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RETOURNER LES SOUMISSIONS À:

Travaux publics et Services gouvernementaux
Canada
Place Bonaventure, portail Sud-Oue
800, rue de La Gauchetière Ouest
7^e étage, suite 7300
Montréal
Québec
H5A 1L6

**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
Travaux publics et Services gouvernementaux Canada
Place Bonaventure, portail Sud-Oue
800, rue de La Gauchetière Ouest
7^e étage, suite 7300
Montréal
Québec
H5A 1L6

Title - Sujet Fermenteurs	
Solicitation No. - N° de l'invitation 01B30-180394/A	Amendment No. - N° modif. 002
Client Reference No. - N° de référence du client 01B30-18-0394	Date 2018-06-12
GETS Reference No. - N° de référence de SEAG PW-\$MTA-405-14879	
File No. - N° de dossier MTA-7-40149 (405)	CCC No./N° CCC - FMS No./N° VME
Solicitation Closes - L'invitation prend fin at - à 02:00 PM on - le 2018-06-26	
Time Zone Fuseau horaire Heure Avancée de l'Est HAE	
F.O.B. - F.A.B. Plant-Usine: <input type="checkbox"/> Destination: <input checked="" type="checkbox"/> Other-Autre: <input type="checkbox"/>	
Address Enquiries to: - Adresser toutes questions à: Séguin, Caroline	Buyer Id - Id de l'acheteur mta405
Telephone No. - N° de téléphone (514) 703-0455 ()	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

AMENDMENT 002

The purpose of this amendment is to publish a summary of the optional site visit held on Tuesday June 5th 2018 at 9:00 (EDT) at Agriculture and Agri-Food Canada's Research and Development Centre.

Also, the purpose of this amendment is to publish questions and answers and to revise certain mandatory technical criteria based on the given answers.

The purpose of this amendment is also to revise the Annex B "Basis of Payment" and Annex C "Project Schedule".

A) Site Visit Summary

The participants visited the laboratory and saw the fermenters that will be replaced via this request for proposal. They got to visualize the exact location where the new fermenters will be installed.

The participants asked the following questions and were given the following answers:

- What is the surface of the location where the bioreactors will be installed?
 - o Answer: The location of the bioreactors has the following dimensions: 20 feet deep by 35 feet long.
- Will a forklift or another piece of equipment be available at the time of delivery and assembly of the bioreactors?
 - o Answer: We have a forklift that can lift up to 3300 pounds with the current forks. If we have to add an extension to the forks, it drops to 2200 pounds due to the slack. We also have two electric jiggers that can lift up to 4400 pounds each. The roller-chain system could also be used as a complement and support up to 1100 pounds.
- Will the client be able to attend the Factory Acceptance Test (FAT) in person?
 - o Answer: Yes, the client should be able to send a representative for the FAT. The Annex A "Requirement" and Annex B "Basis of Payment" have been modified accordingly.

B) Questions and Answers

The following questions and answers are in reference to the Annex A "Requirement" of the solicitation document.

1. 0.3 micron inner roughness is more precise than typical bioprocess industry standards (0.4 micron for product contact), can you explain the need for this?

Answer: Surface roughness of inner vessel wall must be 0.4 micrometre (µm) or less. See modified criteria below.

2. Does the requirement for three (3) impellers apply for Rushton, pitched-blade, and marine – a total of 9 impellers for each bioreactor? Are all impellers to be included in the quote or are any of them to be quoted as options?

Answer: Yes, a total of 9 impellers for each bioreactor: three Rushton impellers, three pitched-blade impellers and three marine impellers.

3. Aeration specifies mixing "...up to two (2) to four (4) different gases..." but then names five gases: air, O₂, N₂, CO₂, and NH₃. Is the requirement for 4 or 5 per bioreactor?

Answer: We need to be able to mix at the same time two, three or four different gases.

Ex: aerobic growing = air

one gas

Aerobic growing = air + O₂

two gases

Microaerophile growing = air + 50% N₂/50% CO₂

three gases

Anaerobic growing = 40% H₂ + 5% CO₂ + 55% N₂

four gases

(with pH control by CO₂ injection at low flow rate)

Air, O₂, N₂, CO₂, and NH₃ are the common gases that we want to use.

