IWK Health Centre
5850/5980 University Ave.
P.O. Box 9700
Halifax, Nova Scotia
Canada, B3K 6R8

IWK Health Centre for Children, Women & Families

REQUEST FOR PROPOSAL (RFP)

the provision of

CONTINUOUS RENAL REPLACEMENT THERAPY (CRRT) SYSTEMS

Issued

FRIDAY SEPTEMBER 8, 2014

by

IWK HEALTH CENTRE

HALIFAX, N.S.

5850/5980 University Ave.
Post Office Box 9700
Halifax, Nova Scotia
Canada, B3K 6R8
http://www.iwk.nshealth.ca/index.cfm

IWK Health Centre for Children, Women & Families

Request for Proposal (RFP)

Continuous Renal Replacement Therapy (CRRT) Systems

Located in Halifax, Nova Scotia, the IWK Health Centre provides quality care to children, youth, women and families in the three Maritime Provinces of eastern Canada and beyond. The IWK is a tertiary care hospital dedicated to education, research, family centered care and health promotion. The Health Centre has a total of 271 beds consisting of 74 adult beds, 76 beds for babies, 78 children's beds & 43 off-site residential program beds.

The Children's Health Program at the IWK has both a pediatric nephrology and intensive care programs that see patients who require different forms of dialysis treatment in both ambulatory and inpatient settings. These treatment options are performed on a wide range of pediatric patients (infant to late teen).

Currently most acute dialysis services are provided by the Regular Dialysis Unit nursing team, incurring on call and overtime charges that are dependent upon minimal staffing. The new CRRT model will support both the PICU and the Pediatric Nephrology programs by allowing trained pediatric intensive care nurses to provide CRRT therapy to critically ill PICU inpatients.

The new model is intended to transfer the responsibility of CRRT done on PICU inpatients to PICU nurses trained in CRRT with an aim of reducing overtime costs, increasing the utilization of CRRT in PICU when evidence indicates diagnosis would benefit from its utilization and support timeliness of the service given more nurses will be trained in its implementation and management. CRRT is becoming a gold standard in PICU patient care, leading to better health outcomes and aligns with our IWK mandate providing tertiary care, with continuity of care within the PICU.

We are requesting proposals for the acquisition of Two (2)

Continuous Renal Replacement Therapy (CRRT) Systems

for the Pediatric Intensive Care Department

FOR ALL INTERESTED VENDORS

All interested vendors should forward their proposals **if they meet** the **following requirements** as outlined in the following required specifications. Please forward **Four (4) copies** of all information which will **include Three (3) hard copies and one (1) electronic copy on DVD or CD** to the attention of

Purchasing Manager IWK, No later than **3:00pm, September 30, 2014**

Delivery Address:

Charter Place Offices, 1465 Brenton Street, 5th Floor Finance, Halifax, NS, B3J 3T3

No facsimiles will be accepted.

Any questions regarding this RFP shall be conducted through the RFP Coordinators Indicated

Any questions, clarifications or discussions regarding this RFP must be conducted through the ***RFP coordinator***s below.

Blair Myers
Purchasing Manager
Blair.Myers@iwk.nshealth.ca
Ph : 902.470.8917

Ted MacLaggan
Manager, Biomedical Engineering
ted.maclaggan@iwk.nshealth.ca
Ph: 902.470.8837

1 TABLE OF CONTENTS

2 TERMS & CONDITIONS

- These Instructions to Bidders, Equipment Requirements, and Terms & Conditions are for the furnishing, installation, start-up, calibration and the testing of medical equipment for the **IWK Health Centre, (Courier only address Charter Place Offices, 1465 Brenton Street, 5th Floor Finance, Halifax, NS, B3J 3T3)**, hereafter referred to as BUYER or IWK.

- **RFP Proposal Evaluations:** Proposals will be evaluated on the basis of, but not limited to … 1) price; 2) conformance to Equipment Requirements and Terms & Conditions; 3) conformance to Biomedical and Information Technology requirements, equipment features, specifications, performance, and reliability; 4) vendor experience; 5) the experience of users with the equipment and vendors; 6) delivery & installation schedule; 7) warranty terms; 8) service capabilities; 9) user training and support services; 10) operating costs and overall responsiveness to this Request for Proposal (RFP).

- **Criteria Selection:** The order in which the above selection criteria are listed is **not** necessarily indicative of their relative importance. It is expected that vendors submitting proposals will demonstrate extensive and substantial qualifications, capabilities, and experience in manufacturing, installing and servicing the equipment sought, including successful provision of similar goods and services to comparable institutions.

- **Vendor Selection:** The BUYER intends to select a vendor on the basis of proposals received in response to this RFP and any other information it obtains from other sources regarding the equipment and the vendor. The BUYER reserves the right to make its final decision independent of any or all of the above factors.

- **Independent Servicing:** The BUYER reserves the right to solicit service contract bids from qualified independent service organizations, in the interest of reducing its technical support costs.

- **Acceptance Testing**: The system shall be subject to and must pass acceptance testing, performed by the IWK Health Centre.

- **Compliance with Applicable Standards:** The system, equipment or device will be tested for compliance with applicable CSA medical standards for electrical safety and manufacturers specifications.

- **Pricing:** All quotations shall be firm for at least 180 days. Pricing shall be net of any taxes proposed/quoted pricing is to be in Canadian $'s and. Items such as delivery/freight costs, set-up fees, in-servicing, taxes, etc. are to be shown as separate line items. ***Note: All pricing proposals are to be delivered to Finance in a separate sealed envelope clearly identified as pricing information.***

- **Additional Terms & Conditions:** Successful Vendor must agree to comply with and be bound by IWK General Terms and Conditions for Purchase Orders in ***Appendix 1.***

- **Governing Laws:** This agreement and all items pertaining to it shall be governed and interpreted in accordance with the laws of the province of Nova Scotia.

- **Vendor Questions:** Any questions regarding this RFP must be directed through the RFP Coordinator who has been specified in this document. The RFP Coordinator will direct the vendor to the most appropriate contact. Information offered from sources, other than the direction given by the RFP coordinator, is not official and may be inaccurate. ALL vendor questions must be submitted to the RFP Coordinator **no later** than the date specified in the Acquisition Schedule that follows. After this date, the RFP Coordinator will post the questions & Answers on the following website for all vendors to see … https://www.gov.ns.ca/tenders/

- **Closing Date:** The RFP Coordinator must receive all proposals at the address specified no later than 3:00 p.m. local time on the date identified in the acquisition schedule. Failure to submit a proposal, by the deadline specified, will result in the rejection of the vendor's proposal.

> 🕮 **Submission of the Proposal constitutes the vendor's acceptance of the procedures, evaluation criteria, and other administrative instructions of the RFP.**
> **It is NOT acceptable to fax the Proposal.**
>
> 🕮 **The BUYER assumes no responsibility for delays in Canada Postal Service or any delivery or courier service that the vendor may select.**
> **Time extensions will not be granted.**

- **Vendor Contact:** Each vendor shall appoint an individual to act in an official capacity on behalf of the vendor for this acquisition. The following information shall be included in the proposal:
  - *Name of the Vendor Representative*
  - *Representative's Title*
  - *Name of the Company*
  - *Company Address*
  - *Telephone /Fax Number*
  - *Cell Phone /Pager Number*
  - *E-mail address*
  -

- **Scheduling & Amendments:** The BUYER reserves the right to change the acquisition schedule or issue amendments to the RFP at any time.

- **Right to Cancel:** The BUYER reserves the right to cancel and/or reissue the RFP if so required.

- **Withdrawing Proposals:** Vendors may withdraw a proposal that has been submitted at any time up to the proposal closing date and time. To accomplish this, a written request signed by the authorized representative of the vendor must be submitted to the RFP Coordinator. After withdrawing a previously submitted proposal, the vendor may submit another proposal at any time up to the closing date and time.

- **Indemnity:** As a governmental unit, the IWK cannot provide an indemnity in the contract.

- **Provincial Initiative:** It is understood that any agreement and/or purchase that results from this tender will be made known to and be available to all Nova Scotia Health Districts (1 through 9) for a twelve (12) month period following the contract award, at each DHA's discretion. While the exact resultant configuration may not be appropriate for any District, it is expected that the vendor will afford the same pricing and/or discount structure to all districts. Each district will be responsible for issuing their own separate Purchase Order and/or contract for services/product.

- **NOTE:** It is a condition, precedent to the IWK Health Centre's acceptance of any tender, that the Vendor confirm that they have no outstanding or pending litigation, action, claim, demand or cause of action against the IWK Health Centre which in any way relates to the subject matter of the RFP or which relates to the supply of goods and services to the IWK Health Centre.

