Title - Sujet



Health Agency of Canada

RETURN BIDS TO: RETOURNER LES SOUMISSIONS À:

Health Canada / Santé Canada

Attn: Erin Massey

Email: erin.massey@canada.ca

REQUEST FOR PROPOSAL DEMANDE DE PROPOSITION

Proposal To: Health Canada We hereby offer to sell to Her Majesty the Queen in right of Canada, in accordance with the terms and conditions set out herein, referred to herein or attached hereto, the goods, services, and construction listed herein and on any attached sheets at the price(s) set out thereof.

Proposition à: Santé Canada

Nous offrons par la présente de vendre à Sa Majesté la Reine du chef du Canada, aux conditions énoncées ou incluses par référence dans la présente et aux annexes ci-jointes, les biens, services et construction énumérés ici sur toute feuille ci-annexées, au(x) prix indiqué(s).

Instructions: See Herein Instructions: Voir aux présentes

Issuing Office - Bureau de distribution Health Canada / Santé Canada 200, Eglantine Driveway Tunney's Pasture Ottawa Ontario K1A 0K9

Urine Sampling: Biomarker of Exposure Testing in Users of Novel Nicotine Delivery Devices and Tobacco Products: Data Collection (5 geographic sites) Solicitation No. - N° de l'invitation Date 1000204974 2019-05-06 Solicitation Closes at - 2:00PM Time Zone Fuseau horaire L'invitation prend fin à on / le - 2019-06-15 F.O.B. - F.A.B. Plant-Usine: **Destination:** ⊠ **Other-Autre:** □ Address Enquiries to: - Adresser toutes questions à : Name: Erin Massey Email: erin.massey@canada.ca Telephone - téléphone : 613-941-2094 Destination - of Goods, Services, and Construction: Destination - des biens, services et construction : See Herein – Voir ici Delivery required - Livraison exigée See Herein – Voir ici Vendor/firm Name and address Raison sociale et adresse du fournisseur/de l'entrepreneur Facsimile No. - N° de télécopieur : Telephone No. - N° de téléphone : Name and title of person authorized to sign on behalf of Vendor/firm Nom et titre de la personne autorisée à signer au nom du fournisseur/de l'entrepreneur (type or print)/ (taper ou écrire en caractères d'imprimerie) **Date** Signature



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PART 1 - GENERAL INFORMATION

1.1 Summary

- a) This bid solicitation is being issued to satisfy the requirement of **Health Canada** for Urine Sampling: Biomarker of Exposure Testing in Users of Novel Nicotine Delivery Devices and Tobacco Products: Data Collection (5 geographic sites).
- b) It is intended to result in the award of up to five (5) contracts, one per geographic site.

1.2 Security Requirements

- 1. At the date of bid closing, the following conditions must be met:
 - (a) the Bidder must hold a valid organization security clearance as indicated in Part 6 Resulting Contract Clauses;
 - (b) the Bidder's proposed individuals requiring access to classified or protected information, assets or sensitive work sites must meet the security requirements as indicated in Part 6 -Resulting Contract Clauses;
 - (c) the Bidder must provide the name of all individuals who will require access to classified or protected information, assets or sensitive work sites;
 - (d) the Bidder's proposed location of work performance and document safeguarding must meet the security requirements as indicated in Part 6 Resulting Contract Clauses;
 - (e) the Bidder must provide the addresses of proposed sites or premises of work performance and document safeguarding as indicated in Part 3 Section IV Additional Information.
- 2. For additional information on security requirements, Bidders should refer to the <u>Contract Security Program of Public Works and Government Services Canada (http://www.tpsgc-pwgsc.gc.ca/esc-src/introduction-eng.html) website.</u>

1.3 Statement of Work

The Work to be performed is detailed under Annex A – Statement of Work.

1.4 Debriefings

Bidders may request a debriefing on the results of the bid solicitation process. Bidders should make the request to the Contracting Authority within 15 working days from receipt of the results of the bid solicitation process. The debriefing may be in writing, by telephone or in person.

1.5 Trade Agreements

The requirement is not subject to the trade agreements as per the following dispositions: Agreement on Internal Trade (AIT): Chapter 5, Article 504 11(h)(ii), World Trade Organization Agreement on Government Procurement (WTO-AGP): Appendix I, Annex I, North American Free Trade Agreement (NAFTA): Chapter 10, Annex 1001.1a-1, Canada - Chile Free Trade Agreement: Annex Kbis-01, 1-1, Canada - Peru Free Trade Agreement: Annex 1401.1-1, Canada-Colombia Free Trade Agreement Annex 1401-1.

PART 2 - BIDDER INSTRUCTIONS

2.1 Standard Instructions, Clauses and Conditions

All instructions, clauses and conditions identified in the bid solicitation by number, date and title are set out in the <u>Standard Acquisition Clauses and Conditions Manual</u> (https://buyandsell.gc.ca/policy-and-guidelines/standard-acquisition-clauses-and-conditions-manual) issued by Public Works and Government Services Canada.

Bidders who submit a bid agree to be bound by the instructions, clauses and conditions of the bid solicitation and accept the clauses and conditions of the resulting contract.

The <u>2003</u> (2018-05-22) Standard Instructions - Goods or Services - Competitive Requirements, are incorporated by reference into and form part of the bid solicitation.

Subsection 5.4 of <u>2003</u>, Standard Instructions - Goods or Services - Competitive Requirements, is amended as follows:

Delete: 60 days Insert: 90 days

2.1.1 SACC Manual Clauses

4008 (2008-12-12), Personal Information

2.2 Submission of Bids

Bids must be submitted only to erin.massey@canada.ca by the date and time indicated on page 1 of the bid solicitation:

Due to the nature of the bid solicitation, bids transmitted by facsimile will not be accepted.

