

DEPARTMENT OF VETERANS AFFAIRS

Justification and Approval

For

Exception to Fair Opportunity Memo

Acquisition Plan Action ID: 629-17-1-7224-0141

1. **Contracting Activity:** Department of Veterans Affairs, VISN 16, 0629 SLVHCS New Orleans Medical Center Project Legacy acquisition
This is a "Justification for Other Than Full and Open Competition" for the purchase of an Autoverification system which allows for the automatic release of results from the Chemistry and Hematology laboratories' patient sample testing equipment. This system is compatible with the VistA Lab AutoRelease 1.0 patch completed in October to allow the capability for VistA to accept in-house verified results from our existing middleware system, Data Innovations Instrument Manager, and automatically release those results to CPRS, etc. Data Innovations, LLC, is the current middleware system in place in Pathology and Laboratory Medicine Service and has created proprietary software to accomplish the Autoverification process.
2. **Description of Action :** The action requested is for the purchase of an Autoverification system to include software, hardware, installation, training and support that will work through the existing Data Innovations System. The contractor's name is Data Innovations, LLC. 120 Kimball Ave, Suite 100, South Burlington, VT 05403. The total expected cost estimate is \$240,945.00.
3. **Description of Supplies or Services:** The intent of this procurement is to purchase an autoverification system for the Chemistry and Hematology laboratories with ability to expand the system into selected other sections of the Pathology and Laboratory Medicine Service. The effect of the purchase of this system will be that patient results will be automatically released to CPRS as they are available from the instrument with the exception of those whose results fall outside of the Rules that will govern the result release. This will be most advantageous with patient samples from the ER, OR, Intensive Care units, etc. as there will be no delay between completion of the test by the analyzer and release to the patient's electronic record for review by the providers.
4. The purchase includes the system which consists of proprietary software, licenses and hardware to access the system as well as installation, training and support in implementing the process. Data Innovations, LLC is the owner of our current Instrument Manager system through which the autoverification will be accomplished. Data innovations, LLC allows no other vendors software to be added to its system and is the sole source of the Autoverification system for its middleware. We will also purchase service agreements for the systems from Data Innovations as it is a proprietary Instrument Manager middleware system and they are the sole distributor. Data Innovations will install and train P&LMS staff and BioMedical Engineering staff on basic and advanced troubleshooting and the writing of rules as specified. The total estimated cost of the procurement is \$240,945.00.

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5. **Statutory Authority:** The statutory authority permitting an exception to fair opportunity is Section 41 U.S.C. 4106(c) as implemented by the Federal Acquisition Regulation (FAR) Subpart 16.505 Subpart 16.505(b)(2)(i):
- () FAR Subpart 16.505(b)(2)(i)(A): The agency need for the supplies or services is so urgent that providing a fair opportunity would result in unacceptable delays.
- (X) FAR Subpart 16.505(b)(2)(i)(B): Only one awardee is capable of providing the supplies or services required at the level of quality required because the supplies or services ordered are unique or highly specialized.
- () FAR Subpart 16.505(b)(2)(i)(C): The order must be issued on a sole-source basis in the interest of economy and efficiency because it is a logical follow-on to an order already issued under the contract, provided that all awardees were given a fair opportunity to be considered for the original order.
- () FAR Subpart 16.505(b)(2)(i)(D): It is necessary to place an order to satisfy a minimum guarantee.
- () FAR Subpart 16.505(b)(2)(i)(E): For orders exceeding the simplified acquisition threshold, a statute expressly authorizes or requires that the purchase be made from a specified source". The statutory authority permitting an exception to fair opportunity for this action is 38 U.S.C. 8127(c), known as the Veterans First Contracting Program which provides the authority to directly contract with a Service-Disabled Veteran-Owned Small Business (SDVOSB) or a Veteran-Owned Small Business (VOSB).
- () FAR Subpart 16.505(b)(2)(i)(F) In accordance with section 1331 of Public Law 111-240 (15 U.S.C. 644(r)), contracting officers may, at their discretion, set aside orders for any of the small business concerns identified in 19.000(a)(3). When setting aside orders for small business concerns, the specific small business program eligibility requirements identified in part 19 apply.
6. **Rationale Supporting Use of Authority Cited Above:** Data Innovations, LLC, (DI) is the only vendor who can add connections to their proprietary Instrument Manager middleware system. Since we currently own 30 connections, the cost of staying with this vendor is far lower than the cost of purchasing a new Instrument Manager middleware system, the 30 needed connections to interface our equipment and the Autoverification systems. Data Innovations, LLC, has the proprietary rights to their software; awarding to any other vendor would void any existing warranties and maintenance agreements. The DI software uses HL7 version 1.6, the current version in use throughout the VA for transmission of patient testing results. The DI Instrument Manager middleware system software allows writing of specific electronic data handling rules to prevent aberrant values transmitting into the patient e-record. The DI Autoverification system was specifically written to link between the Instrument Manager and VistA to allow result verification and transmission directly into the patient's electronic record. The VA has completed the release of a patch which will allow the autoverification of results and DI's system is tested

and compatible with the patch. The national VBECs is the Blood Bank establishment computer and Data Innovations is the only FDA approved middleware available.

