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H5A 1L6
FAX pour soumissions: (514) 496-3822

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.

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Title - Sujet DR pour la plateforme MSFP	
Solicitation No. - N° de l'invitation 9F052-180576/B	**Amendment No. - N° modif.** 003
Client Reference No. - N° de référence du client 9F052-18-0576	**Date** 2020-01-31
GETS Reference No. - N° de référence de SEAG PW-$MTB-550-15587	
File No. - N° de dossier MTB-8-41285 (550)	**CCC No./N° CCC - FMS No./N° VME**
Solicitation Closes - L'invitation prend fin **at - à 02:00 PM** **on - le 2020-02-07**	**Time Zone** **Fuseau horaire** Heure Normale du l'Est HNE
F.O.B. - F.A.B. **Plant-Usine:** ☐ **Destination:** ☑ **Other-Autre:** ☐	
Address Enquiries to: - Adresser toutes questions à: Mirfatahi, Kaveh	**Buyer Id - Id de l'acheteur** mtb550
Telephone No. - N° de téléphone (514) 260-4106 ( )	**FAX No. - N° de FAX** (514) 496-3822
Destination - of Goods, Services, and Construction: **Destination - des biens, services et construction:**	

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Canada

Project Title

MicroPrep System for the International Space Station (ISS)

The above mentioned Request for Information (RFI) is hereby amended as follows:

Note : The slides for the webinar presentation have been made available to suppliers who have signed the NDA.

A. Answer the following the supplier questions:

Question 1:
The answer below is for questions about protein purity that were received:

Answer 1:
The objective of this RFI is to survey industries concerning their interest of developing the instrument and not about the development of specific applications. Details for this new capacity will be known later. However, some answers can be found in various scientific publications authored by the NRC. Namely:

- Microfluidic-based Platform for Universal Sample Preparation and Biological Assays Automation for Life-Sciences Research and Remote Medical Applications – D. Brassard. T. Veres et al. Deep Space Gateway Concept Science Workshop, proceedings of the workshop held February 27-March 1, 2018 in Denver, Colorado. LPI Contribution No. 2063, id.3190 (also available on PIE-ISEP portal);
- Active pumping and control of flows in centrifugal microfluidics – Liviu Clime et al., 2019 https://doi.org/10.1007/s10404-019-2198-x ;
- Automating Protein Immunoprecipitation in Centrifugal Microfluidics – D. Brassard et al., µTAS 2019 23rd International Conference on Miniaturized Systems for chemistry and Life Sciences, 27 - 31 Oct 2019, Basel Switzerland.

Question 2:
The RFI introduction section contains a list of applicable documents. Will the applicable documents list in the Technical and PA Requirements be adjusted to align with the high level list?

Answer 2:
The applicable documents lists from the PAR and FPRD should be considered the actual set of applicable documents. The RFI is not an official contractual document of the project.

Question 3:
Will bids that use a PA plan and EEE parts program that are already in use on the ISS be compliant with the RFP?

Answer 3:
Compliance is determined on a requirement by requirement basis not on an overall program.

Question 4:
Can you provide a rationale and details for the program budget changes?

Answer 4:
The contract budget has been reduced by $1M. This decision is justified by:

- Revised Safety Requirements: use of commercial off-the-shelf permitted and life reduced from 5 years to 1080 hours.
- Revised scope: crew graphical user interface removed, interface for remote access from NRC or Contractor for troubleshooting removed, electrical and data interface between cartridge and

platform removed, power input changed to include NASA provided power block, functionality Demonstration Tool removed.
- Change from EQM-FM approach to EM-PFM.
- Limitation of expenditures for phases A2, B, C instead of Firm Price (phase D will be Firm Price).

Here are the details of the budget: Contract budget - $6,999K maximum
- Budget definition phase (A, B,C): $4,798K maximum;
  - Basis of payment: limitation of expenditure
- Budget Implementation phase (D1-option): $2,001K maximum
  - Basis of payment: firm price
- Budget Commissioning phase (D2-option): $200K maximum
  - Basis of payment: limitation of expenditure

Question 5:
How is risk going to be managed on this program? We recognize a number of proposed changes in the RFI that appear to modify the approach to risk – can you elaborate on the intent?

Answer 5:
The Contractor must have a risk management process to control hardware, software, and documentation. The Contractor must continuously identify and monitor areas of cost, schedule, programmatic, technical, quality and safety risk. The Contractor must report the status of each risk element in the Monthly Progress Report and at all technical reviews. The CSA will maintain an appropriate risk reserve funding during the definition phases (A, B and C). The CSA Project Manager is responsible to initiate any risk realization request based on the Contractor risk assessment, the CSA/PSPC project team's advice and in accordance with the applicable CSA/PSPC directives. In support of a risk realization request, the Contractor will be required to prepare a detailed proposal. Should the risk submission be approved by the CSA/PSPC authorities, a contract amendment will be put in place by PSPC to contractually reflect the decision. As for the implementation phase (Phase D), which is at firm fixed price, the Contractor will maintain its own risk reserve sufficient to successfully complete the project.

