

# DEPARTMENT OF VETERANS AFFAIRS

## Justification and Approval

For

### Other Than Full and Open Competition (Brand Name Only)

1. **Contracting Activity:** This Justification for Other Than Full and Open Competition is prepared by the Department of Veterans Affairs Network Contracting Office (NCO 6) on behalf of the Charles George Veterans Affairs Medical Center in Asheville NC in support of Purchase Request No. 637-15-1-109-0003
2. **Nature and/or Description of the Action Being Processed:** This Justification provides the rationale for soliciting using a brand name only description for Instrumentation Laboratory GEM 3500 and 4000 Blood Gas Analyzers. A competitive RFQ will be issued as full and open. A firm fixed contract is planned with a required deliver date no later than Feb 13, 2015.
3. **Description of Supplies/Services Required to Meet the Agency's Needs:**
  1. Two updated GEM 3500 blood gas analyzers in OR to be in warranty
  2. GEM 3500 Cartridges for BG/HCT/lytes/glu/lac 150 test IQM,
  3. GEM 3500 printer paper,
  4. CVP multipack,
  5. PVP, BG, Lytes, Metabolites,
  6. PVP Crit
  7. GEM 3500 Interface with CPRS
  8. Data management for GEM 3500's
  9. Two updated GEM 4000 blood gas analyzers for Respiratory Care to be in warranty
  10. GEM 4000 Cartridges for BG/HCT/LYTES/G/L/CO-OX 150 Test IQM
  11. GEM 4000 printer paper,
  12. GEM 4000 ampule breaker
  13. CVP1
  14. CVP2
  15. PVP BG, Lytes, Metabolites
  16. GEM 4000 Interface with CPRS
  17. GEM 4000 Data managementEstimated cost \$76,280.04 per year for 5 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):**

For OR blood gases: Blood gases, lytes, hct, ionized calcium, and lactate need to be run in OR in a timely manner to be able to evaluate patients quickly and accurately during surgery.

GEM 3500 is able to perform test at point of care

Need to have the two existing GEM 3500 blood gas analyzers in OR updated with two new GEM 3500's due to being out of warranty. Additional costs would be incurred for time and material for out of warranty instruments needing repair.

Need to have existing GEM 3500 blood gas analyzers replaced with new GEM 3500's due to existing interface and data management systems in place that are unique to the GEM 3500's. It would be time and cost prohibitive to purchase and install new interface and data management systems that would be required with different instrumentation.

New analyzers must have wireless capabilities for transmitting results to CPRS. This is an update that is needed to keep up with existing technology to provide timelier reporting of results and for the need for the analyzers to be mobile in OR rooms. GEM 3500 updates would have wireless capabilities

Existing data management system has to be capable of monitoring and evaluating functions of the analyzers and multiple operators over all shifts and provide troubleshooting capabilities at a central location and provides improved utilization of Point of Care Staff. Again going to different instrumentation for Blood Gases would be time and cost prohibitive due to having to pay for new interface and new data management.

Need analyzers need to have reagents that can be stored at room temperature due to limited refrigerator space and have reagents that require no shipment validation process. GEM 3500 cartridges do not need to be refrigerated or have shipment validation done. Cartridge is validated when initially placed in the GEM 3500 with the CVP. If it does not pass company will replace cartridge at no cost.

Analyzers must have minimal operator maintenance. GEM 3500 has no operator maintenance required

Analyzer in OR must be able to provide results for blood gases, electrolytes, hematocrit, ionized calcium, lactate, and glucose in a single sample. GEM 3500 is able to give results on all the analytes with a single sample.

Analyzer must have continual auto QC and auto evaluation of QC and be able to lock out the analytes that do not pass. GEM 3500 with IQM (Intelligent Quality Management) has this capability. With the new 2016 IQCP requirements( new risk management requirements) this is a must.

For Respiratory Blood gases: Blood gases, ionized calcium, lactate, and co-ox need to be able to be run by Respiratory in a timely manner to be able to evaluate inpatients with various respiratory conditions for treatment. GEM 4000's has these capabilities

Must be able to be performed outside the main lab and Respiratory department. Gem 4000's are set up in SICU.

