or less. |  |  |
|  | The detector shall be wireless connecting interface (802.11n or latest version). The transmission of signal between the system and wireless detectors shall not interfere with vital equipment operation in the hospital. |  |  |
|  | **Three (3) sets of rechargeable batteries for each wireless detector** shall be provided. |  |  |
|  | Virtual grid, or equivalent gridless licence software, shall be provided. |  |  |
|  | Fall log record for user’s reference shall be provided.  |  |  |
|  | **Accessories** |  |  |
|  | **One set (1) of small wireless detector** with imaging area of 24 cm x 30 cm (±5%) with requirements as detailed in Sections A2.6.5 to 2.6.18 shall be provided. The number of pixels detector array of the small detector shall be at least 1500 x 1900. The effective pixel output to other DICOM device shall be at least 1500 x 1900. |  |  |
|  | **One (1) set of anti-scatter grid for each wireless detector** encased in radiolucent and transparent covering for protection against damage shall be provided. |  |  |
|  | **Five (5) sets of lead markers**, including “L” & “R”, “Sitting”, “Supine”, “Erect”, “Semi-Erect”, “Standing”, “Decubitus” & “Horizontal Ray” shall be provided. Lead markers shall be encased in plastic. |  |  |
| **B** | **Implementation Services** |
|  | Without prejudice to the Deadline Completion Date and other time requirements, the potential supplier shall at its own costs perform the implementation services specified in this section B (collectively, “**Implementation Services**” or “**implementation services**”). |  |  |
|  | Integration with other IT Systems |  |  |
|  | The potential supplier shall coordinate with the PACS contractr for all interfacing details to ensure the accomplishment of networking with and provide all necessary information, support and assistance to the contractors overseeing the DICOM compliant systems to ensure successful interfacing. |  |  |
| **C** | **Training** |
|  | On-site operational and service training in Cantonese or English delivered by certified personnel, respectively for a minimum of two operation staff and two maintenance staff, shall be provided at no additional charges. The training equipment should be identical to that of the purchased equipment as far as practicable. |  |  |
|  | The timetable and commencement dates for the courses shall be advised at least three (3) months prior to the commencement of the courses. Detailed syllabuses are also to be submitted for approval. The practical part shall coincide with the delivery and commissioning of the system. |  |  |
| **D** | **Documentation** |
|  | One hardcopy and one soft copy upon delivery of the system shall be submitted, including:1. The latest version of operation and maintenance manual, in English or in Chinese complete with procedures of preventive maintenance (PM) and corrective maintenance (CM) and maintenance interval.
2. PM checklist(s) endorsed by equipment manufacturer.
 |  |  |
| **E** | **Acceptance Tests** |
|  | The complete System shall be subjected to an acceptance test by a medical physicist or delegate after delivery has been completed. |  |  |
|  | The Chinese Medicine Hospital of Hong Kong will not conduct acceptance tests until it has received full certification from the potential supplier that the potential supplier has conducted its own tests and found that the System meets the specifications. |  |  |
| **G** | **Indicative Warranty Service** |
|  | The potential supplier shall guarantee the equipment, or any part thereof (exceptions to be clearly stated with itemized prices, ordering information details and conditions of warranty) for a period of at least 12 months commencing from the date of acceptance of the equipment. The potential supplier shall replace faulty parts and provide software update for all system included in this tender. Both schedule and breakdown maintenance service shall be performed by qualified maintenance personnel. |  |  |
|  | The potential supplier shall, at his own expense, make good, to the satisfaction of CMHHK, any defects on the equipment due to improper workmanship, faulty design or component failure which may arise within a period of at least 12 months from the acceptance of the equipment. Components that have been interchanged during the warranty period shall have a new warranty period for one-year commencing from the date of replacement. |  |  |
|  | The potential supplier shall submit an organization chart or organization description of the maintenance team who will be responsible for carrying out warranty services with brief notes on the areas of responsibility of each post within two (2) weeks after the commencement of the Warranty Period. Those staff who have received factory training for maintain the equipment shall be clearly identified. All warranty services shall be carried out by qualified maintenance personnel.  |  |  |
|  | The potential supplier shall commit to replace two (2) wireless detectors (with detector batteries) of any size free of charge if defect/ malfunctioning is identified within the warranty period and even with evidence showing that the faulty detector has experienced drop/contusion exceeding the threshold of tolerance or similar terms specified by the potential supplier. |  |  |
|  | Preventive Maintenance |  |  |
|  | The potential supplier shall provide preventive maintenance services at least four (4) times within the warranty period, covering full inspection, lubrication and testing in order to keep the System in good operating condition and in accordance with the Technical Specifications. The scope of maintenance shall include the following activities: |  |  |
|  | The preventive maintenance service shall include all necessary repairs, replacement of parts, adjustments, calibration for equipment performance, cleaning and lubrication necessary to ensure that the performance of the System conforms to the performance specifications.  |  |  |
|  | The scope of preventive maintenance shall include the following activities:1. Scheduled preventive maintenance shall include all work (including checking and tuning) to bring the whole system (including accessories) to performance specification.
2. Preventive maintenance and non-urgent repairs shall be scheduled on Saturdays (or in the periods decided by the user department) at no extra charge.
