



National Defence

National Defence Headquarters
Ottawa, Ontario
K1A 0K2

Défense nationale

Quartier général de la Défense nationale
Ottawa (Ontario)
K1A 0K2

REQUEST FOR PROPOSAL / DEMANDE DE PROPOSITION

RETURN BIDS TO / RETOURNER LES SOUMISSIONS À:

Director Services Contracting 3 (D Svcs C 3)
Attention: Scott Serafin, D Svcs C 3-5-3
By e-mail to: Scott.Serafin@forces.gc.ca

Proposal To: National Defence 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 and services listed herein and on any attached sheets at the price(s) set out therefore.

Proposition à: Défense nationale 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 et services énumérés ici et sur toute feuille ci-annexée, au(x) prix indique(s).

Comments – Commentaires

**THIS DOCUMENT CONTAINS A SECURITY REQUIREMENT/
CE DOCUMENT CONTIENT UNE EXIGENCE DE SÉCURITÉ.**

<p>Solicitation Closes / L'invitation prend fin:</p> <p>At / à:</p> <p>02:00 PM Eastern Daylight Time (EDT)</p> <p>On / le:</p> <p>7 September 2022</p>
--

Title / Titre Regulatory Affairs Support Services	Solicitation No. / N° de l'invitation W6369-22-A062
Date of Solicitation / Date de l'invitation 26 July 2022	
Address Enquiries to / Adresser toutes questions à: Scott Serafin, D Svcs C 3-5-3 Scott.Serafin@forces.gc.ca	
Telephone No. / N° de téléphone	FAX No. / N° de fax
Destination See Herein	

Instructions: Municipal taxes are not applicable. Unless otherwise specified herein all prices quoted must include all applicable Canadian customs duties, GST/HST, excise taxes and are to be delivered Delivery Duty Paid including all delivery charges to destination(s) as indicated. The amount of the Goods and Services Tax/Harmonized Sales Tax is to be shown as a separate item.

Instructions : Les taxes municipales ne s'appliquent pas. Sauf indication contraire, les prix indiqués doivent comprendre les droits de douane canadiens, la TPS/TVH et la taxe d'accise. Les biens doivent être livrés « rendu droits acquittés », tous frais de livraison compris, à la ou aux destinations indiquées. Le montant de la taxe sur les produits et services/taxe de vente harmonisée doit être indiqué séparément.

Delivery Required / Livraison exigée See Herein	Delivery Offered / Livraison proposée
Vendor Name and Address / Raison sociale et adresse du fournisseur	
Name and title of person authorized to sign on behalf of vendor (type or print) / Nom et titre de la personne autorisée à signer au nom du fournisseur (caractère d'imprimerie)	
Name – Nom _____	Title – Titre _____
Signature _____	Date _____



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PART 1 – GENERAL INFORMATION

1.1 Security Requirements

- A. Before award of a contract, the following conditions must be met:
- (i) The Bidder must hold a valid organization security clearance as indicated in Part 6 - Resulting Contract Clauses;
 - (ii) 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; and
 - (iii) The Bidder must provide the name of all individuals who will require access to classified or protected information, assets or sensitive work sites.
- B. Bidders are reminded to obtain the required security clearance promptly. Any delay in the award of a contract to allow the successful Bidder to obtain the required clearance will be at the entire discretion of the Contracting Authority.
- C. For additional information on security requirements, Bidders should refer to [Contract Security Program](http://www.tpsgc-pwgsc.gc.ca/esc-src/introduction-eng.html) of Public Works and Government Services Canada (<http://www.tpsgc-pwgsc.gc.ca/esc-src/introduction-eng.html>) website.

1.2 Statement of Work

- A. The Work to be performed is detailed under Article 6.2 of the resulting contract clauses.

1.3 Debriefings

- A. 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.

1.4 Canadian Content

- A. The requirement is limited to Canadian goods and/or services.



PART 2 – BIDDER INSTRUCTIONS

2.1 Standard Instructions, Clauses and Conditions

- A. All instructions, clauses and conditions identified in the bid solicitation by number, date and title are set out in the *Standard Acquisition Clauses and Conditions (SACC) Manual* (<https://buyandsell.gc.ca/policy-and-guidelines/standard-acquisition-clauses-and-conditions-manual>) issued by Public Works and Government Services Canada.
- B. 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.
- C. The 2003 (2022-03-29), Standard Instructions - Goods or Services - Competitive Requirements, are incorporated by reference into and form part of the bid solicitation, with the following modification(s):
- (i) Section 02, Procurement Business Number, is deleted in its entirety;
 - (ii) Section 05, Submission of bids, subsection 2, paragraph d., is deleted in its entirety and replaced with the following:
 - d. send its bid only to the Department of National Defence location specified on page 1 of the bid solicitation or to the address specified in the bid solicitation.
 - (iii) Section 05, Submission of bids, subsection 2, paragraph e., is deleted in its entirety and replaced with the following:
 - e. ensure that the Bidder's name, return address, the bid solicitation number, and bid solicitation closing date and time are clearly visible on the bid; and
 - (iv) Section 05, Submission of bids, subsection 4, is amended as follows:
 - Delete: 60 days
 - Insert: 180 days
 - (v) Section 06, Late bids, is deleted in its entirety;
 - (vi) Section 07, Delayed bids, is deleted in its entirety and replaced with the following:
 - 07 Delayed bids
 - 1. It is the Bidder's responsibility to ensure that the Contracting Authority has received the entire submission. Misrouting or other electronic delivery issues resulting in late submission of bids will not be accepted.
 - (vii) Section 08, Transmission by facsimile, is deleted in its entirety; and
 - (viii) Section 20, Further information, is deleted in its entirety.



2.2 Submission of Bids

- A. Bids must be submitted only to the Department of National Defence (DND) by the date, time, and place indicated on page 1 of the bid solicitation.
- B. Due to the nature of the bid solicitation, bids transmitted by facsimile will not be accepted.

2.2.1 Electronic Submissions

- A. **Individual e-mails that may include certain scripts, formats, embedded macros and/or links, or those that exceed five (5) megabytes may be rejected by Canada's e-mail system and/or firewall(s) without notice to the Bidder or Contracting Authority.** Larger bids may be submitted through more than one e-mail. Canada will confirm receipt of documents. It is the Bidder's responsibility to ensure that their entire submission has been received. Bidders should not assume that all documents have been received unless Canada confirms receipt of each document. In order to minimize the potential for technical issues, bidders are requested to allow sufficient time before the closing date and time to confirm receipt. Bid documents **submitted** after the closing time and date will not be accepted.

2.3 Former Public Servant

- A. 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.

2.3.1 Definitions

- A. 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
 - d. A sole proprietorship or entity where the affected individual has a controlling or major interest in the entity.
- B. "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.



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

2.3.2 Former Public Servant in Receipt of a Pension

- A. As per the above definitions, is the Bidder a FPS in receipt of a pension?
Yes () No ()
- B. If so, the Bidder must provide the following information, for all FPSs in receipt of a pension, as applicable:
- (i) Name of former public servant; and
 - (ii) Date of termination of employment or retirement from the Public Service.
- C. 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: 2019-01](#) and the [Guidelines on the Proactive Disclosure of Contracts](#).

2.3.3 Work Force Adjustment Directive

- A. Is the Bidder a FPS who received a lump sum payment pursuant to the terms of the Work Force Adjustment Directive?
Yes () No ()
- B. 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; and
 - g. Number and amount (professional fees) of other contracts subject to the restrictions of a work force adjustment program.



2.4 Enquiries - Bid Solicitation

- A. All enquiries must be submitted in writing to the Contracting Authority no later than 15 calendar days before the bid closing date. Enquiries received after that time may not be answered.
- B. 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

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

2.6 Basis for Canada's Ownership of Intellectual Property

- A. DND has determined that any intellectual property rights arising from the performance of the Work under the resulting contract will belong to Canada, for the following reasons, as set out in the [Policy on Title to Intellectual Property Arising Under Crown Procurement Contracts](http://www.ic.gc.ca/eic/site/068.nsf/eng/00005.html) (<http://www.ic.gc.ca/eic/site/068.nsf/eng/00005.html>):
- The Intellectual Property in Foreground Information consists of material subject to copyright, with the exception of computer software and all documentation pertaining to that software.

2.7 Bid Challenge and Recourse Mechanisms

- A. Several mechanisms are available to potential suppliers to challenge aspects of the procurement process up to and including contract award.
- B. Canada encourages suppliers to first bring their concerns to the attention of the Contracting Authority. Canada's [Buy and Sell](#) website, under the heading "[Bid Challenge and Recourse Mechanisms](#)" contains information on potential complaint bodies such as:
- Office of the Procurement Ombudsman (OPO)
 - Canadian International Trade Tribunal (CITT)
- C. Suppliers should note that there are **strict deadlines** for filing complaints, and the time periods vary depending on the complaint body in question. Suppliers should therefore act quickly when they want to challenge any aspect of the procurement process.



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PART 3 – BID PREPARATION INSTRUCTIONS

3.1 Bid Preparation Instructions

- A. Canada requests that Bidders provide their bid in separately bound sections as follows:
- Section I: Technical Bid: one (1) soft copy in PDF format by e-mail;
- Section II: Financial Bid: one (1) soft copy in PDF format by e-mail;
- Section III: Certifications: one (1) soft copy in PDF format by e-mail; and
- Section IV: Additional Information: one (1) soft copy in PDF format by e-mail.
- B. Prices must appear in the financial bid only. No prices must be indicated in any other section of the bid.
- C. Canada requests that Bidders follow the format instructions described below in the preparation of their bid:
- (i) Use 8.5 x 11 inch (216 mm x 279 mm) paper; and
 - (ii) Use a numbering system that corresponds to the bid solicitation.

3.2 Section I: Technical Bid

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

3.3 Section II: Financial Bid

- A. Bidders must submit their financial bid in accordance with the Pricing Schedule detailed in Attachment 1 to Part 3.

3.3.1 Electronic Payment of Invoices - Bid

- A. If you are willing to accept payment of invoices by Electronic Payment Instruments, complete Attachment 2 to Part 3, Electronic Payment Instruments, to identify which ones are accepted.
- B. If Attachment 2 to Part 3, Electronic Payment Instruments is not completed, it will be considered as if Electronic Payment Instruments are not being accepted for payment of invoices.
- C. Acceptance of Electronic Payment Instruments will not be considered as an evaluation criterion.

3.3.2 Exchange Rate Fluctuation

- A. The requirement does not offer exchange rate fluctuation risk mitigation. Requests for exchange rate fluctuation risk mitigation will not be considered. All bids including such provision will render the bid non-responsive.



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3.4 Section III: Certifications

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

3.5 Section IV: Additional Information

- A. In Section IV of their bid, bidders should provide:
- (i) A completed, signed, and dated Page 1 of this solicitation;
 - (ii) The name of the contact person (provide also this person's title, mailing address, phone number, and email address) authorized by the Bidder to enter into communications with Canada with regards to their bid, and any contract that may result from their bid;
 - (iii) For Part 2, article 2.3, Former Public Servant, of the bid solicitation: the required answer to each question; and, if the answer is yes, the required information;
 - (iv) For Part 2, article 2.5, Applicable Laws, of the bid solicitation: the province or territory if different than specified;
 - (v) For Part 1, article 1.1, Security Requirement, of the bid solicitation, for each individual who will require access to classified or protected information, assets, or sensitive work sites:
 - (a) the name of the individual;
 - (b) the date of birth of the individual; and
 - (c) if available, information confirming the individual meets the security requirement as indicated in Part 6 - Resulting Contract Clauses; and
 - (vi) Any other information submitted in the bid not already detailed.



ATTACHMENT 1 TO PART 3 – PRICING SCHEDULE

- A. The Bidder must complete this pricing schedule and include it in its financial bid.
- B. The volumetric data included in this pricing schedule are provided for bid evaluated price determination purposes only. They are not to be considered as a contractual guarantee. Their inclusion in this pricing schedule does not represent a commitment by Canada that Canada’s future usage of the services described in the bid solicitation will be consistent with this data.
- C. The firm rates specified below includes all expenses that may need to be incurred to satisfy the terms of any contract that may result from its bid, including the total estimated cost of any travel and living expenses that may need to be incurred for the Work described in Annex A, Statement of Work of the bid solicitation.
- D. Under any resulting contract, Canada will not accept travel and living expenses that may need to be incurred by the contractor for any relocation of resources required to satisfy its contractual obligations.
- E. All prices and costs must be submitted in Canadian Dollars, Applicable Taxes excluded, FOB destination, freight charges included, Canadian customs duties and excise taxes included.