> **Vendors will not be allowed to alter proposal documents after the deadline for submission.**

3 VENDORS PROPOSAL FORMAT

> **All proposals submitted shall follow the format as outlined below…**

3.1 First Section (Compliance Documentation)

- The first section of the vendor's proposal shall include details and compliance claims as they relate to the following sections of this RFP. The vendor shall reference the same line item numbers for easy reference by the BUYER. Provide as many details and information as necessary to avoid unnecessary follow-ups and unwanted frustrations with the vendor that may jeopardize the sale.

> Any mandatory requirement requested by the BUYER in this RFP, is an essential need that must be met by the vendor. Failure to meet a mandatory requirement may be grounds for disqualification and shall be established by **any** of the following conditions: 1) Vendor states that a mandatory requirement cannot be met, 2) Vendor fails to include information necessary to substantiate that a given mandatory requirement has been met, 3) A response of "will comply" is **not** sufficient, 4) Responses must indicate present capability, 5) Representations that future developments will satisfy the requirement, are not sufficient, 6) The vendor presents the information requested by this RFP in a matter inconsistent with instructions stated by any portion of this RFP, 7) Customer references, or site visits, report the vendor's inability to comply with one or more of the mandatory requirements and 8) The vendor fails to include the customer references required.

3.2 Second Section (Supporting Documentation)

- The second section of the proposal shall include any brochures, references, support documentation, training schedules, Medical device Licenses etc.

3.3 Third Section (Pricing)

All pricing proposals are to be delivered in a separate sealed envelope clearly identified as pricing information.

- The third section of the proposal shall be a line-item price quotation that separately lists all of the components of the proposed equipment/system, installation costs and any other costs associated with this acquisition.

- Installation costs should be included in the price. All pricing is to be installed (freight prepaid and included in price proposal), including rigging and inside delivery.

- Each line item, for each quotation, must have both the standard list price as well as any discounted price. This shall include service and equipment.

- Pricing for all options and accessories shall also be included in this section of the proposal.

4 SPECIAL INSTRUCTIONS

4.1 It shall be understood that all legal & financial responsibilities, in complying with the Health Products & Food Branch Inspectorate (HPFBI), Health Canada regulations as they apply to the sale & distribution of medical devices shall be the sole responsibility of the vendor.

4.2 Vendors submitting RFP's, shall do so with a proposal that addresses the following …

4.3 While it is preferred that a single vendor meet ALL of the requirements of each department, the BUYER reserves the right to select multiple vendors/systems at its discretion.

4.4 Should equipment, being proposed, be the same as existing systems, the vendor shall consider proposal options that will allow for upgrades to the existing equipment in order to keep systems at the same version levels.

4.5 The vendor shall propose optional pricing incentives that may allow, "forklift" upgrades, etc. to any of the existing systems presently in use.

4.6 The IWK will also entertain any leasing options that may be available from the vendor.

4.7 It shall be understood, that proposals submitted to the IWK, will be evaluated on the basis of, but **not limited to** the following … Proposals will be evaluated on the basis of, but not limited to … 1) price; 2) conformance to Equipment Requirements and Terms & Conditions; 3) conformance to Biomedical and Information Technology requirements, equipment features, specifications, performance, and reliability; 4) vendor experience; 5) the experience of users with the equipment and vendors; 6) delivery & installation schedule; 7) warranty terms; 8) service capabilities including but not limited to the availability of factory level service training and detailed service manuals; 9) user training and support services; 10) operating costs and overall responsiveness to this Request for Proposal (RFP).

4.8 The basis of this evaluation, will decide which vendor(s) will be invited to provide any presentations, demonstrations, evaluations and/or on-site clinical trials, etc. It is the right of the BUYER, that this decision will be made independent of any or all of the above factors.

NOTE: Submitting a proposal, in response to this RFP, constitutes the vendor's acceptance of procedures, terms & conditions, evaluation criteria, and other administrative instructions of this RFP.

Vendor's ACCEPTANCE …

_____	_____	_____
Signature	Title (Please Print)	Date

5 INSTALLATION, TESTING OF PROPOSED SYSTEM AND COMPONENTS

5.1.1 Vendor is responsible for unpacking, assembling, and performance testing of the CRRT equipment prior to user training and clinical use.

5.1.2 Vendor shall allow Biomedical Engineering to perform acceptance testing as per Health Centre Policy (Verification of Medical Device License, CSA Standards/Approval, Electrical Safety, Performance Testing)

6 ACQUISITION SCHEDULE

The BUYER reserves the right to change the acquisition schedule or issue amendments to the RFP at any time. The BUYER also reserves the right to cancel and/or reissue the RFP.

STEP	EVENT	DATE/ DURATION
1	Posting of RFP to the Vendors	September 8, 2014
2	RFP Responses Due (Fax Not Acceptable).	September 30, 2014
3	Review of Proposals	September 30, 2014 - October 10, 2014
4	Equipment Trial/Evaluation by IWK Representatives (Tentative)	To Be Determined
5	Decision Made on Successful Vendor	October 17, 2014
6	Biomedical Acceptance Testing (Subject to completion of system installation)	Prior to first Clinical application
7	Application Training (Dept. & Biomed)	At time of installation
8	First Clinical / Patient Application	To be agreed upon with successful vendor

7 EQUIPMENT

The proposed Continuous Renal Replacement Therapy (CRRT) Systems must meet IWK Mandatory requirements and general specification requirements. Indicate compliance YES/NO and add comments in this section to assess the proposed system.

Equipment /Technical Specifications and Requirements Worksheet				
	Criteria	Requirement	Indicate Compliance (Yes/No)	Comments
Section A. Overall System Components and Requirements				
A.1	**General Requirements & Performance**			
A.1.1	Systems **must** be proven safe & suitable to intended pediatric and adult clinical applications. Systems must also be proven to have adequately robust construction to withstand the rigours of the intense, tertiary/quaternary care hospital environment.	**Mandatory**		
A.1.2	The system of the vendor of choice **shall** be proven acceptable per all requirements of this specification document via in-house equipment trial in order to confirm selection.	**Mandatory**		
A.1.3	Systems **must** be proven capable of safely and effectively performing both low flow and high flow **pediatric** and adult CRRT procedures. Bidders are invited to detail additional procedures and features, particular to paediatric applications, for which use of their systems is indicated.	**Mandatory**		

A.1.4	Controls and system alarms **must** be proven to be clear, intuitive, & easy to use/understand. Minimization of daughter screens and keystrokes is critical in order to support quality control. IWK reserves the right to select first from devices that are compliant with CAN/CSA 60601-1-6 "Medical electrical equipment – Part 1-6: General requirements for basic safety and essential performance – Collateral standard: Usability".	**Mandatory**		
A.1.5	If short-listed, the CRRT system **must** be proven to exhibit the functionality / control described in this specification by clinical trial prior to endorsement for issue of contract. Systems not averaging at least a "Good" rating with medical and nursing staff during clinical trials may be summarily dismissed by IWK at its sole discretion. Further, a rating of "Fail" by one of the medical staff for any score sheet entry will result in that bid being reviewed, with the potential for of being summarily dismissed.	**Mandatory**		
A.2	**Specific Requirements & Functionality:**			
A.2.1	The CRRT systems **must** be proven to be exhibit the following core functionality or provide the functional/control equivalent:			
A.2.2	Integrated Heparin Pump	**Mandatory**		
A.2.3	Slow Continuous Ultra filtration (SCUF)	**Mandatory**		
A.2.4	Continuous Venovenous Hemodiafiltration (CVVHDF)	**Mandatory**		
A.2.5	Continuous Venovenous Haemodialysis (CVVHD)	**Mandatory**		
A.2.6	Continuous Venovenous Hemofiltration (CVVH)	**Mandatory**		
A.2.7	Blood Leak Detector	**Mandatory**		
A.2.8	Blood Air/Bubble Detector	**Mandatory**		
A.2.9	Temperature control and monitoring	**Mandatory**		
A.2.10	Return Line Clamp	**Mandatory**		
A.2.11	Filter Pressure Sensor	**Mandatory**		
A.2.12	Access Line Pressure Sensor	**Mandatory**		
A.2.13	Return Line Pressure Sensor	**Mandatory**		

