Saint Mary's University

WisdomX

Market Research – Project Phase I

April 28, 2023

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The following information was compiled on a best-efforts basis for WisdomX, based on available data and material as of April 2023. It is intended to be a high-level overview of the process of registering and selling a medical device in Canada and should be supplemented by a specialized consultant and legal parties as the company moves forward.

Medical Device Registration, and Classification

Medical devices in Canada are regulated by Health Canada's Medical Devices Bureau (MDB), which oversees the safety and effectiveness of medical devices sold in the country. Registration with the MDB requires the following steps:

1. Determine the classification of your medical device: Medical devices are classified into four categories based on the level of risk they pose to patients. The classification will determine the requirements and regulatory pathway for the device.
    - In Canada, medical devices are classified into four classes (Class I, II, III, and IV) based on the level of risk they pose to patients. The four classifications of medical devices in Canada are as follows:
        1. Class I: Low-risk medical devices, such as bandages, tongue depressors, and most medical software. These devices are subject to general safety and performance requirements and do not require a medical device license.
        2. Class II: Moderate-risk medical devices, such as contact lenses, ultrasound machines, and dental fillings. These devices require a medical device license and must meet additional safety and effectiveness requirements.
        3. Class III: High-risk medical devices, such as implantable pacemakers, heart valves, and some diagnostic imaging equipment. These devices require a medical device license and must undergo a more rigorous review process, including clinical trials, to demonstrate safety and effectiveness.
        4. Class IV: Very high-risk medical devices, such as artificial hearts and certain types of implants. These devices require a medical device license and undergo the most rigorous review process, including extensive clinical data and testing.
    - The classification of the medical device is based on several factors, such as the intended use of the device, potential risks to patients, and the mechanism of its action. Clinical trial data, proof of concept and system integration, as well as demonstrated efficacy will be relevant information to support approval.
2. Compile your submission: You will need to prepare a submission that includes information about your product, such as its intended use, design, development, and safety and effectiveness data. You may also need to provide evidence of clinical trials or other studies

that support the effectiveness of your solution. Guidance on application in the overview document *How to complete the application for a new medical device*.

3. Submit the application to Health Canada: You can submit your application for registration to Health Canada online through the Medical Devices Bureau's Medical Device Application and Licence Tracking (MDALL) system.
4. Wait for Health Canada's review: The length of time will vary depending on volume of applications as well as the completeness of information supplied. The process is commonly reported as taking 3 to 9 months.
5. Receive a decision: Once Health Canada has reviewed your application and determined that your solution meets the safety and effectiveness requirements, you will receive a Medical Device Licence (MDL) number, which authorizes you to sell your medical product in Canada.

Health Canada's Medical Devices Bureau has published a document entitled 'Guidance on Medical Device Establishment Licensing' which provides further information regarding the same.

The bureau can support businesses through many steps of this process. They can be reached by phone or email.

Phone: 1-613-957-7285 Toll-free: 1-800-267-9675 Email: device.licensing@hc-sc.gc.ca

The department is in Ottawa, at the following mailing address:

Medical Devices Bureau Therapeutic Products Directorate Health Canada
3000A Ottawa, ON K1A 0K9 Canada

The Ministry of Health is the federal government agency in Canada which is responsible for helping Canadians to maintain and improve their health. They can be helpful in navigation of the healthcare system and can be reached by phone at 1-866-225-0709 or by email info@hc-sc.gc.ca. They are also located in Ottawa, Ontario within the Brooke Claxton Building on Colombine Driveway.

Medical Device Regulations

The regulations governing medical devices in Canada are known as the Medical Devices Regulations (MDR), which are part of the Food and Drugs Act, overseen by the Medical Devices Bureau.

The MDR establishes the requirements for the sale, distribution, importation, and manufacture of medical devices in Canada. Some of the key requirements include:

1. Medical Device Licensing (MDL) as mentioned in the above.
2. Good Manufacturing Practices (GMP): Medical device manufacturers must comply with GMP standards for the design, manufacture, and distribution of medical products. The standards cover quality management, design, production and process controls, and product testing.
    a. Manufacturers must have a Quality Management System (QMS) in place to ensure that their products meet the required safety and effectiveness standards. The QMS must be compliant with the ISO 13485 standard. ISO 13485 is based on the ISO 9001 standard for quality management systems, but it includes additional requirements that are specific to the medical device industry. These requirements cover all aspects of the product lifecycle, from design and development through to manufacturing, distribution, and post-market surveillance. Some of the requirements of ISO 13485 include:
        1. Documentation and record-keeping: Manufacturers must maintain documentation and records related to their QMS, including policies, procedures, and work instructions.
        2. Design and development: Manufacturers must establish and maintain a process for their design and development that considers the needs of the patient, regulatory requirements, and other relevant factors.
        3. Manufacturing: Manufacturers must establish and maintain a process for production/replication/further development that ensures consistency and quality.
        4. Post-market surveillance: Manufacturers must establish and maintain a process for monitoring the performance of their solution once they are on the market, and for reporting adverse results and complaints to regulatory authorities.

5. Management review: Senior management must regularly review the performance of the QMS to ensure that it is effective and meeting regulatory requirements.

b. In Canada, the accreditation is managed by the Standards Council of Canada. To attain the accreditation, an accreditation specialist must be engaged – a directory of whom can be found here.

3. Labeling: Labeling and related literature must be accurate and provide clear instructions for use, including any precautions or warnings. Guidance can be found here.
4. Adverse Event Reporting: Manufacturers and distributors of medical devices must report any adverse events associated with their products to Health Canada's Medical Devices Bureau.
    a. Manufacturers are required to report any potential safety issues with their products to Health Canada and may be required to recall products from the market if they are found to pose a risk to patient safety. Incident reporting can be done online, providing complete information for review. Guidance in its entirety can be found in the *Incident reporting for medical devices: Guidance document*.
5. Post-Market Surveillance: Manufacturers must monitor the performance of their product once they are on the market and report any issues to Health Canada. This process should involve continuous automated reporting and communication with market users.
6. Unique Device Identification (UDI): Medical products must have a unique identifier that allows them to be tracked throughout the supply chain or across applications and users.
    a. Canada has proposed to follow the principles outlined by the International Medical Device Regulators Forum. The related application guide can be found here.
7. Clinical evidence: For higher-risk medical devices, such as Class III and IV devices, manufacturers must provide clinical evidence to demonstrate the safety and effectiveness of their products. This may also be requested for related software.