3. This routine service shall include all necessary repairs, replacement of parts, adjustments, calibration, quality assurance test, cleaning and lubrication necessary to ensure that the performance of the equipment conforms to the performance specifications referred to the specifications requirement. Parts shall be included. In case of replacement, it will be free of charge.
4. The potential supplier shall carry out safety test on the equipment at least once per year. The safety standards required shall comply with IEC 60601-1 or equivalent.
 |  |  |
|  | Corrective Maintenance |  |  |
|  | The potential supplier shall provide a 24 hours hotline for fault reporting to ensure prompt fault attendance. Upon notification by the user of a defect (departure from performance specifications) in the operation of the equipment, or part thereof, the potential supplier shall attend to the fault within 4 normal working hours. |  |  |
|  | The potential supplier shall rectify faults and perform replacement of parts, adjustments and calibrations as may be necessary to ensure the System works properly in accordance with the Technical Specifications within 8 hours or such other time agreed. |  |  |
|  | In the event that the potential supplier decides to replace a component of the System, the replaced component shall become the property of the CMH Operator. |  |  |
|  | Upon completion of the corrective maintenance work, the potential supplier shall complete a service report and obtain a signature from the user or his representative certifying that the equipment is in normal operational conditions. A copy of the same shall be provided to the user on the day of completion of maintenance. The potential supplier shall provide service reports detailing the progress of the maintenance work at times requested by the department if the maintenance work lasts for more than 2 working days. |  |  |
| **H** | **Indicative Maintenance Service** |  |  |
|  | The potential supplier shall guarantee the equipment, or any part thereof (exceptions to be clearly stated with itemized prices, ordering information details and conditions of warranty) for a period of at least 12 months commencing from the date of acceptance of the equipment. The potential supplier shall replace faulty parts and provide software update for all system included in this tender. Both schedule and breakdown maintenance service shall be performed by qualified maintenance personnel. |  |  |
|  | The potential supplier shall, at his own expense, make good, to the satisfaction of CMHHK, any defects on the equipment due to improper workmanship, faulty design or component failure which may arise within a period of at least 12 months from the acceptance of the equipment. Components that have been interchanged during the warranty period shall have a new warranty period for one-year commencing from the date of replacement. |  |  |
|  | The potential supplier shall submit an organization chart or organization description of the maintenance team who will be responsible for carrying out warranty services with brief notes on the areas of responsibility of each post within two (2) weeks after the commencement of the Warranty Period. Those staff who have received factory training for maintain the equipment shall be clearly identified. All warranty services shall be carried out by qualified maintenance personnel.  |  |  |
|  | The potential supplier shall commit to replace one (1) wireless detector (with detector batteries) of any size free of charge if defect/ malfunctioning is identified within the warranty period and even with evidence showing that the faulty detector has experienced drop/contusion exceeding the threshold of tolerance or similar terms specified by the potential supplier. |  |  |
|  | Preventive Maintenance |  |  |
|  | The potential supplier shall provide preventive maintenance services at least four (4) times within the maintenance period, covering full inspection, lubrication and testing in order to keep the System in good operating condition and in accordance with the Technical Specifications.  |  |  |
|  | The preventive maintenance service shall include all necessary repairs, replacement of parts, adjustments, calibration for equipment performance, cleaning and lubrication necessary to ensure that the performance of the System conforms to the performance specifications.  |  |  |
|  | The scope of preventive maintenance shall include the following activities:* 1. Scheduled preventive maintenance shall include all work (including checking and tuning) to bring the whole system (including accessories) to performance specification.
	2. Preventive maintenance and non-urgent repairs shall be scheduled on Saturdays (or in the periods decided by the user department) at no extra charge.
	3. This routine service shall include all necessary repairs, replacement of parts, adjustments, calibration, quality assurance test, cleaning and lubrication necessary to ensure that the performance of the equipment conforms to the performance specifications referred to the specifications requirement. Parts shall be included. In case of replacement, it will be free of charge.
	4. The potential supplier shall carry out safety test on the equipment at least once per year. The safety standards required shall comply with IEC 60601-1 or equivalent.
 |  |  |
|  | Corrective Maintenance |  |  |
|  | The potential supplier shall provide a 24 hours hotline for fault reporting to ensure prompt fault attendance. Upon notification by the user of a defect (departure from performance specifications) in the operation of the equipment, or part thereof, the potential supplier shall attend to the fault within 4 normal working hours. |  |  |
|  | The potential supplier shall rectify faults and perform replacement of parts, adjustments and calibrations as may be necessary to ensure the System works properly in accordance with the Technical Specifications within 8 hours or such other time agreed. |  |  |
|  | In the event that the potential supplier decides to replace a component of the System, the replaced component shall become the property of the CMH Operator. |  |  |
|  | Upon completion of the corrective maintenance work, the potential supplier shall complete a service report and obtain a signature from the user or his representative certifying that the equipment is in normal operational conditions. A copy of the same shall be provided to the user on the day of completion of maintenance. The potential supplier shall provide service reports detailing the progress of the maintenance work at times requested by the department if the maintenance work lasts for more than 2 working days. |  |  |