A.2.14	Identify additional functionality provided by the proposed CRRT System. Please provide details.	**Required Response**		
A.2.15	Haemodialysis (HD)			
A.2.16	High Flux Dialysis (HFD)			
A.2.17	High Volume Hemofiltration (HVHF)			
A.2.18	Intermittent Haemodialysis (IHD)			
A.2.19	Intermittent Hemofiltration (HD)			
A.2.20	Plasma adsorption/perfusion (PAP)			
A.2.21	Therapeutic Plasma Exchange (PEX)			
A.2.22	Slow Low Efficient Daily Dialysis (SLEDD)			
A.2.23	Pre/Post Dilution & Anticoagulant Pumps			
A.3	**Specific System Performance**			
A.3.1	The CRRT systems **should** be proven to be exhibit the following core functionality or provide the functional/control equivalent:			
A.3.2	Please provide the fluid balance accuracy. (N.B. **shall** have a minimum accuracy of +\- 10%)	**Mandatory**		
A.3.3	Please detail upgrade capacity, including software updates, features, and associated costs.	**Required Response**		
A.3.4	Please detail all Data Storage & Logging options including costs. (N.B. Includes data cards, centralized storage and Monitoring)	**Required Response**		
A.3.5	Please detail the Low Flow Rates associated with each type of treatment (minimum/maximum Rate).	**Required Response**		
A.3.6	Please detail the High Flow Rates associated with each type of treatment (Minimum/Maximum Rate)	**Required Response**		
A.3.7	Does the system have limitations with respect to low flow rates based on internal catheter diameter, flow rate, pressure, and therapy type? If so please provide this information and detail the impact with respect to treating pediatric patients?	**Required Response**		
A.3.8	Please detail the recommended minimum patient weight/size and other associated limitations.	**Required Response**		
A.3.9	Please provide details on the type of fluid balance system (Gravimetric?)	**Required Response**		
A.3.10	Please provide detail on the system sensors and measured parameters?	**Required Response**		
A.3.11	How often are the fluid balance and other measured parameters updated/refreshed?	**Required Response**		
A.3.12	Please provide detail on the temperature control and monitoring system?	**Required Response**		

A.3.13	Please indicate the blood volume required to prime various treatment sets	**Required Response**		
A.3.14	Please provide details on pre and post dilution administration of replacement fluid and/or the administration of citrate anticoagulant?	**Required Response**		
A.4	**Human Factors, Usability, & Alarm Management**			
A.4.1	Does the system Automatically load patient/extracorporeal set or cassette? Is it user friendly? If so please provide details.	**Required Response**		
A.4.2	Does the system provide on screen Instructions for priming, setup, through to the initiation of treatment? If so please provide details.	**Required Response**		
A.4.3	The machine should manage alarms in such a way that clinicians are provided with information needed to quickly determine the cause of the alarm? Please provide details.	**Required Response**		
A.4.4	Does the system provide Onscreen Details/Explanation of Alarms and instruction on how to resolve? Please provide details.	**Required Response**		
A.4.5	How does the system Manage and prioritize multiple on screen Alarms? How are they organized as to prevent overwhelming the user? (e.g. Highest Priority First) Please provide details.	**Required Response**		
A.4.6	Does the machine clearly identify the most likely cause of an alarm and avoid presenting the user with erroneous potential secondary alarms triggered by the primary alarm event? Please provide Details?	**Required Response**		
A.4.7	Please describe any additional Human Factor Design Features used to increase user friendliness, usability, increase patient safety, and reduce the probability of use errors?	**Required Response**		
A.7	**Engineering & Safety Requirements:**			
A.7.1	Detail any & all engineering & safety requirements. Include at least:			
A.7.2	Power / electrical requirements, typical consumption, & isolation;	**Required Response**		N.B. Include any requirements for UPS, power conditioner, etc.
A.7.3	EMI / EMC specifications;	**Required Response**		
A.7.4	Safety requirements & concerns; & other	**Required Response**		

A.7.5	All equipment **must** be proven as adequately robust to withstand the rigours of Tertiary care intensive care environments.	**Mandatory**		
A.7.6	Proposed system **must** withstand typical hospital reprocessing techniques. Written, validated cleaning/sterilization instructions shall be provided with the tender response. Adequate sterilization procedures &/or alternative measures (e.g. drapes, etc) are to be provided in order to conserve the sterile field.	**Mandatory**		
A.7.7	Vendors shall provide industry standard safety measures.	**Required Response**		
A.7.8	Vendor, as applicable, shall provide a list of required information technology infrastructure (# of data drops/device, server requirements/specification, recommended interfaces, Server Operating System Requirements, SQL Server Requirements, Version Requirements, and all associated minimum requirements)	**Required Response**		
SECTION B: ADMINISTRATION & SUPPORT REQUIREMENTS				
B.1	**Standards & Device Licensing:**			
B.1.1	a) All equipment **must** have Health Canada's Health Protection Branch Therapeutic Device (HPB-TPD) Licensing, as required. Bidders shall confirm their products have such licensing else provide an explanation as to why it is not required.	**Mandatory**		
B.1.2	All equipment **must** be proven to be certified to all appropriate CSA standards (e.g. CSA 60601-1 and respecting latest revisions, interpretations, amendments, supplements, & applicable collaterals) by a recognized agency. Must confirm compliance with respect to electromagnetic immunity and emissions (cf. CSA 60601-1-2).	**Mandatory**		**CAN/CSA 60601-1-2 Compliant? Pass / Fail**
B.1.3	All CRRT equipment and supplies/disposables **must** be proven to be certified to all appropriate CSA and recognized standards for dialysis. Including, but not limited to the CAN/CSA 60601-2-16:14 Particular requirements for the basic safety and essential performance of haemodialysis, haemodiafiltration and haemofiltration equipment, CAN/CSA - ISO8638:12, CAN/CSA-ISO 8637:12 etc...) CAN/CSA-ISO 13958-11	**Mandatory**		**CAN/CSA 60601-2-16:14? Pass/Fail**

B.1.4	Only tentative winning bidders will be asked and required to detail all CSA standards used to design & test their products, including actual Compliance Test detail reports. All equipment components require this approval. If equipment/systems are supplied without such required certification & labelling, the supplier is responsible for all testing & modification costs to make the equipment/system acceptable by CSA standards.	**Required Response**		
B.1.5	All power cords (including the plug), power bars, & power outlets must be hospital grade & CSA approved.	**Mandatory**		
B.2	**Warranty:**			
B.2.1	One year full warranty (parts plus labour), minimum.(N.B. A 2-year, total warranty for the entire system is preferred. The IWK reserves the right to select first from solutions that provide such coverage, providing all mandatory requirements are met.)	**Mandatory**		**Labour coverage duration: _____2_____ Months** **Parts coverage duration: _____ Months**
B.2.1	The vendor shall not start the warranty period until the equipment has been placed into clinical use (Note: 1st day of clinical usage following all user training outlined in B.3.1)	**Mandatory**		
B.2.2	Quote warranty extensions on a per year basis, as applicable.	**Required Response**		
B.3.	**Training:**			
B.3.1	On-site training must be provided for all applicable personnel. On-site in-servicing must be supplied for all affected clinical, Biomedical Engineering, & SPD staff members. In-servicing shall be scheduled at a time mutually agreeable to the IWK & the successful vendor before commencement of the evaluation period. The IWK reserves the right to waive training on equipment with which it is already familiar. Any & all associated costs are to be detailed in the Cost Proposal.	**Mandatory**		

B.3.2	The provision of clinical training prior to and immediately following installation is mandatory. Specify and list all the clinical in servicing provided in the cost proposal for clinical staff.	**Mandatory**		
B.3.3	The vendor must provide a detailed clinical implementation and training plan for items B.3.1 and B.3.2.	**Mandatory**		
B.3.4	Two (2) follow up on-site training (subsequent CRRT procedures) at a mutually agreed upon date is mandatory; the vendor is to supply a follow-up on-site in-servicing as described in B.3.1 and B.3.2 at a time mutually agreeable to the vendor and the Health Centre within a two year period following the go live date.	**Mandatory**		
B.3.5	Describe all on-going training & education opportunities provided.	**Required Response**		
B.3.6	Each vendor shall include and specify all available training material. Preference will be given to vendors that are able to supply interactive multi-media training application programs. (E.g. Video, telecommunication presentations, multimedia).	**Required Response**		

B.3.7	Application/in-service training for all subsequent hardware and/or software upgrades or updates installed on the system will be supplied at the time of the update installation at no additional charge to the Health Centre.	**Mandatory**		
B.3.8	The IWK Health Centre's Biomedical/Clinical Engineering, outside the warranty period, provides the majority of in-house service on electro medical equipment. This is to be supported by the successful proponent.	**Mandatory**		
B.3.9	Separate factory-level technical service training for staff members from Biomedical Engineering shall be included as an option, priced per person; including all travel costs. The IWK's training shall be comparable to the regular technical training provided to the manufacturer's own technical support staff. (Note: A course agenda is to be included in the bid, showing equivalency to the regular technical training provided to the manufacturer's own technical staff.)	**Mandatory**		
B.3.10	A 50% discount from published rates will apply for any additional training within 2 years of installation.	**Mandatory**		
B.3.11	All training is to outline safe practises for handling, cleaning, & reprocessing of equipment, particularly with a view to potentially contaminated equipment.	**Mandatory**		
B.4.	**Maintenance & Support:**			