A forum entitled the International Medical Device Regulators Forum (IMDRF) was established in 2011 with the purpose of 'supporting innovation and timely access to safe and effective medical devices globally'. The IMDRF may be a useful resource to support navigation of the regulatory system as well.

Overview of the Sales Process

The procurement process for a diagnostic technology in Canada may vary depending on the specific hospital or healthcare facility you are working with, particularly based on provincial vs. federal jurisdiction and funding. However, the following is a general outline of what to expect from the procurement process:

1. Needs assessment: The hospital or healthcare facility will typically identify the need and determine the technical specifications and requirements related to a solution (whether they recognize the existence or not). This may involve consultation with medical staff and a review of current equipment and resources as well as screening/diagnostic failures in the system.
    a. All mammography facilities in Canada must be accredited by the Canadian Association of Radiologists (CAR) Mammography Accreditation Program. This accreditation program ensures that facilities meet high standards for quality, safety, and performance in mammography screening.
    b. As of September 2021, there were over 900 mammography facilities in Canada that had CAR Mammography Accreditation Program approval.
2. Request for Proposal (RFP): The hospital or healthcare facility will issue an RFP, which outlines the technical specifications and requirements. The RFP will typically include instructions for vendors to submit their proposals, including pricing and technical specifications. This allows for a more equitable tendering process. Each RFP will have its own submission details and guidelines, but a general consistency around what information is being sought will arise. A sample RFP from a Nova Scotian hospital for another good has been included for reference. It can be noted that much of this content is not specific to the project but is standardized information.
    a. Healthcare RFPs can most often be found using the following sources:
        i. Government procurement websites: The Canadian federal government and provincial governments often publish RFPs and other procurement opportunities on their procurement websites. Some examples include Buyandsell.gc.ca for federal government procurements, and the Ontario government's procurement website, Ontario Tenders Portal.
        ii. Hospital and healthcare facility websites: Hospitals and healthcare facilities in Canada may also publish RFPs and other procurement opportunities on

their websites. The following are breast screening clinics located throughout Nova Scotia.

- Amherst – Cumberland Regional Health Care Centre
- Antigonish – St. Martha's Hospital
- Bridgewater – South Shore Regional Hospital
- Dartmouth – Dartmouth General Hospital
- Halifax – IWK Site Office
- Lower Sackville – Cobequid Community Health Centre
- Kentville – Valley Regional Hospital
- New Glasgow – Aberdeen Hospital
- Sydney – Cape Breton Regional Hospital
- Truro – Colchester East Hants Health Centre
- Yarmouth – Yarmouth Regional Hospital

iii. Tender notification services: You can also subscribe to tender notification services that will alert you to new RFPs and other procurement opportunities in the healthcare industry in Canada. Some popular services include Definitive Healthcare, Biddingo, Global Tenders and MERX.

iv. Industry associations and publications: Industry associations and publications, such as Healthcare Purchasing News, important information relating to trends, funding, and new innovations within healthcare in Canada and can act as a meaningful resource to identify needs within the system related to forthcoming RFPs and other procurement opportunities.

v. . These sources may also be helpful in sizing/scoping the problem.

3. Vendor selection: The hospital or healthcare facility will review the proposals submitted by vendors and select the vendor that best meets their needs and budget. This may involve an evaluation committee or a review by medical staff.
4. Contract negotiation: Once a vendor is selected, the hospital or healthcare facility will negotiate a contract with the vendor that outlines the terms and conditions of the purchase, including payment terms, delivery schedule, and warranties.
5. Installation and training: The vendor will install the program/software and provide training to hospital staff on how to use and maintain it. This may involve additional fees or costs.
6. Maintenance and support: The vendor will provide ongoing maintenance and support for the technology, which may include regular maintenance checks, repairs, and upgrades.

In Nova Scotia, Nova Scotia Health Authority purchases under a predetermined threshold ($121,200) are handled by the authority themselves through a process outlined here. Purchases over this threshold are managed by the Department of Service Nova Scotia and Internal Services (SNS-IS). The related protocols and processes are outlined here.

In contrast, Ontario has a specific organization dedicated to innovation procurement – working to bring in new technologies to fill gaps in the market. Their related procurement processes can be found here.

Landscape

While hospital specific information regarding machines that are currently in use, it can be determined that digital mammography machines (most common), tomosynthesis machines, and analog mammography machines (least common) can be found throughout the country. The most commonly used imaging machines used include:

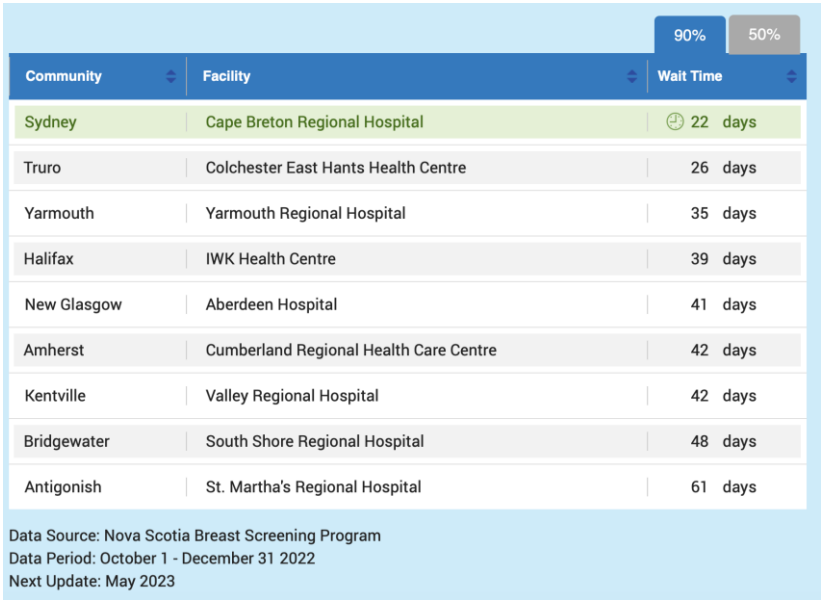
1. Hologic Selenia Dimensions
2. GE Senographe Pristina and Essential
3. Siemens Mammomat Revelation and Inspiration
4. Fujifilm Aspire Cristalle, Amulet Innovality, and Amulet f
5. Philips MicroDose SI

It is important to complete a full competitive analysis to understand the market landscape of mammogram technology in Canada, so that WisdomX can capitalize on their own strengths and fill gaps based on weaknesses of other technologies.