**Part 4 – Implementation Plan**

*(Note to Suppliers: Please provide the estimated time periods required for the completion of the following tasks, counting from the date of issue an order (“Order Date”). Both the start and end date of the Order Date is referenced as* ***Month 0****. The System should be* ***Ready for Use in the last month of the Implementation Plan.****)*

|  |  |
| --- | --- |
| **Tasks of the Implementation Plan** | **Estimated Time Period for** **Performing the Tasks**(The Order Date is set as Month **0**) |
| **Start** (Month) | **End** (Month) |
|  | Order Date *(i.e. the date of order placed by the Government, if any)*  | **0** | **0** |
|  | Submission of Site Preparation Information (if applicable) |  |  |
|  | Design of the System (if applicable) |  |  |
|  | Delivery of the System  |  |  |
|  | Installation of the System |  |  |
|  | Implementation Services (*Please refer to* ***section B in Part 3*** *for details*) |  |  |
|  | Delivery of Documentation (*Please refer to* ***section D in Part 3*** *for details*) |  |  |
|  | Training (*Please refer to* ***section C in Part 3*** *for Details*) |  |  |
|  | Acceptance Tests |  |  |
|  | Any other tasks considered necessary by your company *(Please provide details, use separate sheet if space is insufficient)*: |  |  |
|  | System Ready for Use *(i.e. the date when the System has passed all acceptance tests and accepted by the Government)*  | **0** |  |

**Part 5 – Information on Compliance with International, National and other Recognised Standards** **or Certifications (if applicable)**