2.3 Former Public Servant

Contracts awarded to former public servants (FPS) in receipt of a pension or of a lump sum payment must bear the closest public scrutiny, and reflect fairness in the spending of public funds. In order to comply with Treasury Board policies and directives on contracts awarded to FPSs, bidders must provide the information required below before contract award. If the answer to the questions and, as applicable the information required have not been received by the time the evaluation of bids is completed, Canada will inform the Bidder of a time frame within which to provide the information. Failure to comply with Canada's request and meet the requirement within the prescribed time frame will render the bid non-responsive.

Definitions

For the purposes of this clause, "former public servant" is any former member of a department as defined in the *Financial Administration Act*, R.S., 1985, c. F-11, a former member of the Canadian Armed Forces or a former member of the Royal Canadian Mounted Police. A former public servant may be:

- a) an individual;
- b) an individual who has incorporated;
- c) a partnership made of former public servants; or

 a sole proprietorship or entity where the affected individual has a controlling or major interest in the entity.

"lump sum payment period" means the period measured in weeks of salary, for which payment has been made to facilitate the transition to retirement or to other employment as a result of the implementation of various programs to reduce the size of the Public Service. The lump sum payment period does not include the period of severance pay, which is measured in a like manner.

"pension" means a pension or annual allowance paid under the <u>Public Service Superannuation Act</u> (PSSA), R.S., 1985, c. P-36, and any increases paid pursuant to the <u>Supplementary Retirement</u> <u>Benefits Act</u>, R.S., 1985, c. S-24 as it affects the PSSA. It does not include pensions payable pursuant to the <u>Canadian Forces Superannuation Act</u>, R.S., 1985, c. C-17, the <u>Defence Services Pension</u> <u>Continuation Act</u>, 1970, c. D-3, the <u>Royal Canadian Mounted Police Pension Continuation Act</u>, 1970, c. R-10, and the <u>Royal Canadian Mounted Police Superannuation Act</u>, R.S., 1985, c. R-11, the <u>Members of Parliament Retiring Allowances Act</u>, R.S. 1985, c. M-5, and that portion of pension payable to the <u>Canada Pension Plan Act</u>, R.S., 1985, c. C-8.

Former Public Servant in Receipt of a Pension

As per the above definitions, is the Bidder a FPS in receipt of a pension? Yes () No ()

If so, the Bidder must provide the following information, for all FPSs in receipt of a pension, as applicable:

- a) name of former public servant;
- b) date of termination of employment or retirement from the Public Service.

By providing this information, Bidders agree that the successful Bidder's status, with respect to being a former public servant in receipt of a pension, will be reported on departmental websites as part of the published proactive disclosure reports in accordance with Contracting Policy Notice: 2012-2 and the Guidelines on the Proactive Disclosure of Contracts.

Work Force Adjustment Directive

Is the Bidder a FPS who received a lump sum payment pursuant to the terms of the Work Force Adjustment Directive? **Yes** () **No** ()

If so, the Bidder must provide the following information:

- a) name of former public servant;
- b) conditions of the lump sum payment incentive;
- c) date of termination of employment;
- d) amount of lump sum payment;
- e) rate of pay on which lump sum payment is based;
- f) period of lump sum payment including start date, end date and number of weeks;
- g) number and amount (professional fees) of other contracts subject to the restrictions of a work force adjustment program.

For all contracts awarded during the lump sum payment period, the total amount of fees that may be paid to a FPS who received a lump sum payment is \$5,000, including Applicable Taxes.

2.4 Enquiries - Bid Solicitation

All enquiries must be submitted in writing to the Contracting Authority no later than five (5) calendar days before the bid closing date. Enquiries received after that time may not be answered.

Bidders should reference as accurately as possible the numbered item of the bid solicitation to which the enquiry relates. Care should be taken by Bidders to explain each question in sufficient detail in order to enable Canada to provide an accurate answer. Technical enquiries that are of a proprietary nature must be clearly marked "proprietary" at each relevant item. Items identified as "proprietary" will be treated as such except where Canada determines that the enquiry is not of a proprietary nature. Canada may edit the question(s) or may request that the Bidder do so, so that the proprietary nature of the question(s) is eliminated, and the enquiry can be answered to all Bidders. Enquiries not submitted in a form that can be distributed to all Bidders may not be answered by Canada.

2.5 Applicable Laws

Any resulting contract must be interpreted and governed, and the relations between the parties determined, by the laws in force in Ontario.

Bidders may, at their discretion, substitute the applicable laws of a Canadian province or territory of their choice without affecting the validity of their bid, by deleting the name of the Canadian province or territory specified and inserting the name of the Canadian province or territory of their choice. If no change is made, it acknowledges that the applicable laws specified are acceptable to the Bidders.

PART 3 - BID PREPARATION INSTRUCTIONS

3.1 Bid Preparation Instructions

Canada requests that the Bidder submits its bid in accordance with section 08 of the 2003 standard instructions.

The bid must be gathered per section and separated as follows:

Section I: Technical Bid: One electronic copy Section II: Financial Bid: One electronic copy Section III: Certifications: One electronic copy

Section IV: Additional Information: One electronic copy

Due to the nature of the bid solicitation, bids transmitted by facsimile will not be accepted.

Prices must appear in the financial bid only. No prices must be indicated in any other section of the bid.

Canada requests that bidders follow the format instructions described below in the preparation of hard copy of their bid:

(a) use a numbering system that corresponds to the bid solicitation.

Section I: Technical Bid

In their technical bid, Bidders should explain and demonstrate how they propose to meet the requirements and how they will carry out the Work.

Section II: Financial Bid

Bidders must submit their financial bid in accordance with the Basis of Payment.

Section III: Certifications

Bidders must submit the certifications and additional information required under Part 5.

Section IV: Additional Information

3.2.1 Bidder's Proposed Sites or Premises Requiring Safeguarding Measures

3.2.1.1 As indicated in Part 1 under Security Requirements, the Bidder must provide the full addresses of the Bidder's and proposed individuals sites or premises for which safeguarding measures are required for Work Performance:

Street Number / Street Name, Unit / Suite / Apartment Number City, Province, Territory / State Postal Code / Zip Code Country

3.2.1.2 The Company Security Officer must ensure through the Contract Security Program that the Contractor and individuals hold a valid security clearance at the required level, as indicated in Part 1, clause 1.1, Security Requirements.

