

**U.S. DEPARTMENT OF VETERANS AFFAIRS
VETERANS HEALTH ADMINISTRATION**

**Justification and Approval (J&A)
For
Other Than Full and Open Competition**

1. Contracting Activity:

Department of Veterans Affairs, Network Contracting Office (NCO) 15, Consolidated Mail Outpatient Pharmacy (CMOP) Acquisitions, 3450 S. 4th Street Trafficway, Leavenworth, KS 66048

2. Nature and/or Description of the Action Being Processed:

Description of Requirement:	Cold Chain Management Temperature Study – National CMOP
NAICS Code/Description :	541380 (Testing Laboratories)
Small Business Size Standard*: (https://www.sba.gov/contracting/getting-started-contractor/make-sure-you-meet-sba-size-standards/table-small-business-size-standards)	\$15,000,000
Product Service Code/Description:	H165 (Quality Control Services - Medical, Dental, and Veterinary)
Estimated Period of Performance:	Completion of Study Within 160 Days of Award

3. Description of Supplies/Services Required to Meet the Agency's Needs:

National CMOP is requesting a Contractor to conduct a temperature study simulating extreme transit conditions.

- a) The contractor shall provide all necessary instrumentation and tools, collect and analyze data, and perform all required tasks to accomplish the deliverables described in the performance work statement (PWS) except as otherwise specified.
- b) The contractor shall place sample vials in non-insulated mailers and insulated containers with frozen gel pack(s) to be tested. Packaging must conform to CMOP Packing Standards.
- c) The contractor shall place temperature monitors inside each of the containers and mailers.
- d) After packaging, sealed containers and mailers shall be placed into an environmental chamber for up to 120 hours while exposed to modified International Safe Transit Association (ISTA) Standards for extreme summer and winter transit conditions.
- e) The Contractor shall use a 120 hour summer/winter ISTA modified profile to represent extreme temperatures during summer and winter in a mailbox. For the summer profile the last 10 hours will be kept at 60°C (Phoenix) whereas the last 10 hours of the winter profile will be at -20°C (Fargo). Samples shall be tested by an accredited and certified laboratory to analyze the assay at 120 hour, at 30, 60, 90 and 120 days at controlled room temperature (CRT) similar to patient's home temperature. A second test will be conducted simultaneously with samples tested at 60, 90, and 120 days at 4°C controlled cold temperature (CCT) similar to a patient's refrigerator temperature.

4. Statutory Authority Permitting Other than Full and Open Competition:

41 USC §3304(a)(1), as implemented by Federal Acquisition Regulation (FAR) 6.302-1: *Only one responsible source and no other supplies or services will satisfy agency requirements.*

5. Demonstration that the Contractor's Unique Qualifications or Nature of the Acquisition Requires the Use of the Authority Cited Above:

Proposed Awardee: Impact Analytical, Inc.
DUNS: 080160931
Address: 1940 N. Stark Road
City, State, and Zip Code: Midland, MI 48642-9438

As further described in Item 8 (Description of Market Research Conducted and Results), Impact Analytical was the only Contractor, after extensive solicitation posting and robust Government outreach, who indicated interest in providing service and submitted a proposal, after all competitive solicitation procedures were exhausted on www.fbo.gov by the Contracting Officer that had resulted in no offers submitted for this requirement.

6. Description of Efforts Made to ensure that offers are solicited from as many potential sources as deemed practicable:

As further described in Item 8 (Description of Market Research Conducted and Results), Impact Analytical was the only Contractor, after robust Government outreach, who indicated interest in providing service and submitted a proposal, after all competitive solicitation procedures were exhausted on www.fbo.gov by the Contracting Officer that had resulted in no offers submitted for this requirement.

7. Determination by the Contracting Officer that the Anticipated Cost to the Government will be Fair and Reasonable:

This procurement is for a required completion date of 160 days from award. The Contracting Officer will review proposed pricing of Contractor to ensure price fair and reasonableness in accordance with FAR 13.106-3 (a)(2), including comparison to the government cost estimate. Estimated cost is \$85,900.

8. Description of the Market Research Conducted and the Results, or a Statement of the Reasons Market Research Was Not Conducted:

A sole source award to Impact Analytical is recommended, as the Contracting Officer, on original Solicitation VA770-17-Q-0221, from initial Total Small Business Set-Aside to Full and Open Competition, was unable to successfully obtain offers from Contractors for service cited above. Original Solicitation VA770-17-Q-0221, per rationale shared below, was cancelled by the Contracting Officer, due to no offers being received.

Per original solicitation, to determine suitability to do an SDVOSB set-aside, market research was conducted through Vet Biz and DSBS under NAICS 541380. A random sampling indicated there were some laboratories, but of a more general nature than the specific testing needed by National CMOP. The CO could not reasonably determine that there would be two (2) or more SDVOSB able to submit acceptable offers.