Question 6:
Why did the mandatory criteria M1 change?

Answer 6:
Criterion M1 has been revised to ensure that the bidder has biomedical expertise.

Question 7:
Why is there a need for the contractor to have a biomedical business?

Answer 7:
The CSA is currently developing a space-medicine capability to support the crew on long duration missions. The CSA's long-term objective is to develop, in parallel, terrestrial and space applications. MicroPREP technology is an integral part of the CSA's space-medicine strategy, and therefore, the CSA would like to select a bidder whose business development plan includes the development of biomedical instruments.

Question 8:
Will there be access to the NRC's design prior to submitting a revised bid?

Answer 8:
An additional document with details on the design will be provided when the request for proposal will be officially posted, but the NRC design plans will not be available until the contract is awarded.

Question 9:
Why was the “Functionality Verification Tool” deleted from the project scope?
Answer 9:
The Functional Verification Tool is no longer a mandatory requirement. The plan for verifying the MFSP platform requirements must be proposed by the Contractor (with CSA and NRC support and approval). Any Ground Support Test Equipment must be provided by the Contractor.

Question 10:
Can you elaborate on the change from “Verify” to “Consolidates” in the Contractor Roles and Responsibilities (Section 1.5)?

Answer 10:
The NRC is responsible for verification of the MFSP Cartridge Devices and providing a Cartridge Device level Verification Compliance Matrix (VCM) and related evidence. The Contractor is responsible for incorporating NRC results and documentation into the MFSP System VCM and the NASA VERITAS database.

Question 11:
What are the expectations towards the participants of the webinar?

Answer 11:
The goal of the webinar is to share with Canadian organizations having a potential interest in the CSA MicroPREP project information related to this Request for Information (RFI) and subsequent Request for Proposals (RFP). Through this exchange we seek to encourage collaboration between participants and enhance both the feedback secured through the RFI and participation in the subsequent RFP.

Question 12:
What is the actual technology readiness level of the MicroPrep?

Answer 12:
The PowerBlade has been demonstrated to a TRL 6. The MFSP is based on the PowerBlade functionality and performance, but includes additional requirements for operation on ISS and is therefore at a TRL 3.

Question 13:
Q: What are the perceived challenges for adapting the system and cartridges for use on ISS?

Answer 13:
The biggest challenge related to integrating the MicroPREP to ISS will be meeting the NASA Integration and Safety Requirements. The relevant NASA requirements for these interfaces are captured in the CSA’s Product Assurance Requirements (CSA-MFSP-RD-0002) and Interface Requirements (CSA-MFSP-ID-0001) Documents. NASA and CSA’s experts are ready to assist the Contractor and NRC in all aspects of design, analysis, test and qualification of the payload and encourage an open and collaborative team effort. The interface between the MicroPREP Platform and Cartridge Devices is the next biggest challenge, but this will be mitigated by fostering a close relationship with NRC and CSA and relying on their expertise to develop the Interface Control Document.

Question 14:
Who is responsible for adapting cartridges for MSFP? Or are they expected to be useable as is?

Answer 14:
The NRC will be responsible for the Cartridge Device development. This includes designing an interface that will be compatible with the platform. The Contractor and NRC will have to come to an agreement early in the process (at the Interface Design Review (IDR) and approved by System Requirements Review (SRR)) in order to allow the Contractor to proceed with the development of the platform and NRC

to complete their Cartridge Device design. Leveraging the current interface between the platform and the Cartridge Device would help expedite the Cartridge Device development but this is not mandatory.

Question 15:
What are the required minimum and maximum sample volumes?

Answer 15:
These volumes are different for the two (2) types of Cartridge Devices (CD). The protein purification CD, the raw sample volume can be between 1 and 5 mL. The blood will be collected with a phlebotomy collection tube. For the nucleic acids purification, the maximum raw sample volume is 120 µL. A capillary will be used for the blood collection. While it is not required that the capillary tube be completely filled, a minimum volume of 60 µL is required.

Question 16:
How are samples introduced into cartridges? Is this outside the scope of this work?

Answer 16:
The method(s) used for sample introduction into the Cartridge Devices is under NRC's responsibility. The requirements provided in the platform Functional Performance Requirements Document (FPRD) take this into account. Depending on the type of molecules to be purified, the sample will be introduced into the Cartridge Device in different manners: a blood collection tube for proteins and a capillary tube for nucleic acids.