If this is a Brand Name Justification:

We conducted extensive market research, and determined that these are proprietary items for this brand name procurement. This is a brand name justification in support of FAR 11.105, Items Peculiar to One Manufacturer. Data Innovations, LLC, brand name middleware software is the only software that can continue to build upon SLVHCS's existing Data Innovations, LLC, based Instrument Manager middleware interface system for bi-directional laboratory result transmissions. Data Innovations has proprietary software rights to the operation and connections of the existing Instrument Manager middleware system. No other middleware software can operate on the Data Innovations, LLC, Instrument Manager middleware system.

6. Efforts to Obtain Competition: *A description of efforts made to ensure that offers are solicited from as many potential sources as is practicable.*

Market research was conducted, details of which are in the market research section of this document. This effort did not yield any additional sources that can meet the Government's requirements. There is no competition anticipated for this acquisition.

7. Actions to Increase Competition: *Describe actions taken, or that will be taken, to remove or overcome any barriers to competition before initiating any subsequent acquisitions for the supplies, or services required, including challenges to restrictive data markings, data rights, preparation of a performance based work statement, and etc.*

The Government will continue to conduct market research to ascertain if there are changes in the market place that would enable future actions to be competed.

8. Market Research: *Provide a description of the market research conducted among the contract holders and the results. If market research was not conducted, the reasons it was not conducted should be stated. When citing 16.505(b)(2)(i)(b) or 16.505(b)(2)(i)(e), the only possible way to state in paragraph 5 of the J&A that there is only one contractor who can fulfill the agency's needs is to conduct market research, and it should be summarized here.*


The SLVHCS Laboratory technical expert conducted market research by reviewing other similar Instrument Manager middleware software available. This market research is an ongoing process starting in 1996 and continuously being conducted, as recently as May 2016. The other similar middleware software reviewed included Dawning Technologies, Inc. (which has been purchased by Data Innovations, LLC), and Thermofisher SampleManager LIMS. Dawning products are being replaced in the national VA by Data Innovations, LLC Instrument Manager middleware systems because of the difficulty encountered in accepting patches to the Vista Laboratory Information System in place. Based on reviews of these products, the SLVHCS Laboratory technical expert determined that none of these products can meet the SLVHCS P&LMS interoperability and compatibility requirements previously

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discussed. Additionally, planned future enhancements to the Vista LIS will require the use of Data Innovations, LLC , Instrument Manager middleware software.

9. Other Facts: None

10. Technical and Requirements Certification: I certify that the supporting data under my cognizance, which are included in this justification, are accurate and complete to the best of my knowledge and belief.


Name Michael Farley
Title Asst. Chief P&LMS
Facility SLVHCS

18 Nov 2016
Date

11. Determination that Anticipated Cost is Fair and Reasonable: A determination by the contracting officer that the anticipated cost to the Government will be fair and reasonable: ***(insert the methods that will be used to determine a fair and reasonable price).***

12. Contracting Officer's Certification (required): I certify that the foregoing justification is accurate and complete to the best of my knowledge and belief.

Name
Title
Facility

Date

13. Approvals in accordance with the [VHAPM, Volume 6, Chapter VI: OFOC SOP](#). *This part if filled out by Contracting Staff as part of the Justification*

- a. **Director of Contracting /Designee (Required over \$150K but not exceeding \$700K)**: I certify the justification meets requirements for other than full and open competition.

Name
NCO/PCO XX Director of Contracting or Designee
Facility

Date

- b. **VHA HCA Review and Approval**: I have reviewed the foregoing justification and find it to be complete and accurate to the best of my knowledge and belief and recommend approval (if over \$13.5 million) or approve (\$700K to 13.5 million) for other than full and open competition.

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Name
VHA Head of Contracting Activity (HCA)

Date

- c. **VA Deputy Senior Procurement Executive Approval (over \$13.5 million but not exceeding \$68 million)**: I have reviewed the foregoing justification and find it to be complete and accurate to the best of my knowledge and belief and approve for other than full and open competition.

Name
Deputy Senior Procurement Executive (DSPE)
Office of Acquisition and Logistics
Department of Veterans Affairs

Date

- d. **VHA Senior Procurement Executive Approval (over \$68 million)**: I have reviewed the foregoing justification and find it to be complete and accurate to the best of my knowledge and belief and approve for other than full and open competition.

Jan R. Frye
Deputy Assistant Secretary for Acquisition and Logistics
Senior Procurement Executive (SPE)
Department of Veterans Affairs

Date