PART 4 - EVALUATION PROCEDURES AND BASIS OF SELECTION

4.1 Evaluation Procedures

- (a) Bids will be assessed in accordance with the entire requirement of the bid solicitation including the technical and financial evaluation criteria.
- (b) An evaluation team composed of representatives of Canada will evaluate the bids.

4.1.1 Technical Evaluation

4.1.1.1 Mandatory Technical Criteria

ATTENTION BIDDERS:

Write beside each of the criterion the relevant page number(s) from your bid which addresses the requirement identified in the criteria.

requirement identified in the criteria.					
#	Mandatory Technical Criteria	Met (Yes/No)	Cross- Reference to bid (indicate page #)		
MT1	The Bidder must demonstrate, by providing a detailed project description, that they have completed a similar project involving administration of a questionnaire and associated collection of a biological sample (such as medical diagnostics, insurance claims or applications, research study etc.). Project description must include: 1. The name and contact information of the client; 2. A brief description of the scope and complexity of the work; 3. The timeframe of the project (start and end date). Canada reserves the right to contact the client to validate information provided.				
MT2	The Bidder must demonstrate, by providing complete address(es) that they have facilities in at least one (1) of the five (5) locations across Canada as identified in the Statement of Work. AND The Bidder must provide a copy of each location's valid Canadian Industrial Security Directorate (CISD) clearance verification with their proposal. (Refer to section 6.1.2.2 for more information).				
MT3	The Bidder must demonstrate, by providing a detailed work plan for each proposed location, that they have the capacity to complete the work. For each location, the work plan must:				

	 identify individual(s) to act as a main point of contact (centralized or per location); Detail the proposed tasks and activities for each proposed resource; Describe how they will address all of the tasks described in the Statement of Work at Annex A, Section 3.1. Identify any potential risks and their proposed mitigation strategies.
МТ5	The Bidder must demonstrate, by providing copies of valid certification, that the resources responsible for the shipment of samples in each of the five (5) locations are certified for the transportation of dangerous goods (TDG).

4.1.1.2 Point Rated Technical Criteria

	1.1.2 Point Rated Technical Criteria		
#	Point Rated Technical Criteria	Max Points	Comments
RT1	In addition to the project description required in MT1, the Bidder should demonstrate, by providing up to five (5) additional detailed project descriptions demonstrating they have participated in similar projects involving administration of a questionnaire and associated collection of a biological sample (such as medical diagnostics, insurance claims or applications, research study etc.). Project description must include: 1. The name and contact information of the client; 2. A brief description of the scope and complexity of the work; 3. The timeframe of the project (start and end date). POINTS ALLOCATION: 2 points for each additional project up to a maximum of ten (10) points NO MINIMUM REQUIRED FOR THIS CRITERION.	/10	
	The Bidder's proposal will be evaluated for overall quality and clarity. POINTS ALLOCATION:		
RT2	10 points: The proposal is clear and concise and addresses all of the tasks and activities outlined in the Statement of Work Annex A section 3.1 for up to five (5) of the locations; the points of contact and other proposed resources along with their respective roles and qualifications are clearly identified and substantiated.	/10 (minimum of 5 required)	
	5 points : The proposal is somewhat clear and addresses most of the tasks and activities outlined in the Statement of		

Work Annex A section 3.1 for up to five (5) of the locations; the points of contact and other proposed resources along with their respective roles and qualifications are somewhat clear.		
0 points: The proposal is unclear and/or inconsistent; most of the tasks and activities outlined in the Statement of Work Annex A section 3.1 are not addressed; points of contact and other resources along with their respective roles and qualifications are unclear and/or unsubstantiated.		
MINIMUM SCORE OF 5 POINTS REQUIRED FOR THIS CRITERION.		
ACTUAL SCORE (minimum of 5 points required for RT2):	/20	

4.1.2 Financial Evaluation

ATTENTION BIDDERS:

Write beside each of the criterion the relevant page number(s) from your bid which addresses the requirement identified in the criteria.

#	Mandatory Financial Criteria	Met (Yes/No)	Page #
MF1	The total value of the proposal must not exceed \$40,000.00 per location, for a maximum total of \$200,000 CAD inclusive of applicable taxes.		

4.2 Basis of Selection

4.2.1 Lowest Price per Point per Location

- 1. To be declared responsive, a bid must:
 - a. comply with all the requirements of the bid solicitation;
 - b. meet all mandatory technical evaluation criteria; and
 - c. obtain the required minimum points for the technical evaluation criteria which are subject to point rating.
- 2. Bids not meeting (a) or (b) or (c) will be declared non-responsive. Neither the responsive bid that receives the highest number of points nor the one that proposed the lowest price will necessarily be accepted. The responsive bid with the lowest evaluated price per point per location will be recommended for award of a contract.
- 3. Each location will be evaluated separately and the bidder with the lowest cost per point for each specific location will be recommended for award. Contracts for more than one location may be issued if the supplier is the top rated Bidder for multiple locations.

PART 5 - CERTIFICATIONS AND ADDITIONAL INFORMATION

Bidders must provide the required certifications and additional information to be awarded a contract.

The certifications provided by Bidders to Canada are subject to verification by Canada at all times. Unless specified otherwise, Canada will declare a bid non-responsive, or will declare a contractor in default if any certification made by the Bidder is found to be untrue whether made knowingly or unknowingly, during the bid evaluation period or during the contract period.

The Contracting Authority will have the right to ask for additional information to verify the Bidder's certifications. Failure to comply and to cooperate with any request or requirement imposed by the Contracting Authority will render the bid non-responsive or constitute a default under the Contract.

5.1 Certifications Required with the Bid

Bidders must submit the following duly completed certifications as part of their bid.