1. Pricing Schedule

Currency	CAD\$
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A. INITIAL CONTRACT PERIOD (From Date of Contract Award to 31 March 2024)

Initial Contract Period (Year 1) (from date of Contract Award to 31 March 2023):

Rows	Number of Resources	Resource Category	Estimated Annual Level of Effort (A)	Firm All-Inclusive Hourly Rate Per Resource (B)	Total (C) = (A x B)
1	2	Strategic Level Resource	Up to 400 hours	\$	\$
2	2	General Level Resource	Up to 300 hours	\$	\$
3	1	Administrative Level Resource	Up to 80 hours	\$	\$
Total Evaluated Cost – Initial Contract Period (Year 1) (sum of C rows 1-3)					\$

**Initial Contract Period (Year 2) (from 01 April 2023 to 31 March 2024):**

Rows	Number of Resources	Resource Category	Estimated Annual Level of Effort (A)	Firm All-Inclusive Hourly Rate Per Resource (B)	Total (C) = (A x B)
1	2	Strategic Level Resource	Up to 400 hours	\$	\$
2	2	General Level Resource	Up to 300 hours	\$	\$
3	1	Administrative Level Resource	Up to 80 hours	\$	\$
Total Evaluated Cost – Initial Contract Period (Year 2) (sum of C rows 1-3)					\$

B. EXTENDED CONTRACT PERIOD (Year 3 to Year 5)**Extended Contract Period 1 (Year 3) (from 01 April 2024 to 31 March 2025):**

Rows	Number of Resources	Resource Category	Estimated Annual Level of Effort (A)	Firm All-Inclusive Hourly Rate Per Resource (B)	Total (C) = (A x B)
1	2	Strategic Level Resource	Up to 400 hours	\$	\$
2	2	General Level Resource	Up to 300 hours	\$	\$
3	1	Administrative Level Resource	Up to 80 hours	\$	\$
Total Evaluated Cost – Extended Contract Period 1 (Year 3) (sum of C rows 1-3)					\$

Extended Contract Period 2 (Year 4) (from 01 April 2025 to 31 March 2026):

Rows	Number of Resources	Resource Category	Estimated Annual Level of Effort (A)	Firm All-Inclusive Hourly Rate Per Resource (B)	Total (C) = (A x B)
1	2	Strategic Level Resource	Up to 400 hours	\$	\$
2	2	General Level Resource	Up to 300 hours	\$	\$
3	1	Administrative Level Resource	Up to 80 hours	\$	\$
Total Evaluated Cost – Extended Contract Period 2 (Year 4) (sum of C rows 1-3)					\$



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Extended Contract Period 3 (Year 5) (from 01 April 2026 to 31 March 2027):

Rows	Number of Resources	Resource Category	Estimated Annual Level of Effort (A)	Firm All-Inclusive Hourly Rate Per Resource (B)	Total (C) = (A x B)
1	2	Strategic Level Resource	Up to 400 hours	\$	\$
2	2	General Level Resource	Up to 300 hours	\$	\$
3	1	Administrative Level Resource	Up to 80 hours	\$	\$
Total Evaluated Cost – Extended Contract Period (Year 5) (sum of C rows 1-3)					\$

C. TOTAL EVALUATED COST (for bid evaluation purposes only):

Rows		
1	Total Evaluated Cost – Initial Contract Period (Year 1)	\$
2	Total Evaluated Cost – Initial Contract Period (Year 2)	\$
3	Total Evaluated Cost – Extended Contract Period 1 (Year 3)	\$
4	Total Evaluated Cost – Extended Contract Period 2 (Year 4)	\$
5	Total Evaluated Cost – Extended Contract Period 3 (Year 5)	\$
Total Evaluated Cost (sum of rows 1-5)		\$



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ATTACHMENT 2 TO PART 3 – ELECTRONIC PAYMENT INSTRUMENTS

- A. The Bidder accepts to be paid by any of the following Electronic Payment Instrument(s):
- () Direct Deposit (Domestic and International); and
 - () Wire Transfer (International Only)



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 mandatory and rated technical criteria, and the pricing schedule.
- B. An evaluation team composed of representatives of Canada will evaluate the bids.

4.1.1 Technical Evaluation

- A. Mandatory and point rated technical evaluation criteria are included in Attachment 1 to Part 4, Evaluation Criteria.

4.1.2 Financial Evaluation

- A. The price of the bid will be evaluated in Canadian dollars, Applicable Taxes excluded, FOB destination, freight charges included, Canadian customs duties and excise taxes included.

4.2 Basis of Selection – Highest Combined Rating of Technical Merit (60%) and Price (40%)

- A. To be declared responsive, a bid must:
 - (i) Comply with all the requirements of the bid solicitation; and
 - (ii) Meet all mandatory criteria; and
 - (iii) Obtain the required minimum of 202 points overall for the technical evaluation criteria which are subject to point rating. The rating is performed on a scale of 337 points.
- B. Bids not meeting (i) or (ii) or (iii) will be declared non-responsive.
- C. The selection will be based on the highest responsive combined rating of technical merit and price. The ratio will be 60% for the technical merit and 40% for the price.
- D. To establish the technical merit score, the overall technical score for each responsive bid will be determined as follows: total number of points obtained / maximum number of points available multiplied by the ratio of 60%.
- E. To establish the pricing score, each responsive bid will be prorated against the lowest evaluated price and the ratio of 40%.
- F. For each responsive bid, the technical merit score and the pricing score will be added to determine its combined rating.
- G. Neither the responsive bid obtaining the highest technical score nor the one with the lowest evaluated price will necessarily be accepted. The responsive bid with the highest combined rating of technical merit and price will be recommended for award of a contract.

The table below illustrates an example where all three bids are responsive and the selection of the contractor is determined by a 60/40 ratio of technical merit and price, respectively. The total available points equals 135 and the lowest evaluated price is \$45,000 (45).



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Basis of Selection – Highest Combined Rating Technical Merit (60%) and Price (40%)

		Bidder 1	Bidder 2	Bidder 3
Overall Technical Score		115/135	89/135	92/135
Bid Evaluated Price		\$55,000.00	\$50,000.00	\$45,000.00
Calculations	Technical Merit Score	$115/135 \times 60 = 51.11$	$89/135 \times 60 = 39.56$	$92/135 \times 60 = 40.89$
	Pricing Score	$45/55 \times 40 = 32.73$	$45/50 \times 40 = 36.00$	$45/45 \times 40 = 40.00$
Combined Rating		83.84	78.56	80.89
Overall Rating		1st	2nd	3rd

- B. Should two (2) or more responsive bids achieve an identical highest combined rating of technical merit and price. The bid received first based on the date and time stamp of the email will be recommended for award of a contract.



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ATTACHMENT 1 TO PART 4 – EVALUATION CRITERIA

- A. In their proposals, bidders must demonstrate they meet the following mandatory criteria. Failure to meet any of the mandatory criteria will render the bid non-compliant and it will be given no further consideration.

1.0 EVALUATION CRITERIA

- A. The Bidder must submit the résumés of each proposed resource for each labour category to demonstrate the resources experience in response to the mandatory and point rated technical criteria.
- B. The Bidder must demonstrate its experience and each proposed resource's experience in terms of months. Unless otherwise specified, 1 year of experience is equivalent to 1200 hours. For the purpose of calculating months and years of experience, overlapping experience will only be counted once (e.g. Project #1 time frame is July 2016 to December 2016; Project #2 time frame is October 2016 to January 2017; the total experience for these two project references is seven (7) months).
- C. Demonstrated concurrent experience will be accepted for evaluation purposes.
- D. University degree requirements specified under the labour categories must be from a recognized Canadian university, or the equivalent, as established by a recognized Canadian academic credentials assessment service*, if obtained outside Canada.

* The list of recognized organizations can be found under the Canadian Information Centre for International Credentials website, at the following Internet link: <http://www.cicic.ca/indexe.stm>

- E. Where the post-secondary degree or diploma was completed and obtained outside of Canada, Canada reserves the right to request a Canadian equivalency document to be provided by the Bidder and issued by recognized academic credentials assessment organization showing the academic level obtained.
- F. In evaluating resource past performance experience, compliance must be demonstrated through a well written, coherent, brief (if possible), past project description containing the following as a minimum:
- Name of the project. (E.g. prepared cardiac drug NDS, etc.);
 - Description of the type of Drug or Medical Product;
 - Resources' position;
 - Resources' work start date;
 - Resources' work completion date;
 - Duration of the experience in months;
 - Description of the project and other relevant details that document how this experience has been acquired by the Bidder (for corporate level criteria) and proposed resources (for proposed resource criteria); and
 - An explanation how this experience meets the specific criteria of this solicitation.



- G. If the Bidder submits more than one (1) resource for the Administrative level resource category, or more than two (2) resources for the Strategic and General level resource categories, Canada will only evaluate the first named resource presented in the proposal for the Administrative level resource category, and only the first two (2) named resources in the proposal for the Strategic and General level resource categories.

2.0 MANDATORY TECHNICAL CRITERIA

- A. At bid closing time, the Bidder must comply with the following mandatory criteria and provide the necessary documentation to support compliance. Any bid which fails to meet the following mandatory criteria will be declared non-responsive. Each criterion should be addressed separately.
- B. The following criteria will be applied to the evaluation. This table should be completed and submitted by each Bidder.

#	MANDATORY REQUIREMENT	BIDDER SUBSTANTIATION (INCLUDES LOCATION WITHIN PROPOSAL; TITLE, PAGE, ETC.)
THE BIDDER'S CORPORATE EXPERIENCE		
M1	<p>The Bidder must demonstrate that it has obtained Health Canada approval of at least ten (10) submissions for Schedule "D" or "F" drugs, as defined in the Canadian Food and Drugs Act.</p> <p>In order to demonstrate this, the Bidder must provide examples of submission approvals obtained within the last ten (10) years as of the closing date of this RFP. The submission approvals must include each of the following categories:</p> <ol style="list-style-type: none"> 1. Two (2) submission approvals for the issuance of Notice of Compliance (NOC) for a New Drug Submissions (NDS); 2. Two (2) submission approvals for Drug Identification Number (DIN); 3. Two (2) submission approvals for No Objection Letter (NOL); and, 4. Any other four (4) submission approvals. <p>Evidence of this track record should not contain proprietary information. Inclusion of dates of approvals along with the drug category is required. Acceptance at screening for further review does not constitute Health Canada approval.</p>	



THE BIDDER'S PROPOSED RESOURCES		
TWO (2) STRATEGIC LEVEL RESOURCES		
PROPOSED RESOURCE (1) NAME:		
PROPOSED RESOURCE (2) NAME:		
		BIDDER SUBSTANTIATION (INCLUDES LOCATION WITHIN PROPOSAL; TITLE, PAGE, ETC.)
M2.1	<p><u>Resource (1):</u> The Bidder must demonstrate that one (1) of the proposed Resource has completed a Health Sciences PhD degree from an accredited Canadian university, or equivalent, as established by a recognized Canadian academic credentials assessment service.</p> <p><u>Resource (2):</u> The Bidder must demonstrate that one (1) of the proposed Resources has completed a Health Sciences Master's degree, from an accredited Canadian university, or equivalent, as established by a recognized Canadian academic credentials assessment service, in one (1) of the following fields:</p> <ul style="list-style-type: none"> - Chemistry; - Microbiology; - Toxicology; - Pharmacy; - Biochemistry; - Pharmacology; - Biology; or - Other Health Scientific equivalent field as recognized by the Faculty of Science of a Canadian University <p>The necessary documentation to support the bid in meeting this criterion must include a copy of the degree for each proposed Resource.</p>	
M2.2	<p>Resources (1) and (2):</p> <p>The Bidder must demonstrate that each of the proposed Resources have a minimum of eight (8) years' experience, within the last fifteen (15) years as of the closing date of the RFP, in the interpretation of Canadian regulatory requirements, or Canadian and International* regulatory requirements as they pertain to medical products.</p>	



	<p>*NOTE: International is defined as a region for which its regulatory jurisdiction is either a founding (regulatory/industry) or standing (regulatory) member of the International Council on Harmonisation or the regulatory jurisdiction has a Good Manufacturing Practices Mutual Recognition Agreement with Health Canada.</p> <p>Refer to ATTACHMENT 1 TO PART 4 - EVALUATION CRITERIA, Section 1 for the required detailing experience on resumes and products.</p>	
M2.3	<p>Resources (1) and (2):</p> <p>The Bidder must demonstrate that both of the proposed Resources have a combined experience of a minimum of eight (8) years, within the last fifteen (15) years as of the closing date of this RFP, in the interpretation of Canadian regulatory requirements, or Canadian and International* regulatory requirements as they pertain to drugs.</p> <p>For example: if Resource (1) has five (5) years' experience, then Resource (2) must have at least three (3) years' experience.</p> <p>*NOTE: International is defined as a region for which its regulatory jurisdiction is either a founding (regulatory/industry) or standing (regulatory) member of the International Council on Harmonisation or the regulatory jurisdiction has a Good Manufacturing Practices Mutual Recognition Agreement with Health Canada.</p> <p>Refer to ATTACHMENT 1 TO PART 4 - EVALUATION CRITERIA, Section 1 for the required detailing experience on resumes and products.</p>	
M2.4	<p>Resources (1) and (2):</p> <p>The Bidder must demonstrate that both of the proposed Resources have a combined experience of a minimum of five (5) years within the last fifteen (15) years as of the closing date of this RFP, in the interpretation of Canadian regulatory requirements, or</p>	



	<p>Canadian and International* regulatory requirements as they pertain to medical devices.</p> <p>For example: if Resource (1) has three (3) years' experience, then Resource (2) must have at least two (2) years' experience.</p> <p>*NOTE: International is defined as a region for which its regulatory jurisdiction is either a founding (regulatory/industry) or standing (regulatory) member of the International Council on Harmonisation or the regulatory jurisdiction has a Good Manufacturing Practices Mutual Recognition Agreement with Health Canada.</p> <p>Refer to ATTACHMENT 1 TO PART 4 - EVALUATION CRITERIA, Section 1 for the required detailing experience on resumes and products.</p>	
<p>TWO (2) GENERAL LEVEL RESOURCES PROPOSED RESOURCE (1) NAME: PROPOSED RESOURCE (2) NAME:</p>		
		<p>BIDDER SUBSTANTIATION (INCLUDES LOCATION WITHIN PROPOSAL; TITLE, PAGE, ETC.)</p>
<p>M3.1</p>	<p>Resources (1) and (2):</p> <p>The Bidder must demonstrate that each of the proposed Resources have a Health Sciences BSc. degree from an accredited Canadian university, or equivalent, as established by a recognized Canadian academic credentials assessment service, in one (1) of the following fields:</p> <ul style="list-style-type: none"> - Chemistry; - Microbiology; - Toxicology; - Pharmacy; - Biochemistry; - Pharmacology; - Biology; or - Other Health Scientific equivalent field as recognized by the Faculty of Science of a Canadian University. 	