A competitive analysis includes collecting information on each of your competitors, including their products or services, pricing, marketing strategies, target audience, and any available reviews or feedback (whether through primary research or reviewing previously published materials). Key attributes and points of differentiation should be made clearer through this process, further empowering the sales process. More on business design and modelling will be covered in the coming strategy sessions planned for WisdomX and the Arthur L. Irving Entrepreneurship Centre.

Additional Facts about Breast Health in Nova Scotia

- Nova Scotia Health recommends routine screenings for women beginning at the age of 40, with no symptoms. Women who meet these criteria are able to self-refer by calling a booking hotline.
- Current wait times for diagnostic mammography are as follows:



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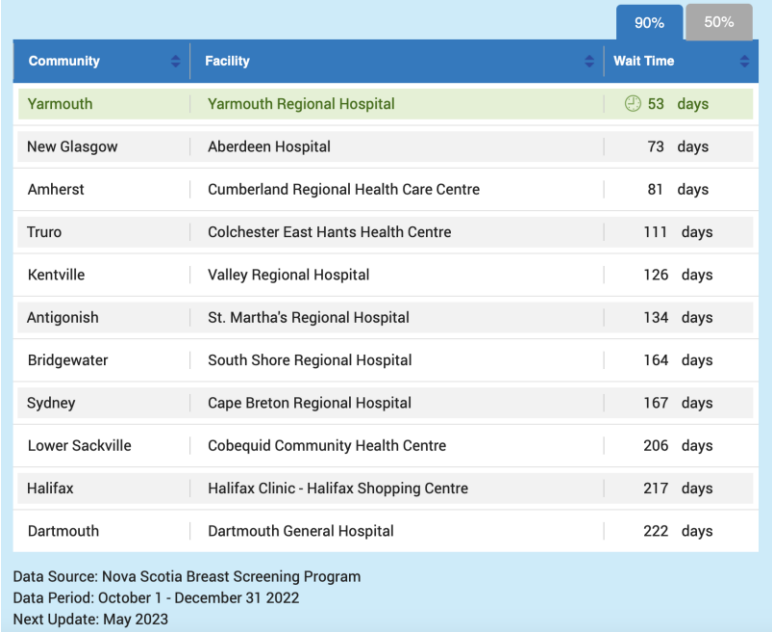
Community	Facility	Wait Time
Sydney	Cape Breton Regional Hospital	22 days
Truro	Colchester East Hants Health Centre	26 days
Yarmouth	Yarmouth Regional Hospital	35 days
Halifax	IWK Health Centre	39 days
New Glasgow	Aberdeen Hospital	41 days
Amherst	Cumberland Regional Health Care Centre	42 days
Kentville	Valley Regional Hospital	42 days
Bridgewater	South Shore Regional Hospital	48 days
Antigonish	St. Martha's Regional Hospital	61 days

Data Source: Nova Scotia Breast Screening Program
Data Period: October 1 - December 31 2022
Next Update: May 2023

https://waittimes.novascotia.ca/procedure/mammography-diagnostic

- Current wait times for screening exams:



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Community	Facility	Wait Time
Yarmouth	Yarmouth Regional Hospital	53 days
New Glasgow	Aberdeen Hospital	73 days
Amherst	Cumberland Regional Health Care Centre	81 days
Truro	Colchester East Hants Health Centre	111 days
Kentville	Valley Regional Hospital	126 days
Antigonish	St. Martha's Regional Hospital	134 days
Bridgewater	South Shore Regional Hospital	164 days
Sydney	Cape Breton Regional Hospital	167 days
Lower Sackville	Cobequid Community Health Centre	206 days
Halifax	Halifax Clinic - Halifax Shopping Centre	217 days
Dartmouth	Dartmouth General Hospital	222 days

Data Source: Nova Scotia Breast Screening Program
Data Period: October 1 - December 31 2022
Next Update: May 2023

https://waittimes.novascotia.ca/procedure/mammography-screening

- According to the Canadian Cancer Society's 2020 statistics, an estimated 1,450 women in Nova Scotia will be diagnosed with breast cancer and 200 will die from the disease that year.
    - Breast cancer is the most common cancer diagnosed in women in Nova Scotia, accounting for about 26% of all new cancer cases among women.
    - Breast cancer incidence rates in Nova Scotia have been relatively stable over the past several years, with an average of 120 new cases diagnosed per 100,000 women annually.
- According to Statistics Canada, as of July 1, 2021, the estimated population of Nova Scotia was approximately 979,000. Of this total population, approximately 50.4% were female, which means that there are an estimated 494,000 females living in Nova Scotia.
    - As of most recent census data, approximately 47% of the total female population living in Nova Scotia are over 40 – an indication of approximately 232,180 people.
- Based on the 2021-2022 Provincial Budget of Nova Scotia, the government planned to spend $5.9 billion on healthcare in the fiscal year 2021-2022.
    - The 2023-2024 budget invests $6.5 billion into healthcare, an increase of 21.8% over 2021-2022.
        - This also represents 45% of the provincial government's spending going toward healthcare related projects.