Need to have the two existing GEM 4000 blood gas analyzers used by Respiratory updated with two new GEM 4000's due to being out of warranty. Additional costs would be incurred for time and material for out of warranty instruments needing repairs.

Need to have existing GEM 4000 blood gas analyzers replaced with new GEM 4000's due to existing interface and data management systems in place that are unique to the GEM 4000's. It would be cost and time prohibitive to purchase and install new interface and data management systems that would be required with different instrumentation.

Existing data management system has to be capable of monitoring and evaluating functions of the analyzers and multiple operators over all shifts and provide troubleshooting capabilities at a central location and provides improved utilization of Point of Care Staff. Again going to different instrumentation for Blood Gases would be time and cost prohibitive due to having to pay for new interface and new data management.

Need analyzers to have reagents that can be stored at room temperature due to limited refrigerator space and have reagents that require no shipment validation process. GEM 4000 cartridges do not need to be refrigerated or have shipment validation done. Cartridge is validated when initially placed in the GEM 3500 with the CVP. If it does not pass company will replace cartridge at no cost.

Analyzers must have minimal operator maintenance. GEM 4000 analyzers need no operator maintenance.

Analyzer for Respiratory care must be able to provide results for blood gases, ionized calcium, lactate, and Coox results in a single sample. The GEM 4000's analyzers can provide these test with a single sample.


Analyzer must have continual auto QC and auto evaluation of QC and be able to lock out the analytes that do not pass. GEM 4000 with IQM (Intelligent Quality Management) has this capability. With the new 2016 IQCP requirements( new risk management requirements) this is a must.

Additionally, both the GEM 3500 and GEM 4000 have the same methodology/ system for tests performed to remove any variability between two different test systems.

6. **Description of Efforts Made to ensure that offers are solicited from as many potential sources as deemed practicable:** A sources sought notice was posted on Federal Business Opportunity (FBO) under VA246-15-N-0051 from 11/07/2014 until 11/12/2014. One response was received from Werfen USA, LLC stating they can provide the analyzers on a lease.
7. **Determination by the Contracting Officer that the Anticipated Cost to the Government will be Fair and Reasonable:** The estimated cost to the Government is in line with prior lease of GEM 3500 and GEM 4000. The price is consistent with the pricing when the analyzers were on GSA contract.
8. **Description of the Market Research Conducted and the Results, or a Statement of the Reasons Market Research Was Not Conducted:** Market research was conducted on GSA Advantage and GSA E-Library. The analyzer is no longer on contract and is considered open market while the contract is in the process of being re-established.
9. **Any Other Facts Supporting the Use of Other than Full and Open Competition:** All facts supporting this proposed action are included in this Justification and Approval for Other than Full and Open Competition.
10. **Listing of Sources that Expressed, in Writing, an Interest in the Acquisition:** Werfen USA, LLC.
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:** For future requirements and subsequent acquisition of this type, in order to overcome any barriers to competition, market research will be used as a single guide to determine whether or not the market for competition exists.

**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.

  
DWAYNE E TILLERY  
Contracting Officer  
Network Contracting Office 6

Date

1/27/2015


- b. **NCO 6 Quality Assurance Compliance Review (required \$3K and above):**

JEFFERY A. BENTON  
538499  
JEFFERY A. BENTON  
Quality Assurance and Compliance Officer  
Network Contracting Office 6

Digitally signed by JEFFERY A. BENTON 538499  
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0.9.2342.19200300.100.1.1=jeffery.benton@va.gov,  
cn=JEFFERY A. BENTON 538499  
Date: 2015.01.28.15:19:44 -05'00'

Date

- c. **NCM/PCM/Designee (Required \$3K and above):** I certify the justification meets requirements for other than full and open competition.

  
AUDREY WOOTEN  
Branch Chief, Commodities Team 2  
Network Contracting Office 6

Date

1/28/2015