B.4.1	Schedules for projected end-of-production (EOP) & end-of-support (EOS) life are to be provided for all quoted equipment. EOS life is to be greater than or equal to seven (7) years from date of purchase. => N.B. Equipment purchased that has an EOS date within less than seven (7) years will be subject to remedial action if this EOS date is excluded or incorrect in the response to this tender.	**Mandatory**		
B.4.2	Vendors are to provide ready access to knowledgeable staff for problem solving support during IWK's normal business hours. Vendors are to detail any & all charges associated with service support consultation, including both service representative visits & phone consultations for in-house staff.	**Mandatory**		
B.4.3	Vendors are to include upon **product shipment** two (2) user's manuals plus one (1) service manual or like documentation per installation site. Electronic copies of the manuals are to be provided with the bid for analysis. The manuals collectively should contain at least the following:	**Mandatory**		
B.4.4	Detail any & all specialized maintenance equipment (test equipment, adapters, proprietary tools) required to fully maintain the equipment throughout its estimated life cycle. This same detail (along with the associated pricing or annual license fees) is also to be included in the Price Proposal.	**Required Response**		
B.4.5	Validated cleaning & sterilization instructions;	**Required Response**		
B.4.6	Technical specifications;	**Required Response**		
B.4.7	Circuit documentation & theory of operation;	**Required Response**		
B.4.8	Calibration & preventive maintenance procedures;	**Required Response**		
B.4.9	Trouble-shooting guides and error codes	**Required Response**		
B.4.10	Proprietary Tools equipment (Test Circuits/Jigs, Extender Boards, calibration devices, test equipment)	**Required Response**		
B.4.11	Diagnostic & service software	**Required Response**		
B.4.12	passwords/access codes	**Required Response**		
B.4.13	schematics & diagrams	**Required Response**		

B.4.14	Special maintenance equipment requirements;	**Required Response**		
B.4.15	Proprietary tools, diagnostic/service software, test circuits, access codes/passwords required to fully service/support the equipment must be provided upon product shipment and, if necessary, included as an option in the pricing proposal.	**Mandatory**		
B.4.16	The proponent agrees that the Proprietary tools, service manuals, diagnostic/service software, test circuits, access codes/passwords provided with Biomedical/Clinical Engineering Factory Service Training may be shared with other employees of the IWK Health Centre.	**Mandatory**		
B.4.17	The vendor, free of charge, is to supply regular updates/service bulletins throughout the equipment's lifecycle detailing any changes to the service manual as detailed in B.4.3	**Mandatory**		
B.4.18	Vendors are to include upon product shipment a minimum of two license copies of all service support software tools as required to provide Biomedical Engineering Service & Support. The software tools should be comparable to the software tools available to the vendor's service	**Mandatory**		
B.4.19	The vendor shall provide service contract pricing options within the pricing proposal. The service contract pricing should include PM Only, full PM/Repair, and shared service options (Biomedical Dept. Front Line) for 1, 3, and 5 years.	**Mandatory**		
B.4.20	Bidders are to specify where sales & service support originate. Bidders are to have readily accessible sales & technical support. Bidders are to describe their various sales & service mechanisms, including but not limited to:	**Mandatory**		
B.4.21	Current contact names together with role definition, phone / e-mail, etc. (organization charts would be helpful, in addition);	**Required Response**		
B.4.22	Maximum & typical response & delivery time periods, else negotiated penalty; => Minimum phone response within 60 minutes	**Mandatory**		Actual guaranteed phone response time: _____ mins

B.4.23	Typical parts sources & ph factory service support (e.g. parts & factory service support depots).	**Required Response**		
B.4.24	sales & applications support personnel source	**Required Response**		Actual guaranteed phone response time: _____ mins
B.4.25	service support personnel source	**Required Response**		Location of service support personnel: _____
B.4.26	Indicate who will be responsible for shipping costs for repairs. Clarify if specialized shipping containers are required.	**Required Response**		
B.5	**Supply, Delivery, & Installation:**			
B.5.1	Vendors must describe the various initial supply schedule data, including expected date of delivery & any terms of the quote. Please reference	**Required Response**		
B.5.2	This is a "supply & install" acquisition. Bidders must furnish the equipment & associated consumables, etc. Bidders are also required to perform all installation, set-up, calibration, & testing required for the equipment to be used, except where indicated.	**Required Response**		
B.5.3	The successful Bidder must install & configure all system equipment & software.	**Required Response**		
B.5.4	All building system requirements are to be relayed in the Technical Proposal for consideration. Unless otherwise specified &/or negotiated, IWK Health Centre or its agents will perform all building systems renovations & upgrades.	**Required Response**		

B.5.5	Vendor must supply a list of disposables, including cost, average cost/treatment, and pricing options.	**Required Response**		
B.6	**History & Upgrades:**			
B.6.1	Vendors must supply product history for IWK's assessment, including a detail of all recalls over the previous five (5) years as well as any & all litigation associated with the proffered products(s) – both completed & incomplete. N.B. The IWK reserves the right to disqualify - at its sole discretion - any bids for which it deems have unsatisfactory recall issues and/or resolution.	**Required Response**		
B.6.2	Vendors must provide references & current install-base details for proffered products for IWK's assessment. Please include both clinical & technical references. Vendors are requested to comment on this listing to show how their products have proven their worth prior to this current application. (Vendors are to include past or present IWK users of their products on their reference lists.)	**Required Response**		
B.6.3	The Vendor must provide a Minimum of 2 Pediatric References using this equipment in an intensive care setting. (Canadian Preferred)	**Required Response**		
N.B.>	With regards to B.6.2 and B.6.3; The IWK reserves the right to disqualify - at its sole discretion - any bids for which it cannot obtain satisfactory references.	**Mandatory**		
B.6.4	Future development upgrade paths for obsolescence protection for the various system components are to be detailed, if known.	**Mandatory**		
B.7	**Technology Upgrades:**			
B.7.1	Further to clause B.4.1, if the vendor changes manufacturing/support status of the proffered model(s) and introduces a replacement model that would also meet the clinical requirements described in this RFP after a purchase order has been placed but before installation, the vendor will offer IWK the option of supplying the newer model at no additional cost.	**Mandatory**		

8 SOFTWARE (IF APPLICABLE)

> 🕮 **All software options and fees are to be priced out separately and included in pricing section.**

8.1 The vendor will list ALL software components available on the SPECT/CT GAMMA CAMERA with separate pricing indicated in the pricing section of the proposal.

8.2 The vendor must clearly outline any licensing fees, associated with software support, upgrades and the frequency of payment for these.

8.3 These licensing fees are to include any necessary fees associated with servicing software, networking archival support etc.

> 🕮 **NOTE: New regulations are required for Medical Device licensing of "Patient Management Software"; See the section on Medical Device Regulations.**

9 START UP OF SYSTEM

9.1 The successful vendor will be responsible for costs related to start up and testing of the system including, but not limited to …

(a) Manuals, Support
(b) Performance Assurance & Associated Supplies/Disposables
(c) CSA Field Inspections

10 ACCESSORIES

10.1 The vendor shall provide the description and cost of any relevant disposables and accessories required and/or available.

10.2 Provide information on other options, configurations and features available, including pricing in the pricing section of the proposal.

10.3 Specification or data sheets for all equipment components are to be provided, including weights and dimensions of all components, environmental tolerances, and power and utility requirements.

11 DELIVERY & INSTALLATION

11.1 The vendor shall confirm that they are in agreement with the equipment delivery date and the timeline set in the Acquisition Schedule outlined earlier in this document.

11.2 If this cannot be achieved, please clearly state the delivery, installation and training times required for the proposed equipment/system.

12 STANDARDS

This installation and the equipment proposed must meet the following standards. The current edition of the CSA standard, "Canadian Electrical Code C22.1". The equipment shall be CSA approved meeting all the requirements set forth in the following CSA Medical standards: CAN/CSA-C22.2 No.601.1, Medical Electrical Equipment Part 1: General Requirements for Safety respecting latest revisions, interpretations, amendments, supplements, & applicable collaterals.

12.1 This equipment/system shall be in compliance with CSA Standard, CAN/CSA C22.2 No. 601.1.2 Medical Electrical Equipment, Part 2: Collateral Standard: Electromagnetic Compatibility Requirements and Tests. The vendor MUST provide to Biomedical, a copy of documented proof of testing and its results, if requested.

12.2 The system and all its components MUST be labelled as CSA approved to the medical standards referenced above.

12.3 Any system/equipment proposed, that is not approved to the medical standards indicated above, and not properly labelled as such, will not be accepted until such time that this is performed and reviewed to the satisfaction of the Biomedical Engineering Department.