Per original solicitation market research, the CO, on basis of Vet Biz, was not able to determine whether or not two (2) or more SDVOSB were able to meet this requirement. Next, the CO looked at Vet Biz to see if there were any suitable VOSB available to meet this requirement under NAICS 541380. While there were approximately 35 VOSB listed, the CO similar to process used above for SDVOSB, could not reasonably determine that there would be two (2) or more VOSB that could submit acceptable offers.

Per original solicitation, to determine suitability to do a Small Business set-aside after determining that there were not at least two (2) or more SDVOSB or VOSB capable, market research was conducted through DSBS under NAICS 541380. Per DSBS, there were approximately 4,594 of SB listed under this NAICS. This included potential small business sources identified through market research of the Program Office. The CO sampled SB listed to determine their ability to provide relevant services for this requirement. There were at least two (2) or more suitable SB able to potentially meet this requirement. Thus, requirement was proposed to be done as SB set-aside, to be posted at www.fbo.gov.

Contracting Officer posted solicitation to www.fbo.gov on 3-10-2017, as Total Small Business Set-Aside. Deadline was 3-17-2017 for written technical questions to be submitted by offerors and deadline was 3-27-2017 for offers to be submitted.

Additionally, the Contracting Officer reached out to the potential small business sources identified by the program office and sent them a courtesy notice of the solicitation being posted to FBO.

Upon passing of this deadline, not a single small business offeror either asked technical questions or submitted an offer. On this basis and due to the urgency of this requirement, the Contracting Officer requested and obtained approval on modified VA Form 2268 on 3-28-2017 to conduct a Full and Open, Unrestricted competition on www.fbo.gov. Small businesses were given fair opportunity to submit offers under Full and Open competition.

Solicitation Amendment A00001 was posted to www.fbo.gov on 3-28-2017, extending deadline to 4-11-2017, withdrawing Small Business set-aside, and changing solicitation to Full and Open, Unrestricted.

Solicitation Amendment A00002 was posted to www.fbo.gov on 4-11-2017, extending the deadline for offers to 4-19-2017.

As no offers were submitted by 4-19-2017, the Contracting Officer, with Program Office support, reached out to NCO 15 Small Business Liaison and U.S. Small Business Administration on 4-19-2017 (SBA) to determine if there was possibility of 8(a) sole source or competitive set-aside. SBA identified one (1) potential offeror. Since it was not clear at time whether or not this offeror could submit offer to justify an 8(a) set-aside or sole source, the Contracting Officer posted Solicitation Amendment A00003 to www.fbo.gov on 4-21-2017, extending the offer deadline to 4-28-2017. The Contracting Officer again e-mailed courtesy notices of this amendment to additional sources.

Upon passing of this deadline on 4-28-2017, there were no offers received. The Contracting Officer, with support of Program Office, cancelled the solicitation via Special Notice to www.fbo.gov on 4-28-2017.

The Program Office then indicated to Contracting Officer that they would try robust outreach to several not-profit organizational to see if they would be interested in submitting an offer for sole source consideration. These organizations were not interested.

Next, another potential awardee and Small Business was contacted to do a sole source, but efforts to work with them and award contract did not happen, as Jordi Labs withdrew from procurement process.

All market research approaches were used and fully exhausted in getting this requirement awarded.

9. Any Other Facts Supporting the Use of Other than Full and Open Competition:

Not Applicable

10. Listing of Sources that Expressed, in Writing, an Interest in the Acquisition:

Not Applicable

11. A Statement of the Actions, if any, the Agency May Take to Remove or Overcome any Barriers to Competition before Making subsequent acquisitions for the supplies or services required:

At present, there is no anticipated need for competition beyond this contract as this is intended to be a one-time service procurement to supply non-recurring deliverable (temperature study). However, if the Government identifies the need for an updated study or similar study for other CMOP areas, the Government will conduct robust market research with the intent to identify potential sources and ensure a competitive solicitation going forward with emphasis on setting aside (in order of priority) to Service Disabled Veteran Owned Small Businesses, Veteran Owned Small Businesses, and other Small Businesses. Full and Open Competition would be considered only if set-aside options cited above are not practicable or if acceptable offers are not submitted by higher-priority small businesses.

12. Requirements Certification:

I certify that the requirement outlined in this justification is a Bona Fide Need of the Department of Veterans Affairs and that the supporting data under my cognizance, which are included in the justification, are accurate and complete to the best of my knowledge and belief.

James Hinspeter
Contracting Officer Representative (COR)
National CMOP

7/27/2017

Date

13. Approvals:

Contracting Officer:

I certify that the foregoing justification is accurate and complete to the best of my knowledge and belief.

Douglas H. Reed
Contracting Officer, NCO 15/CMOP Acquisitions

Date