	<p>The necessary documentation to support the bid in meeting this criterion must include a copy of the degree for each proposed Resource.</p>	
M3.2	<p><u>Resources (1) and (2):</u></p> <p>The Bidder must demonstrate that each of the proposed Resources have a minimum of three (3) years' experience, within the last ten (10) years as of the closing date of this RFP, in Canadian regulatory affairs drafting regulatory submissions including summarizing study reports and annotating submission sections for medical products.</p> <p>Refer to ATTACHMENT 1 TO PART 4 - EVALUATION CRITERIA, Section 1 for the required detailing experience on resumes and products.</p>	
M3.3	<p><u>Resources (1) and (2):</u></p> <p>The Bidder must demonstrate that both of the proposed Resources have a combined experience of a minimum of three (3) years, within the last ten (10) years as of the closing date of this RFP, in Canadian regulatory affairs drafting regulatory submissions including summarizing study reports and annotating submission sections for drugs.</p> <p>For example: if Resource (1) has two (2) years' experience, then Resource (2) must have at least one (1) year' experience.</p> <p>Refer to ATTACHMENT 1 TO PART 4 - EVALUATION CRITERIA, Section 1 for the required detailing experience on resumes and products.</p>	
M3.4	<p><u>Resources (1) and (2):</u></p> <p>The Bidder must demonstrate that both of the proposed Resources have a combined experience of a minimum of three (3) years, within the last ten (10) years as of the closing date of this RFP, in Canadian regulatory affairs in drafting regulatory submissions including summarizing study reports and annotating submission sections for medical devices.</p>	



	<p>For example: if Resource (1) has two (2) years' experience, then Resource (2) must have at least one (1) year' experience.</p> <p>Refer to ATTACHMENT 1 TO PART 4 - EVALUATION CRITERIA, Section 1 for the required detailing experience on resumes and products.</p>	
<p>ONE (1) ADMINISTRATIVE LEVEL RESOURCE PROPOSED RESOURCE NAME:</p>		
		<p>BIDDER SUBSTANTIATION (INCLUDES LOCATION WITHIN PROPOSAL; TITLE, PAGE, ETC.)</p>
<p>M4.1</p>	<p>The Bidder must demonstrate that the proposed Resource has a minimum of one (1) year' experience, within the last ten (10) years as of the closing date of this RFP, in the assembly of regulatory submission binders including the preparation and labeling of dividers, photocopying and document formatting.</p> <p>Refer to ATTACHMENT 1 TO PART 4 - EVALUATION CRITERIA, Section 1 for the required detailing experience on resumes and products.</p>	

3.0 POINT RATED EVALUATION CRITERIA

- 3.1 Bids which meet all the mandatory technical criteria will be evaluated and scored as specified in the tables inserted below.
- 3.2 Bids which fail to obtain the required minimum number of points specified will be declared non-responsive. Each point rated technical criterion should be addressed separately.

#	POINT RATED CRITERIA	SCORING CRITERIA	MAX POINTS	BIDDER SUBSTANTIATION (INCLUDES LOCATION WITHIN PROPOSAL; TITLE, PAGE, ETC.)
<p>THE BIDDER'S CORPORATE EXPERIENCE</p>				
<p>R1</p>	<p>The Bidder should demonstrate its experience within the last six (6) years as of the closing date of this RFP, in the negotiation with Health Canada of regulatory submissions</p>	<p>1 to 10 submissions = 5 points</p> <p>11 to 20 submissions = 10 points</p>	<p>15 points</p>	



	<p>with associated performance targets as outlined in the Management of Drug Submissions Guidance Document and Management of Applications for Medical Device Licenses and Investigational Testing Authorizations.</p> <p>Refer to ATTACHMENT 1 TO PART 4 - EVALUATION CRITERIA, Section 1 for the required detailing experience on resumes and products.</p>	<p>More than 20 submissions = 15 points</p>		
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THE BIDDER'S PROPOSED RESOURCES

TWO (2) STRATEGIC LEVEL RESOURCES
PROPOSED RESOURCE (1) NAME:
PROPOSED RESOURCE (2) NAME:

R2.1	<p>Resource (1) and (2):</p> <p>The Bidder should demonstrate that each of the proposed Resources hold a Canadian, European Union or a United States Regulatory Affairs Certificate.</p> <p>The necessary documentation to support the bid in meeting this criterion should include a copy of the certificate.</p>	<p>5 points per Certificate per Resource</p>	<p>10 points</p>	
R2.2	<p><u>Resource (1) and (2):</u></p> <p>The Bidder should demonstrate that each of the proposed Resources have experience within the last six (6) years as of the closing date of this RFP, in the preparation of the following Canadian regulatory documents for medical products:</p> <ul style="list-style-type: none"> a. New Drug Submissions (NDS) and related supplements; b. Clinical Trial Applications (CTA); c. Drug Development Plans (DDP); 	<ul style="list-style-type: none"> a. 2 points per NDS per Resource (max 10 points per Resource); b. 1 point per CTA per Resource (max 5 points per Resource) c. 2 points per DDP per Resource (max 10 points per Resource) d. 2 points per MDLA per Resource (max 	<p>100 points</p>	



	<p>d. Medical Device License Applications (MDLA);</p> <p>e. Investigational Testing Applications (ITA); or</p> <p>f. Medical Device Development Plans (MDDP).</p> <p>Refer to ATTACHMENT 1 TO PART 4 - EVALUATION CRITERIA, Section 1 for the required detailing experience on resumes and products.</p>	<p>10 points per Resource)</p> <p>e. 1 point per ITA per Resource (max 5 points per Resource)</p> <p>f. 2 points per MDDP per Resource (max 10 points per Resource)</p>		
R2.3	<p><u>Resource (1) and (2):</u></p> <p>The Bidder should demonstrate that each of the proposed Resources have experience within the last six (6) years as of the closing date of this RFP, in the development of a pharmaceutical product.</p> <p>Product development experience includes provision of final technical/scientific documents as specified below:</p> <p>a. Requirements Analysis: e.g. analysis of currently held documentation and identification of further studies required by Health Canada to complete a submission;</p> <p>b. Technical/Scientific Reviews of candidate medical products;</p> <p>c. Development of pharmaceutical preclinical Studies and clinical Trial designs;</p> <p>d. Assessments of the application of Good Laboratory Practices (GLP), Good Clinical Practices (GCP), and Good Manufacturing Practices (GMP): e.g. assessment of current practices, identification of deficiencies and</p>	<p>a. 1 point per Analysis per Resource (max 5 points per Resource)</p> <p>b. 1 point per Review per Resource (max 5 points per Resource)</p> <p>c. 1 point per Study and Trial per Resource (max 5 points per Resource)</p> <p>d. 1 point per Assessment per Resource (max 5 points per Resource)</p> <p>e. 1 point per Assessment per Resource (max 5 points per Resource)</p> <p>1 point per Strategy per Resource (max 5</p>	60 points	



	<p>recommendations for deficiency resolution;</p> <p>e. Quality control and assurance Assessments: e.g. assessment of current practices, identification of deficiencies and recommendations for deficiency resolution; or</p> <p>f. Development of regulatory Strategies for candidate products.</p> <p>Refer to ATTACHMENT 1 TO PART 4 - EVALUATION CRITERIA, Section 1 for the required detailing experience on resumes and products.</p>	points per Resource)		
R2.4	<p><u>Resource (1) and (2):</u></p> <p>The Bidder should demonstrate that each of the proposed Resource have experience within the last six (6) years as of the closing date of this RFP, in the development of a medical device.</p> <p>Medical device development experience includes provision of final technical/scientific documents as specified below:</p> <p>a. Requirements Analysis: e.g. analysis of currently held documentation and identification of further studies required by Health Canada to complete an application;</p> <p>b. Technical/scientific Reviews of candidate medical devices;</p> <p>c. Development of Investigational Testing Designs;</p> <p>d. Assessments of the application of the most recent Health Canada Recognized Standards for Medical Devices: e.g.</p>	<p>a. 1 point per Analysis per Resource (max 5 points per Resource)</p> <p>b. 1 point per Review per Resource (max 5 points per Resource)</p> <p>c. 1 point per Design per Resource (max 5 points per Resource)</p> <p>d. 1 point per Assessment per Resource (max 5 points per Resource)</p> <p>e. 1 point per Assessment per Resource (max 5 points per Resource)</p>	60 points	



	<p>assessment of current practices, identification of deficiencies and recommendations for deficiency resolution;</p> <p>e. Quality control and assurance Assessments: e.g. assessment of current practices, identification of deficiencies and recommendations for deficiency resolution; or</p> <p>f. Development of regulatory Strategies for candidate medical devices.</p> <p>Refer to ATTACHMENT 1 TO PART 4 - EVALUATION CRITERIA, Section 1 for the required detailing experience on resumes and products.</p>	f. 1 point per Strategy per Resource (max 5 points per Resource)		
R2.5	<p><u>Resources (1) and (2):</u></p> <p>The Bidder should demonstrate that each of the proposed Resource have experience within the last six (6) years as of the closing date of this RFP, in chairing meetings between Health Canada and sponsor representatives.</p> <p>Refer to ATTACHMENT 1 TO PART 4 - EVALUATION CRITERIA, Section 1 for the required detailing experience on resumes and products.</p>	2 points per Meeting per Resource (max 10 points per Resource)	20 points	
R2.6	<p><u>Resources (1) and (2):</u></p> <p>The Bidder should demonstrate that each of the proposed Resources have experience within the last five (5) years as of the closing date of this RFP, in the critical Evaluations of the following, as related to medical products:</p> <p>a. Pre-clinical study reports;</p> <p>b. Clinical study reports; or</p>	<p>a. 1 point per Evaluation per Resource (max 5 points per Resource)</p> <p>b. 1 point per Evaluation per Resource (max 5 points per Resource)</p>	30 points	



	<p>c. Chemistry, Manufacturing and Controls reports.</p> <p>Refer to ATTACHMENT 1 TO PART 4 - EVALUATION CRITERIA, Section 1 for the required detailing experience on resumes and products.</p>	<p>1 point per Evaluation per Resource (max 5 points per Resource)</p>		
<p>TWO (2) GENERAL LEVEL RESOURCES PROPOSED RESOURCE (1) NAME: PROPOSED RESOURCE (2) NAME:</p>				
R3.1	<p>The Bidder should demonstrate that each of the proposed Resources have completed a Canadian post-graduate regulatory Certification program or holds a Canadian Regulatory Affairs Certificate (RAC).</p> <p>The necessary documentation to support the bid in meeting this criterion should include a copy of the certification/certificate.</p>	<p>5 points per Certification or Certificate per Resource</p>	<p>10 points</p>	
R3.2	<p>The Bidder should demonstrate that each of the proposed Resource have experience within the last six (6) years as of the bid closing date of this RFP, in the critical evaluation of the following, as related to medical products:</p> <ul style="list-style-type: none"> a. New Drug Submissions (NDS) and related supplements; b. Clinical Trial Application (CTA); c. Medical Device License Applications (MDLA); or d. Investigational Testing Application (ITA) <p>Refer to ATTACHMENT 1 TO PART 4 - EVALUATION CRITERIA, Section 1 for the required detailing experience on resumes and products.</p>	<ul style="list-style-type: none"> a. 1 point per NDS per Resource (max 5 points per Resource) b. 1 point per CTA per Resource (max 3 points per Resource) c. 1 point per MDLA per Resource (max 5 points per Resource) d. 1 point per ITA per Resource (max 3 points per Resource) 	<p>32 points</p>	



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MAXIMUM POINTS AVAILABLE	337	
MINIMUM POINTS REQUIRED	202	



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PART 5 - CERTIFICATIONS AND ADDITIONAL INFORMATION

- A. Bidders must provide the required certifications and additional information to be awarded a contract.
- B. 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.
- C. 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

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

5.1.1 Integrity Provisions - Declaration of Convicted Offences

- A. In accordance with the Integrity Provisions of the Standard Instructions, all bidders must provide with their bid, **if applicable**, the Integrity declaration form available on the [Forms for the Integrity Regime](http://www.tpsgc-pwgsc.gc.ca/ci-if/declaration-eng.html) 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

- A. 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 specified will render the bid non-responsive.

5.2.1 Integrity Provisions - Required Documentation

- A. In accordance with the section titled "Information to be provided when bidding, contracting, or entering into a real procurement agreement" of the [Ineligibility and Suspension Policy](http://www.tpsgc-pwgsc.gc.ca/ci-if/politique-policy-eng.html) (<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.

5.2.2 Federal Contractors Program for Employment Equity - Bid Certification

- A. By submitting a bid, the Bidder certifies that the Bidder, and any of the Bidder's members if the Bidder is a Joint Venture, is not named on the Federal Contractors Program (FCP) for employment equity "[FCP Limited Eligibility to Bid](https://www.canada.ca/en/employment-social-development/programs/employment-equity/federal-contractor-program.html#)" list available at the bottom of the page of the [Employment and Social Development Canada \(ESDC\) - Labour's](https://www.canada.ca/en/employment-social-development/programs/employment-equity/federal-contractor-program.html#) website (<https://www.canada.ca/en/employment-social-development/programs/employment-equity/federal-contractor-program.html#>).



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- B. Canada will have the right to declare a bid non-responsive if the Bidder, or any member of the Bidder if the Bidder is a Joint Venture, appears on the “FCP Limited Eligibility to Bid” list at the time of contract award.

5.2.3 Status and Availability of Resources

- A. The Bidder certifies that, should it be awarded a contract as a result of the bid solicitation, every individual proposed in its bid will be available to perform the Work as required by Canada's representatives and at the time specified in the bid solicitation or agreed to with Canada's representatives. If for reasons beyond its control, the Bidder is unable to provide the services of an individual named in its bid, the Bidder may propose a substitute with similar qualifications and experience. The Bidder must advise the Contracting Authority of the reason for the substitution and provide the name, qualifications and experience of the proposed replacement. For the purposes of this clause, only the following reasons will be considered as beyond the control of the Bidder: death, sickness, maternity and parental leave, retirement, resignation, dismissal for cause or termination of an agreement for default.
- B. If the Bidder has proposed any individual who is not an employee of the Bidder, the Bidder certifies that it has the permission from that individual to propose his/her services in relation to the Work to be performed and to submit his/her résumé to Canada. The Bidder must, upon request from the Contracting Authority, provide a written confirmation, signed by the individual, of the permission given to the Bidder and of his/her availability. Failure to comply with the request may result in the bid being declared non-responsive.