(*Note to Suppliers: Please indicate in the box below whether the proposed mobile x-ray machines can meet with the standards stated in Column I* ***by inserting a tick in an appropriate box under Column III****. If your proposed mobile x-ray machines does not meet the standards stated in Column I, please indicate the equivalent standards met by your proposed mobile x-ray machines in Column IV. In any case,* ***please attach copies of relevant valid certificates to prove compliance with such standards****.*)

|  |  |  |  |
| --- | --- | --- | --- |
| **Column I** | **Column II** | **Column III** | **Column IV** |
| International, National and other Recognised Standards or Certifications | Requirements  | Comply with the Standard in Column I? | Comply with the following equivalent standard (*If “****No****” in Column III*) |
| Yes | No |
| ISO  | 13485 |  |  |  |
| IEC  | 60601-1-1 |  |  |  |
| IEC  | 60601-1-2 |  |  |  |
| IEC  | 60601-1-3 |  |  |  |
| IEC | 60601-2-28 |  |  |  |
|  |  |  |  |  |
| Compliance with other international, national and recognised standard(s) or certification(s) in addition to the above (*please specify*) |
|  |  |  |  |  |

**Part 6 – Information on Licencing, Marketing Authorization and MDACS Listing (if applicable)**

(*Note to Suppliers: Please advise whether your company and the proposed System have the following licence, marketing authorization and Medical Device Administrative Control System (“MDACS”) listing. If affirmative, please provide copies of relevant licences, confirmation and certificates for our reference.)*

| Question | Licensing/Certification/Listing Information of the System |  *(Please tick in the appropriate box)* |
| --- | --- | --- |
| #Yes | No |
| 1 | Does your company have valid licence(s) to sell, deal with, possess and use irradiating apparatus in Hong Kong issued under the Radiation Ordinance (Chapter 303 of the Laws of Hong Kong) (“IA Licence”)? |  |  |
| 2 | Has the proposed System been listed in a valid IA Licence? |  |  |
| 3 | Dose the proposed System have marketing authorization of Food and Drug Administration (FDA) of the United States? |  |  |
| 4 | If the proposed System has marketing authorization of FDA, please specify below the type of marketing authorization (i.e. approval, clearance or exemption). \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |  |  |
| 5 | Does the proposed System have marketing authorization of the European Union (EU) for affixing of CE marking on the product? |  |  |
| 6 | If the proposed System has marketing authorization of EU, please state the type of supporting document (\*delete which is not applicable).* + - * 1. \*Declaration of conformity by the manufacturer; or
				2. \*Certificate of conformity issued by a notified body.
 |  |  |
| 7 | Does the proposed System have marketing authorization in country/region other than United States and EU? Please specify below if your answer is “Yes”.Country / Region : \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |  |  |
| 8 | Has your proposed System been listed in the MDACS of the Department of Health?  |  |  |
| 9 | What class of medical device is your proposed System (if applicable)?1. EU : Class \_\_\_\_\_\_
2. United States : Class \_\_\_\_\_\_
3. Other country/region (please specify below):
* Country/Region \_\_\_\_\_\_\_\_\_
* Class \_\_\_\_\_\_\_\_\_
 |  |  |

#Please provide a copy of the licence/confirmation/certificate for reference.

**Part 7 – Indicative Price Information**

(*Note* *to Suppliers: The price information provided in this Part 7 is for Government’s consideration only and shall not constitute any commitment on the part of the Government or your company. Nevertheless, please provide the information as accurate as possible.*)

**(a) Indicative Price Information for the System**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Item** | **Description** | **Estimated****Quantity** | **Unit Price** | **Estimated Goods Price** |
| **One-time Unit Price(HK$)** | **Estimated Goods Price for the Item specified opposite****(HK$)** |
|  |  | **(a)** | **(b)** | **(c) = (a) x (b)** |
| 1 | Supply and installation of the System and related items as more particularly specified in **Section A1-3 in Part 3**, including the provision of a minimum 12-months warranty period. | 2 sets |  | ***(Please also provide breakdown cost for key components of the System, if any)*** |
| 2 | Provision of implementation services as detailed in **Section B in Part 3** | 1 lot |  |  |
| 3 | Provision of training services as detailed in S**section C in Part 3**  | 2 courses |  |  |
| 4 | Documentation as detailed in **Section D in Part 3** | 1 lot |  |  |
| 5 | Other (please specify) | (please specify) |  |  |
| **Total One-time Charge**(i.e. Sum of Estimated Goods Prices of Item 1- 5) |  |