Other Important Contacts

Invest Nova Scotia

CanSummit – medical devices and diagnostics consultants

Nova Scotia

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REQUEST FOR PROPOSALS
FOR

Provision Transfusion Medicine Reagents

For the Izaak Walton Killam HEALTH CENTRE
(the “IWK")

RFP Number: IWK-2023-0104
Date Issued: April 6, 2023
Deadline Proposals: May 19, 2023 @PM 2:00 Atlantic Time

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PART 1 – INVITATION AND SUBMISSION INSTRUCTIONS

1.1 Invitation to Proponents

This Request for Proposals (the "RFP") is an invitation by the Izaak Walton Killam HEALTH CENTRE "IWK" to prospective proponents to submit proposals for the provision of Transfusion Medicine Reagents. This RFP is being conducted pursuant to the Nova Scotia Sustainable Procurement Policy and Procurement Manual.

The IWK Health Centre is the Maritime region's leading health care and research centre dedicated to the well-being of women, children, youth and families. In addition to providing highly specialized and complex care, the IWK provides certain primary care services and is a strong advocate for the health of families. The IWK is a global leader in research and knowledge sharing, and a partner in educating the next generation of health professionals.

1.2 RFP Contact

For the purposes of this procurement process, the "RFP Contact" shall be:

Jennifer Wang
Strategic Sourcing Coordinator
jennifer.wang@iwk.nshealth.ca

Proponents and their representatives are not permitted to contact any employees, officers, agents, elected or appointed officials or other representatives of the IWK, other than the RFP Contact or their designate, concerning this RFP. Failure to adhere to this rule may result in the disqualification of the proponent and the rejection of the proponent's proposal.

1.3 Type of Contract for Deliverables

The selected proponent will be requested to enter into direct contract negotiations to finalize an agreement with the IWK for the provision of the Deliverables. The terms and conditions found in the **Form of Agreement (Appendix A)** are to form the basis for commencing negotiations between the IWK and the selected proponent. The final agreement will be substantially in the form of Appendix A, subject to negotiation within the framework of this RFP. **The term of the agreement will be for a period of Five (5) years with optional two (2) consecutive 1-year renewals.**

1.4 RFP Timetable

Item	Date
Issue Date of RFP	April 6, 2023
Deadline for Submission of Questions	April 21, 2023 @ PM 2:00 Atlantic Time
Question Responses Provided	May 5,2023
Submission Deadline Date and Time	May 19, 2023 @PM 2:00 Atlantic Time
Notification of Intent to Execute an Agreement	June 2, 2023
Anticipated Execution of Agreement	June 16, 2023

The RFP timetable is tentative only and may be changed by the IWK at any time.

1.5 Submission of Proposals

1.5.1 Proposals to be submitted in Prescribed Format

Proponents are to submit their proposal via by email file transfer to the RFP Contact.

The file name should include an abbreviated form of the proponent's name and RFP#. Unless specifically requested in this solicitation document, proponents should not submit product catalogues, swatches, or other marketing materials with their proposal.

The IWK will not accept proposals submitted by hard copy or facsimile transfer.

1.5.2 Proposals to be submitted on Time

Proposals must be submitted on or before the Submission Deadline as indicated in section 1.4. Proposals submitted after the Submission Deadline will be rejected. The IWK's time clock will be deemed to be correct.

Respondents are responsible for ensuring bid submissions are submitted on time. IWK Health will not be responsible for any delay or failure of the transmission or receipt of the bid including, but not limited to, the following:

a) receipt of a garbled, corrupted or incomplete bid;
b) internet connectivity or availability issues;
c) incompatibility between the sending and receiving equipment;
d) delay in transmission or receipt of the bid;
e) failure of the Bidder to properly identify the bid;
f) illegibility of the bid; or
g) security of bid data.

1.5.3 Amendment of Proposals Prior to Submission Deadline

Proponents may amend their proposals prior to the Submission Deadline by submitting the amendment in the same manner as 1.5.1 prominently marked with the RFP title and number and the full legal name and return address of the proponent. Any amendment must clearly indicate which part of the proposal the amendment is intended to amend or replace. Any amendments received after the Submission Deadline will not be accepted. Amendment must be signed by the person who signed the original bid submission, or a person authorized to sign on his or her behalf.

1.5.4 Proposal Irrevocable after Submission Deadline

Proposals shall be irrevocable for a period of ninety (90) days from the Submission Deadline

[End of Part 1]

PART 2 – EVALUATION AND NEGOTIATION

2.1 Stages of Evaluation and Negotiation

The IWK will conduct the evaluation of proposals and negotiations in the following four stages:

Stage I: Mandatory Submission Requirements
Stage II: Evaluation
Stage III: Pricing
Stage IV: Ranking and Contract Negotiations

2.2 Stage I – Mandatory Submission Requirements

Stage I will consist of a review to determine which proposals comply with all of the mandatory submission requirements. If a proposal fails to satisfy all of the mandatory submission requirements, the IWK will issue the proponent a rectification notice identifying the deficiencies and providing the proponent an opportunity to rectify the deficiencies. If the proponent fails to satisfy the mandatory submission requirements within the Rectification Period, its proposal will be excluded from further consideration. The Rectification Period will begin to run from the date that IWK issues a rectification notice to the proponent.

The mandatory submission requirements are as follows:

2.2.1 No Amendment to Forms

Other than inserting information requested on the mandatory submission forms set out in the RFP, a respondent may not make any changes to any of the forms. Any proposal containing any such changes, whether on the face of the form or elsewhere in the proposal, will be disqualified.

2.2.2 Submission Form (Appendix B)

Each proposal must include a Submission Form (Appendix B) completed and signed by an authorized representative of the proponent.

2.2.3 Submission Pricing Form (Appendix C)

Each proposal must include a Submission Pricing Form (Appendix C) completed according to the instructions contained in the form.

2.2.4 Submission Item List (Appendix D-D.1)

2.2.5 Submission Requirements Form (Appendix D – D.2)

2.2.6 Shipping schedules for the items listed in Appendix D-D.1 (Please include expected delivery date, the product and the amount for each shipment)

2.2.7 Submission Reference Form (Appendix E)

Each proposal must include a Submission Proponent References (Appendix E) completed according to the instructions contained in the form.