Question 17:
The SOW states that the concept is based on the NRC PowerBlade Platform, however, during the original RFP, very little technical information was provided on the NRC solutions. Without detailed technical information regarding the design, testing and results of the PowerBlade Platform, it will be difficult to model our solution off it. Can additional information be provided?

Answer 17:
A dedicated document describing in detail the PowerBlade Technology was provided during the first RFP. That document has been updated and augmented and will be available during this second RFP. Testing and results data will not be shared during the RFP. However, the SOW provides for NRC expert and a PowerBlade demonstration to be made available for a one (1) week period to the Contractor for the review of the design following the Kick Off Meeting.

Question 18:
From Honeywell's experience, containment of chemicals and biologics is a major concern during safety review board meetings, and hardware design. In the case of this SOW, pre-loaded cartridges are provided and loaded into the unit. Will CSA and NRC be handling the safety component of the chemicals and biologics? Can it be assumed the cartridge is the first level of containment?

Answer 18:
Yes. The safety reviews for the Platform and Cartridge Devices will be performed concurrently; the NRC will provide the Flight Safety Data for the Cartridge Devices and the Contractor will be responsible for incorporating or referencing this information at a system level. And yes, the cartridge is the first level of containment.

Question 19:
Emergency breaking of the rotary module has a very strict timing requirement. At 1000rpm this sudden stop would cause a major torque moment within the ISS rack, causing concern with mechanical/safety requirements. By requirement the unit cannot spin without being closed and locked. It is recommended to allow a ESTOP to disengage the motor immediately, but allow for controlled braking to ease the rotary

platform to zero. The mechanism would remain closed and locked during this operation, maintaining safety for the Astronauts. Can the requirements be revised to allow for this approach?

RM-32: The Rotary Module shall be equipped with emergency braking capable of stopping completely the rotation in less than 2 seconds.
PM-11: The Pump Module shall be able to switch between extreme output pressure levels in less than 1 second.
SM-11: The system shall have a clearly identified and easily accessible E-stop button that instantly places the system into a safe state.

Answer 19:
Thank you for this input and yes, this can be modified to allow a broader range of solutions. Crew safety is the priority, followed by mission success and integrity of the MFSP system. This approach would ultimately be determined acceptable or not by the NASA ISS Safety Review Panel.

Question 20:
The accuracy of the pump module is very fine, adding to the complexity of the design and testing of the unit. Can this be relaxed?

PM-4: The control pressure shall be from -5 psig (-3.45x10^4 Pa) suction to 10 psig (6.89x10^4 Pa) pressurization.
PM-10: The Pump Module shall control the output pressure within 0.1 psi when output is blocked (i.e. flow rate = 0)
PM-11: The Pump Module shall be able to switch between extreme output pressure levels in less than 1 second.

Answer 20:
The specification is based on the current PowerBlade platform design. The NRC had no particular issues meeting these specifications nor did they perform any extraordinary optimizations. The current Cartridge Device's operations and performance have been designed with these requirements as well and any changes would impact them directly.

Question 21:
Assuming every session is running at full speed (1000rpm) for minutes, 220 sessions per increment pair over 5 years will exceed the life of most commercially available slip rings that handle both pneumatic and power/data. Relaxing this requirement will open the design team to more commercial part availability. Can this be considered?

OPSAM-1: At least 220 sessions per increment pair.
OPSAM-2: At least 5 years of operations before the System's disposal.

Answer 21:
These requirements have already been changed in FPRC Rev B. OPSAM-1: At least 1080

Question 22:
Having two independently controlled manifolds with 8 individually controlled pneumatic outlets causes the slip ring size and cost to increase (assuming all solinoids and controls are on the static side to reduce G-loading failure concerns). If this requirement could allow for both cartridges to run the same recipe, the number of controllable pneunamic lines could be reduced to 8 from 16, reducing cost, complexity and size of the slip and overall design.

RM-18: The Rotary Module shall have two (2) independent manifolds, each with eight (8) individually-controlled pneumatic outlets per cartridge interface, capable of supporting the full range of vacuum and pressurization as defined in section 3.3.6 Pump Module Requirements.

Answer 22:

The FPRD revision B has been amended to allow a single manifold to drive each set of 8-fold pneumatic ports, thereby allowing both Cartridge Devices to run on the same Execution Sequence:

RM-18: The Rotary Module shall have a manifold, with eight (8) individually controlled pneumatic outlets per Cartridge Device interface, capable of supporting the full range of vacuum and pressurization as defined in section 3.3.6 Pump Module Requirements.

ALL OTHER TERMS AND CONDITIONS OF THE RFI REMAIN UNCHANGED.