



RETURN BIDS TO:
RETOURNER LES SOUMISSIONS À:
Bid Receiving - PWGSC / Réception des soumissions
- TPSGC
Place du Portage, Phase III
Core 0B2 / Noyau 0B2
11 Laurier St./11, rue Laurier
Gatineau
Québec
K1A 0S5
Bid Fax: (819) 997-9776

SOLICITATION AMENDMENT MODIFICATION DE L'INVITATION

The referenced document is hereby revised; unless otherwise indicated, all other terms and conditions of the Solicitation remain the same.

Ce document est par la présente révisé; sauf indication contraire, les modalités de l'invitation demeurent les mêmes.

Comments - Commentaires

Vendor/Firm Name and Address
Raison sociale et adresse du
fournisseur/de l'entrepreneur

Issuing Office - Bureau de distribution
Shared Systems Division (XL)/Division des systèmes
partagés (XL)
4C1, Place du Portage Phase III
11 Laurier St./11, rue Laurier
Gatineau
Québec
K1A 0S5

Title - Sujet Quality Management Software	
Solicitation No. - N° de l'invitation 39903-170873/A	Amendment No. - N° modif. 002
Client Reference No. - N° de référence du client 39903-170873	Date 2017-06-29
GETS Reference No. - N° de référence de SEAG PW-\$\$XL-140-31565	
File No. - N° de dossier 140x1.39903-170873	CCC No./N° CCC - FMS No./N° VME
Solicitation Closes - L'invitation prend fin at - à 02:00 PM on - le 2017-07-13	
Time Zone Fuseau horaire Eastern Daylight Saving Time EDT	
F.O.B. - F.A.B. Plant-Usine: <input type="checkbox"/> Destination: <input type="checkbox"/> Other-Autre: <input type="checkbox"/>	
Address Enquiries to: - Adresser toutes questions à: Egan, Tara	Buyer Id - Id de l'acheteur 140x1
Telephone No. - N° de téléphone (819) 420-5280 ()	FAX No. - N° de FAX () -
Destination - of Goods, Services, and Construction: Destination - des biens, services et construction:	

Instructions: See Herein

Instructions: Voir aux présentes

Delivery Required - Livraison exigée	Delivery Offered - Livraison proposée
Vendor/Firm Name and Address Raison sociale et adresse du fournisseur/de l'entrepreneur	
Telephone No. - N° de téléphone Facsimile No. - N° de télécopieur	
Name and title of person authorized to sign on behalf of Vendor/Firm (type or print) Nom et titre de la personne autorisée à signer au nom du fournisseur/ de l'entrepreneur (taper ou écrire en caractères d'imprimerie)	
Signature	Date

Solicitation Amendment 002 is raised to answer the following industry questions:

Question #1: Is it fine with the organization if the vendor is from outside Canada?

Answer #1: There is no restriction on where vendors must be located.

Question #2: Do we need to submit an "intent to participate/bid"? If so, by what date?

Answer #2: No.

Question #3: Do you have an editable version of the RFP to enable consistent formatting for responses?

Answer #3: The Request for Proposal documents are not available in an editable version.

Question #4: Where/how can we obtain/discover our "Procurement Business Number"?

Answer #4: <http://www.cra-arc.gc.ca/tx/bsnss/tpcs/bn-ne/menu-eng.html>

Question #5: Is the agency using BlackBerries or is that part of the RFP template? Is BB access a requirement or is access from a phone, tablet, laptop (mobile) sufficient?

Answer #5: Yes, the agency does currently use BlackBerries. The "Ability to access via BlackBerry, smart phone or tablet" is a desirable functionality that is rated as per table 3.3.1 in the Evaluation Criteria. It is not a mandatory requirement. The ability is BlackBerry OR smart phone OR tablet, therefore it can be any one of the three or any combination of the three.

Question #6: Can you help us understand how many concurrent users the agency will have (# users accessing the system at the same time)? We want to ensure we estimate correctly.

Answer #6: All laboratories at the CFIA are accredited to ISO/IEC 17025. As per ISO/IEC 17025 section 4.3.2.2, documents that are "essential to the effective functioning of the laboratory" must be accessible at all times. Therefore, all users must have the capability to access the system at the same time. For a description of user types, see the Statement of Requirements, Table 2. For the number of users by type, see Annex B, Table 1, Item No. 1 (40 Super Users, 191 Supervisors, 630 Users, and 73 Viewers).