4. Is there a preferred biomass instrument that achieves 7×10^5 cell density measurement?

Answer: Total cell density from 1×10^5 to 3×10^{10} cell/ml with 5% error (or better accuracy). See modified criteria below. The total cell density measurement must be based on optical density measurement system.

5. Are two point pH calibrations acceptable?

Answer: No, it is possible that we have to grow microorganism at high pH. The system must have a linear standard three-point curve or a linear multizone standard curve: from pH 4-7, from pH 7-10.

6. Please confirm the number of required access levels. Section 14 appears to indicate 4 levels, but it is unclear if "Engineer / Maint. Administrator" is one level or two.

Answer: 4 levels: Operator, Supervisor, Maintenance, Administrator. See modified criteria below.

7. Are the stainless steel feeding containers required to be included in CIP/SIP operations?

Answer: Yes

If not, what is the protocol for cleaning and sterilizing them? Is glass an acceptable alternative for any of these feed containers?

Answer: We need a versatile system to meet the laboratory needs as much as possible, therefore we require stainless steel containers.

8. What is the preferred IP rating for the six (6) peristaltic pumps required for each bioreactor?

Answer: IP33. See modified criteria below.

9. Clarify number of filters – Section 8 mentions dual inlet filters and an exhaust filter, but also "...two (2) chemically inert polytetrafluoroethylene (PTFE) membrane filter cartridges... for incoming and outgoing air." Is the intent for dedicated sparge and overlay filters, with a single exhaust filter?

Answer: The aeration must contain at least two (2) chemically inert polytetrafluoroethylene (PTFE) membrane filter cartridges (in filter housing) which are inherently used as air and gas-sterilizing filters for incoming air (at least one (1) PTFE filter) and outgoing air (at least one (1) PTFE filter). See modified criteria below.

10. Are the alternate spargers (fluted, sintered, or otherwise) to be included in the offer, or should they be listed as options?

Answer: Alternate spargers must be included in the bid.

11. Please clarify whether magnetic agitation is acceptable – Section 7 mentions magnetic agitation, then specifies "...motor, a double mechanical seal, a stirring shaft, and impellers."

Answer: Magnetic agitation is acceptable as long as it is compliant with the speed spectra from 0 rpm to at least 1200 rpm.

12. What is the intent of the "Main Air Fault" alarm?

Answer: This has been replaced by "Other gas flow fault". The system must have the critical alarms and warnings mentioned in the table below.

13. Does the facility have a CIP skid already?

Answer: Yes.

If so, what is the pressure/flow rate of the CIP pump? If not, is a CIP system to be included in the bid?

Answer: If we know the flow rate you need to do the CIP correctly, then we will use the proper pump because we have a wide variety of pumps (and flow rates).

C) Revision of mandatory technical criteria

In reference to Annex A "Requirement":

At page 17 of 37, section 5. Technical Specifications:

DELETE:

- Surface roughness of inner vessel wall must be 0.3 micrometre (µm) or less. Surface roughness of outer vessel wall must be 0.8 µm or less (passivated, polished and free of imperfection).

AND REPLACE WITH:

- Surface roughness of inner vessel wall must be **0.4 micrometre (µm) or less**. Surface roughness of outer vessel wall must be 0.8 µm or less (passivated, polished and free of imperfection).

At page 20 of 37, section 8 "Aeration system":

DELETE:

- The aeration system must contain at least two (2) chemically inert polytetrafluoroethylene (PTFE) membrane filter cartridges which are inherently hydrophobic used as air and gas-sterilizing filters for incoming and outgoing air. The aeration system must contained an automatic gas flow control system (O2, N2, CO2, NH3) using a MFC. An automatic pressure control system in the fermenter vessel must mount on the exhaust airline.

AND REPLACE WITH:

- The aeration system must contain at least two (2) chemically inert polytetrafluoroethylene (PTFE) membrane filter cartridges (**in filter housing**) which are inherently used as air and gas-sterilizing filters for incoming air (at least one (1) PTFE filter) and outgoing air (at least one (1) PTFE filter). The aeration system must contained an automatic gas flow control system (O2, N2, CO2, NH3) using a MFC. An automatic pressure control system in the fermenter vessel must mount on the exhaust airline.