5.1.1 Integrity Provisions - Declaration of Convicted Offences

In accordance with the Integrity Provisions of the Standard Instructions, all bidders must provide with their bid, **if applicable**, the declaration form available on the <u>Forms for the Integrity Regime</u> website (http://www.tpsgc-pwgsc.gc.ca/ci-if/declaration-eng.html), to be given further consideration in the procurement process.

5.2 Certifications Precedent to Contract Award and Additional Information

The certifications and additional information listed below should be submitted with the bid, but may be submitted afterwards. If any of these required certifications or additional information is not completed and submitted as requested, the Contracting Authority will inform the Bidder of a time frame within which to provide the information. Failure to provide the certifications or the additional information listed below within the time frame provided will render the bid non-responsive.

5.2.1 Integrity Provisions – Required Documentation

In accordance with the section titled Information to be provided when bidding, contracting or entering into a real procurement agreement of the <u>Ineligibility and Suspension Policy</u> (http://www.tpsgc-pwgsc.gc.ca/ci-if/politique-policy-eng.html), the Bidder must provide the required documentation, as applicable, to be given further consideration in the procurement process.

5.2.3 Additional Certifications Precedent to Contract Award

5.2.3.1 Status and Availability of Resources

SACC Manual clause A3005T (2010-08-16), Status and Availability of Resources

PART 6 - RESULTING CONTRACT CLAUSES

The following clauses and conditions apply to and form part of any contract resulting from the bid solicitation.

6.1 Security Requirements

- **6.1.1** The following security requirements (SRCL and related clauses provided by the Contract Security Program) apply and form part of the Contract.
 - The Contractor personnel requiring access to protected information, assets or sensitive work site(s) must EACH hold a valid **reliability status**, granted or approved by Health Canada/PHAC or the Canadian Industrial Security Directorate (CISD), Public Works and Government Services Canada (PWGSC).
 - 2. The Contractor must not remove any protected information or assets from the identified work site(s), and the Contractor must ensure that its personnel are made aware of and comply with this restriction.
 - 3. Subcontracts which contain security requirements are not to be awarded without the prior written permission of CISD/PSPC
 - 4. The Contractor must comply with the provisions of the:
 - a) Security Requirements Check List and security guide (if applicable), attached at Annex C.
 - b) Industrial Security Manual (Latest Edition)

6.1.2 Contractor's Sites or Premises Requiring Safeguarding Measures

6.1.2.1 Where safeguarding measures are required in the performance of the Work, the Contractor must diligently maintain up-to-date, the information related to the Contractor's and proposed individuals' sites or premises for the following addresses:

Street Number / Street Name, Unit / Suite / Apartment Number City, Province, Territory / State Postal Code / Zip Code Country

6.1.2.2 The Company Security Officer must ensure through the <u>Contract Security Program</u> that the Contractor and individuals hold a valid security clearance at the required level of document safeguarding capability.

6.2 Statement of Work

The Contractor must perform the Work in accordance with the Statement of Work at Annex A.

6.3 Standard Clauses and Conditions

All clauses and conditions identified in the Contract by number, date and title are set out in the <u>Standard Acquisition Clauses and Conditions Manual</u> (https://buyandsell.gc.ca/policy-and-guidelines/standard-acquisition-clauses-and-conditions-manual) issued by Public Works and Government Services Canada.

6.3.1 General Conditions

<u>2010B</u> (2018-06-21), General Conditions - Professional Services (Medium Complexity) apply to and form part of the Contract.

6.3.2 Supplemental General Conditions

SACC Manual clause 4008 (2008-12-12), Personal Information

6.4 Term of Contract

6.4.1 Period of the Contract

The period of the Contract is from date of Contract to September 30, 2019 inclusive.

6.5 Authorities

Directorate:

6.5.1 Contracting Authority

Name: Erin Massey

Title: Senior Procurement and Contracting Officer

Health Canada

Chief Financial Officer Branch Materiel and Assets Management

Address: 200 Eglantine Driveway, Ottawa, ON K1A 0K9

Telephone: 613-941-2094

E-mail address: erin.massey@canada.ca

The Contracting Authority is responsible for the management of the Contract and any changes to the Contract must be authorized in writing by the Contracting Authority. The Contractor must not perform work in excess of or outside the scope of the Contract based on verbal or written requests or instructions from anybody other than the Contracting Authority.

6.5.2 Project Authority (to be identified at contract award)

Name:		
Title:	_	
Organization:		
Address:		
Telephone:		
E-mail address:		

The Project Authority is the representative of the department or agency for whom the Work is being carried out under the Contract and is responsible for all matters concerning the technical content of the Work under the Contract. Technical matters may be discussed with the Project Authority, however the Project Authority has no authority to authorize changes to the scope of the Work. Changes to the scope of the Work can only be made through a contract amendment issued by the Contracting Authority.

6.5.3 Contractor's Representative (to be identified at contract award)

Name:	
Title:	_
Organization:	
Address:	
Telephone:	
E-mail address:	

6.6 Proactive Disclosure of Contracts with Former Public Servants

By providing information on its status, with respect to being a former public servant in receipt of a <u>Public Service Superannuation Act</u> (PSSA) pension, the Contractor has agreed that this information will be

reported on departmental websites as part of the published proactive disclosure reports, in accordance with <u>Contracting Policy Notice: 2012-2</u> of the Treasury Board Secretariat of Canada.

6.7 Payment

6.7.1 Basis of Payment (Firm Unit Price)

In consideration of the Contractor satisfactorily completing all of its obligations under the Contract, the Contractor will be paid a firm unit price as specified in Annex B for a cost of \$ _____. Customs duties are included and Applicable Taxes are extra.

Canada will not pay the Contractor for any design changes, modifications or interpretations of the Work, unless they have been approved, in writing, by the Contracting Authority before their incorporation into the Work.