2.3 Stage II – Evaluation

The following is an overview of the categories and weighting for the rated criteria of the RFP. Proponents who do not meet a minimum threshold score for a category will not proceed further in the evaluation process.

Rated Criteria Category	Weighting (Points)	Minimum Threshold (Points)
Specific Technical Requirements	**35 points**	
Service & Support Requirements	**15 points**	
Delivery Ability	**15 points**	
References (3 required all with health care experience)	**5 points**	
Subtotal A	**70 points**	**40 points**
Pricing	**30 points**	**N/A**
Total Points	**100 points**	

2.4 Stage III – Pricing

Stage III will consist of a scoring of the submitted pricing of compliant proposals in accordance with the price evaluation method set out in the Submission Pricing Form (Appendix C). The evaluation of price will be undertaken after the evaluation of mandatory submission requirements, mandatory technical requirements, and rated criteria has been completed.

2.5 Stage IV – Ranking and Contract Negotiations

2.5.1 Ranking of Proponents

After the completion of Stage III, all scores from Stage II and Stage III will be added together and each proponent will be ranked based on its total score. The top-ranked proponent will receive a written invitation to enter direct contract negotiations to finalize an agreement with the IWK. Upon finalization of the Agreement with the IWK, the proponent shall thereafter be known as the successful Proponent.

2.5.2 Consecutive Negotiations Process

Any negotiations will be subject to the process rules contained in the terms and conditions of the RFP Process (Part 3) and will not constitute a legally binding offer to enter into a contract on the part of the IWK or the proponent and there will be no legally binding relationship created with any proponent prior to the execution of a written agreement. The terms and conditions found in the Form of Agreement (Appendix A) are to form the basis for commencing negotiations between the IWK and the selected proponent. Negotiations may include requests by the IWK for supplementary information from the proponent to verify, clarify or supplement the information provided in its proposal or to confirm the conclusions reached in the evaluation, and may include requests by the IWK for improved pricing or performance terms from the proponent. The selected proponent will be required to present any requested changes to the agreement upon commencement of the Consecutive Negotiations Process.

2.5.3 Time Period for Negotiations

The IWK intends to conclude negotiations and finalize an agreement with the top-ranked proponent during the Contract Negotiation Period, commencing from the date the IWK invites the top-ranked proponent to enter negotiations. A proponent invited to enter into direct contract negotiations should therefore be prepared to provide requested information in a timely fashion and to conduct its negotiations expeditiously. Requested changes are to be identified during the Consecutive Negotiations Process (Section 2.5.2.). The IWK is not obligated to entertain further changes following

the conclusion of this phase.

2.5.4 Failure to Enter into Agreement

If the top-ranked proponent and the IWK cannot conclude negotiations and finalize the agreement for the Deliverables within the Contract Negotiation Period, the IWK may, upon notice, discontinue negotiations with the top-ranked proponent and may invite the second ranked proponent to enter into negotiations. This process shall continue until an agreement is finalized, until there are no more proponents remaining that are eligible for negotiations or until the IWK elects to cancel the RFP process.

2.5.5 Notification to Other Proponents

Once an agreement is finalized and executed by the IWK with a proponent, the other proponents will be notified in accordance with the Terms and Conditions of the RFP Process (Part 3). Upon finalization of an agreement with the IWK, the proponent shall thereafter be known as the successful proponent.

[End of Part 2]

PART 3 – TERMS AND CONDITIONS OF THE RFP PROCESS

3.1 General Information and Instructions

3.1.1 Proponents to Follow Instructions

Proponents should structure their proposals in accordance with the instructions in this RFP. Where information is requested in this RFP, any response made in a proposal should reference the applicable section numbers of this RFP.

3.1.2 Language

All proposals are to be in English, or both English and French. If there is a conflict or inconsistency between the English version and the French version of the proposal, the English version of the proposal shall prevail.

3.1.3 No Incorporation by Reference

The entire content of the proponent's proposal should be submitted in a fixed form, and the content of websites or other external documents referred to in the proponent's proposal but not attached will not be considered to form part of its proposal.

3.1.4 References and Past Performance

In the evaluation process, the IWK may include information provided by the proponent's references and may also consider the proponent's past performance or conduct on previous contracts with the IWK.

3.1.5 Information in RFP Only an Estimate

The IWK makes no representation, warranty or guarantee as to the accuracy of the information contained in this RFP, received from the RFP Contact, or issued by way of addenda. Any quantities shown or data, or opinion contained in this RFP or provided by way of addenda are estimates only and are for the sole purpose of indicating to proponents the general scale and scope of the Deliverables. It is the proponent's responsibility to obtain all the information necessary to prepare a proposal in response to this RFP.

3.1.6 Proponents to Bear Their Own Costs

The proponent shall bear all costs associated with or incurred in the preparation and presentation of its proposal, including, if applicable, costs incurred for interviews or presentations.

3.1.7 Proposal to be retained by the IWK

The IWK will not return the proposal or any accompanying documentation submitted by a proponent.

3.1.8 Third Party Assistance with Evaluation

The IWK reserves the right to engage, as necessary, subject matter experts as advisors/consultants to assist with the evaluation of submissions and to provide technical guidance. The assignment by the IWK of any one or more of these advisors/consultants will be at the IWK's sole and absolute discretion. The IWK may use any such advisors/consultants in any way it, in its discretion, considers necessary.

3.2 Business Registration

Proponents may be required to be registered to carry on business in accordance with applicable laws. For information on the business registration requirements of the Nova Scotia Registry of Joint Stock Companies, please consult:
http://www.novascotia.ca/snsmr/access/business/registry-joint-stock-companies.asp

The status of a proponent's business registration does not preclude the submission of a proposal in response to this RFP. A proposal can be accepted for evaluation, regardless of (i) whether the company is registered, or (ii) whether its business registration is in good standing. However, a contract cannot be awarded unless the successful proponent is registered and in good standing, in accordance with applicable laws.

If the proponent's business is not required to register in Nova Scotia, the proponent will be required to submit registration from their applicable jurisdiction.