12.4 Any system/equipment that requires special acceptance testing to be certified to CSA standards must have had this carried out, prior to shipment to the Health Centre, by an agency that has been accredited with the Standards Council of Canada. Copies of any inspection reports, for this special inspection, MUST be submitted to Biomedical Engineering at the time of delivery.

12.5 Vendors must comply with CSA Z317.13-12 Infection control during construction, renovation, and maintenance of healthcare facilities.

12.6 The vendor must provide proof of certification to the above standards.

13 DATE & TIME

13.1 The equipment/system must be capable of properly recognizing any future date transitions and time and capable of performing correct date calculations.

13.2 The equipment/system shall be able to handle dates for a period of not less than fifty years after purchase.

13.3 If there are any limitations to the date recognition, these must be clearly identified and submitted with this proposal.

14 MEDICAL DEVICE REGULATIONS

14.1 Medical Devices

Any system/equipment sold in Canada, must now meet the Medical Device Regulations, as set forth by the Health Protection Branch at Health Canada.

14.1.1 The manufacturer **must** meet one or all of the following conditions, providing license numbers where requested.

14.1.2 In accordance with these regulations, if the equipment being proposed is classified as Class I, as defined by these regulations, then the vendor **must** include their current Establishment License with this proposal.

14.1.3 In accordance with these regulations, if the equipment being proposed is classifieds Class II, III or IV, as defined by these regulations, then the vendor **must** include the current Device License, for each piece of equipment indicated in this system.

14.1.4 Copies of the licenses **for the current year must be included** in this proposal. Any proposals that **DO NOT** meet these requirements will not be accepted.

14.2 Patient Management Software

On August 31, 2009, the Medical Devices Bureau of Health Canada sent out notices to manufacturers, importers and distributors of medical devices software that patient management software is classified as a medical device and is subject to compulsory licensing under the Food and Drugs Act and Medical Devices Regulation. Patient management software can fall into one of two classes.

They are defined as …

Class I … Any patient management software used only for archiving or viewing information or images, and not involved in the primary acquisition, manipulation and transfer of data is considered a Class 1 medical device. Although Class I medical devices do not require a license, any manufacturer, distributor or importer must have an Establishment License.

Class II … Patient management software involved in data manipulation, data analysis, data editing, image generation, recording of measurements, graphing, flagging of results or performing calculations is considered a Class II medical device and must have it's own license.

📖 Companies in doubt as to whether their software is a Class I or Class II device can contact Health Canada's Medical Devices Bureau for a ruling. To initiate an action for a ruling, send an email containing a basic description of your company and the software in question (very brief) together with contact information for someone in your company who can discuss the application with Health Canada. The email can be sent to: DEVICE_LICENSING@hc-sc.gc.ca. Health Canada will contact you to discuss the process and any additional information required. More information can be found on the Health Canada website.

14.2.1 The vendor will identify which patient management software packages offered, fall under the definition of Class I, as defined above. For those devices, the vendor will provide their establishment licence no.

14.2.2 The vendor will identify which patient management software packages offered, fall under the definition of Class II, as defined above. For those devices, the vendor will provide the medical device licence nos. for each.

14.2.3 Copies of the licenses **for the current year** shall **be included** with this proposal.

15 *PATIENT PRIVACY & INFORMATION SECURITY (IF APPLICABLE)*

📖 It is essential that the Health Centre ensure that the privacy aspects and protection of information have been properly addressed as it relates to the following provincial and federal "ACTS". The vendor shall indicate compliance to the following…

15.1 Provincial Legislation

15.1.1 **Hospitals Act …** is an Act relating to Hospitals and in particular Section 71(1) of the *Hospitals Act* provides that the hospital records and particulars of patients are confidential and shall not be made available to any person or agency except with the consent or authorization of the patient concerned. Section 71 of the *Hospitals Act* prevails over the disclosure provisions of the *FOIPOP Act*, such that the availability of patient records and particulars falls under the *Hospitals Act* and not under the *FOIPOP Act*.

15.1.2 The **Personal Health Information Act (PHIA) …** is an Act respecting the collection, use, disclosure and retention of personal health information. The purpose of this Act is to govern the collection, use, disclosure, retention, disposal and destruction of personal health information in a manner that recognizes both the right of individuals to protect their personal health information and the need of custodians to collect, use and disclose personal health information to provide, support and manage health care.

15.1.3 PIIDPA … Nova Scotia's Personal Information International Disclosure Protection Act was created to protect the personal information of Nova Scotians from being disclosed outside Canada. PIIDPA affects Nova Scotian public bodies and public body service providers.

15.1.4 FOIPOP … Freedom of Information and Protection of Privacy Act. An act respecting the right of access to documents of public bodies in Nova Scotia and a right of privacy with respect to personal information held by public bodies in Nova Scotia.

15.2 Federal Legislation

15.2.1 PIPEDA ... Personal Information Protection and Electronic Documents Act. An act to support and promote electronic commerce by protecting personal information that is collected, used or disclosed in certain circumstances, by providing for the use of electronic means to communicate or record information or transactions and by amending the Canada Evidence Act, the Statutory Instruments Act and the Statute Revision Act

15.3 **Patient Information Impact Assessment**

15.3.1 MDS^2… Manufacturer Disclosure Statement for Medical Device Security. The vendor must provide with this proposal, a "Patient Information Impact Assessment" for possible privacy-related consequences of equipment and/or system that use or disclose personal patient information or data including "electronic Protected Health Information" (ePHI).

The Manufacturer Disclosure Statement for Medical Device Security (MDS^2)provides manufacturer's model-specific description of the following …

- ***The equipment or system's ability to maintain and/or transmit ePHI.***
- ***The security features & safeguards associated with the equipment or system***

15.3.2 The vendor shall submit a fully completed MDS^2 form for the equipment or system being proposed in this RFP. The *pdf file is available at the following web address; ***http://www.himss.org/content/files/MDS2FormInstructions.pdf***)

15.3.3 See Appendix 2 for a "sample" of the MDS^2 form.

15.3.4 **Privacy Impact Assessment** … Please note the IWK Health Centre requires that a Privacy Impact Assessment (PIA) be completed by the vendor of choice prior to the signing of a purchase agreement.

15.3.5 Vendor Confidentiality Agreement

15.3.6 The vendor will be required to sign a Vendor Confidentiality Agreement for servicing. See **Appendix 3** for a "sample" of the Form

16 SOFTWARE

16.1 Include the vendor's/manufacturer's policy on notification of hardware and software

16.2 Updates on this equipment/system through its life expectancy during both warranty and after warranty.

17 IT SERVICES -TECHNICAL STANDARDS

The following tables and notes outline the IWK Health Centre technical standards for vendors who are supplying software and/or hardware as part of their proposal. **Please indicate your compliance** in the appropriate column of the tables and **written responses to the associated notes** in the space provided. Attach additional supporting technical specifications and documentation to your response.

Communications

Protocol	Version	Mandatory/Preferred	Comply
TCP/IP	Version 4	Mandatory	

Wireless Communications

Protocol	🕮	Mandatory/Preferred	Comply
802.11 (A, B, G, N)	See Note 3	Mandatory	

Interoperability Standards & Protocols

Protocol	Version	Mandatory/Preferred	Comply
HL7	2.X	Mandatory	
HL7	3.0	Supported	
CCOW	1.5	Preferred	

Operating System & Hardware

Platform	Operating System	Make	🕮	Mandatory/Preferred	Comply
Intel Server	Windows 2003/2008	Dell/Hp	See Notes 1 & 2	Preferred	
Desktop	Windows 7	Dell	See Notes 1 & 2	Preferred	

Application Database

Platform	Database	🕮	Mandatory/Preferred	Comply
Intel	SQL 2005		Preferred	

Storage Requirements

Component	🕮	Mandatory Preferred	Comply
Storage Estimates	Provide expected storage needs for this system. Include requirements for first year as well as expected increases over the next 5 years.	Mandatory	
Storage Technologies	Identify the type and capacity of storage provided with your system,	Mandatory	
Archiving Capabilities	Identify any Data Archiving techniques that are provided with your system. And or can be applied to your system.	Preferred	

Security Standards

(Confidentiality Integrity Availability)