Question #7: In section 3.3 – Security Requirements, there is a mention of ISO/IEC 27001 and needing a certificate. We just wanted to verify if this was a requirement or a suggestion.

Answer #7: A certificate of compliance (to ISO/IEC 27001), from an accredited certification body, for the software AND the hosting datacenter service provider is a mandatory requirement.

Question #8: At page 71, they say that this is a mandatory element:

Démontrer que le logiciel est conforme à la norme ISO/IEC 27001.	Certificat de conformité du
--	-----------------------------

Our software has no such certificate... it does the job but it has not been certified by any outside party... Does it mean that our dossier will be rejected?

Answer #8: A certificate of compliance (to ISO/IEC 27001), from an accredited certification body, for the software AND the hosting datacenter service provider is a mandatory requirement. As per Part 4, section 4.2, (a) (i), "Bids that do not comply with each and every mandatory requirement will be declared non-responsive and be disqualified."

Question #9: Our software meets every single functionality requirement, however we do not meet Mandatory items M5 and M6. Our Data Center currently holds the SSAE16 and PCI certifications. We do comply with every aspects of the ISO 27001, but we currently do not have an official certification for it. The short-term intent is to be fully ISO 27001 certified within a 6 month period and we are ready to commit contractually to it. We recognize this is not fully compliant with mandatory items M5 and M6 so we

are enquiring if that would position us in a non-responsive category? Or if you are open to adjust the M5 and M6 to allow a delay to provide official certifications.

Answer #9: A certificate of compliance (to ISO/IEC 27001), from an accredited certification body, for the software AND the hosting datacenter service provider is a mandatory requirement. As per Part 4, section 4.2, (a) (i), "Bids that do not comply with each and every mandatory requirement will be declared non-responsive and be disqualified." The CFIA does not wish to adjust the M5 and M6 to allow a delay to provide official certifications.

Question #10. 7.5 Contractor's Site's or Premises Requiring Safeguarding Measures – The Company Security Officer (CSO) must ensure through the Industrial Security Program (ISP) that the contractor and individual(s) hold a valid security clearance at the required level. What is the required security clearance level? Is this applicable and if so where can we find information regarding the ISP?

Answer #10: Delete in its entirety Article 7.5 Contractor's Site's or Premises Requiring Safeguarding Measures

Question #11. While European countries are typically ISO/IEC 27001 certified, US companies obtain SOC Type 2 certified. Will SOC Type 2 certification be acceptable in lieu of ISO/IEC 27001?

Answer #11: A certificate of compliance to ISO/IEC 27001, from an accredited certification body, for the software AND the hosting datacenter service provider is a mandatory requirement. SOC Type 2 certification will not be accepted in lieu of ISO/IEC 27001.

Question #12. Will the CFIA data contain any Personally Identifiable Information (PII)?

Answer #12: No, the CFIA data will not contain any Personally Identifiable Information. All CFIA data has been deemed unclassified.

Question #13. Will you hold a session where we can ask questions and for clarification?

Answer #13: No, the CFIA will not hold a session for questions and clarification. Enquiries must be submitted as per Section 2.4 of the Request for Proposal, "Bidder Instructions.

Question #14: When does Canada plan to:

- Finish evaluation?
- Award a contract?

Answer #14: Canada may, at its discretion award a contract within the bid validity period found at Section 2.1 (e)

All other terms and conditions remain unchanged.

