

DEPARTMENT OF VETERANS AFFAIRS

Justification and Approval

For

Other Than Full and Open Competition

1. **Contracting Activity:** Department of Veterans Affairs, Network Contract Office 18, Mesa, AZ, on behalf of the Phoenix Arizona VA Health Care System (PAVAHCS) Microbiology Department of Pathology and Laboratory Medicine Services (P&LMS). This document serves as a Justification for Other than Full and Open Competition for purchase request 644-15-1-034-0024, BD Phoenix reagents, and consumables.
2. **Nature and/or Description of the Action Being Processed:**
The Department of Veterans Affairs proposes to enter into a new contract on the basis of other than full and open competition for microbiological reagents and consumables used on brand-name Becton Dickinson Phoenix Instrument System manufactured by Becton Dickinson (BD). The machine was purchased by PAVAHCS during a previous fiscal year, is still in good working order and does not need replacement. The reagents and consumables used on the machine are proprietary to the manufacturer and are not re-sold through any other vendor. This procurement is for the purchase of molecular reagents and consumables to be used on the BD Phoenix Instrument System to perform bacterial identifications and antimicrobial susceptibilities. This procurement is in accordance with FAR 13.5 Test Program for Certain Commercial Items and specifically FAR 13.501 Special Documentation Requirements, where acquisitions conducted under Simplified Acquisition Procedures are exempt from the requirements of FAR Part 6, but still require justification using the format of FAR 6.303-2. This requirement comes from the PAVAHCS Microbiology Department of Pathology and Laboratory Medicine, in Phoenix, Arizona, where in accordance with FAR 6.001(a), acquisitions conducted under FAR 13 for SAP are exempt from the requirements of FAR Part 6, but still requires a justification using the format of FAR 6.303-2. The estimated FY2015 price for the reagents is approximately \$41,313.10, with a total five-year contract estimate of \$206,565.50, accounting for inflation provided option years are exercised.
3. **Description of Supplies/Services Required to Meet the Agency's Needs:**
The procurement is to provide a lot sequester for successive twelve-month periods of molecular reagents, and consumables used with those reagents. The reagents and consumables support diagnostic testing that is crucial in performing patient management decisions in the clinical setting. The estimated value is \$206,565.50, including option years.
4. **Statutory Authority Permitting Other than Full and Open Competition:**
(X) (1) Only One Responsible Source and No Other Supplies or Services Will Satisfy Agency Requirements per FAR 6.302-1;
() (2) Unusual and Compelling Urgency per FAR 6.302-2;
() (3) Industrial Mobilization, Engineering, Developmental or Research Capability or Expert Services per FAR 6.302-3;
() (4) International Agreement per FAR 6.302-4
() (5) Authorized or Required by Statute FAR 6.302-5;
() (6) National Security per FAR 6.302-6;
() (7) Public Interest per FAR 6.302-7

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

The justification required under FAR 6.302-1 (Only One Responsible Source) is that the needed reagents and consumables are specifically licensed and patented for the PAVAHCS laboratory's previously purchased BD Phoenix Instrument System manufactured by Becton Dickinson. No other source is able to provide FDA-approved reagents or consumables to perform these tests since BD owns the patent and license. The equipment will not function without these highly specialized reagents, and substitutions will adversely affect the performance and test results of the system, making purchase of these reagents essential to carrying out the Government's mission.

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

Under normal circumstances this acquisition would fall under usual requirements for open-market competition and be open to bidding by any and all eligible contractors. However, the vendor has exclusive rights to this system and the reagents used on it, and are the only vendor that can fulfill the Government's requirement for the system. A Fair Opportunity notice (ID VA258-15-Q-0078) was posted on November 7, 2014 and remained open until November 14, 2014, with no parties expressing an interest in this acquisition, whatsoever.