Component	Consideration	🕮	Mandatory Preferred Comply	Comply
Confidentiality	Authentication Model	Identify the Authentication Model that your product leverages. List also the password change polices that can be applied and any lockout setting that are relevant to your solution	Mandatory	
		The IWK Leverages Microsoft Active Directory as our Primary directory service. It is preferred that all new applications are directly tied into Active Directory to	Preferred	

		simplify account management and ensure that password policies are consistent across all systems.		
	Infrastructure Locations	What safeguards are in place on your servers and workstations to prevent data loss caused by lost or stolen equipment? Items could include encryption of data as well as the recommendation to store equipment in physical secure locations.	Mandatory	
		To ensure the security of the data that your servers are collecting the IWK would like to locate servers in the IWK Data Centre ensures they are physically secure, under UPS power and in an air conditioned environment.	Preferred	
		Note Storing of the server infrastructure in IWK Data Centre may require your system to function using Layer 3 connectivity. Identify if having your workstation and servers on different subnets introduces concerns with the functionality of your solution	Preferred	
Integrity	Auditing	Identify the full auditing capabilities of the system	Mandatory	
		Auditing of Patient information should have the ability to identify the following as a minimum but more details are preferred. • Data and Time of access • Patient Identifier • Staff member that accessed the information	Mandatory	
	Data Integrity	Identify how your system deals with changes/corrections to data. If a change is made after the fact does your solution allow an audit to identify the original information recorded? If your system does not inherently achieve this what techniques can be used in conjunction with your system to ensure Data Integrity? This may be in the form of Data Archiving Technology that can be leveraged.	Mandatory	
Availability	Disaster Recovery	Please identify your Disaster Recovery processes to ensure that in the event of a failure we understand the timeline of unavailability of the solution. These processes need to cover the rebuilding and or restoration of Operating System, Applications and all collected Data back to the last backup completed. What is the extent of potential data loss?	Mandatory	
		The IWK leverages EMC Networker Backup products to provide local and offsite backups of systems on our network.	Preferred	
	Redundancy	Identify redundancy options with your system that can mitigate both hardware and software faults. They can include items like redundant power supplies and hard drives as well as hot standby or active failover components that may be available with your solution	Preferred	

Application Support and Deployment

Component	🕮	Mandatory Preferred	Comply
Hardware	Provide Minimum/Preferred system requirements for each type of server and workstation component.	Mandatory	
	Do Workstation/Server components have to be purchased from your company or can the IWK leverage our existing Workstation and Server Vendors?	Preferred	
Software	Provide details surrounding Server and Workstation software installation processes	Mandatory	
	Will the Software function with only "User" rights on the Workstations	Preferred	
	Is the software Windows XP and Windows 7 compliant	Preferred	
	What Antivirus products are approved for your network attached workstations and servers?	Mandatory	

	IWK Currently leverages Symantec Endpoint 12. Is this a supported product on servers and workstations?	Preferred	
Installation	Will the IWK be able to leverage Microsoft System Centre to Deploy software to workstations?	Preferred	
	Is your software professionally packaged in MSI files that support fully automated deployments? If not does the executable have switches for silent installs and right assignments	Preferred	
	It is the IWK's preference to have Windows Based devices integrated into our Active Directory/ Is this a supported configuration?	Preferred	

🕮 NOTES

Note 1:

Access to the IWK corporate network will be granted to equipment configured to be a member of the IWK Active Directory Domain. Devices will run the Health Centre's central Anti Virus solution and be managed using Microsoft System Centre.

Vendor Response to Note 1

Note 2:

Currently IWK Health Centre is delivering Microsoft updates via an internal update server. Vendors must outline the process for applying Microsoft patches and critical updates to the hardware they provide. **Also include a list of all certified patches and critical updates** that your application is currently certified for. Any limitations on IWK Health Centre IT Services applying Microsoft patches and critical updates to any relevant client PCs must also be outlined. Absence of this information may disqualify your response from further consideration.

Vendor Response to Note 2

The vendor should provide details of any wireless communications capability including security and privacy compliance and performance guarantees. Access to the IWK Corporate wireless network must be using WPA2 with AES encryption.

Note 3:

Vendor Response to Note 3

18 TRAINING

18.1 On-site training must be provided for all applicable personnel (mandatory). On-site in-servicing must be supplied for all affected clinical, Biomedical Engineering, & SPD staff members. In-servicing shall be scheduled at a time mutually agreeable to the IWK & the successful vendor before commencement of the evaluation period. The IWK reserves the right to waive training on equipment with which it is already familiar. Any & all associated costs are to be detailed in the Cost Proposal.

18.2 The provision of clinical training prior to and immediately following installation is mandatory. Specify and list all the clinical in servicing provided in the cost proposal for clinical staff.

18.3 The vendor must provide a detailed clinical implementation and training plan for items 19.1 and 19.2.

18.4 Two (2) follow up on-site training at a mutually agreed upon date is mandatory; the vendor is to supply a follow-up on-site in-servicing as described in 19.1 and 19.2 at a time mutually agreeable to the vendor and the Health Centre within a two year period following the go live date.

18.5 Describe all on-going training & education opportunities provided.

18.6 Each vendor shall include and specify all available training material. Preference will be given to vendors that are able to supply interactive multi-media training application programs. (E.g. Video, telecommunication presentations, multimedia).

18.7 A 50% discount from published rates will apply for any additional training within 2 years of installation

18.8 Application/in-service training for all subsequent hardware and/or software upgrades or updates installed on the system will be supplied at the time of the update installation at no additional charge to the Health Centre.

18.9 All training is to outline safe practises for handling, cleaning, & reprocessing of equipment, particularly with a view to potentially contaminated equipment.

19 TECHNICAL SERVICE TRAINING & TOOLS

19.1 The IWK Health Centre's Biomedical/Clinical Engineering, outside the warranty period, provides the majority of in-house service on electro medical equipment. This is to be supported by the successful proponent.

19.2 Separate factory-level technical service training for (two) staff members from Biomedical Engineering shall be included as an option, priced per person; including all travel costs. The IWK's training shall be comparable to the regular technical training provided to the manufacturer's own technical support staff.

19.2.1 The vendor shall include details on the following.

- Program length and format
- Course location
- Course content
- Qualifications of instructors
- Written materials provided
- Tuition fee
- Flight, accommodation, meals, & ground transportation
- Service tools, documentation, etc. that may be provided with tuition

19.3 Detail any & all specialized maintenance equipment (test equipment, adapters, proprietary tools) required to fully maintain the equipment throughout its estimated life cycle. This same detail (along with the associated pricing or annual license fees) is also to be included in the Price Proposal. (E.g. tools, test circuits/jigs, extender boards, diagnostic & service software, access codes, test equipment, calibration devices, all printed material (schematics, error codes, diagrams). Any costs for these, including annual license fees shall be included.

19.4 Proprietary tools, service manuals, diagnostic/service software, test circuits, access codes/passwords required to fully service/support the equipment must be provided upon product shipment and, if necessary, included as an option in the pricing proposal.

19.5 The proponent agrees that the Proprietary tools, service manuals, diagnostic/service software, test circuits, access codes/passwords provided with Biomedical/Clinical Engineering Factory Service Training may be shared with other employees of the IWK Health Centre.

19.6 IT Training and Education (if applicable). The vendor must provide technical training for IT personnel if required

20 SITE REQUIREMENTS & LAYOUT

20.1 Vendor must provide a complete and detailed description of the requirements for the proposed equipment/system that may include, but not be limited to:

- Shielding
- Electrical
- Mechanical (HVAC and plumbing)
- Medical gases
- Structural and access requirements.
- A complete description of environmental conditions required
- Ceiling, wall, and floor loading
- Any special utility and electrical power system needs.

21 ACCEPTANCE TESTING

21.1 The proposed system shall be subject to and must pass acceptance testing, performed by the IWK Health Centre. The system will be tested for compliance with applicable CSA medical standards for electrical safety and manufacturers specifications

21.2 The system shall be subject to and must pass acceptance testing, performed by IT personnel if applicable.

21.3 Before going live, the system shall successfully demonstrate its backup and recovery procedure to resume operation after a disaster. As bound by the provincial guidelines for Nova Scotia, and Health Canada, devices will be checked that they meet the device license and/or establishment license requirements as defined and set forth in the Medical Devices regulations stated earlier. Any proposals for equipment that do not meet the requirements of these new Medical Devices Regulations or CSA medical standards, **will not be considered in the tendering process**.

21.4 In addition, if applicable the physicians from each department have to accept that all the features in the system are fully functioning to their satisfaction.

22 DOCUMENTATION

📖 Manuals **DO NOT** have to be included in this RFP submission, but **must be included if** the Health Centre requests **an evaluation**.