5.2.4 Education and Experience

- A. The Bidder certifies that all the information provided in the résumés and supporting material submitted with its bid, particularly the information pertaining to education, achievements, experience and work history, has been verified by the Bidder to be true and accurate. Furthermore, the Bidder warrants that every individual proposed by the Bidder for the requirement is capable of performing the Work described in the resulting contract.

5.2.5 Canadian Content Certification

- A. The Contractor warrants that the certification of Canadian Content submitted by the Contractor is accurate and complete, and that the goods, services or both to be provided under the Contract are in accordance with the definition contained in clause [A3050T](#).
- B. The Contractor must keep proper records and documentation relating to the origin of the goods, services or both provided to Canada. The Contractor must not, without obtaining before the written consent of the Contracting Authority, dispose of any such records or documentation until the expiration of six (6) years after final payment under the Contract, or until settlement of all outstanding claims and disputes under the Contract, whichever is later. All such records and documentation must at all times during the retention period be open to audit, inspection and examination by the representatives of Canada, who may make copies and take extracts. The Contractor must provide all facilities for such audits, inspections and examinations, and must furnish all such information as the representatives of Canada may from time to time require with respect to such records and documentation.
- C. Nothing in this clause must be interpreted as limiting the rights and remedies which Canada may otherwise have pursuant to the Contract.



5.2.6 Canadian Content Definition

- A. **Canadian good:** A good wholly manufactured or originating in Canada is considered a Canadian good. A product containing imported components may also be considered Canadian for the purpose of this policy when it has undergone sufficient change in Canada, in a manner that satisfies the definition specified under the [Canada-United States-Mexico Agreement \(CUSMA\)](#) Rules of Origin. For the purposes of this determination, the reference in the CUSMA Rules of Origin to "territory of one or more of the Parties" is to be replaced with "Canada". (Consult [Section 3.130](#) and [Annex 3.6](#) of the Supply Manual for further information.)
- B. **Canadian service:** A service provided by an individual based in Canada is considered a Canadian service. Where a requirement consists of only one service, which is being provided by more than one individual, the service will be considered Canadian if a minimum of 80 percent of the total bid price for the service is provided by individuals based in Canada.
- C. **Variety of goods:** When requirements consist of more than one good, one of the two methods below is applied:
- i) aggregate evaluation: no less than 80 percent of the total bid price must consist of Canadian goods; or,
 - ii) item by item evaluation: in some cases, the bid evaluation may be conducted on an item-by-item basis and contracts may be awarded to more than one supplier. In these cases, suppliers will be asked to identify separately each item that meets the definition of Canadian goods.
- D. **Variety of services:** For requirements consisting of more than one service, a minimum of 80 percent of the total bid price must be provided by individuals based in Canada.
- E. **Mix of goods and services:** When requirements consist of a mix of goods and services, no less than 80 percent of the total bid price must consist of Canadian goods and services (as defined above). For more information on how to determine the Canadian content for a mix of goods, a mix of services or a mix of goods and services, consult [Annex 3.6](#), Example 2, of the Supply Manual.
- F. **Other Canadian goods and services:** Textiles: Textiles are considered to be Canadian goods according to a modified rule of origin, copies of which are available from the Clothing and Textiles Division, Commercial and Consumer Products Directorate.

5.2.7 Security Requirements – Required Documentation

- A. In accordance with the requirements of the [Contract Security Program of Public Works and Government Services Canada](#) (<http://www.tpsgc-pwgsc.gc.ca/esc-src/introduction-eng.html>), the Bidder must provide a completed Contract Security Program Application for Registration (AFR) form to be given further consideration in the procurement process.
- B. Bidders are reminded to obtain the required security clearance and, as applicable, security capabilities promptly. As indicated above, bidders who do not provide all the required information at bid closing will be given the opportunity to complete any missing information from the AFR form within a period set by the Contracting Authority. If that information is not provided within the timeframe established by the Contracting Authority (including any extension granted by the Contracting Authority in its discretion), or if Canada requires further information from the bidder in connection with assessing the request for security clearance (i.e., information not required by the AFR form), the Bidder will be required to submit that information within the time period established



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by the Contracting Authority, which will not be less than 48 hours. If, at any time, the Bidder fails to provide the required information within the timeframe established by the Contracting Authority, its bid will be declared non-compliant.



PART 6 - RESULTING CONTRACT CLAUSES

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

ARTICLES OF AGREEMENT

6.1 Security Requirements

A. The following security requirements apply and form part of the Contract:

1. The Contractor/Offeror must, at all times during the performance of the Contract/Standing Offer, hold a valid Designated Organization Screening (DOS), issued by the Contract Security Program (CSP), Public Works and Government Services Canada (PWGSC).
2. The Contractor/Offeror personnel requiring access to sensitive site(s) must EACH hold a valid RELIABILITY STATUS, granted or approved by the CSP, PWGSC.
3. Subcontracts which contain security requirements are NOT to be awarded without the prior written permission of the CSP, PWGSC.
4. The Contractor/Offeror must comply with the provisions of the:
 - a) Security Requirements Check List and security guide (if applicable), attached at Annex C; and
 - b) *Contract Security Manual* (Latest Edition).

6.2 Statement of Work

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

6.2.1 Task Authorization

A. The Work or a portion of the Work to be performed under the Contract will be on an "as-and-when requested basis" using a Task Authorization (TA). The Work described in the TA must be in accordance with the scope of the Contract.

6.2.1.1 Task Authorization Process

A. The Task Authorization Process is as follows:

- (i) The Technical Authority will provide the Contractor with a description of the task using the DND 626, Task Authorization Form specified in Annex D;
- (ii) The TA will contain the details of the activities to be performed, a description of the deliverables, and a schedule indicating completion dates for the major activities or submission dates for the deliverables. The TA will also include the applicable basis (bases) and methods of payment as specified in the Contract;



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- (iii) The Contractor must provide the Technical Authority, within 5 calendar days of its receipt, the proposed total estimated cost for performing the task and a breakdown of that cost, established in accordance with the Basis of Payment specified in the Contract; and
- (iv) The Contractor must not commence work until a TA authorized by the Technical Authority has been received by the Contractor. The Contractor acknowledges that any work performed before a TA has been received will be done at the Contractor's own risk.

6.2.1.2 Task Authorization Limit

- A. The Technical Authority may authorize individual task authorizations up to a limit of \$25,000.00, Applicable Taxes included, inclusive of any revisions.
- B. Any task authorization to be issued in excess of that limit must be authorized by the Contracting Authority before issuance.

6.2.1.3 Minimum Work Guarantee - All the Work - Task Authorizations

- A. In this clause:
 - (i) "Maximum Contract Value" means the amount specified in the "Limitation of Expenditure" clause set out in the Contract; and
 - (ii) "Minimum Contract Value" means \$5,000.00.
- B. Canada's obligation under the Contract is to request Work in the amount of the Minimum Contract Value or, at Canada's option, to pay the Contractor at the end of the Contract in accordance with paragraph C. In consideration of such obligation, the Contractor agrees to stand in readiness throughout the Contract period to perform the Work described in the Contract. Canada's maximum liability for work performed under the Contract must not exceed the Maximum Contract Value, unless an increase is authorized in writing by the Contracting Authority.
- C. In the event that Canada does not request work in the amount of the Minimum Contract Value during the period of the Contract, Canada must pay the Contractor the difference between the Minimum Contract Value and the total cost of the Work requested.
- D. Canada will have no obligation to the Contractor under this clause if Canada terminates the Contract in whole or in part for default.

6.2.1.4 Periodic Usage Reports - Contracts with Task Authorizations

- A. The Contractor must compile and maintain records on its provision of services to the federal government under authorized Task Authorizations issued under the Contract.

The Contractor must provide this data in accordance with the reporting requirements detailed below or in Annex F. If some data is not available, the reason must be indicated. If services are not provided during a given period, the Contractor must still provide a "nil" report.

The data must be submitted on a quarterly basis to the Contracting Authority.

The quarterly periods are defined as follows:

- 1st quarter: April 1 to June 30;
- 2nd quarter: July 1 to September 30;



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3rd quarter: October 1 to December 31; and
4th quarter: January 1 to March 31.

The data must be submitted to the Contracting Authority no later than 30 calendar days after the end of the reporting period.

6.2.1.5 Task Authorization - Department of National Defence

- A. The administration of the Task Authorization process will be carried out by the Regulatory Affairs Group of the Department of National Defence. This process includes monitoring, controlling and reporting on expenditures of the contract with task authorizations to the Contracting Authority.

6.3 Standard Clauses and Conditions

- A. All clauses and conditions identified in the Contract by number, date and title are set out in the [Standard Acquisition Clauses and Conditions \(SACC\) Manual](https://buyandsell.gc.ca/policy-and-guidelines/standard-acquisition-clauses-and-conditions-manual) (<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

- A. [2040](#) (2022-05-12), General Conditions – Research and Development, apply to and form part of the Contract, with the following modification:

- (i) Article 01, Interpretation, "Canada", "Crown", "Her Majesty" or "the Government", is deleted in its entirety and replaced with the following:

"Canada", "Crown", "Her Majesty" or "the Government"

means Her Majesty the Queen in right of Canada as represented by the Minister of National Defence and any other person duly authorized to act on behalf of that minister or, if applicable, an appropriate minister to whom the Minister of National Defence has delegated his or her powers, duties or functions and any other person duly authorized to act on behalf of that minister.

6.3.2 Supplemental General Conditions

- A. The following Supplemental General Conditions apply to and form part of the Contract:

- (i) [4007](#) (2010-08-16), Canada to Own Intellectual Property Rights in Foreground Information;
- (ii) [4013](#) (2021-11-29), Compliance with on-site measures, standing orders, policies, and rules:

The Contractor must comply and ensure that its employees and subcontractors comply with all security measures, standing orders, policies or other rules in force at the site where the Work is performed; and

- (iii) [4014](#) (2021-11-29), Suspension of the work:

1. The Contracting Authority may at any time, by written notice, order the Contractor to suspend or stop the Work or part of the Work under the Contract for a period of up to 180 days. The Contractor must immediately comply with any such order in a



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way that minimizes the cost of doing so. While such an order is in effect, the Contractor must not remove any part of the Work from any premises without first obtaining the written consent of the Contracting Authority. Within these 180 days, the Contracting Authority must either cancel the order or terminate the Contract, in whole or in part, under section(s): Default by the Contractor or Termination for convenience of general conditions.

2. When an order is made under subsection 1, unless the Contracting Authority terminates the Contract by reason of default by the Contractor or the Contractor abandons the Contract, the Contractor will be entitled to be paid its additional costs incurred as a result of the suspension plus a fair and reasonable profit.
3. When an order made under subsection 1 is cancelled, the Contractor must resume work in accordance with the Contract as soon as practicable. If the suspension has affected the Contractor's ability to meet any delivery date under the Contract, the date for performing the part of the Work affected by the suspension will be extended for a period equal to the period of suspension plus a period, if any, that in the opinion of the Contracting Authority, following consultation with the Contractor, is necessary for the Contractor to resume the Work. Any equitable adjustments will be made as necessary to any affected conditions of the Contract

6.4 Term of Contract

6.4.1 Period of the Contract

- A. The period of the Contract is from date of Contract award to March 31, 2024.

6.4.2 Option to Extend the Contract

- A. The Contractor grants to Canada the irrevocable option to extend the term of the Contract by up to three (3) additional one-year period(s) under the same conditions. The Contractor agrees that, during the extended period of the Contract, it will be paid in accordance with the applicable provisions as set out in the Basis of Payment.
- B. Canada may exercise this option at any time by sending a written notice to the Contractor at least 30 calendar days before the expiry date of the Contract. The option may only be exercised by the Contracting Authority, and will be evidenced for administrative purposes only, through a contract amendment.

6.5 Authorities

6.5.1 Contracting Authority

- A. The Contracting Authority for the Contract is:

Name: Scott Serafin
Title: Senior Procurement Officer, D Svcs C 3-5-3
Organization: Director Services Contracting 3 (D Svcs C 3)
Address: Department of National Defence
101 Colonel By Drive
Ottawa ON
K1A 0K2



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Telephone: 343-542-3058
E-mail: Scott.Serafin@forces.gc.ca

- B. 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 Technical Authority

- A. The Technical Authority for the Contract is:

[Contact information to be detailed in the resulting contract]

Name: _____
Title: _____
Organization: _____
Address: Department of National Defence (DND)
101 Colonel By Drive
Ottawa ON
K1A 0K2
Telephone: _____
E-mail: _____

- B. The Technical 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 Technical Authority; however, the Technical 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

[Contact information to be detailed in the resulting contract]

Name: _____
Title: _____
Address: _____

Telephone: _____
E-mail: _____

6.6 Proactive Disclosure of Contracts with Former Public Servants

- A. By providing information on its status, with respect to being a former public servant in receipt of a [Public Service Superannuation Act](#) (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 [Contracting Policy Notice: 2019-01](#) of the Treasury Board Secretariat of Canada.



6.7 Payment

6.7.1 Basis of Payment – Individual Task Authorisations

- A. The Contractor will be paid for the Work specified in the authorized task authorization, in accordance with the Basis of payment at Annex B.
- B. Canada's liability to the Contractor under the authorized task authorization must not exceed the limitation of expenditure specified in the authorized task authorization. Custom duties are included and Applicable Taxes are extra.
- C. No increase in the liability of Canada or in the price of the Work specified in the authorized task authorization resulting from any design changes, modifications or interpretations of the Work will be authorized or paid to the Contractor unless these design changes, modifications or interpretations have been authorized, in writing, by the Contracting Authority before their incorporation into the Work.