Annex C - Quality Management Software as a Service for CFIA Laboratories Evaluation Criteria

B.1 Evaluation Table

B.2 Mandatory Requirements

Ref.	Mandatory Requirements	Required Supporting Documentation	Provided (Yes/No)	Reference
M1	Submit evidence to demonstrate that the software service is fully bilingual (English and French) including: <ul style="list-style-type: none"> The software user interface, Documentation for use of the software Training resources Support services. 	Examples (including but not limited to): <ul style="list-style-type: none"> Screen capture to show bilingual interface Software manual that outlines how to switch interface from English to French or vice-versa. 		
M2	Submit a plan for the migration of the documents into the system.	A plan. (see Rated Requirements R1 to R7 for how the plan will be evaluated)		
M3	Submit a plan for the remote configuration.	A plan. (see Rated Requirements R8 to R14 for how the plan will be evaluated)		
M4	Submit 3 references where the software as a service was implemented in an ISO/IEC 17025 accredited laboratory.	Reference information must include: <ul style="list-style-type: none"> company name, contact name, contact title, telephone number, email address, services period a brief description of the services provided. 		
M5	Submit evidence to demonstrate that the software is ISO/IEC 27001 compliant.	Certificate of compliance, from an accredited certification body, for the software.		
M6	Submit evidence to demonstrate that the owner of the hosting datacenter service provider is ISO/IEC 27001 compliant.	Certificate of compliance, from an accredited certification body, for the hosting datacentre service provider.		

B.3 Rated Requirements

Section #	Section Title	Max Points	Points Received
3.1	Migration Plan	70	
3.2	Configuration Plan	70	
3.3	Desirable Functionalities	504	
3.4	Future Direction	50	

3.1 Migration Plan

The migration plan will be evaluated as follows:

Ref.	Rated Requirements	Max Points	Points Received	Reference
R1	Roles and responsibilities of Contractor are outlined in the plan	Yes =10 No = 0		
R2	Roles and responsibilities of CFIA are outlined in the plan	Yes =10 No = 0		
R3	Contractor resources are outlined in the plan (i.e. # of personnel assisting with the migration)	Yes =10 No = 0		
R4	Sequence of migration for all 14 sites is outlined in the plan	Yes =10 No = 0		
R5	Time estimate for migration of all documents for each site is outlined in the plan	Yes =10 No = 0		
R6	Required document preparation by the CFIA is outlined in the plan (i.e. documents are dropped into a folder, a spreadsheet must be prepared, etc.)	Yes =10 No = 0		
R7	Time estimate for CFIA to provide the documents is outlined in the plan	Yes =10 No = 0		

3.2 Configuration Plan

The configuration plan will be evaluated as follows:

Ref.	Rated Requirements	Max Points	Points Received	Reference
R8	Roles and responsibilities of Contractor are outlined in the plan	Yes =10 No = 0		
R9	Roles and responsibilities of CFIA are outlined in the plan	Yes =10 No = 0		
R10	Contractor resources are outlined in the plan (i.e. # of personnel assisting with the configuration)	Yes =10 No = 0		
R11	Sequence of configuration for all 14 sites is outlined in the plan	Yes =10 No = 0		
R12	Time estimate for configuration at each site is outlined in the plan	Yes =10 No = 0		
R13	Required preparation by the CFIA is outlined in the plan	Yes =10 No = 0		
R14	Time estimate for participation of CFIA personnel for configuration at each site is outlined in the plan	Yes =10 No = 0		

3.3 Desirable functionalities

The desirable functionalities will be evaluated as follows:

Table 3.3.1: Evaluation of desirable functionalities

Description	Definition	Points
Off the Shelf (OTS)	The requirement can be met by “off the shelf” functionality of the software.	3
Configurable (CF)	In addition to the off the shelf capability, the product has the flexibility to meet the requirement in several ways through configuration by a Super User. It does not require any coding changes or intervention of the Contractor.	Additional 5 points for each configurable OTS feature.
Customization (CM)	This requirement can be met by customization of the software by the Contractor.	1 point
Cannot comply (CC)	The requirement cannot be met.	0 points

Example:

If the desirable functionality is “Ability to access all functionality of the system via any web browser”:

- If all functionality of the system can be accessed via any web browser using the off the shelf product: 3 points; and,
- If the user can configure which browser is used as the default browser: + 5 points.

The total points allocated for this example would be 3 points (for OTS) + 5 points (for configurable), for a total of 8 points (the maximum points available).