DELETE ENTIRELY:

- Aeration system must include dual inlet filters (with filter housings) for entry and a jacketed exhaust filter housing.

At page 21 of 37, section 10 "Feeding / Sampling":

INSERT UNDER TABLE 2:

- The stainless steel feeding containers must be included in CIP/SIP operations.

INSERT UNDER TABLE 3:

IP rating for the peristaltic pumps for each bioreactor must be IP33.

At page 22 of 37, section 12 "Mobility":

DELETE:

- Bioreactor no2 must be fixed to the floor and must have a staircase. The staircase must be resistant to water, acid, base and steam. The staircase surface must be anti-seizing.
- Bioreactor no3 must be fixed to the floor and must have a staircase, platform, ramp or safety barrier. The platform must be able to support 1000 pounds. The staircase, platform, ramp or safety barrier must be resistant to water, acid, base, and steam. The staircase and platform surface must be anti-seizing. The size of the platform must not exceed 8 feet wide by 16 feet long by 12 feet high.

AND REPLACE WITH:

- Bioreactor no2 must be fixed to the floor and must have a staircase. The staircase must be resistant to water, acid, base and steam. The staircase surface must be **anti-slipping**.
- Bioreactor no3 must be fixed to the floor and must have a staircase, platform, ramp or safety barrier. The platform must be able to support 1000 pounds. The staircase, platform, ramp or safety barrier must be resistant to water, acid, base, and steam. The staircase and platform surface must be **anti-slipping**. The size of the platform must not exceed 8 feet wide by 16 feet long by 12 feet high.

At page 24 of 37, section "Software control system":

DELETE:

The control system must be able to regulate feeding rate of substrates according to different parameters:

- ☐ Dissolved oxygen
- ☐ Oxydation-reduction potential (REDOX)
- ☐ Cell density 1×10^5 to 7×10^{10} with 5% error (or better) accuracy
- ☐ Ethanol (as an auxiliary input)
- ☐ Conductivity (as an auxiliary input)

AND REPLACE WITH:

The control system must be able to regulate feeding rate of substrates according to different parameters:

- ☐ Dissolved oxygen
- ☐ Oxydation-reduction potential (REDOX)
- ☐ **Total cell density from 1×10^5 to 3×10^{10} cell/milliliter with 5% error (or better accuracy).**
- ☐ Ethanol (as an auxiliary input)
- ☐ Conductivity (as an auxiliary input)

At page 25 of 37, section 14 "Software control system":

DELETE:

The "Alarm" table represented at page 25.

Access Level permissions: for different user (All, Operator, Supervisor, Engineer / Maint. Administrator).
Permissions to each type of user must be configurable for at least these permissions:

- o Screen navigation
- o Change device mode to Auto
- o Change device mode to Auto, Manual and Off
- o Change Alarm Setpoints, Time Delay and Dead band
- o Enable/Disable Alarms
- o Acknowledge Alarms
- o Change Analog Output Value
- o Change Analog Output Mode
- o Change PID Loop Gain, Rate and Reset Constraints
- o Change PID Loop Setpoints and Modes

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01B30-180394/A
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002
File No. - N° du dossier
MTA-7-40149

Buyer ID - Id de l'acheteur
MTA405
CCC No./N° CCC - FMS No./N° VME

AND REPLACE WITH:

Revised "Alarm" table represented below.

Access level permissions: for different user (**Operator, Supervisor, Maintenance, and Administrator**).