6.7.2 Limitation of Expenditure - Cumulative Total of all Task Authorizations

- A. Canada's total liability to the Contractor under the Contract for all authorized Task Authorizations (TAs), inclusive of any revisions, must not exceed the sum of \$**amount to be detailed in the resulting contract**. Customs duties are included and Applicable Taxes are extra.
- B. No increase in the total liability of Canada will be authorized or paid to the Contractor unless an increase has been approved, in writing, by the Contracting Authority.
- C. The Contractor must notify the Contracting Authority in writing as to the adequacy of this sum:
 - (i) when it is 75 percent committed; or
 - (ii) four (4) months before the contract expiry date; or
 - (iii) as soon as the Contractor considers that the sum is inadequate for the completion of the Work required in all authorized TAs, inclusive of any revisions;whichever comes first.
- D. If the notification is for inadequate contract funds, the Contractor must provide to the Contracting Authority, a written estimate for the additional funds required. Provision of such information by the Contractor does not increase Canada's liability.

6.7.3 Method of Payment – Monthly Payments

- A. Canada will pay the Contractor on a monthly basis for work performed during the month covered by the invoice in accordance with the payment provisions of the Contract if:
 - (i) an accurate and complete invoice and any other documents required by the Contract have been submitted in accordance with the invoicing instructions provided in the Contract;
 - (ii) all such documents have been verified by Canada;



- (iii) the Work performed has been accepted by Canada.

6.7.4 Electronic Payment of Invoices - Contract

- A. The Contractor accepts to be paid using any of the following Electronic Payment Instrument(s):

[List to be updated in the resulting contract]

- (i) Direct Deposit (Domestic and International); and
- (ii) Wire Transfer (International Only)

6.7.6 Discretionary Audit

- A. The following are subject to government audit before or after payment is made:

- (i) The amount claimed under the Contract, as computed in accordance with the Basis of Payment, including time charged.
- (ii) The accuracy of the Contractor's time recording system.
- (iii) The estimated amount of profit in any firm-priced element, firm time rate, firm overhead rate, or firm salary multiplier, for which the Contractor has provided the appropriate certification. The purpose of the audit is to determine whether the actual profit earned on a single contract if only one exists, or the aggregate of actual profit earned by the Contractor on a series of negotiated contracts containing one or more of the prices, time rates or multipliers mentioned above, during a particular period selected, is reasonable and justifiable based on the estimated amount of profit included in earlier price or rate certification(s).
- (iv) Any firm-priced element, firm time rate, firm overhead rate, or firm salary multiplier for which the Contractor has provided a "most favoured customer" certification. The purpose of such audit is to determine whether the Contractor has charged anyone else, including the Contractor's most favoured customer, lower prices, rates or multipliers, for like quality and quantity of goods or services.

- B. Any payments made pending completion of the audit must be regarded as interim payments only and must be adjusted to the extent necessary to reflect the results of the said audit. If there has been any overpayment, the Contractor must repay Canada the amount found to be in excess.

6.7.7 Time Verification

- A. Time charged and the accuracy of the Contractor's time recording system are subject to verification by Canada, before or after payment is made to the Contractor. If verification is done after payment, the Contractor must repay any overpayment, at Canada's request.

6.7.8 Cost Submission - Limitation of Expenditure or Ceiling Price

- A. If requested by the Contracting Authority or auditor designated by the Contracting Authority, the Contractor must submit to the Contracting Authority or the auditor as applicable, a cost



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submission, upon completion of the Contract or annually for multi-year contracts spanning more than one contractor fiscal year.

- B. The cost submission must contain a breakdown of all applicable cost elements as detailed in the Contract and must be signed and certified accurate by the Contractor's Senior Financial Officer, unless stated otherwise in writing.
- C. Supporting information for each cost element must be available in sufficient detail to allow for an in-depth audit.

6.8 Invoicing Instructions

- A. 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.
- B. Each invoice must be supported by:
 - (i) A copy of time sheets to support the time claimed;
 - (ii) A copy of the invoices, receipts, vouchers for all direct expenses, and all travel and living expenses;
 - (iii) A breakdown of the cost elements.
- C. Invoices must be distributed as follows:
 - (i) The original and one (1) copy must be forwarded to the address shown on page 1 of the Contract for certification and payment. (address to be inserted at award on contract)
 - (ii) Upon request, one (1) copy must be forwarded to the Contracting Authority identified under the section entitled "Authorities" of the Contract.

6.9 Certifications and Additional Information

6.9.1 Compliance

- A. 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.

6.9.2 Certifications - Contract

- A. Compliance with the certifications provided by the Contractor in its bid is a condition of the Contract and subject to verification by Canada during the term of the Contract. If the Contractor does not comply with any certification or it is determined that any certification made by the Contractor in its bid is untrue, whether made knowingly or unknowingly, Canada has the right, pursuant to the default provision of the Contract, to terminate the Contract for default.

6.10 Applicable Laws



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- A. The Contract must be interpreted and governed, and the relations between the parties determined, by the laws in force in **Ontario** **[or as specified by the bidder in its bid, if applicable]**.

6.11 Priority of Documents

- A. 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:
- (i) The Articles of Agreement;
 - (ii) The Supplemental General Conditions [4007](#) (2010-08-16), [4013](#) (2021-11-29), and [4014](#) (2021-11-29);
 - (iii) [2040](#) (2022-05-12), General Conditions – Research and Development;
 - (iv) Annex A, Statement of Work;
 - (v) Annex B, Basis of Payment;
 - (vi) Annex C, Security Requirements Checklist (SRCL);
 - (vii) Annex D, DND 626 Task Authorisation Form
 - (viii) Annex F, Non-Disclosure Agreement;
 - (ix) The signed Task Authorizations (including all of its annexes, if any); and
 - (x) the Contractor's bid dated **[date to be specified in the resulting contract]**, as clarified on **[date to be specified in the resulting contract, if required]**, and as amended on **[date to be specified in the resulting contract, if required]**.

6.12 Defence Contract

- A. The Contract is a defence contract within the meaning of the *Defence Production Act*, R.S.C. 1985, c. D-1 (<http://laws-lois.justice.gc.ca/eng/acts/d-1/>), and must be governed accordingly.
- B. Title to the Work or to any materials, parts, work-in-process or finished work must belong to Canada free and clear of all claims, liens, attachments, charges or encumbrances. Canada is entitled, at any time, to remove, sell or dispose of the Work or any part of the Work in accordance with section 20 of the *Defence Production Act*.

6.13 Canadian Forces Site Regulations

- A. The Contractor must comply with all standing orders or other regulations, instructions and directives in force on the site where the Work is performed.

6.14 Insurance

- A. The Contractor is responsible for deciding if insurance coverage is necessary to fulfill its obligation under the Contract and to ensure compliance with any applicable law. Any insurance acquired or maintained by the Contractor is at its own expense and for its own benefit and protection. It does not release the Contractor from or reduce its liability under the Contract.



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6.15 Non-Disclosure Agreement

- A. The Contractor must obtain from its employee(s) or subcontractor(s) the completed and signed non-disclosure agreement, attached at Annex G, and provide it to the Contracting Authority before they are given access to information by or on behalf of Canada in connection with the Work.

6.16 Dispute Resolution

- A. The parties agree to maintain open and honest communication about the Work throughout and after the performance of the contract.
- B. The parties agree to consult and co-operate with each other in the furtherance of the contract and promptly notify the other party or parties and attempt to resolve problems or differences that may arise.
- C. If the parties cannot resolve a dispute through consultation and cooperation, the parties agree to consult a neutral third party offering alternative dispute resolution services to attempt to address the dispute.
- D. Options of alternative dispute resolution services can be found on Canada's Buy and Sell website under the heading "[Dispute Resolution](#)".

6.17 Canadian Content Certification

- A. The Contractor warrants that the certification of Canadian Content submitted by the Contractor is accurate and complete, and that the goods, services or both to be provided under the Contract are in accordance with the definition contained in clause [A3050T](#).
- B. The Contractor must keep proper records and documentation relating to the origin of the goods, services or both provided to Canada. The Contractor must not, without obtaining before the written consent of the Contracting Authority, dispose of any such records or documentation until the expiration of six (6) years after final payment under the Contract, or until settlement of all outstanding claims and disputes under the Contract, whichever is later. All such records and documentation must at all times during the retention period be open to audit, inspection and examination by the representatives of Canada, who may make copies and take extracts. The Contractor must provide all facilities for such audits, inspections and examinations, and must furnish all such information as the representatives of Canada may from time to time require with respect to such records and documentation.
- C. Nothing in this clause must be interpreted as limiting the rights and remedies which Canada may otherwise have pursuant to the Contract.



ANNEX A –STATEMENT OF WORK

1.0 OBJECTIVE

- 1.1. The objective of this requirement is to acquire the professional services of a team of regulatory affairs and product development specialists to prepare and file regulatory submissions to meet Health Canada (HC) regulations for drugs and medical devices. The team must comprise of the following:
- a. Two (2) Strategic Level Resources (Regulatory Affairs Professionals);
 - b. Two (2) General Level Resources; and,
 - c. One (1) Administrative Level Resource.

2.0 BACKGROUND

- 2.1. It is the mandate of Regulatory Affairs of the Department of National Defence (DND) / Canadian Armed Forces (CAF) to seek regulatory approval for operationally required drugs and medical devices. These regulatory approvals are sought from Health Canada (HC) through its Special Access Programme and other HC processes.
- 2.2. A team knowledgeable in the Canadian *Food and Drug Act* and Regulations is required to assist DND with a wide variety of regulatory and product development issues related to drugs and medical devices (henceforth referred to as medical products), as well as to research, prepare, review and negotiate regulatory submissions for medical products of interest to DND. Therefore, there is a requirement to prepare and file regulatory submissions to meet HC regulations and to develop and/or review complex industry documentation for scientific and regulatory suitability.

3.0 SCOPE

- 3.1. The Contractor must provide a team of five (5) resources as follows:
- 3.1.1. Strategic Level Support (2 Resources): providing in-depth technical regulatory advice, input and oversight on all Deliverables, including drafting regulatory strategies and interpretation of Canadian and International regulatory requirements as they pertain to medical products. Although the Strategic Resources may not action all components of a Deliverable, the Resources must be responsible for oversight and sign-off on all Deliverables;
 - 3.1.2. General Level Support (2 Resources): providing mid-level regulatory input such as submission drafting, including summarizing study reports and annotating submission sections; and
 - 3.1.3. Administrative Level Support (1 Resource): providing administrative support, including photocopying, assembling submission binders, preparing and labelling dividers, and document formatting.
- 3.2. The Contractor must be able to commence work no later than five (5) business days subsequent to the receipt of each Task Authorization, not including Federal Government statutory-holidays;
- 3.3. Email and phone inquiries from the Technical Authority must be acknowledged by the Contractor within 24 hours of receipt (not including weekends and Federal Government statutory-holidays).



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- 3.4. The Work may require occasional presence of the resource outside of business hours (7:00am – 5:00pm), on weekends, and Federal Government statutory-holidays.
- 3.5. As and when required, the Contractor must agree to dedicate additional resources to the tasking to ensure its timely completion. Additional resources will be evaluated and approved by the Technical Authority in accordance with Appendix A to Annex A, prior to undertaking the work.

4.0 TASKS AND DELIVERABLES

- 4.1. The Contractor must provide services on an “as and when requested” basis, in accordance with the Task Authorization process described in the Contract. Tasks and Deliverables to be completed include, but are not limited to:
 - 4.1.1. Preparing, reviewing, publishing and filing Canadian regulatory submissions in a format acceptable to Health Canada (HC) or other International Conference on Harmonization (ICH) countries;
 - 4.1.2. Determining the suitability of foreign or domestic dossiers for filing;
 - 4.1.3. Creating Product Monographs, Investigator’s Brochures, Quality Overall Summaries, Certified Product Information Documents and summary/overview documents for filing;
 - 4.1.4. Providing drug development analysis and formulating drug development plans;
 - 4.1.5. Attending meetings/teleconferences and participating in discussions and negotiations with HC, other medical regulatory agencies, allied medical product projects, medical product firms and other stakeholders;
 - 4.1.6. Preparing and delivering briefings to senior managers and officials up to the ministerial level;
 - 4.1.7. Liaising with industry with respect to product manufacturing, storage, and testing;
 - 4.1.8. Researching and providing documentation for regulatory issues, such as regulatory compliance, product development, and Good Laboratory, Clinical and Manufacturing Practices;
 - 4.1.9. Developing training materials, and quality assurance and control processes relating to deliverables to the Crown; and
 - 4.1.10 Providing advice on regulatory and product development aspects of medical products.
- 4.2. All Deliverables must be submitted to the Technical Authority for approval. All Deliverables completed in response to the Task Authorization will be evaluated, on the basis of suitability, quality and adherence to established schedule and standards, as defined by the Task Authorization.
- 4.3. Format of Deliverables:
 - 4.3.1. All Deliverables must be in, one or both of, the following formats, as designated by the Technical Authority in each Task Authorization:



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- a) Microsoft (MS) Office Suite of software applications and an eCTD software, including but not limited to: MS Word, Excel and PowerPoint; or,
- b) Paper format.

4.3.2. All documentation, reports and working papers must be legible, properly indexed and cross-referenced in the format approved by the Technical Authority as specified by the Task Authorization.

5.0 WORK LOCATION

- 5.1. The Work must be conducted primarily on the premises of the Contractor. The Contractor may be required to attend occasional meetings of one (1) day duration at DND premises in the National Capital Region (NCR), at the discretion of the Technical Authority. It is anticipated that these meetings will be held approximately once per year. The Contractor will not be reimbursed for travel within the NCR.
- 5.2. The work may arise in regions throughout Canada, the United States and overseas, for which travel may be required. These travel requirements may arise at short notice and the Contractor must be responsive to these requirements.