***Responses must identify any assumptions or constraints with respect to the functionality.**

Ref.	Desirable Functionalities	Point Criteria	Max. Points	Points Received				Reference
				OTS	C F	C M	C C	
GENERAL								
R15	Ability to access all functionality of the system via any web browser	As per table 3.3.1	8					
R16	Ability to access via blackberry, smart phone or tablet	As per table 3.3.1	8					
R17	Ability to add an unlimited number of documents, workflows, and fields	As per table 3.3.1	8					
R18	Ability for automatic and escalating email notifications	As per table 3.3.1	8					

Ref.	Desirable Functionalities	Point Criteria	Max. Points	Points Received				Reference
				OTS	C F	C M	C C	
R19	Ability for email notifications to be sent to specific employees, roles, or groups.	As per table 3.3.1	8					
R20	Ability to configure the system by location structure and organizational hierarchy	As per table 3.3.1	8					
R21	Ability to roll up information at the corporate level to view national metrics and ability to filter to the site specific level	As per table 3.3.1	8					
R22	Ability to share and restrict access by document type across all locations.	As per table 3.3.1	8					
R23	Ability to create, change, and configure defined fields for flexibility as processes change	As per table 3.3.1	8					
R24	Ability to capture an audit trail of system activities which includes the identification of the user, date and time for all modules.	As per table 3.3.1	8					
ACTION/TASK MANAGEMENT								
R25	Ability to create, change, and configure user defined business rules	As per table 3.3.1	8					
R26	Ability to attach files to required actions	As per table 3.3.1	8					
R27	Ability for automatic notification upon action assignment	As per table 3.3.1	8					
R28	Ability to reassign actions	As per table 3.3.1	8					
R29	Ability to display pending and overdue actions in the user dashboard	As per table 3.3.1	8					
R30	Ability to automatically escalate through the user hierarchy after a defined period for overdue actions	As per table 3.3.1	8					

Ref.	Desirable Functionalities	Point Criteria	Max. Points	Points Received				Reference
				OTS	C F	C M	C C	
R31	Ability to define escalation rules	As per table 3.3.1	8					
R32	Ability for notification of action completion	As per table 3.3.1	8					
R33	Ability to receive task notifications through email, with any email software (i.e. GroupWise, Outlook, etc.)	As per table 3.3.1	8					
DOCUMENT CONTROL								
R34	Ability to store documents under various categories and sub-categories	As per table 3.3.1	8					
R35	Ability for Super Users to define and add new categories and sub categories	As per table 3.3.1	8					
R36	Ability to maintain version control and revision history	As per table 3.3.1	8					
R37	Ability to relate documents and link documents within the system (e.g. link an SOP to the associated work instructions and forms)	As per table 3.3.1	8					
R38	Ability to handle an unlimited number of documents without affecting the amount of time to access and display the documents	As per table 3.3.1	8					
R39	Ability to store any file format or type	As per table 3.3.1	8					
R40	Ability to search documents by categories, sub-categories, key words and full text search.	As per table 3.3.1	8					
R41	Ability to generate a report or master list of the status of the controlled documents by location and nationally	As per table 3.3.1	8					
R42	Ability to set a review schedule with automatic notifications	As per table 3.3.1	8					

Ref.	Desirable Functionalities	Point Criteria	Max. Points	Points Received				Reference
				OTS	C F	C M	C C	
R43	Ability to add annotations during the review period	As per table 3.3.1	8					
R44	Ability to set parallel review and approval of documents	As per table 3.3.1	8					
R45	Ability to set serial review and approval of documents	As per table 3.3.1	8					
R46	Ability to automatically move documentation through the cycle from initiating the review, to the reviewers, to the approvers.	As per table 3.3.1	8					
R47	Ability to add comments during review and approval of documents	As per table 3.3.1	8					
R48	Ability to automatically publish approved documents and automatically archive superseded versions.	As per table 3.3.1	8					
R49	Ability to capture and display an audit trail of all document control activities including who created, reviewed, authorized, read, modified and archived the document and when.	As per table 3.3.1	8					
R50	Ability for electronic approval of documents	As per table 3.3.1	8					
R51	Ability to automatically notify relevant groups of users of document changes	As per table 3.3.1	8					
R52	Ability to assign reading of new or revised documents to groups or selected individuals and the ability to track completion	As per table 3.3.1	8					
R53	Ability to have a different process by document type	As per table 3.3.1	8					
R54	Ability to control print function based on user rights	As per table 3.3.1	8					