6.7.3 Method of Payment (Monthly Payments)

SACC Manual clause H1008C (2008-05-12), Monthly Payment

6.8 Invoicing Instructions

 The Contractor must submit invoices in accordance with the section entitled "Invoice Submission" of the general conditions. Invoices cannot be submitted until all work identified in the invoice is completed.

Each invoice must be supported by:

- b. a copy of the release document and any other documents as specified in the Contract;
- 2. Invoices must be distributed as follows:
 - a. One (1) copy must be forwarded to https://nc.p2p.east.invoices-factures.est.sc@canada.ca and the Project Authority for certification and payment.

6.9 Certifications and Additional Information

6.9.1 Compliance

Unless specified otherwise, the continuous compliance with the certifications provided by the Contractor in its bid or precedent to contract award, and the ongoing cooperation in providing additional information are conditions of the Contract and failure to comply will constitute the Contractor in default. Certifications are subject to verification by Canada during the entire period of the Contract.

6.10 Applicable Laws

The Contract must be interpreted and governed, and the relations between the parties determined, by the laws in force in Ontario.

6.11 Priority of Documents

If there is a discrepancy between the wording of any documents that appear on the list, the wording of the document that first appears on the list has priority over the wording of any document that subsequently appears on the list.

- (a) the Articles of Agreement;
- (b) the supplemental general conditions <u>4008</u> (2008-12-12), Personal Information;
- (c) the general conditions 2010B (2018-06-21), Professional Services (medium complexity);
- (d) Annex A, Statement of Work;

- (e) (f)
- Annex B, Basis of Payment; Annex C, Security Requirements Check List; Annex D, Non-Disclosure Agreement the Contractor's bid dated _____
- (ġ)
- (h)

6.12 Insurance

SACC Manual clause G1005C (2016-01-28) Insurance – No Specific Requirement

ANNEX A - STATEMENT OF WORK

1. Title

Biomarker of Exposure Testing in Users of Novel Nicotine Delivery Devices and Tobacco Products: Data Collection (5 geographic sites)

2. Scope

2.1. Introduction

With an estimated 45,000 deaths attributable to smoking in Canada in 2012, leading to nearly 600,000 potential years of life lost for premature mortality, tobacco use remains the leading preventable cause of disease and premature death in Canada. Health Canada is responsible for helping Canadians protect, maintain, and improve their health, while respecting individual choices and circumstances. To achieve this goal, Health Canada takes into account available high-quality scientific data to inform its work.

The renewal of Canada's Tobacco Strategy provides an opportunity to chart a new course in tobacco control and further protect Canadians from the devastating impacts of tobacco use. At the same time, the emergence of alternative products¹, such as vaping products and heated tobacco products, is shifting the tobacco and nicotine use landscape in a manner that may have significant implications for public health in Canada.

The Tobacco Control Directorate (TCD) is undertaking this study to investigate urinary biomarkers of chemical exposures of users of alternative products. The results of this study will inform decision making within the program, the planning of future studies, and the public.

TCD lacks the capacity to perform a study involving users of several categories of products, particularly participant interviews and surveys and urine sample collection for biomarkers of exposure. Therefore, Health Canada is seeking the services of a Contractor to undertake collection of questionnaire data and samples for a study to investigate the chemical exposures of various categories of alternative products.

2.2. Objectives of the Requirement

The objective of this requirement is to collect urine samples from pre-recruited participants including smokers, non-smokers, and users of alternative products. Administration of a questionnaire to participants on demographic and pattern of use information is required.

2.3. Background and Specific Scope of the Requirement

There is a paucity of independent research on the health effects of alternative products, especially in humans. The bulk of the health-related studies on alternative products involve aerosol generation and chemical analysis of commonly investigated tobacco smoke toxicants. The matrices of these alternative products can be both simpler and more complex, and may result in exposure to chemicals not found in tobacco smoke. More importantly, the use patterns of alternative products differ substantially from that of

Vaping products are also known as electronic cigarettes, e-cigarettes, vaping, and electronic nicotine delivery system (ENDS). Vaping products are varied in design but tend to include a battery, heating element, reservoir, and mouthpiece. The heating element is used to produce a vapour from vape-liquid (e-liquid) that come in a variety of flavours and may or may not contain nicotine. Vaping products come in many forms including basic disposable devices and refillable kits using a cartridge or tank system.

Heated tobacco products contain tobacco and a heating element. They are also referred to as heat not burn and tobacco heating products.

¹ For the purposes of this document *alternative products* include *vaping* and *heated tobacco products*.

cigarettes, which are a relatively homogenous product category and generally smoked in a similar manner. Vaping products, especially newer devices, are customisable, allowing the user to adjust nearly every parameter involved in aerosol generation. This introduces a number of methodological problems when designing experiments involving aerosol generation. Experiments that avoid aerosol generation and instead measure in vivo metabolites in users can avoid these methodological issues. In particular, analysis of biomarkers of exposure provides a reliable surrogate of exposure resulting from real-world use conditions, and can avoid the issues with accurate aerosol generation and delivery.

The pattern of alternative product use changes geographically throughout Canada, therefore, sampling will be required in five (5) locations across Canada (Vancouver BC, Edmonton, AB, Toronto, ON, Ottawa, ON and Montreal, QC). Up to 300 subjects will be recruited across Canada, grouped into cigarette smokers (N=50), vaping product users (N=100), heated product users (N=0 to 50), dual users (N=50) and non-exposed controls (N=50). The Contractor will provide an information session; go through the consent process including witnessing signing of the consent form; collecting urine samples, splitting urine samples into aliquots and shipping them on dry ice to the Health Canada laboratories in Ottawa; and collecting questionnaire data and shipping them to TCD offices in Ottawa.