3.3 Communication after Issuance of RFP

3.3.1 Proponents to Review RFP

Proponents shall promptly examine all of the documents comprising this RFP, and report any errors, omissions, or ambiguities; and direct questions or seek additional information in writing by email to the RFP Contact, as set out in section 1.2, on or before the Deadline for Questions.

The IWK is not obligated to respond to questions or comments received after this period has passed. No such communications are to be directed to anyone other than the RFP Contact. The IWK is under no obligation to provide additional information, and the IWK will not be responsible for any information provided by or obtained from any source other than the RFP Contact. It is the responsibility of the proponent to seek clarification from the RFP Contact on any matter it considers to be unclear. The IWK will not be responsible for any misunderstanding on the part of the proponent concerning this RFP or its process.

3.3.2 All New Information to Proponents by Way of Addenda

This RFP may be amended only by addendum in accordance with this section. If the IWK, for any reason, determines that it is necessary to provide additional information relating to this RFP, such information will be communicated by addendum on the Nova Scotia Procurement Web Portal. Each addendum forms an integral part of this RFP and may contain important information, including significant changes to this RFP. Proponents are responsible for obtaining all addenda issued by the IWK.

3.3.3 Post-Deadline Addenda and Extension of Submission Deadline

If the IWK determines that it is necessary to issue an addendum after the Deadline for Issuing Addenda, the IWK may extend the Submission Deadline for a reasonable period of time.

3.3.4 Verify and Clarify

During the evaluation process, the IWK may request further information from the proponent or third parties in order to verify or clarify the information provided in the proponent's proposal, including but not limited to, clarification with respect to whether a proposal meets the mandatory technical requirements set out in Section D.2 of the RFP Particulars (Appendix D). The IWK may revisit and re-evaluate the proponent's response or ranking on the basis of any such information.

3.4 Notification

3.4.1 Notification of Outcome of Procurement Process

Once an agreement is executed by the IWK with a proponent, notification of the outcome of the procurement process will be posted on the Nova Scotia Procurement Web Portal.

3.5 Conflict of Interest and Prohibited Conduct

3.5.1 Conflict of Interest

The IWK may disqualify a proponent for any conduct, situation or circumstance, determined by IWK, in its sole and absolute discretion, to constitute a Conflict of Interest. For the purposes of this Section, "Conflict of Interest" has the meaning ascribed to it in the Submission Form (Appendix B).

3.5.2 Disqualification for Prohibited Conduct

The IWK may disqualify a proponent, or rescind an invitation to negotiate, if in its sole and absolute discretion, determines that the proponent has engaged in any conduct prohibited by this RFP.

IWK may terminate an Agreement, if in its sole and absolute discretion, it determines that the proponent has engaged in any conduct prohibited by this RFP.

3.5.3 Prohibited Proponent Communications

A proponent shall not engage in any communications that could constitute a Conflict of Interest and must take note of the Conflict of Interest declaration set out in the Submission Form (Appendix B).

3.5.4 Proponent not to Communicate with Media

A proponent may not at any time directly, or indirectly, communicate with the media in relation to this RFP or any agreement entered into pursuant to this RFP without consent of the IWK, and then only in coordination with the IWK.

3.5.5 No Lobbying

A proponent shall not, in relation to this RFP or the evaluation and selection process, engage directly or indirectly in any form of political or other lobbying whatsoever to influence the selection of the successful proponent.

3.5.6 Illegal or Unethical Conduct

Proponents shall not engage in any illegal business practices, including activities such as bid-rigging, price-fixing, bribery, fraud, coercion or collusion. Proponents shall not engage in any unethical conduct, including lobbying, as described above, or other inappropriate communications; offering gifts to any employees, officers, agents, elected or appointed officials or other representatives of the IWK; submitting proposals containing misrepresentations or other misleading or inaccurate information; or any other conduct that compromises or may be seen to compromise the competitive process provided for in this RFP.

3.5.7 Rejection of Bids

The IWK may reject a bid based on past performance or based on inappropriate conduct, including but not limited to the following:

(a) illegal or unethical conduct as described above;
(b) the refusal of the Contractor to honour its submitted pricing or other commitments;

(c) any conduct, situation or circumstance determined by the IWK, in its sole and absolute discretion, to have constituted an undisclosed Conflict of Interest; or
(d) IWK's past experience with the bidder within the last 18 months for similar or related services

3.6 Confidential Information

3.6.1 Confidential Information of the IWK

All information provided by or obtained from the IWK in any form in connection with this RFP either before or after the issuance of this RFP

(a) is the sole property of the IWK and must be treated as confidential;
(b) is not to be used for any purpose other than replying to this RFP and the performance of the agreement for the Deliverables; and
(c) must not be disclosed without prior written authorization from the IWK
(d) must be returned by the proponent to the IWK immediately upon request of the IWK

3.6.2 Confidential Information of Proponent

A proponent should identify any information in its proposal or any accompanying documentation supplied in confidence for which confidentiality is to be maintained by the IWK. The confidentiality of such information will be maintained by the IWK, except as otherwise required by law or by order of a court or tribunal. Proponents are advised that their proposals will, as necessary, be disclosed, on a confidential basis, to advisers retained by the IWK to advise or assist with the RFP process, including the evaluation of proposals.

3.6.3 Personal Information International Disclosure Protection Act

The *'Personal Information International Disclosure Protection Act*' (PIIDPA), creates obligations for the IWK and its service providers when personal information is collected, used or disclosed. A copy of the Act is available online at:

http://nslegislature.ca/legc/statutes/persinfo.htm

3.7 Procurement Process Non-binding

3.7.1 No Contract A and No Claims

This procurement process is not intended to create or be deemed to create a formal, legally binding bidding process and shall instead be governed by the law applicable to direct commercial negotiations. For greater certainty and without limitation, this RFP shall not give rise to any Contract A-based tendering law duties or any other legal obligations arising out of any process contract or collateral contract.

3.7.2 No Contract until Execution of Written Agreement

This RFP process is intended to identify prospective suppliers for the purposes of negotiating a potential agreement for the Deliverables. No legal relationship or obligation regarding the procurement of any good or service shall be created between a proponent and the IWK by this RFP process until the successful negotiation and execution of a written agreement between a proponent and the IWK for the acquisition of such goods and/or services.