**Part 8 – Indicative Maintenance Charges and Spare Parts Price**

(Notes to Suppliers for completion of Part 8)

1. *Pursant to item 1 of Part 7(a) above, the proposed System shall have a warranty period of not less than 12 months. The indicative warranty service requirements are stipulated in* ***section G in Part 3****, which are subject to changes at the sole discretion of the Government.*
2. *Indicative maintenance service requirements after the free warranty period are stipulated in* ***section H in Part 3****, which are subject to changes at the sole discretion of the Government*
3. *It is expected that the maintenance services shall be comprehensive, all inclusive and shall cover all parts, components, labour and software support services. If your company considers that any components of the System may not be covered by the maintenance services (****saving that the labour shall always be covered by the maintenance services****) and may need to be charged separately, please indicate replacement costs of these components and their replacement frequency.*
4. *The annual maintenance charge within the serviceable life of the proposed System* ***is adjustable in accordance with the consumer price index (B) upon the expiry of each 12-months period of maintenance service****.*
5. **Indicative Maintenance Prices of the Proposed System**

| **Year** | **Annual Maintenance Charge****(HK$ per annum)** |
| --- | --- |
| First 12-months period of maintenance service after the end of warranty period |  |

1. **Indicative Replacement Prices of System’s Components not covered by the Maintenance Services (if applicable) (***Leave the following table blank if not applicable***)**

(*Note to Suppliers:* ***The labor costs for replacement of these components shall always be covered by the maintenance charges for the provision of the maintenance services*** *regardless whether the prices for the supply of these components are covered by the maintenance services or not.)*

|  |  |  |  |
| --- | --- | --- | --- |
| Item | Name of Items | Indicative Replacement Price (HK$/no.) | Indicative Replacement Frequency (*e.g. once every 3 years*) |
| 1 |  |  |  |
| 2 |  |  |  |
| 3 |  |  |  |

1. **Indicative overtime charges for provision of maintenance services after office hours (if applicable)**

(*Office hours mean 9 am to 6 pm from Monday to Friday excluding public holidays*)

|  |  |  |
| --- | --- | --- |
| (a) | Rates of overtime charges for maintenance service outside the office hours | HK$ per hour |
| (b) | Minimum service hour(s) per call |  service hour(s) per call |

1. **Indicative Prices for Replacement of Other Spare Parts (if applicable)**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Item | Name of Items | Price (HK$/no.) | Indicative Replacement Frequency (*e.g. once every 3 years*) | Expected time for delivery (weeks) |
| 1 |  |  |  |  |
| 2 |  |  |  |  |
| 3 |  |  |  |  |
| 4 |  |  |  |  |
| 5 |  |  |  |  |
| 6 |  |  |  |  |

1. **Indicative Price for Annual Support Services of Software (if applicable)**

(*Note to Suppliers:* Please provide below annual charge for support services of the System’s software during the serviceable life of the System for the CMH Operator’s consideration. *The support services should include but not limited to:*

1. *provision and renewal of software toolkits, access codes, passwords, software keys and hardware keys, etc. necessary for all kinds of adjustments, in-depth diagnosis and trouble shooting of the System; and*
2. *version upgrade of the software.)*

|  |  |
| --- | --- |
|  | (a) Free of charge during serviceable life  |
|  |  |
|  | (b) Yearly cost at $\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |

**Part 9 – Supplementary Information**

1. Number of proposed System Already Installed (leave blank if information is not available)

In Hong Kong : \_\_\_\_\_\_\_\_\_\_ sets

Globally : \_\_\_\_\_\_\_\_\_\_ sets

1. Year of Launch of the Proposed System (leave blank if information is not available)

My/our proposed System was first launched in the market in Year \_\_\_\_\_\_\_\_\_\_\_\_\_

1. Pre-Installation Requirements of the Proposed System (if any)

*(Pre-installation requirements may include any preparation work and provisions that are necessary for the installation of the System, such as the requirements of ceiling mount support, power supply requirements, etc.)*

**END**