3. Requirements

3.1. Tasks, Activities, Deliverables and/or Milestones

The Contractor will:

- 1. Apply for local ethics board approval if applicable.
- 2. Provide sufficient trained staff to liaise with the company responsible for recruiting participants to ensure participants understand the study they are participating via an information sheet in, validate participant eligibility, collect samples and questionnaires, and ensure remuneration of participants upon completion.
- 3. Keep a record of how many participants were eligible, how many were ineligible, reasons for ineligibility, how many agreed to participate, how many agreed but did not sign consent, how many signed consent but did not complete the questionnaire and urine sample.
- 4. Develop a system to identify each participant (without using personal information such as names) to be used on questionnaires and samples.
- 5. Provide sufficient trained staff and clinical space to administer the information sheet to participants, administer ,witness, review, store and ship participant consent forms, administer, collect, review, store and ship participant questionnaires;
- 6. Provide washroom facilities for participants and qualified laboratory technicians to collect, handle, process, store and ship the urine samples. Due to the nature of the samples, shipment must be completed by an individual who is certified under the Transportation of Dangerous Goods (TDG). Provide a freezer (-40 to -80 °C) storage for all urine samples in a secured room and secure storage for the participant consent forms and questionnaires.
- 7. Ensure the privacy, confidentiality and safety of all participants as per industry standards. All information collected under this contract must be kept secure and separate and not entered or included in the contractor's general patient database.
- 8. Ship completed consent forms, questionnaires and samples to Health Canada on a regular basis as per procedures to be provided upon contract award.
- 9. Provide progress report and final reports to Health Canada.

3.2. Method and Source of Acceptance

The Project Authority at Health Canada will review all project deliverables (draft reports, final report) for quality, performance of required tasks, and format, and will indicate in writing to the Contractor within 10 working days whether a specific deliverable has been accepted, and will identify any required changes to the deliverable. The Contractor will have 10 working days to revise the deliverable unless both parties agree to an alternative deadline. At that point, the Project Authority at Health Canada will re-review the deliverable and determine if it is acceptable or requires revision (at no cost to Health Canada).

3.3. Reporting Requirements

The Contractor shall deliver the services using the methods agreed upon, in the format requested, and within the timelines established in this contract. The Contractor shall submit one (1) electronic copy of each to the Project Authority. The Contractor shall submit periodic progress/status reports, with each report outlining the accomplishments for the given period, any open issues, and upcoming milestones. Refer to Section 3.1 for associated details on reporting requirements.

3.4. Privacy Requirements

- The contractor is required to adhere to all aspects of the Privacy Act and Regulations, Treasury Board and PSPC privacy-policies, directives and standards, including https://buyandsell.gc.ca/policy-and-guidelines/standard-acquisition-clauses-and-conditions-manual/4/4008 (SACC).
- The contractor must submit the raw data from the research to Health Canada/PHAC. However the contractor must not submit any data (e.g., names, addresses, IP addresses) that can be used to individually identify participants. As per section 12 of SACC Manual Clause 4008, Canada exercises its rights to request that the contractor destroy any link between statistical data and individual respondents once the survey is completed and all survey data has been complied and validated.
- The contractor is required to protect the information until it has been destroyed or rendered completely anonymous.
- The contractor may only collect the minimum (and only that which is demonstrably necessary) personal information to achieve the requirements of the research described in the SOW.
- If a participant discloses personal information in the collection of research, any identifying information must be removed from the data.
- When warranted, instructions will be provided to participants to remind them not to provide details about specific cases.
- Health Canada/PHAC must be given the opportunity to review and approve the research instrument from a privacy perspective.
- The information collected can only be used for the purpose of fulfilling contract deliverables and cannot be used or disclosed for any other purpose without Health Canada/PHAC's approval.

3.5. Project Management Control Procedures

The Project Authority shall monitor the progress of the work, ensure that the work under this Contract is on target and of acceptable quality. In addition to the measures outlined in section 3.1 and 3.4, the reports for this Contract may be submitted, at the Departmental Representative's discretion, to an internal and/or external peer review prior to acceptance.

4. Additional Information

4.1. Canada's Obligations

Health Canada will:

- Receive approval from Health Canada's Research Ethics Board, and report on adverse events during the study.
- Ensure appropriate Privacy Assessments have been performed, and develop Privacy Obligations sign off document for field personnel.
- Work with the contractor to communicate with the participants on the purpose and procedure of the study.
- Provide participant information sheet, consent form and questionnaires.
- Communicate with the contractor as required to review the testing protocol, verify details for completeness and to assess progress.
- Assume responsibility for the laboratory analysis biologic samples of urine.
- Provide comments on draft reports and final reports to the Contractor within ten (10) working days.
- Conduct analyses on the samples and statistical analysis of data, and interpret findings.

4.2. Contractor's Obligations

- Unless otherwise specified, the Contractor must use its own equipment and software for the performance of this Statement of Work.
- Provide an information session for the participants on the purpose and procedure of the study.
- Administer participant information sheet, consent form and questionnaires.
- Collect and prepare urine samples (collection, handling, processing, storage, and shipping).
- The Contractor shall treat all information that comes to his/her attention by virtue of carrying
 out the work under this agreement as privileged and confidential and will not disclose it to any
 third party either during the course of or after termination of this agreement except as may be
 necessary to perform the duties hereunder. All personal information must be kept in a secure
 area when not being used.

4.3. Location of Work, Work site and Delivery Point

The work outlined in this contract will be conducted at the Contractor's site or normal place of business, with the submission of deliverables to Health Canada's facilities as specified herein. Due to existing workload and deadlines, all personnel assigned to this contract must be ready to work in close and frequent contact with the Project Authority and other departmental personnel as needed.

4.4. Language of Work

The language of work for this contract will be English.

5. Project Schedule

5.1. Schedule and Estimated Level of Effort (Work Breakdown Structure)

Task	Time
Screening and consent	
Includes administration of participant information sheet, consent forms and questionnaire.	Ongoing
Data collection	
Includes collection, handling, processing and storage of urine samples, consent forms, and questionnaire.	Ongoing

Transfer of samples and data	
Includes the shipment of samples and completed consent forms and questionnaires to Health Canada.	On or before September 30, 2019

ANNEX B - BASIS OF PAYMENT

In consideration of the Contractor satisfactorily completing all of its obligations under the Contract, the Contractor will be paid a firm unit price as identified below. Customs duties are included and Applicable Taxes are extra.