6.0 LANGUAGE OF WORK

- 6.1. All Work must be performed in English. It is required that the Resources be fluent in the English language, both for oral and written communications.

7.0 CLIENT SUPPORT

- 7.1. The Technical Authority will provide information to the Contractor, as specified in each individual Task Authorization. This may include, but is not limited to:
 - 7.1.1. Background information;
 - 7.1.2. Guidance on Government and DND requirements and practices; and
 - 7.1.3. Access to any available documentation required for the completion of each task.
- 7.2. The Contractor must return all documentation provided by the TA upon the completion of a Task.



APPENDIX A TO ANNEX A – TASKING ASSESSMENT PROCEDURE AND TECHNICAL CRITERIA AT TASK AUTHORIZATION STAGE

1.0 TASKING ASSESSMENT PROCEDURE

- A. Where a requirement for a specific task is identified, a draft Task Authorization Form (TA Form) as attached at Annex D will be provided to the Contractor in accordance with the allocation methodology stated in the Contract Article titled "Allocation of Task Authorizations". Once a draft TA Form is received, the Contractor must submit to the Project Authority a quotation of rates to supply the requested Resource Categories based on the information identified in the TA Form, as well as its corresponding proposed resource(s). The quotation must be signed and submitted to Canada within the time for response identified in the TA Form. The Contractor will be given a minimum of 5 working days (or any longer time period specified in the draft TA) turnaround time to submit a quotation.
- B. With each quotation the Contractor must propose the required number of resources and for each proposed resource the Contractor must supply a résumé, the requested security clearance information and must complete the Response Tables at Appendix A of Annex A applicable to the Resource Categories identified in the draft TA. The same individual must not be proposed for more than one Resource Category. The résumés must demonstrate that each proposed individual meets the qualification requirements described (including any educational requirements, work experience requirements, and professional designation or membership requirements). With respect to the proposed resources:
- (i) Proposed resources may be employees of the Contractor or employees of a subcontractor, or these individuals may be independent contractors to whom the Contractor would subcontract a portion of the Work.
 - (ii) For educational requirements for a particular degree, designation or certificate, Canada will only consider educational programs that were successfully completed by the resource before the date the draft TA was first issued to the Contractor.
 - (iii) For requirements relating to professional designation or membership, the resource must have the required designation or membership by the time of draft TA issuance and must continue, where applicable, to be a member in good standing of the profession or membership throughout the assessment period and Contract Period. Where the designation or membership must be demonstrated through a certification, diploma or degree, such document must be current, valid and issued by the entity specified in this Contract or if the entity is not specified, the issuer must have been an accredited or otherwise recognized body, institution or entity at the time the document was issued.
 - (iv) For work experience, Canada will not consider experience gained as part of an educational program, except for experience gained through a formal co-operative program at a post-secondary institution.
 - (v) For any requirements that specify a particular time period (e.g., 2 years) of work experience, Canada will disregard any information about experience if the résumé does not include the relevant dates (month and year) for the experience claimed (i.e., the start date and end date). Canada will evaluate only the duration that the resource actually worked on a project or projects (from his or her start date to end date), instead of the overall start and end date of a project or a combination of projects in which a resource has participated.
 - (vi) A résumé must not simply indicate the title of the individual's position, but must demonstrate that the resource has the required work experience by explaining the



responsibilities and work performed by the individual while in that position. Only listing experience without providing any supporting data to describe responsibilities, duties and relevance to the requirement, or reusing the same wording as the TA Form, will not be considered "demonstrated" for the purposes of the assessment. The Contractor should provide complete details as to where, when, month and year, and how, through which activities/responsibilities, the stated qualifications / experience were obtained. In situations in which a proposed resource worked at the same time on more than one project, the duration of any overlapping time period will be counted only once toward any requirements that relate to the individual's length of experience.

- C. The qualifications and experience of the proposed resources will be assessed against the requirements set out in Appendix A to Annex A to determine each proposed resource's compliance with the mandatory and rated criteria. Canada may request proof of successful completion of formal training, as well as reference information. Canada may conduct reference checks to verify the accuracy of the information provided. If reference checks are done, they will be conducted in writing by e-mail (unless the contact at the reference is only available by telephone). Canada will not assess any points or consider a mandatory criterion met unless the response is received within 5 working days. On the third working day after sending out the e-mails, if Canada has not received a response, Canada will notify the Contractor by e-mail, to allow the Contractor to contact its reference directly to ensure that it responds to Canada within 5 working days. Wherever information provided by a reference differs from the information supplied by the Contractor, the information supplied by the reference will be the information assessed. Points will not be allocated or a mandatory criteria considered as met if the reference customer is not a customer of the Contractor itself (for example, the customer cannot be the customer of an affiliate of the Contractor). Nor will points be allocated or a mandatory criteria considered as met if the customer is itself an affiliate or other entity that does not deal at arm's length with the Contractor. Crown references will be accepted.
- D. During the assessment of the resources proposed, should the references for two or more resources required under that TA either be unavailable or fail to substantiate the required qualifications of the proposed resources to perform the required services, the Contractor's quotation may be found to be non-responsive.
- E. Only quotations that meet all of the mandatory criteria will be considered for assessment of the point rated criteria. Each resource proposed must attain the required minimum score for the point rated criteria for the applicable Resource Category. If the minimum score for any proposed resource is less than what is required, the Contractor's quotation will be found to be non-responsive.
- F. Once the quotation has been accepted by the Project Authority, the TA Form will be signed by Canada and provided to the Contractor for signature. The TA Form must be appropriately signed by Canada prior to commencement of any work. The Contractor must not commence work until a validly issued TA Form (the Task Authorization) has been received, and any work performed in its absence is done at the Contractor's own risk.



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2.0 TECHNICAL CRITERIA AT TASK AUTHORIZATION STAGE

2.1. INSTRUCTIONS

A. It is recommended that the Contractor include a grid in its TA responses, cross-referencing statements of compliance with the supporting data in its responses. Note: the compliance grid, by and of itself does not constitute demonstrated evidence. The Contractor must submit a detailed CV for each of its proposed Supplementary Team resources.

B. Education must have been obtained from a recognized* Canadian university, college or high school, or the equivalent as established by a recognized* Canadian academic credentials assessment service, if obtained outside Canada. The Contractor must include copies of any degrees, diplomas or certificates.

*The list of recognized Canadian academic credentials assessment service providers can be found under the Canadian Information Centre for International Credentials website, at the following Internet link: <http://www.cicic.ca/indexe.stm>.

C. The Contractor is advised that only listing experience without providing any supporting data to describe where and how such experience was obtained will not constitute “demonstrated” for the purpose of the evaluation.

D. Each project/contract summary should include the name, phone number or e-mail of client reference. Canada reserves the right to request and contact Client references to validate information in the responses.

E. It is recommended that the Contractor also include in the CV, the current level of personnel security held by the proposed resource and their corresponding Canadian Industrial Security Directorate (CISD) file number.

3.0 MANDATORY EVALUATION CRITERIA

A. TA responses must meet the mandatory technical criteria specified below. The Contractor must provide the necessary documentation to support compliance with this requirement.

B. TA responses which fail to meet the mandatory technical criteria will be declared non-responsive. Each mandatory technical criterion should be addressed separately.

#	MANDATORY REQUIREMENT	BIDDER SUBSTANTIATION (INCLUDES LOCATION WITHIN PROPOSAL; TITLE, PAGE, ETC.)
STRATEGIC LEVEL RESOURCE		
M1.1	The Contractor must demonstrate that the proposed Resource has completed a Health Sciences PhD degree from an accredited Canadian university, or equivalent, as	



	<p>established by a recognized Canadian academic credentials assessment service.</p> <p><u>OR</u></p> <p>The Contractor must demonstrate that the proposed resource has completed a Health Sciences Master's degree, from an accredited Canadian university, or equivalent, as established by a recognized Canadian academic credentials assessment service, in one (1) of the following fields:</p> <ul style="list-style-type: none"> - Chemistry; - Microbiology; - Toxicology; - Pharmacy; - Biochemistry; - Pharmacology; - Biology; or - Other Health Scientific equivalent field as recognized by the Faculty of Science of a Canadian University 	
M1.2	<p>The Bidder must demonstrate that the proposed resource has a minimum of eight (8) years' experience, within the last fifteen (15) years, in the interpretation of Canadian regulatory requirements, or Canadian and International* regulatory requirements as they pertain to medical products.</p> <p>*NOTE: International is defined as a region for which its regulatory jurisdiction is either a founding (regulatory/industry) or standing (regulatory) member of the International Council on Harmonisation or the regulatory jurisdiction has a Good Manufacturing Practices Mutual Recognition Agreement with Health Canada.</p>	
M1.3	<p>The Contractor must demonstrate that the proposed resource has a minimum of eight (8) years' experience, within the last fifteen (15) years, in the interpretation of Canadian regulatory requirements, or Canadian and International* regulatory requirements as they pertain to drugs.</p> <p>*NOTE: International is defined as a region for which its regulatory jurisdiction is either a founding (regulatory/industry) or standing</p>	



	(regulatory) member of the International Council on Harmonisation or the regulatory jurisdiction has a Good Manufacturing Practices Mutual Recognition Agreement with Health Canada.	
M1.4	<p>The Contractor must demonstrate that the proposed resource has a minimum of five (5) years' experience within the last fifteen (15) years, in the interpretation of Canadian regulatory requirements, or Canadian and International* regulatory requirements as they pertain to medical devices.</p> <p>*NOTE: International is defined as a region for which its regulatory jurisdiction is either a founding (regulatory/industry) or standing (regulatory) member of the International Council on Harmonisation or the regulatory jurisdiction has a Good Manufacturing Practices Mutual Recognition Agreement with Health Canada.</p>	
GENERAL LEVEL RESOURCE		
M2.1	<p>The Contractor must demonstrate that the proposed resource has a Health Sciences BSc. degree from an accredited Canadian university, or equivalent, as established by a recognized Canadian academic credentials assessment service, in one (1) of the following fields:</p> <ul style="list-style-type: none"> - Chemistry; - Microbiology; - Toxicology; - Pharmacy; - Biochemistry; - Pharmacology; - Biology; or - Other Health Scientific equivalent field as recognized by the Faculty of Science of a Canadian University. 	
M2.2	The Contractor must demonstrate that the proposed resource has a minimum of three (3) years' experience, within the last ten (10) years, in Canadian regulatory affairs drafting regulatory submissions including summarizing study reports and annotating submission sections for medical products .	



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M2.3	The Contractor must demonstrate that the proposed resource has a minimum of three (3) years' experience, within the last ten (10) years, in Canadian regulatory affairs drafting regulatory submissions including summarizing study reports and annotating submission sections for drugs .	
M3.3	The Contractor must demonstrate that the proposed resource has a minimum of three (3) years, within the last ten (10) years, in Canadian regulatory affairs in drafting regulatory submissions including summarizing study reports and annotating submission sections for medical devices .	
ADMINISTRATIVE LEVEL RESOURCE		
M4.1	The Contractor must demonstrate that the proposed resource has a minimum of one (1) year' experience, within the last ten (10) years, in the assembly of regulatory submission binders including the preparation and labeling of dividers, photocopying and document formatting.	



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ANNEX B – BASIS OF PAYMENT

A. Initial Contract Period (from date of Contract Award to 31 March 2024)

During the period of the Contract, for Work performed in accordance with the Contract, the Contractor will be paid as specified below.

A-1. Professional Fees

The Contractor will be paid all-inclusive fixed time rates as follows:

Resource Category	All-Inclusive Firm Hourly Rate (CAD\$)
Initial Contract Period (Year 1) (from date of Contract Award to 31 March 2023)	
Strategic Level Resource	\$ _____
General Level Resource	\$ _____
Administrative Level Resource	\$ _____
Initial Contract Period (Year 2) (from 01 April 2023 to 31 March 2024)	
Strategic Level Resource	\$ _____
General Level Resource	\$ _____
Administrative Level Resource	\$ _____

For the purpose of this Contract, a day is defined as 7.5 hours of work, exclusive of meal breaks. Payment will be made for days actually worked, with no provision for annual leave, statutory holidays and sick leave. If time worked is more or less than a day, the all-inclusive fixed daily rate must be prorated to reflect the actual time worked.

Total Estimated Cost of Professional Fees: \$_____ (to be completed at contract award)

A-2. Cost Reimbursable Expenses

A-2.1 Authorized travel and living expenses for Work

Concerning the requirements to travel described in section 13 of the Statement of Work in Annex “A”, the Contractor will be paid for its authorized travel and living expenses reasonably and properly incurred in the performance of the Work done, delivered or performed outside the National Capital Region (NCR) defined in the *National Capital Act (R.S.C., 1985, c. N-4)*, available on the Justice Website ([National Capital Act \(justice.gc.ca\)](http://www.justice.gc.ca)), at cost, without any allowance for profit and administrative overhead, in accordance with the meal and private vehicle expenses provided in Appendices B, C and D of the [National Joint Council Travel Directive](#); and with the other provisions of the directive referring to "travellers", rather than those referring to "employees".

Canada will not accept travel and living expenses that may need to be incurred by the Contractor for any relocation of resources required to satisfy its contractual obligations.”

All travel must have the prior authorization of the Technical Authority.

The authorized travel and living expenses will be paid upon submission of an itemized statement supported by receipt vouchers. All payments are subject to government audit.



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Total Estimated Cost of Authorized Travel and Living Expenses:

Initial Contract Period: \$16,000.00

A-3. Total Estimated Cost – Contract Period: \$ _____ (to be completed at contract award)

With the exception of the all-inclusive fixed time rates specified above, the amounts shown in this section of the annex are estimates only. Minor changes to these estimates will be accepted for billing purposes as the Work proceeds, provided that these changes have the prior approval of the Technical Authority, and provided that the total estimated cost of the Contract does not exceed the aforementioned Limitation of Expenditure (Applicable taxes extra).

