

# DEPARTMENT OF VETERANS AFFAIRS

## Justification and Approval (J&A) For Other Than Full and Open Competition (>\$150K)

Acquisition Plan Action ID: 36C252-18-AP-0005

1. **Contracting Activity:** Department of Veterans Affairs, Veterans Integrated Service Network (VISN) 12, Great Lakes Acquisition Center (GLAC) on behalf of the Edward Hines Jr. VA Hospital PLMS (Pathology & Laboratory Medicine Service) and multiple facilities within VISN 12.

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

This is a single source justification to establish a new firm fixed-price contract with Radiometer America Inc. for automated Blood Gas system lease to include reagents and service and maintenance. This will be for VISN 12 locations at Jesse Brown VA Hospital, Chicago, IL; Edward Hines Jr. VA Hospital, Hines, IL; James Lovell Federal Health Care Center, North Chicago, IL; Clement J. Zablocki VA Hospital, Milwaukee, WI, William Middleton VA Hospital, Madison, Oscar Johnson VA Medical Center, Iron Mountain, IL and Tomah VA Medical Center, Tomah, WI.

**FAR13.5 Simplified Procedures for Certain Commercial Items:** This procurement is in accordance with FAR 13.5 Simplified Procedures 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 a justification using the format of FAR 6.303-2.

3. **Description of Supplies/Services Required to Meet the Agency's Needs:** VISN 12 PLMS requires the ability to continue to conduct Automated Blood Gas testing of patient samples via Food and Drug Administration (FDA) approved panels. The contractor will maintain the currently deployed instrument platform in all laboratory locations and provide all reagents, ancillary supplies, and service and maintenance as part of the instrument lease. The contract will be for a base plus one option period with an optional extension of up to 6 months. The period of performance and value will be the following:

Base period (10/12/18 through 10/11/19): \$256,446.00

Option period 1 (10/12/19 through 10/11/20): \$256,446.00

Optional 6 month extension (10/12/20 through 04/11/2021): \$128,223.00

**Estimated total value: \$641,115.00**

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

**FAR13.5 Simplified Procedures for Certain Commercial Items:** The authority for applying the Simplified Procedures for Commercial Items of FAR 13.5 is 41 U.S.C. 1901 and is implemented by for restricting competition on this procurement via FAR 13.106-1(b)(2).

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

In 2016, an award based on competition was made to Radiometer America for Automated Blood Gas testing and instruments were deployed within all lab locations across VISN 12, including Hines

Respiratory and Jesse Brown Anesthesia departments, to conduct testing in accordance with the contractor's National Acquisition Center (NAC) Federal Supply Schedule (FSS) for a base period with four, one-year option periods. Due to unforeseen circumstances a new schedule is not readily available to exercise the third option, however, because of the likelihood of unacceptable delays and to avoid significant duplication of effort to solicit and deploy a new system it is prudent to continue utilizing the currently deployed instrumentation for the remaining useable life of the instruments.

When new laboratory instruments are deployed, it is necessary to undergo validations on the instrument. Validations serve to verify and document that the instrument is performing consistently and reporting out results that are accurate and reliable, a meticulous and elaborate process, especially in a patient care setting, generally taking three to six months to accomplish. During the validation process it is also necessary to develop a standard operating procedure (SOP). In accordance with College of American Pathologists (CAP) accreditation and Clinical Laboratory Improvement Amendments (CLIA) certification standards the SOP that is developed outlines instrument operation instructions; how to run samples; how to interpret information received; frequency in which to run and interpret results on quality control reagents; and troubleshooting. Placing a new instrument in the laboratories will require development of a new SOP on any new system and also rewriting training documents for a new platform, retraining staff on a new instrument at all laboratory locations, validations of the new instrument against the current system, assessing lab staff competency on the new instrument, assessing lab staff competency on interpreting results, and retraining nurses and other staff on gathering patient specimen.

Based on the amount of resources required to place new instruments and go-live it would be significantly more costly to place a new platform than would be anticipated to gain in cost savings through resoliciting the requirement at this time. Also, due to the sensitive nature of testing blood gases, this type of testing is not suitable to be conducted at a reference lab and must be conducted in-house.

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

Due to the need to continue this requirement effective October 12, 2018 a new system would not be validated and ready to process patient samples. A notice of intent to sole source to the incumbent has been posted to federal business opportunities (FBO.gov) under notice 36C25219Q0014.

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

The initial award to the incumbent was made in accordance with the NAC FSS contract schedule pricing on schedule V797P-7140A. Pricing was deemed fair and reasonable at the time of award by the NAC Contracting Officer. Additionally, the contractor will continue to honor the NAC FSS pricing at the same NAC FSS contract service level for the remaining time period of the previously awarded agreement.

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

In accordance with the Vets First Contracting Program, 38 U.S.C. 8127 & 8128 Implementation Policy and Procedures, a search was conducted on the Vendor Information Pages using NAICS 334516 and yielded 84 results. A search of NAICS 334516 and keywords "blood gas" yielded 0 contractors. A search keyword "Radiometer" yielded one result, however the contractor does not list capabilities on Radiometer for laboratory and is not involved in laboratory requirements. Capabilities

were not found on Dynamic Small Business search, AbilityOne, Unicor, NAC FSS, open market search.

9. **Any Other Facts Supporting the Use of Other than Full and Open Competition:** The incumbent is the only contractor that can maintain testing without service disruption.

10. **Listing of Sources that Expressed, in Writing, an Interest in the Acquisition:** None.

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:**

Due to the anticipated need to continue this particular testing it is anticipated that, prior to conclusion of this proposed contract, a solicitation will be developed as necessary regarding available sources of supply in an attempt to foster competition. An implementation period will be afforded to validate new platforms and go-live.

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.

DONNA WRAY  
BUSINESS MANAGER, PLMS  
EDWARD HINES JR VA HOSPITAL

13. **Approvals in accordance with the [VHAPM Part 806.3 OFOC SOP:](#)**

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

JESSICA RASMUSSEN  
CONTRACTING OFFICER  
GREAT LAKES ACQUISITION CENTER, NCO 12

- b. **One Level Above the Contracting Officer (Required over \$150K but not exceeding \$700K):**  
I certify the justification meets requirements for other than full and open competition.

RICKY BOND  
DIVISION MANAGER  
GREAT LAKES ACQUISITION CENTER, NCO 12