3.7.3 Non-binding Price Estimates

While the pricing information provided in proposals will be non-binding prior to the execution of a written agreement, such information will be assessed during the evaluation of the proposals and the ranking of the proponents. Any inaccurate, misleading or incomplete information, including withdrawn or altered pricing, could adversely impact any such evaluation or ranking or the decision of the IWK to enter into an

agreement with a proponent for the Deliverables.

3.7.4 Cancellation

The IWK may cancel the RFP process without liability at any time prior to the execution of a written agreement between the IWK and a proponent.

3.7.5 Non- Exclusive

The agreement would not be exclusive. The IWK could get the reagents from other vendors if needed.

3.8 Governing Law and Interpretation

These terms and conditions of the RFP Process (Part 3):

(a) are intended to be interpreted broadly and independently (with no particular provision intended to limit the scope of any other provision);

(b) are non-exhaustive and shall not be construed as intending to limit the pre-existing rights of the parties to engage in pre-contractual discussions in accordance with the common law governing direct commercial negotiations; and

(c) are to be governed by and construed in accordance with the laws of the Province of Nova Scotia and the federal laws of Canada applicable therein.

[End of Part 3]

APPENDIX A – FORM OF AGREEMENT

Refer to separate pdf document entitled APPENDIX A – FORM OF AGREEMENT

APPENDIX B – SUBMISSION FORM

B.1 Proponent Information

Please fill out the following form, naming one person to be the proponent's contact for the RFP process and for any clarifications or communication that might be necessary.	
Full Legal Name of Proponent:	
Any Other Relevant Name under which Proponent Carries on Business:	
Street Address:	
City, Province/State:	
Postal Code / Zip Code:	
Phone Number:	
Company Website:	
Proponent Contact Name and Title:	
Proponent Contact Phone:	
Proponent Contact Email:	
Nova Scotia Registry of Joint Stock Number (Leave blank if NOT applicable):	
HST / GST Registration Number (Leave blank if NOT applicable):	
SIN # (only required if you do not have an HST/GST or NSRJST number):	

B.2 Acknowledgment of Non-binding Procurement Process

The proponent acknowledges that the RFP process will be governed by the terms and conditions of the RFP, and that, among other things, such terms and conditions confirm that this procurement process does not constitute a formal, legally binding bidding process (and for greater certainty, does not give rise to a Contract A bidding process contract), and that no legal relationship or obligation regarding the procurement of any good or service shall be created between the IWK and the proponent unless and until the IWK and the proponent execute a written agreement for the Deliverables.

B.3 Ability to Provide Deliverables

The proponent has carefully examined the RFP documents and has a clear and comprehensive knowledge of the Deliverables. The proponent represents and warrants its ability to provide the Deliverables in accordance with the requirements of the RFP for the rates set out in the completed Pricing Form (Appendix C).

B.4 Mandatory Forms

The Proponent encloses as part of the proposal the mandatory forms set out below:

FORM	INITIAL TO ACKNOWLEDGE
Appendix B - Submission Form	
Appendix C - Submission Pricing Form	
Appendix D-D.1 - Item List	
Appendix D-D.2 -Supplement -RFP Requirements	
Shipping schedules for the items listed in Appendix D-D.1 (Please include expected delivery date, the product and the amount for each shipment)	
Appendix E - Proponent References	

B.5 Non-binding Pricing

The proponent has submitted it's pricing in accordance with the instructions in the RFP and in the Pricing Form (Appendix C). The proponent confirms that the pricing information provided is accurate. The proponent acknowledges that any inaccurate, misleading or incomplete information, including withdrawn or altered pricing, could adversely impact the acceptance of its proposal or its eligibility for future work with the IWK.

B.6 Addenda

The proponent is deemed to have read and taken into account all addenda issued by the IWK.

B.7 No Prohibited Conduct

The proponent declares that it has not engaged in any conduct prohibited by this RFP.

B.8 Conflict of Interest

For the purposes of this RFP, the term "Conflict of Interest" includes, but is not limited to, any situation or circumstance where:

in relation to the RFP process, the proponent has an unfair advantage or engages in conduct, directly or indirectly, that may give it an unfair advantage, including but not limited to (i) having, or having access to, confidential information of the IWK in the preparation of its proposal that is not available to other proponents, (ii) communicating with any person with a view to influencing preferred treatment in the RFP process (including but not limited to the lobbying of decision makers involved in the RFP process), or (iii) engaging in conduct that compromises, or could be seen to compromise, the integrity of the open and competitive RFP process or render that process non-competitive or unfair; or in relation to the performance of its contractual obligations under an agreement for the Deliverables, the proponent's other commitments, relationships or financial interests (i) could, or could be seen to, exercise an improper influence over the objective, unbiased and impartial exercise of its independent judgement, or (ii) could, or could be seen to, compromise, impair or be incompatible with the effective performance of its contractual obligations.

Proponents should disclose the names and all pertinent details of all individuals (employees, advisers, or individuals acting in any other capacity) who participated in the preparation of the proposal; AND were

employees, associates, Board Members or otherwise affiliated with the IWK within twelve (12) months prior to the Submission Deadline.

If the box below is left blank, the proponent will be deemed to declare that (a) there was no Conflict of Interest in preparing its proposal; and (b) there is no foreseeable Conflict of Interest in performing the contractual obligations contemplated in the RFP.

Otherwise, if the statement below applies, check the box.

☐ The proponent declares that there is an actual or potential Conflict of Interest relating to the preparation of its proposal, and/or the proponent foresees an actual or potential Conflict of Interest in performing the contractual obligations contemplated in the RFP.

If the proponent declares an actual or potential Conflict of Interest by marking the box above, the proponent must set out below details of the actual or potential Conflict of Interest:

B.9 Disclosure of Information

The proponent hereby agrees that any information provided in this proposal, even if it is identified as being supplied in confidence, may be disclosed where required by law or by order of a court or tribunal. The proponent hereby consents to the disclosure, on a confidential basis, of this proposal by the IWK to the advisers retained by the IWK to advise or assist with the RFP process, including with respect to the evaluation of this proposal.