Ref.	Desirable Functionalities	Point Criteria	Max. Points	Points Received				Reference
				OTS	C F	C M	C C	
R55	Ability to add and print an electronic signature with the document	As per table 3.3.1	8					
R56	Ability to add and print a watermark in the document background	As per table 3.3.1	8					
NONCONFORMITY/CAPA								
R57	Ability to add the information fields to capture all relevant data required by CFIA (e.g. ability to replicate existing nonconformity forms and processes within the system).	As per table 3.3.1	8					
R58	Ability to set standardized attributes for nonconformities	As per table 3.3.1	8					
R59	Ability for all users to initiate a nonconformity	As per table 3.3.1	8					
R60	Ability to capture all details related to the nonconformity and attach relevant records	As per table 3.3.1	8					
R61	Ability for automatic generation of a notification message	As per table 3.3.1	8					
R62	Ability to automatically route the nonconformity report for evaluation and review based on business rules	As per table 3.3.1	8					
R63	Ability for the user to link and track all information related to each nonconformity from initiation to completion.	As per table 3.3.1	8					
R64	Ability to associate non-conformities with other non-conformities for trend analysis	As per table 3.3.1	8					
R65	Ability to track progress at each stage of the nonconformity process	As per table 3.3.1	8					
R66	Ability to assign action items from the nonconformity and CAPA process to users	As per table 3.3.1	8					

Ref.	Desirable Functionalities	Point Criteria	Max. Points	Points Received				Reference
				OTS	C F	C M	C C	
R67	Ability for electronic approval of non-conformities and CAPAs	As per table 3.3.1	8					
R68	Ability to classify root cause and trend root causes at the national and site specific levels	As per table 3.3.1	8					
R69	Ability to automatically route rejected actions back to the originator with reviewer comments.	As per table 3.3.1	8					
R70	Ability to assign due dates to action items and schedule automatic reminders	As per table 3.3.1	8					
R71	Ability to report on nonconformity and CAPA process and status.	As per table 3.3.1	8					
REPORTING								
R72	Ability for Super Users to generate ad-hoc custom reports by location or nationally	As per table 3.3.1	8					
R73	Ability to support standardized reporting through use of templates. The response should include examples of which type of templates are provided with the off the shelf product and the extent of Super User configurability for the templates.	As per table 3.3.1	8					
R74	Ability to automatically convert and display numerical information to graphical representation.	As per table 3.3.1	8					
R75	Ability to display dashboards for users which represents the status of their items (notifications, actions, tasks).	As per table 3.3.1	8					
R76	Ability to display dashboards for supervisors that represents their individual employee statuses and an aggregate of the status of	As per table 3.3.1	8					

Ref.	Desirable Functionalities	Point Criteria	Max. Points	Points Received				Reference
				OTS	C F	C M	C C	
	items for users defined as reporting to them.							
R77	Ability for users to configure the dashboard.	As per table 3.3.1	8					

3.4 Future Direction

The purchase of an “additional capability” is outside the scope of this procurement process. The potential for the Contractor to provide additional capabilities, through the purchase of additional modules of the software as a service, will be evaluated as follows:

Ref.	Rated Requirements	Max Points	Points Received	Reference
R78	The Contractor has an additional capability for training management.	Yes = 10 No = 0		
R79	The Contractor has an additional capability for audit management.	Yes = 10 No = 0		
R80	The Contractor has an additional capability for equipment management.	Yes = 10 No = 0		
R81	The Contractor has an additional capability for inventory management.	Yes = 10 No = 0		
R82	The Contractor has an additional capability for Safety Data Sheet management.	Yes = 10 No = 0		