B. Option to Extend the Term of the Contract

This section is only applicable if the option to extend the Contract is exercised by Canada.

During the extended period of the Contract specified below, the Contractor will be paid as specified below to perform all the Work in relation to the Contract extension.

B-1. Extended Contract Period 1 (from 01 April 2024 to 31 March 2025)

Resource Category	All-Inclusive Firm Hourly Rate (CAD\$)
Extended Contract Period 1 (from 01 April 2024 to 31 March 2025)	
Strategic Level Resource	\$ _____
General Level Resource	\$ _____
Administrative Level Resource	\$ _____

For the purpose of this Contract, a day is defined as 7.5 hours of work, exclusive of meal breaks. Payment will be made for days actually worked, with no provision for annual leave, statutory holidays and sick leave. If time worked is more or less than a day, the all-inclusive fixed daily rate must be prorated to reflect the actual time worked.

Total Estimated Cost of Professional Fees: \$ _____ (to be completed at contract award)

B-1.1. Cost Reimbursable Expenses – Authorized Travel and Living Expenses for Work

Concerning the requirements to travel described in section 13 of the Statement of Work in Annex “A”, the Contractor will be paid for its authorized travel and living expenses reasonably and properly incurred in the performance of the Work done, delivered or performed outside the National Capital Region (NCR) defined in the *National Capital Act (R.S.C., 1985, c. N-4)*, available on the Justice Website (<http://laws-lois.justice.gc.ca/eng/acts/N-4/page-9.html#docCont>), at cost, without any allowance for profit and administrative overhead, in accordance with the meal and private vehicle expenses provided in Appendices B, C and D of the [National Joint Council Travel Directive](#); and with the other provisions of the directive referring to "travellers", rather than those referring to "employees".

Canada will not accept travel and living expenses that may need to be incurred by the Contractor for any relocation of resources required to satisfy its contractual obligations.

All travel must have the prior authorization of the Technical Authority.



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The authorized travel and living expenses will be paid upon submission of an itemized statement supported by receipt vouchers. All payments are subject to government audit.

Total Estimated Cost of Authorized Travel and Living Expenses:

Extended Contract Period 1: \$8,000.00

B-1.2. Total Estimated Cost – Extended Contract Period 1: \$ _____ (to be completed at contract award)

With the exception of the all-inclusive fixed time rates specified above, the amounts shown in this section of the annex are estimates only. Minor changes to these estimates will be accepted for billing purposes as the Work proceeds, provided that these changes have the prior approval of the Technical Authority, and provided that the total estimated cost of the Contract does not exceed the aforementioned Limitation of Expenditure (Applicable taxes extra).

B-2. Extended Contract Period 2 (from 01 April 2025 to 31 March 2026)

Resource Category	All-Inclusive Firm Hourly Rate (CAD\$)
Extended Contract Period 2 (from 01 April 2025 to 31 March 2026)	
Strategic Level Resource	\$ _____
General Level Resource	\$ _____
Administrative Level Resource	\$ _____

For the purpose of this Contract, a day is defined as 7.5 hours of work, exclusive of meal breaks. Payment will be made for days actually worked, with no provision for annual leave, statutory holidays and sick leave. If time worked is more or less than a day, the all-inclusive fixed daily rate must be prorated to reflect the actual time worked.

Total Estimated Cost of Professional Fees: \$ _____ (to be completed at contract award)

B-2.1. Cost Reimbursable Expenses – Authorized Travel and Living Expenses for Work

Concerning the requirements to travel described in section 13 of the Statement of Work in Annex "A", the Contractor will be paid for its authorized travel and living expenses reasonably and properly incurred in the performance of the Work done, delivered or performed outside the National Capital Region (NCR) defined in the *National Capital Act (R.S.C., 1985, c. N-4)*, available on the Justice Website (<http://laws-lois.justice.gc.ca/eng/acts/N-4/page-9.html#docCont>), at cost, without any allowance for profit and administrative overhead, in accordance with the meal and private vehicle expenses provided in Appendices B, C and D of the [National Joint Council Travel Directive](#); and with the other provisions of the directive referring to "travellers", rather than those referring to "employees".

Canada will not accept travel and living expenses that may need to be incurred by the Contractor for any relocation of resources required to satisfy its contractual obligations.

All travel must have the prior authorization of the Technical Authority.

The authorized travel and living expenses will be paid upon submission of an itemized statement supported by receipt vouchers. All payments are subject to government audit.



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Total Estimated Cost of Authorized Travel and Living Expenses:

Extended Contract Period 1: \$8,000.00

B-2.2. Total Estimated Cost – Extended Contract Period 2: \$ _____ (to be completed at contract award)

With the exception of the all-inclusive fixed time rates specified above, the amounts shown in this section of the annex are estimates only. Minor changes to these estimates will be accepted for billing purposes as the Work proceeds, provided that these changes have the prior approval of the Technical Authority, and provided that the total estimated cost of the Contract does not exceed the aforementioned Limitation of Expenditure (Applicable taxes extra).

B-3. Extended Contract Period 3 (from 01 April 2026 to 31 March 2027)

Resource Category	All-Inclusive Firm Hourly Rate (CAD\$)
Extended Contract Period 3 (from 01 April 2026 to 31 March 2027)	
Strategic Level Resource	\$ _____
General Level Resource	\$ _____
Administrative Level Resource	\$ _____

For the purpose of this Contract, a day is defined as 7.5 hours of work, exclusive of meal breaks. Payment will be made for days actually worked, with no provision for annual leave, statutory holidays and sick leave. If time worked is more or less than a day, the all-inclusive fixed daily rate must be prorated to reflect the actual time worked.

Total Estimated Cost of Professional Fees: \$ _____ (to be completed at contract award)

B-3.1. Cost Reimbursable Expenses – Authorized Travel and Living Expenses for Work

Concerning the requirements to travel described in section 13 of the Statement of Work in Annex “A”, the Contractor will be paid for its authorized travel and living expenses reasonably and properly incurred in the performance of the Work done, delivered or performed outside the National Capital Region (NCR) defined in the *National Capital Act (R.S.C., 1985, c. N-4)*, available on the Justice Website (<http://laws-lois.justice.gc.ca/eng/acts/N-4/page-9.html#docCont>), at cost, without any allowance for profit and administrative overhead, in accordance with the meal and private vehicle expenses provided in Appendices B, C and D of the [National Joint Council Travel Directive](#); and with the other provisions of the directive referring to "travellers", rather than those referring to "employees".

Canada will not accept travel and living expenses that may need to be incurred by the Contractor for any relocation of resources required to satisfy its contractual obligations.

All travel must have the prior authorization of the Technical Authority.

The authorized travel and living expenses will be paid upon submission of an itemized statement supported by receipt vouchers. All payments are subject to government audit.

Total Estimated Cost of Authorized Travel and Living Expenses:

Extended Contract Period 3: \$8,000.00





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B-3.2. Total Estimated Cost – Extended Contract Period 3: \$ _____ (to be completed at contract award)

With the exception of the all-inclusive fixed time rates specified above, the amounts shown in this section of the annex are estimates only. Minor changes to these estimates will be accepted for billing purposes as the Work proceeds, provided that these changes have the prior approval of the Technical Authority, and provided that the total estimated cost of the Contract does not exceed the aforementioned Limitation of Expenditure (Applicable taxes extra).



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ANNEX C – SECURITY REQUIREMENTS CHECKLIST (SRCL)

Government of Canada / Gouvernement du Canada

Contract Number / Numéro du contrat
W6369-22-A062

Security Classification / Classification de sécurité
UNCLASS

SECURITY REQUIREMENTS CHECK LIST (SRCL)

LISTE DE VÉRIFICATION DES EXIGENCES RELATIVES À LA SÉCURITÉ (LVERS)

PART A - CONTRACT INFORMATION / PARTIE A - INFORMATION CONTRACTUELLE		
1. Originating Government Department or Organization / Ministère ou organisme gouvernemental d'origine	Dept of National Defence	2. Branch or Directorate / Direction générale ou Direction DHSO
3. a) Subcontract Number / Numéro du contrat de sous-traitance	3. b) Name and Address of Subcontractor / Nom et adresse du sous-traitant	
4. Brief Description of Work / Brève description du travail There is a requirement for a regulatory affairs support contract to prepare and file regulatory submissions to meet Health Canada regulations and to develop and/or review complex industry documentation for scientific and regulatory suitability.		
5. a) Will the supplier require access to Controlled Goods? / Le fournisseur aura-t-il accès à des marchandises contrôlées? <input checked="" type="checkbox"/> No <input type="checkbox"/> Yes / Non <input type="checkbox"/> Oui <input type="checkbox"/>		
5. b) Will the supplier require access to unclassified military technical data subject to the provisions of the Technical Data Control Regulations? / Le fournisseur aura-t-il accès à des données techniques militaires non classifiées qui sont assujetties aux dispositions du Règlement sur le contrôle des données techniques? <input checked="" type="checkbox"/> No <input type="checkbox"/> Yes / Non <input type="checkbox"/> Oui <input type="checkbox"/>		
6. Indicate the type of access required / Indiquer le type d'accès requis		
6. a) Will the supplier and its employees require access to PROTECTED and/or CLASSIFIED information or assets? / Le fournisseur ainsi que les employés auront-ils accès à des renseignements ou à des biens PROTÉGÉS et/ou CLASSIFIÉS? (Specify the level of access using the chart in Question 7. c.) / (Préciser le niveau d'accès en utilisant le tableau qui se trouve à la question 7. c.) <input checked="" type="checkbox"/> No <input type="checkbox"/> Yes / Non <input type="checkbox"/> Oui <input type="checkbox"/>		
6. b) Will the supplier and its employees (e.g. cleaners, maintenance personnel) require access to restricted access areas? No access to PROTECTED and/or CLASSIFIED information or assets is permitted. / Le fournisseur et ses employés (p. ex. nettoyeurs, personnel d'entretien) auront-ils accès à des zones d'accès restreintes? L'accès à des renseignements ou à des biens PROTÉGÉS et/ou CLASSIFIÉS n'est pas autorisé. <input type="checkbox"/> No <input checked="" type="checkbox"/> Yes / Non <input type="checkbox"/> Oui <input type="checkbox"/>		
6. c) Is this a commercial courier or delivery requirement with no overnight storage? / S'agit-il d'un contrat de messagerie ou de livraison commerciale sans entreposage de nuit? <input checked="" type="checkbox"/> No <input type="checkbox"/> Yes / Non <input type="checkbox"/> Oui <input type="checkbox"/>		
7. a) Indicate the type of information that the supplier will be required to access / Indiquer le type d'information auquel le fournisseur devra avoir accès		
Canada <input checked="" type="checkbox"/>	NATO / OTAN <input type="checkbox"/>	Foreign / Étranger <input type="checkbox"/>
7. b) Release restrictions / Restrictions relatives à la diffusion		
No release restrictions / Aucune restriction relative à la diffusion <input checked="" type="checkbox"/>	All NATO countries / Tous les pays de l'OTAN <input type="checkbox"/>	No release restrictions / Aucune restriction relative à la diffusion <input type="checkbox"/>
Not releasable / À ne pas diffuser <input type="checkbox"/>		
Restricted to: / Limité à: <input type="checkbox"/>	Restricted to: / Limité à: <input type="checkbox"/>	Restricted to: / Limité à: <input type="checkbox"/>
Specify country(ies): / Préciser le(s) pays:	Specify country(ies): / Préciser le(s) pays:	Specify country(ies): / Préciser le(s) pays:
7. c) Level of information / Niveau d'information		
PROTECTED A / PROTÉGÉ A <input type="checkbox"/>	NATO UNCLASSIFIED / NATO NON CLASSIFIÉ <input type="checkbox"/>	PROTECTED A / PROTÉGÉ A <input type="checkbox"/>
PROTECTED B / PROTÉGÉ B <input type="checkbox"/>	NATO RESTRICTED / NATO DIFFUSION RESTREINTE <input type="checkbox"/>	PROTECTED B / PROTÉGÉ B <input type="checkbox"/>
PROTECTED C / PROTÉGÉ C <input type="checkbox"/>	NATO CONFIDENTIAL / NATO CONFIDENTIEL <input type="checkbox"/>	PROTECTED C / PROTÉGÉ C <input type="checkbox"/>
CONFIDENTIAL / CONFIDENTIEL <input type="checkbox"/>	NATO SECRET / NATO SECRET <input type="checkbox"/>	CONFIDENTIAL / CONFIDENTIEL <input type="checkbox"/>
SECRET / SECRET <input type="checkbox"/>	COSMIC TOP SECRET / COSMIC TRÈS SECRET <input type="checkbox"/>	SECRET / SECRET <input type="checkbox"/>
TOP SECRET / TRÈS SECRET <input type="checkbox"/>		TOP SECRET / TRÈS SECRET <input type="checkbox"/>
TOP SECRET (SIGINT) / TRÈS SECRET (SIGINT) <input type="checkbox"/>		TOP SECRET (SIGINT) / TRÈS SECRET (SIGINT) <input type="checkbox"/>

TBS/SCT 350-103(2004/12)

Security Classification / Classification de sécurité
UNCLASS





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Government of Canada

Gouvernement du Canada

Contract Number / Numéro du contrat W6369-22-A062
Security Classification / Classification de sécurité UNCLASS

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 renseignements ou à des biens COMSEC désignés PROTÉGÉS et/ou CLASSIFIÉS?
If Yes, indicate the level of sensitivity.
Dans l'affirmative, indiquer le niveau de sensibilité:

No / Non Yes / Oui

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?