📖 When the system(s) is purchased, the following documentation must be included …

22.1 **One (1) hard copy** and **one CD/DVD copy** of the **service manual** for each system & all major components proposed. The service manual must contain but not limited to:

- Mechanical & electronic schematics
- Electronic component layouts
- Mechanical component breakdown
- Complete electronic, electrical & mechanical parts list
- Circuit descriptions & theory of operation
- Calibration/PM procedures & schedules
- Troubleshooting procedures
- Equipment specifications
- Installation requirements/manuals
- System wiring diagrams
- Error code listing, w/descriptions/problems & how to access these
- Codes/Passwords to access all service and configuration menus and functions
- Note: Service manual should be the same service manual as delivered to field service technicians. Service manuals should also contain an updated list of service bulletins, service manual updates, and PM procedures

22.2 Operators Manuals

The following departments must receive a hard copy of the operator's manual(s) for each system purchased except where noted …

22.2.1 Biomedical Engineering …
22.2.2 Require a hard copy for each of the systems proposed
22.2.3 Require a CD/DVD copy for each of the systems proposed
22.2.4 Information Technology (IT) … Require any documentation that relates to networking, interfacing, software packages, etc.

23 SERVICE CAPABILITIES

23.1 The vendor shall provide a description of local and regional factory-based service capabilities, including the following:

- The number and qualifications of service engineers
- Their training
- Their base locations
- The locations of backup service engineers
- The location of primary and backup spare parts locations
- The time for delivery of parts after notification

23.2 The vendor shall indicate the company's response times are to the following …

Response to service calls placed
Service rep. on-site response

24 PROBLEM NOTIFICATIONS

24.1 The following will be provided for the life of the system…

24.1.1 Immediate notification of any alerts affecting any part of the system.
24.1.2 Notification of manufacturer's technical service bulletins
24.1.3 Immediate notification of any software or hardware threats (viruses, worms, etc.) for any other threats to any computer- based equipment/software that may be used.

24.2 These notifications will automatically be sent directly to Biomedical by a means agreeable to both parties.

24.3 The manufacturer shall arrange for free access to the manufacturer's web site for downloading of any applicable updates, software patches, corrections, etc. that are required in maintaining a reliable, effective and safe working system.

24.4 All problem notification shall be provided at no additional cost to the Health Centre.

24.5 If the Health Centre should agree to purchase the equipment being proposed, then, as a condition of sale, the VENDOR must comply, agree and sign the Notification Agreement as shown in **Appendix 4**.

25 SERVICE CONTRACTS

25.1 The pricing section shall include vendor proposed service agreements for a One (1), Three, (3), and five (5) year periods. Include all agreement terms, conditions and fees, minimum and maximum remedial maintenance response time, credit to the BUYER if the selected vendor fails to meet guaranteed response time, availability of trained technicians and parts, system hardware enhancements and upgrades, software maintenance, engineering support, software license, and any other factors that should be considered by the BUYER in evaluating the vendor's proposal. The price for each yearly period shall be clearly indicated and binding.

25.1.1 Full-service package (24 hours/7 days)
25.1.2 Full-service package (8:00am to 5:00pm/5 days)
25.1.3 First-screen/shared service package (Biomedical)
25.1.4 Preventative Maintenance package
25.1.5 Time and Materials service

26 WARRANTY

26.1 The vendor shall provide a description of warranty contracts including your standard warranty and any special extended warranties offered. Provide a description of proposed warranty terms including any partial (less than one year), or extended warranties.

26.2 It should be understood that the warranty period shall not begin until all proposed system(s) are approved by the Health Centre's Biomedical Engineering, IT, as well as the respective physicians of each department receiving a system or after the first clinical application.

27 CONSUMABLE PRODUCTS

27.1 The vendor shall identify all consumable items used with this equipment (e.g. Filters, etc.) and provide guaranteed prices for these items for a period of five (5) years after acceptance of the systems by the BUYER.

27.2 Prices for consumable items shall be subject to negotiation with BUYER before contract award under this RFP.

27.3 Indicate whether supplies, that are to be used with this equipment, are to be purchased only from the manufacturer or from other companies as well (**specify**).

28 EVALUATION

28.1 The BUYER may select and inviting vendors to do presentations, demonstrations, evaluations and/or clinical on-site trials. It shall be understood that this decision will be made based upon, but not limited to the following … price; conformance to equipment requirements and terms & conditions; conformance to biomedical & information technology requirements, equipment features, specifications, vendor experience; the experience of other users with the equipment and vendors; delivery & installation schedule; warranty terms; service capabilities; user training and support services; operating costs and overall responsiveness to this RFP. The BUYER reserves the right to make their decision, independent of any or all of the above factors.

28.2 If an on-site clinical evaluation of the equipment is not possible, the vendor shall include arrangements for site visits by Health Centre representatives which will include …

- Three (3) reps from the applicable department
- One (1) Biomedical Engineering rep

28.3 The vendor will indicate the reference sites that will be included in these site visits.

29 REFERENCES

29.1 IWK may make such investigation as it deems necessary to determine the ability of any Proponent to provide products and services and may utilize the results of such investigation in awarding the Contract

29.1.1 A list of references (Canadian References preferred) from similar institutions that are presently using the equipment proposed, complete with the name and telephone numbers of the contacts for the following, must be included with this proposal …If proposed equipment is a different configuration specify the difference

29.1.2 Clinical User
29.1.3 In-house service representative
29.1.4 IT contacts (if applicable)

30 PROPOSAL COST

30.1 Proposals are to be F.O.B. Hospital

30.2 Pricing quoted is to be in Canadian funds.

31 TERMS OF PAYMENT

31.1 Include the proposed equipment payment terms, including any cancellation fees and any alternatives that result in a cost saving to the BUYER.

31.2 Include a proposed method for determining price changes (if any) if a delivery date longer than one (1) year from the proposed delivery date is requested by BUYER.

32 SUBSTITUTION

32.1 The vendor shall include a proposed method that allows the BUYER to substitute, at its discretion, new equipment introduced by the vendor after the award, but before delivery, that more suitably meets BUYER's clinical requirements. Specifically address potential cost differences. The vendor shall make no substitutions without agreement by BUYER.

33 PROPOSAL COPIES

33.1 Please include (3) complete copies of this proposal for the following:

- Biomedical Engineering
- Diagnostic Imaging
- Purchasing

Please include at least 1 electronic copy of this proposal on CD / DVD or USB Drive

APPENDIX 1 - IWK GENERAL TERMS & CONDITIONS – UPDATED (MAY 31/12)

1. The IWK acknowledges that any information submitted in confidence by a vendor, if disclosed to third parties, could reasonably be expected to cause financial harm or harm the competitive position of the vendor. Any information contained in a proposal that is considered confidential by the vendor must therefore be clearly identified as confidential. The IWK and its representatives shall, to the extent permitted by law**, respect the confidential nature of any information so identified. ***Please note that as a public body, IWK is subject to the Freedom of Information and Protection of Privacy Act, and may be required to release information relating to this RFP and/or the resultant contract. IWK would endeavor to consult the affected proponent(s) to the extent permitted by law.*

2. The vendor agrees that it shall not seek information regarding this purchase or any proposals or decisions relating to this purchase by application under the Freedom of Information and Protection of Privacy Act (Nova Scotia). The vendor acknowledges that all information and records relating to this procurement process may be released to the vendor only at the discretion of the IWK and subject to the procurement process, applicable law and confidentiality concerns.

3. IWK reserves the right to
   a. cancel the process at any stage;
   b. cancel the process at any stage and issue a new RFP for the same or similar deliverables;
   c. reject any or all proposals; and
   d. reject any and all proposals submitted and to negotiate with the compliant proposal offering the "best value" in any manner necessary, to serve the best interests of IWK.

   Neither the responsive proposal that scores the highest number of rated points nor the one that contains the lowest price will necessarily be accepted or considered the best value proposal.

4. The IWK will not pay for the information solicited by any RFP. All costs incurred by a vendor in the preparation of a proposal are the responsibility of the vendor. The IWK makes no representation or assurance regarding

the outcome of proposals, and specifically reserves the right to terminate the tendering process without consequence or liability.

5. All bid materials will become the property of the IWK, unless otherwise specified by the vendor.

6. The vendor represents and warrants that none of the bid materials infringe any intellectual property rights of third parties.

7. The IWK reserves the right to provide clarification on existing requirements contained in any RFP. Should additional requirements be identified, they will be submitted to all vendors in writing as an addendum to this document.

8. References identified in the proposal may be contacted by the IWK to substantiate the proposal's solutions capabilities and reliability, as well as proponent performance, and overall service. Proponents are expected to cooperate fully in helping IWK to verify Proponent claims.

9. The successful Proponent will be required to execute a contract in the IWK standard form. The Proponent's proposal shall be attached as a schedule and incorporated by reference into this standard form agreement to the extent applicable.

10. All proposed services/equipment/goods/furniture (as applicable) must comply with all relevant laws, codes and standards, and where appropriate be approved to applicable standards, e.g. CSA standards.

11. All vendors and any subcontractors performing work at the IWK must be registered in the Province of Nova Scotia under the Corporations Registration Act or the Partnerships and Business Names Registration Act.

12. All prices / costs are to be quoted in Canadian dollars and exclusive of any taxes. Items such as delivery, set-up fees, in-servicing, taxes, etc are to be shown as separate line items.

