



## 676-2016 ADDENDUM 1

### SUPPLY AND INSTALLATION OF AN INDUCTIVELY COUPLED PLASMA MASS SPECTROMETERY INSTRUMENT

#### **URGENT**

**PLEASE FORWARD THIS DOCUMENT TO WHOEVER IS IN POSSESSION OF THE REQUEST FOR PROPOSAL**

ISSUED: September 23, 2016  
BY: Courtney Diduck  
TELEPHONE NO. 204 - 986-4752

**THIS ADDENDUM SHALL BE INCORPORATED INTO THE REQUEST FOR PROPOSAL AND SHALL FORM A PART OF THE CONTRACT DOCUMENTS**

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**Please note the following and attached changes, corrections, additions, deletions, information and/or instructions in connection with the Request for Proposal, and be governed accordingly. Failure to acknowledge receipt of this Addendum in Paragraph 9 of Form A: Proposal may render your Proposal non-responsive.**

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#### **PART B – Bidding Procedures**

B2.1 The Submission Deadline is 12:00 noon Winnipeg time, October 6, 2016.

#### **PART D – SUPPLEMENTAL CONDITIONS**

Revise 10.1 to read:

D10.1 Goods shall be delivered within thirty (30) business days of the placing of an order, f.o.b. destination, freight prepaid to:

Courtney Diduck

Analytical Services Branch Head

2230 Main Street

Winnipeg, MB R2V 4T8

#### **PART E – SPECIFICATION**

Revise E2.4 (i) to read;

(i) Be able to collect (analyze) and report multiple sub lists of elements for individual samples (analyze one sample for only one element and a different sample for five (5) elements and other samples for a whole spectrum) within the batch to save time and allow for ease of analysis. The use of multiple methods to achieve this is not acceptable as this introduces the potential for incorrect method selection or deviations between the methods.

Revise E2.4 (y) to read:

(y) comply with electronic records section of 21 CFR (Code of Federal Regulation) Part 11

The following functions are required;

- With the ability to discern invalid or altered records (reprocessing and reporting the same data)
- Ability to generate accurate and complete copies of records in both human readable and electronic form suitable for inspection, review, and copying. (this makes it possible to push the data to another system, such as LIMS, or reporting results to EPA), or to be pulled/mapped from another system, with no way of altering the electronic record (during transmission). The database can be accessed by Microsoft® SQLServer 2008 R2 or similar tool. Or it produces a secure file that can be accessed by such.

- Protection of records to enable their accurate and ready retrieval throughout the records retention period. (usually by password protected user logon, etc.) It shall also be an automated function, such as the generating a PDF report for each sample. Once reported, the user could still reprocess and generate new reports, but they would NOT overwrite the existing ones, but would have some revision counter.
  - Limiting access to non-authorized personnel.
  - Preventative use of duplicate password or usernames.
- Use of secure, computer-generated, time-stamped audit trails to independently record the date and time of operator entries and actions that create, modify, or delete electronic records. Record changes shall not obscure previously recorded information.
- Revision and change control procedures to maintain an audit trail that documents time-sequenced development and modification of systems. (Documentation of method/operational changes, ex: if the operator changes the flow rate in an existing method, there should be a record/form within the software for documenting these changes. It should also have the ability to report a list or history of the changes (if any are done). This is often accomplished through reporting software;printing the “method setup or method parameters, integration events, etc.”.

Revise E2.6 (c) to read;

(c) A cooling system (chiller) which cools the ICP-MS. The chiller must be able to maintain a constant stable temperature for 8 hours even if the surrounding room temperature is at 30°C, which happens occasionally in the laboratory.

Revise E5.1 (d) to read;

(d) Included with access maintenance videos and/or tutorial available online for viewing and/or for downloading or be preinstalled on the computer

## **QUESTIONS AND ANSWERS**

- Q1** With regards to Form Line 8 Consumables. Should the prices for each item listed in E2.9 be on separate lines or provide as a group?
- A1** Provide one price for all consumables listed in E2.9 for line 8. A detailed price list for each item may be provided in the proposal.
- Q2** With regards to E3.1 (f); What is the intent is it validation or to demonstrate that the instrument passes its performance specifications?
- A2** Installation is to demonstrate that the instrument passes its performance specifications with real samples and or standards.