Canada will not pay the Contractor for any design changes, modifications or interpretations of the Work, unless they have been approved, in writing, by the Contracting Authority before their incorporation into the Work.

Bidders may bid on one or more locations below:

LOCATION	DESCRIPTION	FIRM UNIT PRICE (A)	ESTIMATED NUMBER OF UNITS (PARTICIPANTS) (B)	ESTIMATED TOTAL (C = AXB)
Vancouver BC,	Participant preparation (information sheet, consent, questionnaire); and Collecting, handling, processing and storing participant urine samples, consent forms, and	\$	Up to 60	\$
	questionnaires; and Shipping of participant urine samples, consent forms, and questionnaires			
Edmonton, AB,	Participant preparation (information sheet, consent, questionnaire); and Collecting, handling, processing and storing participant urine samples, consent forms, and questionnaires; and Shipping of participant urine samples, consent	\$	Up to 60	\$
Toronto, ON,	forms, and questionnaires Participant preparation (information sheet, consent, questionnaire); and Collecting, handling, processing and storing participant urine samples,	\$	Up to 60	\$

	consent forms, and questionnaires; and Shipping of participant urine samples, consent forms, and questionnaires			
Ottawa, ON	Participant preparation (information sheet, consent, questionnaire); and Collecting, handling, processing and storing participant urine samples, consent forms, and questionnaires; and Shipping of participant urine samples, consent forms, and questionnaires	\$	Up to 60	\$
Montreal, QC	Participant preparation (information sheet, consent, questionnaire); and Collecting, handling, processing and storing participant urine samples, consent forms, and questionnaires; and Shipping of participant urine samples, consent forms, and questionnaires	\$	Up to 60	\$
	Applicable taxes			\$
	Estimated total contract value (must not exceed \$40,000.00 per location, up to a maximum value of \$200,000.00 CAD including taxes)			\$

ANNEX C - SECURITY REQUIREMENTS CHECKLIST

	Government	Gouvernement	•	Contract Number / Numéro du contrat				
7	of Canada	du Canada			1000204974			
				Security (Classification / Classification de unclassified	sécurité		
SECURITY REQUIREMENTS CHECK LIST (SRCL) LISTE DE VÉRIFICATION DES EXIGENCES RELATIVES À LA SÉCURITÉ (LVERS) PART A - CONTRACT INFORMATION / PARTIE A - INFORMATION CONTRACTUELLE								
		Ament or Organization		2. Branch	or Directorate / Direction géné	rale ou Direction		
		ernemental d'origina	Health Canada		B/TCD			
3. a) Subcontract Number / Numéro du contrat de sous-traitance 3. b) Name and Address of Subcontractor / Nom et adresse du sous-traitant								
	Brief Description of Work / Brève description du travail							
Blomarker	of Exposure Testing in	Users of Novel Nicotine	B Delivery Devices and Tobacco	Products: Data Collection (1	of 5 geographic sites)			
		cess to Controlled Go		ranne ar regiment and a free record to a record and a second a second and a second		No Yes		
l.		ès à des marchandise	es controlees? illitary technical data subjec	I to the provisions of the	racholeal Data Control	Non Oui		
Regulati	ons?			•		Non Oui		
	Isseur aura-t-il acci intrôle des données		hniques militaires non class	ifiées qui sont assujetties	aux dispositions du Règlement			
		quired / Indiquer le ty	pe d'accès requis					
6. a) Will the	supplier and its em	ployees require acce	ss to PROTECTED and/or (CLASSIFIED information of	or assets?	No Yes		
Le fourn	isseur ainsi que les	employés auront-ils using the chart in Qu	accès à des renseignement	ts ou à des biens PROTÉ	GES et/ou CLASSIFIÉS?	Non Lyfoul		
(Précise	r le niveau d'accès	en utilisant le tablear	u qui se trouve à la question	7. c)				
			s, maintenance personnel) : or assets is permitted.	require access to restricte	d access areas? No access to	✓ No Yes		
Le fourn	isseur et ses emplo	yés (p. ex, nettoyeur	s, personnel d'entretien) au	ront-ils accès à des zone:	d'accès restreintes? L'accès	Non L Oul		
			ÉS el/ou CLASSIFIÉS n'est			No Yes		
			ent with no overnight storag on commerciale sans entre			No Yes		
7, a) Indicate	the type of informa	tion that the supplier	will be required to access /	Indiquer le type d'informa	lion auquel le fournisseur devra	avoir accès		
	7	7	NATO / OTAN	7	Foreign / Étranger	· · · · · · · · · · · · · · · · · · ·		
7, b) Release	restrictions / Restri	ictions relatives à la		<u> </u>				
No release r		71	All NATO countries		No release restrictions Aucune restriction relative	<u> </u>		
à la diffusion	riction relative	<u>v</u>	Tous les pays de l'OTAN	<u></u>	à la diffusion			
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	Information / Nivea	u d'information						
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PROTÉGÉ E			NATO DIFFUSION REST	REINTE	PROTÉGÉ B			
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CONFIDEN	riel L		NATO SECRET		CONFIDENTIEL			
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TBS/SCT 35	50-103(2004/12)		Security Classification / C			(1)		
			uncla	ssified		Canadä		

Contract Number / Numéro du contrat



Contract Number / Numéro du contrat 1000204974 Security Classification / Classification de sécurité unclassified