- o Screen navigation
- o Change device mode to Auto
- o Change device mode to Auto, Manual and Off
- o Change Alarm Setpoints, Time Delay and Dead band
- o Enable/Disable Alarms
- o Acknowledge Alarms
- o Change Analog Output Value
- o Change Analog Output Mode
- o Change PID Loop Gain, Rate and Reset Constraints
- o Change PID Loop Setpoints and Modes

"Alarm" Table to be inserted at page 25 of 37

User-defined Alarm or Informational Message	Critical Alarm	Stackpole Light Illumination (color/flashing)	Informational Message	Response	
				Interlock (s)	Operator Procedural
Mandatory Alarms					
High Temperature	X		X	X	X
Low Temperature	X		X	X	X
Deviation Temperature	X		X	X	
High Agitation Speed	X		X	X	X
Low Agitation Speed	X		X	X	X
Deviation Agitation Speed	X		X	X	
High OD	X		X	X	X
Low OD	X		X	X	X
High pH	X		X	X	X
Low pH	X		X	X	X
High Air Flow	X		X	X	X
Low Air Flow	X		X	X	X
High Oxygen Flow	X		X	X	X
Low Oxygen Flow	X		X	X	X
Motor Faults	X	X		X	X
Optional Alarms					
High Carbon Dioxide	X		X	X	X
Low Carbon Dioxide	X		X	X	X
Rupture Disc Failure	X		X	X	X
Other Gas Flow Fault	X		X	X	
High Vessel Level	X		X	X	X
Low Vessel Level	X		X	X	X
Emergency stop	X	X	X	X	X
Control Platform Communication Watchdog	X		X	X	X
Control Power Fault	X		X	X	X
Control Platform Battery Low Warning		X	X		

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At page 27 of 37, section 18 "Certification":

INSERT:

- A Factory Acceptance Test (FAT) must be completed before the shipment of the system. A written proof detailing the test results must be provided to the client before the shipment of the equipment. The client must attend the FAT, either in person or via videoconference.

D) Annex B "Basis of Payment" and Annex C "Project Schedule"

DELETE

Annex B "Basis of Payment"
Annex C "Project Schedule"

AND REPLACE WITH

Annex B "Basis of Payment (modified)"
Annex C "Project Schedule (modified)"

All other terms and conditions remain unchanged.

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ANNEX "B"

BASIS OF PAYMENT (modified)

The prices indicated below exclude applicable taxes.

A) BASE ITEMS

Milestone	Milestone description	Contract value (%)	Milestone price *	Estimated milestone payment date
1	Workshop drawings	5%	\$ _____	
2	Materials required for system construction	35%	\$ _____	
3	Factory Acceptance Test (FAT) for the entire system	15%	\$ _____	
4	Site Acceptance Test (SAT) for the entire system	40%	\$ _____	
5	Transportation and delivery fees to address mentioned in Annex A “Requirement”		\$ _____	
6	Installation fees		\$ _____	
7	On-site training to address mentioned in Annex A “Requirement”	5%	\$ _____	
8	User manual (French and/or English)		\$ _____	
TOTAL			\$ _____	

* Currency (if other than CAD) : _____

B) OPTIONAL ITEMS

Polytetrafluoroethylene (PTFE) membrane filter cartridges : \$ _____

Optional alarms :

User-defined Alarm or Informational Message	Critical Alarm	Stackpole Light Illumination (color/flashing)	Informational Message	Response Interlock (s)	Operator Procedural
Optional Alarms					
High Carbon Dioxide	X		X	X	X

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User-defined Alarm or Informational Message	Critical Alarm	Stackpole Light Illumination (color/flashing)	Informational Message	Response	
				Interlock (s)	Operator Procedural
Low Carbon Dioxide	X		X	X	X
Rupture Disc Failure	X		X	X	X
Other Gas flow fault	X		X	X	
High Vessel Level	X		X	X	X
Low Vessel Level	X		X	X	X
Emergency stop	X	X	X	X	X
Control Platform Communication Watchdog	X		X	X	X
Control Power Fault	X		X	X	X
Control Platform Battery Low Warning		X	X		

ANNEX "C"

PROJECT SCHEDULE

This project schedule will be updated before contract award based on the Gantt chart submitted in the bid and accepted by the Technical Authority.

Item	Item description	Estimated timeline (eg. X weeks from contract award)	Delivery date
1	Workshop drawings to be approved by Technical Authority		
2	Materials		
3	Factory Acceptance Test (SAT) for the entire system		
4	Delivery of the control system		
5	Delivery of the bioreactors Small Large		
6	Site Acceptance Test (SAT) for the entire system		
7	Installation of fermenters and control system		
7	On-site training		