13. The IWK qualifies for government and educational discounts from various vendors. All applicable discounts are to be identified in the price section.

14. It is a condition precedent to the IWK's acceptance of any tender that the vendor confirms that they have no outstanding or pending litigation, action, claim, demand, or cause of action against the IWK which in any way relates to the subject matter of the RFP or which relates to the supply of goods and services to the IWK.

15. A vendor's proposal must be signed by an authorized signing officer of, or authorized person for, the vendor, certifying that all information contained in the proposal is accurate and agreeing to comply with all of the terms, conditions, and provisions of the RFP.

16. All Proponents must provide full-disclosure of any and all funding of "in-kind" programs that have been provided to IWK. Furthermore all Proponents must disclose the name(s) of and person(s) employed at IWK who is under contract, or represents the Proponent in any capacity which may be viewed as a conflict of interest

17. Vendors must clearly identify any Third Party software or hardware components, if applicable, including optional vendor modules that are not included as part of the vendor's pricing response.

18. Provincial Initiative: It is understood that any agreement and/or purchase that results from this tender are available to all Nova Scotia District Health Authorities (DHAs 1 through 9) for a twelve (12) period following the contract award, at their discretion. While the exact resultant configuration may not be appropriate for any given DHA, it is expected that the vendor will afford the same pricing and/or discount structure to all districts. Each district will be responsible for issuing their own P.O.

19. The IWK encourages the use of electronic commerce for business transactions; therefore, vendors are requested to include a description of their capabilities and experience with electronic commerce. Vendors should also include any discount structure they offer with this.

20. Vendors submitting bids involving the collection, use, or disclosure of personal information are required to certify that the vendor's business is fully compliant with the Personal Information Protection and Electronic Documents Act (Canada).

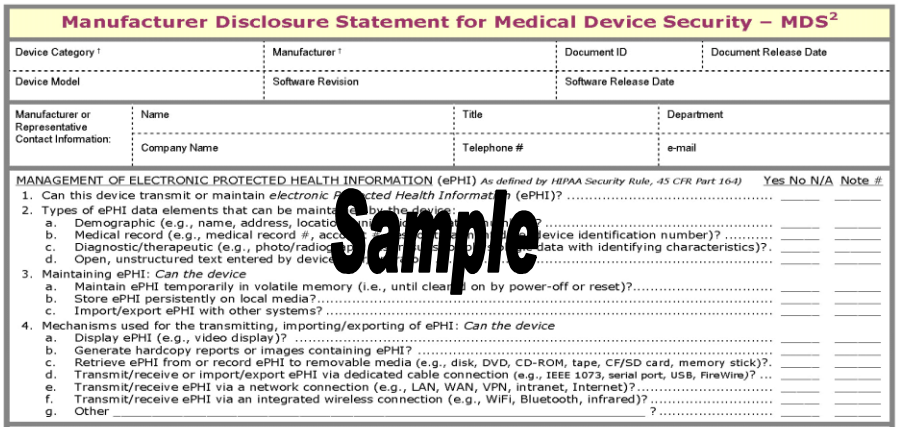
21. All prices are to be FOB destination (freight included) upon delivery to the IWK.

22. The vendor shall identify any component of their shipment that includes hazardous materials requiring the IWK to take any environmental or personnel precautions.

23. Proponents submitting proposals hereby certify that the Proponent's business is fully compliant with the *Personal Information Protection and Electronic Documents Act* (Canada), the Freedom of Information and Protection of Privacy Act and the Personal Information International Disclosure Act. Proponents submitting proposals hereby certify that all information necessary to allow the IWK to determine compliance with the *Personal Information International Disclosure Act* has been provided to the IWK.

24. All purchase orders, contracts, and tender documents (RFPs, RFQs, etc) and all items pertaining to them shall be governed and interpreted in accordance with the laws of the province of Nova Scotia.

APPENDIX 2 - MANUFACTURER DISCLOSURE STATEMENT FOR MEDICAL DEVICE SECURITY – MDS2



Manufacturer Disclosure Statement for Medical Device Security – MDS²

Device Category †	Manufacturer †	Document ID	Document Release Date
Device Model	Software Revision	Software Release Date	

Manufacturer or Representative Contact Information:	Name	Title	Department
	Company Name	Telephone #	e-mail

MANAGEMENT OF ELECTRONIC PROTECTED HEALTH INFORMATION (ePHI) *As defined by HIPAA Security Rule, 45 CFR Part 164)* Yes No N/A Note #

1. Can this device transmit or maintain *electronic Protected Health Information* (ePHI)? .....
2. Types of ePHI data elements that can be maintained [illegible]?
   a. Demographic (e.g., name, address, location [illegible]) .....
   b. Medical record (e.g., medical record #, acc[illegible] device identification number)? .....
   c. Diagnostic/therapeutic (e.g., photo/radio[illegible] data with identifying characteristics)? .....
   d. Open, unstructured text entered by devic[illegible] .....
3. Maintaining ePHI: *Can the device*
   a. Maintain ePHI temporarily in volatile memory (i.e., until cleared on by power-off or reset)? .....
   b. Store ePHI persistently on local media? .....
   c. Import/export ePHI with other systems? .....
4. Mechanisms used for the transmitting, importing/exporting of ePHI: *Can the device*
   a. Display ePHI (e.g., video display)? .....
   b. Generate hardcopy reports or images containing ePHI? .....
   c. Retrieve ePHI from or record ePHI to removable media (e.g., disk, DVD, CD-ROM, tape, CF/SD card, memory stick)? .....
   d. Transmit/receive or import/export ePHI via dedicated cable connection (e.g., IEEE 1073, serial port, USB, FireWire)? .....
   e. Transmit/receive ePHI via a network connection (e.g., LAN, WAN, VPN, intranet, Internet)? .....
   f. Transmit/receive ePHI via an integrated wireless connection (e.g., WiFi, Bluetooth, infrared)? .....
   g. Other _____ ? .....

APPENDIX 3 - VENDOR CONFIDENTIALITY AGREEMENT

IWK Health Centre
5850/5980 University Avenue
P.O. Box 9700
Halifax, Nova Scotia
B3K 6R8

{V E N D O R}
{V e n d o r a d d r e s s}

{VENDOR} acknowledges during the course of performing it's obligations hereunder, **{VENDOR}** and their employees, officers, directors or other Client approved personnel or independent contractors may become aware of/have access to information from Client that is not publicly known, including but not limited to; information relating to the identity, condition, history, care or treatment of Client's patients and Client personnel information or Client business information.

{VENDOR} agrees to ensure that all of **{VENDOR}** employees, officers, directors, or other Client approved personnel or independent contractors engaged by **{VENDOR}** who become aware of/have access to such information, shall treat all information as strictly confidential.

Such information shall not be disclosed to any non- **{VENDOR}** employees or representatives or entity without prior written approval of Client. The obligation of confidentiality in this paragraph shall apply regardless of whether the subject information was supplied to **{VENDOR}** or whether the information was learned by **{VENDOR}** inadvertently during the course of its performance, or otherwise. The obligation of confidentiality in this paragraph shall survive the termination of this agreement regardless of the method or timing of its termination.

{ VENDOR }	_____
Vendor	*Vendor Rep. Name (print)*
_____	_____
Vendor Rep. Name (Signature)	*Vendor Rep. Title (Print)*

_____
Date

APPENDIX 4 - USER NOTIFICATION OF HAZARDS/RECALLS/DEFECT NOTICES, COMPUTER & SOFTWARE VIRUSES/WORMS AND TECHNICAL SERVICE BULLETINS

USER NOTIFICATION OF HAZARDS/RECALLS/DEFECT NOTICES,
COMPUTER & SOFTWARE VIRUSES/WORMS and TECHNICAL SERVICE BULLETINS

IWK Health Centre
5850/5980 University Ave.
P.O. Box 9700
Halifax, Nova Scotia
Canada, B3k 6R8

{Vendor} shall automatically notify Biomedical Engineering, at the IWK Health Centre, of any product hazards, recalls, defect notices, software or hardware viruses/worms and any technical service bulletins issued that relate to any of the equipment quoted being manufactured and/or delivered to BUYER under the terms of this RFP. Any of these notifications shall be made to Biomedical Engineering Department within [five (5)] days of the earliest announcement in any nation by the manufacturer or device regulatory body. This agreement shall remain in effect for the life of the equipment and/or system. **{Vendor}** understands that failure to comply with this requirement may lead to a one (1) year BUYER ban on the purchase of all products from **{Vendor}**.

The undersigned hereby acknowledges that he/she and all representatives of his/her company will adhere to the above protocol.

Signature: _____

Name: _____

Title: _____

Date: _____