_____
Signature of Proponent Representative

_____
Name of Proponent Representative

_____
Title of Proponent Representative

_____
Date

I have the authority to bind the proponent

APPENDIX C – SUBMISSION PRICING FORM

C.1 Instructions on How to Complete Submission Pricing Form

(a) All bids shall be provided in Canadian funds.
(b) Price should be exclusive of HST.

C.2 Evaluation of Pricing

Pricing is worth (30) points of the total score.

Pricing will be scored based on a relative pricing formula using the rates set out in the Pricing Form. Each proponent will receive a percentage of the total possible points allocated to price for the particular category it has bid on, which will be calculated by dividing that proponent's price for that category into the lowest bid price in that category. For example, if a proponent bids $120.00 for a particular category and that is the lowest bid price in that category, that proponent receives 100% of the possible points for that category (120/120 = 100%). A proponent who bids $150.00 receives 80% of the possible points for that category (120/150 = 80%), and a proponent who bids $240.00 receives 50% of the possible points for that category (120/240 = 50%).

Lowest rate

---------- X Total available points = Score for second-lowest rate

Second-lowest rate

Lowest rate

---------- X Total available points = Score for third-lowest rate

Third-lowest rate

And so on, for each proposal.

C.3 Pricing Form

Scope	Unit Price				
Provision of Transfusion Medicine Reagents	**YEAR 1**	**YEAR 2**	**YEAR 3**	**YEAR 4**	**YEAR 5**
Annual cost for Transfusion Medicine Reagents – as per Appendix D-D.1 (enter the total calculated values from cells shaded blue)	$	$	$	$	$

APPENDIX D – RFP PARTICULARS

D.1 Deliverables

IWK Health is issuing this Request for Proposals to prospective proponents to submit proposals for the provision of Transfusion Medicine Reagents.
The deliverables/actions listed below must be performed:

Reagents

1. Any products added after the contract is signed shall be at the same level of discount, including the costs associated with the comparisons.
2. Reagents shall be available from a Canadian based supplier or proponent shall agree to assume any associated costs for customs, duty, and brokerage for the lifetime of the proposed devices.
3. Reagents which are damaged during shipping to IWK are to be replaced at no additional cost.

Service

1. Notification for orders that are backordered, ETA and suggested replacement.
2. Replacement reagents to be shipped within 24-48 hours of notification.
3. Appropriate packaging of reagents and shipping temperatures.
4. Provide shipping schedule for standing orders.
5. Provide a direct contact for technical or material issues with products.

D.2 MANDATORY TECHNICAL REQUIREMENTS

The Mandatory Technical Requirements can be found in the Appendix D - D.2 -Supplement – RFP Requirements.

**** Please review and complete attached separate document –**
APPENDIX D – D.2 -Supplement – RFP Requirements **

D.3 TECHNICAL AND SERVICE REQUIREMENTS

The Technical and Service Requirements can be found in the Appendix D - D.2 -Supplement – RFP Requirements.

**** Please review and complete attached separate document –**
APPENDIX D – D.2 -Supplement – RFP Requirements **

D.4 RATED CRITERIA

D.4.1 Specific Technical Requirements

Tab 3 of **APPENDIX D – D.2 -Supplement – RFP Requirements**

D.4.2 Service & Support Requirements

Tab 4 of **APPENDIX D – D.2 -Supplement – RFP Requirements**

D.4.3 Delivery Ability

Delivery Ability is a critical factor in the evaluation of proposals. We will assess proponents based on their ability to deliver the items on time and within the specified scope and budget. This includes evaluating their track record of meeting deadlines, their capacity to handle unexpected changes or delays, and their ability to scale up or down as needed. We expect vendors to provide specific examples of successful delivery of similar projects in the past, and to outline their process for managing delivery, including any contingency plans in place for unexpected delays or disruptions. Please include but is not limited to the following information:

1. Are replacements costs covered?
2. Response time of delivery.
3. Notification process if unable to fill order and time of availability.

Please also provide Shipping schedules for the items listed in Appendix D-D.1 (Please include expected delivery date, the product and the amount for each shipment)

D.4.4 References

Each proponent is required to provide three (3) references from health care clients who have obtained goods or services similar to those requested in this RFP from the proponent in the last five (5) years.

The reference information provided should identify name and contact information, name and size of the project and detail the extent of previous experience, clients' overall satisfaction with services and the results achieved, including adherence to interim and final deadlines.

Proponents will be evaluated based on the references' previous experience with customer satisfaction, responsiveness, prompt attention and general satisfaction.

The IWK will only evaluate three references. If more than three (3) references are provided by the proponent only the first three (3) listed in the proposal will be evaluated.

APPENDIX E - PROPONENT REFERENCES

Each proponent must provide three (3) references from clients who have obtained goods or services like those requested in this RFP from the proponent in the past three (3) years. It is preferred that at least one (1) of the references must come from a client in Nova Scotia. You may also include references from clients in the Atlantic Provinces, and Canada.

The reference information provided should identify name and contact information, name and size of the project and detail the extent of previous experience, clients' overall satisfaction with services and the results achieved, including adherence to interim and final deadlines.

Proponents will be evaluated based on the references' previous experience with customer satisfaction, responsiveness, prompt attention and general satisfaction. The IWK will only evaluate three references. If more than three (3) references are provided by the proponent only the first three (3) listed in the proposal will be evaluated.

Reference Information	
Organization Name	
Contact Name	
Role in the Project	
Contact Telephone #	
Contact E-Mail address	
Length of Agreement	
Contract Value/Size of Agreement	

Reference Information	
Organization Name	
Contact Name	
Role in the Project	
Contact Telephone #	
Contact E-Mail address	
Length of Agreement	
Contract Value/Size of Agreement	

Reference Information	
Organization Name	
Contact Name	
Role in the Project	
Contact Telephone #	
Contact E-Mail address	
Length of Agreement	
Contract Value/Size of Agreement	