No / Non Yes / Oui

Short Title(s) of material / Titre(s) abrégé(s) du matériel:
Document Number / Numéro 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

<input checked="" type="checkbox"/> RELIABILITY STATUS COTE DE FIABILITÉ	<input type="checkbox"/> CONFIDENTIAL CONFIDENTIEL	<input type="checkbox"/> SECRET SECRET	<input type="checkbox"/> TOP SECRET TRÈS SECRET
<input type="checkbox"/> TOP SECRET-SIGINT TRÈS SECRET - SIGINT	<input type="checkbox"/> NATO CONFIDENTIAL NATO CONFIDENTIEL	<input type="checkbox"/> NATO SECRET NATO SECRET	<input type="checkbox"/> COSMIC TOP SECRET COSMIC TRÈS SECRET
<input type="checkbox"/> SITE ACCESS ACCÈS AUX EMPLACEMENTS			

Special comments:
Commentaires spéciaux: _____

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.

10. b) May unscreened personnel be used for portions of the work?
Du personnel sans autorisation sécuritaire peut-il se voir confier des parties du travail?
If Yes, will unscreened personnel be escorted?
Dans l'affirmative, le personnel en question sera-t-il escorté?

No / Non Yes / Oui

No / Non Yes / Oui

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?

No / Non Yes / Oui

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 / Non Yes / Oui

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?

No / Non Yes / Oui

INFORMATION TECHNOLOGY (IT) MEDIA / SUPPORT RELATIF À 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 propres systèmes informatiques pour traiter, produire ou stocker électroniquement des renseignements ou des données PROTÉGÉS et/ou CLASSIFIÉS?

No / Non Yes / Oui

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?

No / Non Yes / Oui

TBS/SCT 350-103(2004/12)

Security Classification / Classification de sécurité
UNCLASS





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Défense nationale

National Defence Headquarters
Ottawa, Ontario
K1A 0K2

Quartier général de la Défense nationale
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Government of Canada / Gouvernement du Canada

Contract Number / Numéro du contrat W6369-22-A062
Security Classification / Classification de sécurité UNCLASS

PART C - (continued) / PARTIE C - (suite)

For users completing the form **manually** use the summary chart below to indicate the category(ies) and level(s) of safeguarding required at the supplier's site(s) or premises.
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	PROTECTED / PROTÉGÉ			CLASSIFIED / CLASSIFIÉ			NATO				COMSEC					
	A	B	C	CONFIDENTIAL	SECRET	TOP SECRET	NATO RESTRICTED	NATO CONFIDENTIAL	NATO SECRET	COSMIC TOP SECRET	PROTECTED / PROTÉGÉ			CONFIDENTIAL	SECRET	TOP SECRET
				CONFIDENTIEL		TRES SECRET	NATO DIFFUSION RESTREINTE	NATO CONFIDENTIEL		COSMIC TRES SECRET	A	B	C	CONFIDENTIEL		TRES SECRET
Information / Assets / Renseignements / Biens / Production																
IT Media / Support TI																
IT Link / Lien électronique																

12. a) Is the description of the work contained within this SRCL PROTECTED and/or CLASSIFIED?
La description du travail visé par la présente LVERS est-elle de nature PROTÉGÉE et/ou CLASSIFIÉE? No / Non Yes / Oui
- If Yes, classify this form by annotating the top and bottom in the area entitled "Security Classification".**
Dans l'affirmative, classifiez le présent formulaire en indiquant 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? No / Non Yes / Oui
- 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, classifiez 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 UNCLASS
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[Page 4 of the SRCL to be inserted in the resulting contract]



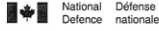
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ANNEX D – DND 626 TASK AUTHORIZATION FORM



TASK AUTHORIZATION AUTORISATION DES TÂCHES

All invoices/progress claims must show the reference Contract and Task numbers. Toutes les factures doivent indiquer les numéros du contrat et de la tâche.		Contract no. – N° du contrat
		Task no. – N° de la tâche
Amendment no. – N° de la modification	Increase/Decrease – Augmentation/Réduction	Previous value – Valeur précédente
To – À	<p>TO THE CONTRACTOR</p> <p>You are requested to supply the following services in accordance with the terms of the above reference contract. Only services included in the contract shall be supplied against this task. Please advise the undersigned if the completion date cannot be met. Invoices/progress claims shall be prepared in accordance with the instructions set out in the contract.</p> <p>À L'ENTREPRENEUR</p> <p>Vous êtes prié de fournir les services suivants en conformité des termes du contrat mentionné ci-dessus. Seuls les services mentionnés dans le contrat doivent être fournis à l'appui de cette demande. Prière d'aviser le signataire si la livraison ne peut se faire dans les délais prescrits. Les factures doivent être établies selon les instructions énoncées dans le contrat.</p>	
Delivery location – Expédié à	Date _____ for the Department of National Defence pour le ministère de la Défense nationale	
Delivery/Completion date – Date de livraison/d'achèvement		
Contract item no. N° d'article du contrat	Services	Cost Prix
		GST/HST TPS/TVH
		Total
<p>APPLICABLE ONLY TO PWGSC CONTRACTS: The Contract Authority signature is required when the total value of the DND 626 exceeds the threshold specified in the contract.</p> <p>NE S'APPLIQUE QU'AUX CONTRATS DE TPSGC : La signature de l'autorité contractante est requise lorsque la valeur totale du formulaire DND 626 est supérieure au seuil précisé dans le contrat.</p> <p>_____ for the Department of Public Works and Government Services pour le ministère des Travaux publics et services gouvernementaux</p>		

DND 626 (01-05)

Design: Forms Management 993-4050
Conception: Gestion des formulaires 993-4062



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ANNEX E – QUARTERLY REPORTING

Reporting Requirement – Details

A detailed and current record of all authorized tasks must be kept for each contract with a task authorization process. This record must contain:

For each authorized task:

- i. the authorized task number or task revision number(s);
- ii. a title or a brief description of each authorized task;
- iii. the total estimated cost specified in the authorized Task Authorization (TA) of each task, exclusive of Applicable Taxes;
- iv. the total amount, exclusive of Applicable Taxes, expended to date against each authorized task;
- v. the start and completion date for each authorized task; and
- vi. the active status of each authorized task, as applicable.

For all authorized tasks:

- i. the amount (exclusive of Applicable Taxes) specified in the contract (as last amended, as applicable) as Canada's total liability to the Contractor for all authorized TAs; and
- ii. the total amount, exclusive of Applicable Taxes, expended to date against all authorized TAs.



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ANNEX F – NON DISCLOSURE AGREEMENT

I, _____, recognize that in the course of my work as an employee or subcontractor of _____, I may be given access to information by or on behalf of Canada in connection with the Work, pursuant to Contract W6369-22-A062 between Her Majesty the Queen in right of Canada, represented by the Minister of National Defence and _____, including any information that is confidential or proprietary to third parties, and information conceived, developed or produced by the Contractor as part of the Work. For the purposes of this agreement, information includes but not limited to: any documents, instructions, guidelines, data, material, advice or any other information whether received orally, in printed form, recorded electronically, or otherwise and whether or not labeled as proprietary or sensitive, that is disclosed to a person or that a person becomes aware of during the performance of the Contract.

I agree that I will not reproduce, copy, use, divulge, release or disclose, in whole or in part, in whatever way or form any information described above to any person other than a person employed by Canada on a need to know basis. I undertake to safeguard the same and take all necessary and appropriate measures, including those set out in any written or oral instructions issued by Canada, to prevent the disclosure of or access to such information in contravention of this agreement.

I also acknowledge that any information provided to the Contractor by or on behalf of Canada must be used solely for the purpose of the Contract and must remain the property of Canada or a third party, as the case may be.

I agree that the obligation of this agreement will survive the completion of the Contract W6369-22-A062.

Signature

Date



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ANNEX G – APPLICATION FOR REGISTRATION FORM

Please use the link [Contract security program \(CSP\) - Application for registration \(AFR\) \(cans.ns.ca\)](https://cans.ns.ca) to access the document in its original format and for guidance on completing the form.



Public Services and
Procurement Canada

Services publics et
Approvisionnement Canada

Organization #

Protected (once completed)

CONTRACT SECURITY PROGRAM (CSP)

APPLICATION FOR REGISTRATION (AFR) for Canadian legal entities

Instructions for completing the Application for Registration (AFR)

Privacy notice for Canadian entities registering in the CSP

Part of the information collected in this form includes personal information which is collected under the authority of subsection 7(1) of the *Financial Administration Act* and is mandatory in accordance with Treasury Board's *Policy on Government Security and Standard on Security Screening* for the purposes of security assessment and registration in the Contract Security Program (CSP) of Public Services and Procurement Canada (PSPC). The personal information will be used to assess your eligibility to hold a security status or security clearance and for your organization to be registered in the Contract Security Program. The information provided may be disclosed to the Royal Canadian Mounted Police and Canadian Security Intelligence Service to conduct the requisite checks and / or investigation in accordance with the *Policy on Government Security and Standard on Security Screening*. Additionally, the information may be disclosed to and used by other federal institutions that may require this information as part of their functions or investigation under Canadian Law or to the industrial security programs of foreign governments (with which Canada has bilateral security instruments) for foreign assurances.

Personal information is protected, used and disclosed in accordance with the Privacy Act and is described in the Info Source under the Personal Information Bank PWGSC PPU 015 ([Access to Information and Privacy - PSPC \(tpsnc-pwgsc.gc.ca\)](https://www150.computer.gc.ca/Access-to-Information-and-Privacy-PSPC)) and the TBS standard personal information bank Personal Security Screening PSU 917 ([Standard personal information banks - Canada.ca](https://www150.computer.gc.ca/Standard-personal-information-banks-Canada)). Under the Privacy Act, you have the right to access and correct your personal information, if erroneous or incomplete. The personal information from paper sources that accompanies an organization registration is retained for two years after the last administrative action, and then destroyed. The personal information from paper sources that accompanies a foreign ownership, control, or influence assessment is kept for two years, and then destroyed if there are no changes to the organization that are reported to the foreign ownership, control, or influence evaluation office during this period. The personal information from paper sources that accompanies the personnel security screening process or foreign assurance process will be retained for a minimum period of two years after the last administrative action, and then destroyed. The Contract Security Program's retention period and disposal standards of personal information in electronic format may vary from the above retention period.

If you have concerns or require clarification about this privacy notice, you can contact PSPC's Access to Information and Privacy Directorate by email at TPSGC.ViePrivee-Privacy.PWGSC@tpsnc-pwgsc.gc.ca. If you are not satisfied with the response to your privacy concern or if you want to file a complaint about the handling of your personal information, you may wish to contact the Office of the Privacy Commissioner of Canada.

General Instructions:

- This form is used for registering Canadian legal entities **ONLY**. The CSP does not register foreign based organizations. **ALL** Foreign based firms must contact the [International Industrial Security Directorate \(IISD\)](#) for more information on the security screening process. Canadian subsidiaries of foreign based firms may be eligible to register with the CSP.
- This form and all supporting documentation requested must be provided in English or French
- In any instance where this form does not allow enough space for a complete answer, please include additional pages or rows to the table as required.

For organizations that do not yet have a clearance, refusal to provide required information, the provision of a false statement, misleading information, concealment or failure to disclose of any material fact on this application will result in the CSP not granting, or upgrading, a security clearance.

In the case of already cleared organizations; a denial or revocation of your organization's existing security clearance may occur and any personnel reliability statuses and/or personnel security clearances issued to your organization will be administratively closed out along with the organization's clearance with the Contract Security Program. This will immediately prohibit your eligibility to perform work on contracts requiring organization security clearances.



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Public Services and Procurement Canada / Services publics et Approvisionnement Canada

Organization #

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CONTRACT SECURITY PROGRAM (CSP)

SECTION D - LIST OF BOARD OF DIRECTORS

Add additional rows or attachments as needed

Position Title on the Board	Surname	Given name	Citizenship(s)	Country of primary residence/National domicile
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SECTION E - OWNERSHIP INFORMATION - PLEASE COMPLETE FOR EACH LEVEL OF OWNERSHIP

Please complete for each level of ownership

Identify all entities, individuals, public or private corporations that have an ownership stake in your organization being registered. Indicate if the entity has a valid Facility Security Clearance from Public Services and Procurement Canada's Contract Security Program or any other country. For publicly traded corporations, identify stock exchange. If there are more than three levels of ownership; please submit on an additional page to include all levels of ownership from direct to ultimate.

Note: The organization structure chart with percentages of ownership must be included with your submission

SECTION E-1 - OWNERSHIP LEVEL 1 (direct ownership) if more than three - please provide on additional sheet

Ownership - Level 1 (Direct Parent)

Name of organization or individual
Address
Type of entity (e.g. private or public corporation, state-owned)
Stock exchange identifier (if applicable)
Facility security clearance (FSC) yes/no
Percentage of ownership
Country of jurisdiction or citizenship



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CONTRACT SECURITY PROGRAM (CSP)

SECTION F - JUSTIFICATION (FOR RENEWING ORGANIZATIONS)

Add additional rows or attachments as needed

Please provide all current procurement rationales that have security requirements - i.e. contracts, leases, RFP, RFI, ITQ, supply arrangements, standing offers, etc.

Contract, lease, SA, SO, etc. number	Client / contracting authority	Security Type & level	Expiry date (dd-mm-yyyy)
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SECTION G - CERTIFICATION AND CONSENT (ONLY AN OFFICER IDENTIFIED IN SECTION C MAY COMPLETE THIS SECTION)

I, the undersigned, as the Officer authorized by the organization, have read the Privacy Notice to this application and do hereby certify that the information contained in this application is true, complete and correct. I acknowledge and agree to comply with the responsibilities outlined in the Public Services and Procurement Canada's Contract Security Manual and consent to the collection, use and disclosure of my personal information for the purposes as described above. **I agree to notify the Contract Security Program of any changes to the organization including but not limited to: change of address, phone number, contact information, change in security officers, officers and directors, board members, partners, management / leadership team and ownership.**

Surname	Given name
Position title	Telephone number (include extension number if any)
Facsimile number	Email address
Signature	Date (dd-mm-yyyy)

FOR USE BY THE PSPC'S CONTRACT SECURITY PROGRAM

Recommendations	
Recommended by e-signature	Approved by e-signature