PART A (continued) / PARTIE A (suite) 8. Will the supplier require access to PROTECTED and/or CLASSIFIED COMSEC information or assets? Le fournisseur aura-t-il accès à des enseignements ou à des biens COMSEC désignés PROTÉGÉS et/ou CLASSIFIÉS? If Yes, indicate the level of sensitivity: Dans l'affirmativé, indiquer le niveau de sensibilité ;								
9. Will the supplier require access to extremely sensitive INFOSEC information or assets? Le fournisseur aura-t-il accès à des renseignements ou à des biens INFOSEC de nature extrêmement délicate? Von Von Oui								
Short Tille(s) of material / Titre(s) abrégé(s) du matériel ; Document Number / Numèro du document :								
PART B - PERSONNEL (SUPPLIER) / PARTIE B - PERSONNEL (FOURNISSEUR) 10. a) Personnel security screening level required / Niveau de contrôle de la sécurité du personnel requis								
RELIABILITY STATUS COTE DE FIABILITÉ	CONFIDENTIAL SECRET SECRET	TOP SECRE TRES SECRE						
TOP SECRET - SIGINT TRÈS SECRET - SIGINT	NATO CONFIDENTIAL NATO SECRET		P SECRET ÉS SECRET					
SITE ACCESS ACCES AUX EMPLACEMENTS								
Special comments: Commentaires spéciaux :	A CONTRACTOR OF THE PROPERTY O	**************************************						
NOTE: If multiple levels of screening are identified, a Security Classification Guide must be provided, REMARQUE: SI plusieurs niveaux de contrôle de sécurité sont requis, un guide de classification de la sécurité doit être fourni.								
 b) May unscreened personnel be used for portions Du personnel sans autorisation sécuritaire peut- 			Non Oui					
If Yes, will unscreened personnel be escorted? Dans l'affirmative, le personnel en question sera	a-t-il escorté?		No Yes Non Oul					
PART C - SAFEGUARDS (SUPPLIER) / PARTIE C - MESURES DE PROTECTION (FOURNISSEUR) INFORMATION / ASSETS / RENSEIGNEMENTS / BIENS								
11, a) Will the supplier be required to receive and store PROTECTED and/or CLASSIFIED information or assets on its site or premises? Le fournisseur sera-t-il tenu de recevoir et d'entreposer sur place des renseignements ou des biens PROTÉGÉS et/ou CLASSIFIÉS?								
11. b) Will the supplier be required to safeguard COMSEC information or assets? Le fournisseur sera-t-il tenu de protéger des renseignements ou des biens COMSEC? No								
PRODUCTION								
11. c) Will the production (manufacture, and/or repair and/or modification) of PROTECTED and/or CLASSIFIED material or equipment occur at the supplier's site or premises? Les installations du fournisseur serviront-elles à la production (fabrication et/ou réparation et/ou modification) de matériel PROTÉGÉ et/ou CLASSIFIÉ?								
INFORMATION TECHNOLOGY (IT) MEDIA / SUPPORT RELATIF A LA TECHNOLOGIE DE L'INFORMATION (TI)								
11, d) Will the supplier be required to use its IT systems to electronically process, produce or store PROTECTED and/or CLASSIFIED Information or data? Le fournisseur sera-t-il tenu d'utiliser ses proprès systèmes informatiques pour trailer, produire ou stocker électroniquement des renseignements ou des données PROTEGES el/ou CLASSIFIES?								
11. e) Will there be an electronic link between the supplier's IT systems and the government department or agency? Disposera-t-on d'un lien électronique entre le système informatique du fournisseur et celui du ministère ou de l'agence gouvernementale? Non Yes Non Qui								
TBS/SCT 350-103(2004/12)	Security Classification / Classification de sécurité unclassified		Canadä					

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	Governmen
*	of Canada

Gouvernement du Canada Contract Number / Numéro du contrat

1000204974

Security Classification / Classification de sécurité unclassified

PART C - (continued) I PARTIE C - (suite)
For users completing the form manually use the summary chart below to indicate the category(les) and level(s) of safeguarding required at the supplier's Les utilisateurs qui remplissent le formulaire manuellement doivent utiliser le tableau récapitulatif ci-dessous pour indiquer, pour chaque catégorie, les niveaux de sauvegarde requis aux installations du fournisseur, For users completing the form online (via the internet), the summary chart is automatically populated by your responses to previous questions.

Dans le cas des utilisateurs qui remplissent le formulaire en ligne (par internet), les réponses aux questions précédentes sont automatiquement saisies dans le tableau récapitulatif. SUMMARY CHART / TABLEAU RÉCAPITULATIF Category Catégorie CLASSIFIED CLASSIFIÉ NATO COMSEC PROTECTED PROTÉGÉ NATO CONFIDENTIAL COSMIC TOP SECRET COSMIC TRÈS CONFIDENTIAL SECRET CONFIDENTIAL CONFIDENTIEL TRÈS NATO IFFUSION NATO Confidentiel В CONFIDENTIEL TRES SECRET RESTREINTE Information / Assets Renseignements / Blen Production IT Media Support TI IT Link / Lien électroniqu 12, a) Is the description of the work contained within this SRCL PROTECTED and/or CLASSIFIED? La description du travall visé par la présente LVERS est-elle de nature PROTÉGÉE et/ou CLASSIFIÉE? ✓ Non Non If Yes, classify this form by annotating the top and bottom in the area entitled "Security Classification".

Dans l'affirmative, classifier le présent formulaire en Indiquent le niveau de sécurité dans la case intitulée « Classification de sécurité » au haut et au bas du formulaire. 12. b) Will the documentation attached to this SRCL be PROTECTED and/or CLASSIFIED?

La documentation associée à la présente LVERS sera-t-elle PROTÉGÉE et/ou CLASSIFIÉE? If Yes, classify this form by annotating the top and bottom in the area entitled "Security Classification" and indicate with attachments (e.g. SECRET with Attachments). Dans l'affirmative, classifier le présent formulaire en indiquant le niveau de sécurité dans la case intitulée « Classification de sécurité » au haut et au bas du formulaire et indiquer qu'il y a des pièces jointes (p. ex. SECRET avec des pièces jointes).

TBS/SCT 350-103(2004/12)

Security Classification / Classification de sécurité unclassified Canada