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

The IGE for this procurement was determined by comparing historical data from past years usage with the BD Phoenix Instrument System, prices paid previously for similar items and market research performed by the Government Technical Representative and Contract Specialist. The estimated FY2015 price for the reagents and consumables is approximately \$41,313.10, with a total five-year contract estimate of \$206,565.50. The justification required under FAR 6.302-1 (Only One Responsible Source) is that the needed reagents and consumables are specifically licensed and patented for the PAVAHCS laboratory's previously purchased BD Phoenix Instrument System manufactured by Becton Dickinson. Since Becton Dickinson owns the patent and license, no other source, to include substitutions and sub-contractors, is able to provide FDA-approved reagents and consumables compatible with the BD Phoenix Instrument System. The instrument system was very expensive and is still in good working form. It is cost-prohibitive and wasteful to purchase new equipment every time the service line runs out of reagents. Since the instrument system will not function properly without these specialized reagents, and substitutions will adversely affect the performance and test results, it is determined both fair and reasonable to purchase the requested reagents and consumables from Becton Dickinson, in accordance with FAR 6.303-2(a)(7) (Determination of Fair and Reasonable Cost). Further price analysis will be conducted by the Contracting Officer on receipt of the proposal to ensure prices quoted are both fair and reasonable and in line with past years pricing.

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

A survey of the market place was done on the Federal Supply Schedule where it was determined that, while there are multiple vendors of molecular reagents, there were no other vendors offering reagents that are compatible with the particular BD Phoenix instrument in use at PAVAHCS. A search was done on the internet where, as described in item 7, no sellers were found that provided a reasonable-priced alternative to the BD reagents that did not require PAVAHCS to also purchase a new instrument.

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

The instrument manufactured by BD and owned by PAVAHVS is very expensive and still in good working form. It is cost-prohibitive and wasteful to purchase new equipment every time the service line runs out of reagents. It is in the best interest of the Government to continue to

purchase reagents for existing functional equipment until such time as equipment replacement is required, at which competition can be expanded to include other manufacturers.

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

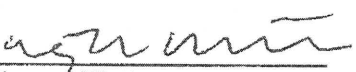
A FBO notice was posted on 11/07/2014 and remained open for 5 business days. No parties expressed an interest in this acquisition.

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 such a time as the PAVAHCS desires to replace the molecular testing equipment it is currently using, competition can be broadened. As the current requirement is not to replace equipment but only to refresh the supply of reagents for it, as described in Section 9 above, there are no actions to take to broaden competition.

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.

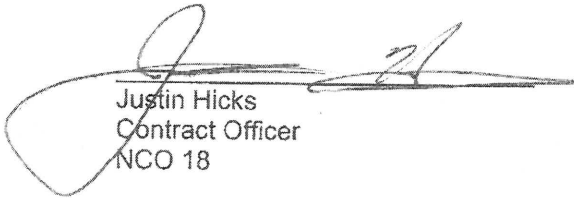


Anthony Millett
Microbiology Supervisor
Phoenix Arizona VA Health Care System

11-10-2014
Date

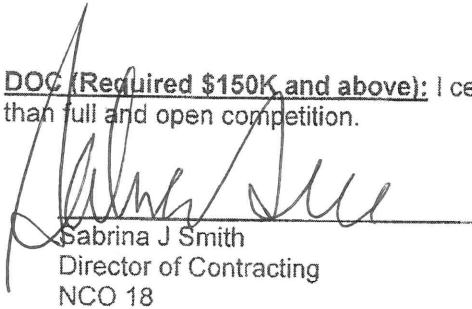
13. Approvals in accordance with FAR 6.304

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


Justin Hicks
Contract Officer
NCO 18

Date 11/10/14

- b. DOC (Required \$150K and above): I certify the justification meets requirements for other than full and open competition.


Sabrina J Smith
Director of Contracting
NCO 18

Date 11/25/14

- c. SAO (If over 650K): I certify the justification meets requirements for other than full and open competition.

Delia A. Adams, MBA, CPCM
Director, SAO West

Date

- d. 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 \$12.5 million) or approve (\$650K to 12.5 million) for other than full and open competition.

Name
VHA Head of Contracting Activity (HCA)

Date