ANNEX B

BASIS OF PAYMENT

Table 1 - Initial Deliverable List

Item No.	Description	Price
1	Provide pricing for the license to use the software: <ul style="list-style-type: none"> For all 14 sites, including 40 Super Users, 191 Supervisors, 630 Users, and 73 Viewers Includes documentation for use of the solution in English and French (i.e. manual) (at least one copy in each language per site or capability to reproduce, as needed). 	
2	Provide pricing for the migration of documentation into the system: <ul style="list-style-type: none"> For all 14 sites, including 10,000 documents from standard file formats (.pdf, .xlsx, .wpd, .docx, web links) from electronic document management system (OpenText DM), network drives (Microsoft servers), the CFIA intranet and external websites into the software service). 	
3	Provide pricing for the configuration of the software: <ul style="list-style-type: none"> For all 14 sites, including 2 business days of remote configuration per each site 	
4	Provide pricing for training : <ul style="list-style-type: none"> For all 14 sites, including 40 Super Users The training must be provided in the following format: <ul style="list-style-type: none"> remote, instructor-led, provide participants the opportunity to ask questions in real time provided in English and in French Includes writeable copies of all training resources in English and French	
5	Provide pricing for full maintenance and support services for Year 1: <ul style="list-style-type: none"> For all 14 sites Includes all software upgrades Includes hosting all data Includes data back-up Includes technical support, available from Monday through Friday from 8 am to 8 pm EST to ensure cross-Canada support, in English and French 	
	Sub-Total	
For Evaluation Purposes, the Sum of Sub-Total Rates for Item 1 + Item 2 + Item 3 + Item 4 + Item 5 Will Be Used To Calculate The Total Bid Price.		

Table 2 – Optional Deliverables (Year 1)

Item No.	Optional Deliverables (Year 1)	Price
1	Provide a flat rate price for the purchase of additional licenses to use the software: <ul style="list-style-type: none"> One additional Super User One additional Supervisor One additional Lab User One additional Viewer 	
2	Provide a flat rate price for the migration of additional documents: <ul style="list-style-type: none"> 1-100 additional documents 	
3	Provide a flat rate price for additional configuration: <ul style="list-style-type: none"> 4 additional hours 	
4	Provide a flat rate price for additional training: <ul style="list-style-type: none"> 1-10 additional personnel 	
	Sub-Total	
For Evaluation Purposes, the Sum of Sub-Total Rates for Item 1 + Item 2 + Item 3 + Item 4 Will Be Used To Calculate The Total Bid Price.		

Table 3 – Optional Deliverables (Years 2-10)

Item No.	Description of Deliverables (Years 2-10)	Price
1	Provide pricing for the license to use the software: <ul style="list-style-type: none"> For all 14 sites, including 40 Super Users, 191 Supervisors, 630 Users, and 73 Viewers 	
2	Provide pricing for full maintenance and support services (annual price, fixed for Years 2-10)For all 14 sites: <ul style="list-style-type: none"> Includes all software upgrades Includes hosting all data Includes data back-up Includes technical support, available from Monday through Friday from 8am to 8pm EST to ensure cross-Canada support, in English and French	
3	Provide a flat rate price for the purchase of additional licenses to use the software: <ul style="list-style-type: none"> One additional Super User One additional Supervisor One additional Lab User One additional Viewer 	
4	Provide a flat rate price for additional training: <ul style="list-style-type: none"> For up to 50 personnel, from any of the 14 sites The training must be provided in the following format: <ul style="list-style-type: none"> remote, instructor-led, provide participants the opportunity to ask questions in real time The training must be provided in English and in French 	

Contract No. - N° du contrat
39903-170873/A

Amd. No. - N° de la modif.
002

Buyer ID - Id de l'acheteur
140XL

Client Ref. No. - N° de réf. du client
39903-170873

File No. - N° du dossier

CCC No./N° CCC - FMS No./N° VME

	<ul style="list-style-type: none">Includes providing writeable copies of all training resources in English and French	
Sub-Total		
For Evaluation Purposes, the Sum of Sub-Total Rates for Item 1 + Item 2 + Item 3 + Item 4 Will Be Used To Calculate The Total Bid Price.		

Table 4 – Total Bid Price for Evaluation Purposes

Item No.	Description	Price	
1	Firm annual price for the initial contract period	Sub-Total CAD\$ from Table 1	
2	Firm annual price for Option Year 1, Year 2-10	Sub-Total CAD\$ from Tables 2 & 3	
3	Firm Price for Training Services	The Sum of Sub-Total CAD\$ from Tables 1 & 3	
Total Bid Price (TBP) For Evaluation Purposes			
For Evaluation Purposes, the Sum of Sub-Total Rates for Item 1 + Item 2 + Item 3 Will Be Used To Calculate The Total Bid Price.			

ALL OTHER TERMS AND CONDITIONS REMAIN UNCHANGED.