DEPARTMENT OF VETERANS AFFAIRS

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

Acquisition Plan Action ID: 36C776-19-AP-3498

1. Contracting Activity: Department of Veterans Affairs, Program Contracting Activity Central, PCAC

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

This is a **Brand Name** justification in accordance with Federal Acquisition Regulation (FAR) Part 13.5 Simplified Procedures for Certain Commercial Items, 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.

The purpose of the requirement is to integrate the preexisting GE Healthcare anesthesia system with the equipment that will be located in the new Ambulatory Care Center (ACC) being constructed. The expansion of the system is for the ACC Operating Rooms.

Estimated Dollar Value:

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

Item #	Description/Part Number*	Qty	Price	Total Amount
	JSN M0630	5		
1	GE Anesthesia Unit, Model Aisys CS2 / 1011-9050-000	5		
2	Frame Trolley – 4 drawer / 2065401-001	5		
3	Manuals and Software / 2097747-001	5		
4	DISS Pipeline Fittings, ANSI Colors / 2065381-001	5		
5	N2O Pipeline DISS Fitting / 2065359-001	5		
6	Pressure Control Modes / 2064584-001	5		
7	Spontaneous Breathing Modes / 2064585-001	5		
8	CPAP PSV Ventilation Mode / 2064587- 001	5		
9	ecoFLow Software / 2064588-001	5		

10	Patient Monitor Mount Vertical / 2065378-001	5	
11	Bag Support Arm / 10098159-000	5	T
12	Active adjustable flow AGSS. High vacuum, variable flow with bag indicator (with scavenging bag) / 5814440	5	
13	120V NEMA socket / 1011-8289-000	5	
14	Non-circle (switched) SCGO / 1011-8072- 000	5	
15	O2 Cylinder Connection, Pin Index Yoke, Inboard / 1011-8040-000	5	
16	Air Cylinder Connection, Pin Index / 1011-8050-000	5	
17	N2O Cylinder Connection, Pin Index Yoke, Outboard / 1011-8058-000	5	
18	O2 Gas Power Outlet DISS / 1011-8074- 000	5	
19	Folding Side Table / 1011-8320-000	5	
20	Cable Management Arm with Post / 1011-8336-000	5	
21	Suction Regulator 3 Mode DISS Pipeline Fitting / 2065395-001	5	
22	Suction Bottle Mounting Arm / 1009-864- 000	5	
23	Remote switch on/standby / 1009-5935- 000	5	
24	Network Connectivity Supported / 2106803-001	5	
25	Respiratory Module / M1199109	5	
26	Water Trap 1 Case 10 units / M1182629	5	
27	Exhaust Line with Coulter Fitting / CF-8004463	5	
28	Cassette for Sevoflurane - 1100-9030-000	5	
29	Cassette for Suprane (Desflurane) / 1100- 9025-000	5	
30	Cassette Filler Guard / M1135098	5	
31	EZ Change Module / 1407-7021-000	5	
32	ABS Bag Arm Connector / CF-8004459	10	
33	Patient Hyrel Tube, Adult Reusable, .09M / 2096534-003	10	

34	Absorber Canister Box of 8 / 2105489-003	5	
35	Standard Disposable Flow Sensor / 2089610-001-S	10	
36	Flow Sensor Module / 1407-7022-000	5	
37	Evac hose assemblies DISS VAC hand twist / 1009-8201-000	5	
38	Suction Mounting Post / 1006-8082-000	5	
39	Worksurface Cover Kit / M1074608	5	
40	Caster Guards Set of 4 / 1001-3269-000	5	
41	Plug O2 Port Kit / 1503-3857-000	5	
42	Auxiliary lamp kit / 1001-8896-000	5	
43	O2 Hose Assembly DISS Hand Twist / 0231-1118-810	5	
44	N2O Hose Assembly DISS Hand Twist / 0231-1118-811	5	
45	Vac Hose Assembly DISS Hand Twist / 0231-1118-812	5	
46	Air Hose Assembly DISS Hand Twist / 0231-1118-813	5	
47	Cylinder Gasket / 0210-5022-300	5	
48	Cover for Gas Hose Zipper / 8502570-S	5	
49	Periop Training and Services Onsite User Training / M11909160	4	
50	Aisys CS2 Technical Service Training (5 day class) Tuition only / 2020786-324	2	

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

FAR 13.5 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 FAR 13.106-1(b)(2) for restricting competition on this procurement.

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

The proposed GE Healthcare anesthesia system for the new ACC will integrate and be compatible with the existing system supporting the facility and will additionally provide a cost savings for the supply and maintenance contract. This will allow the VA Omaha ACC machines to integrate with the current GE Monitoring System (M850) used in both facilities to standardize the anesthesia units throughout the NWIHCS facilities. No other brand system is capable of integrating with the current

Page **3** of **7**

OFOC SOP Revision 08
Original Date: 03/22/11

Revision 08 Date: 04/18/2018

GE anesthesia system. These GE Anesthesia Machines are used in the operating room to deliver and manage the anesthesia dosage for the patient undergoing care. GE Aisys Anesthesia integrates with the Philips ARK Anesthesia Record Keeping System currently networked with a multiplex that took a great deal of coordination to configure. This effort would not be expected to be recovered through competition of a new system. The ARK system cannot be configured with more than one manufacturer/model on the same server. Additionally, GE has digital vaporizer cassettes that control the automatic record keeping of the set agent concentrations and agent usage calculations with up to two (2) times the accuracy of traditional vaporizers and includes a low agent alarm for all agents.

The system will also reduce life cycle costs by standardizing the operation, supplies, training, and maintenance requirements for aneneshesia in both hospital and ACC. The facility already owns this existing technology and the proprietary GE equipment. This purchase will maintain standardization within the hospital. The users are already trained on the existing GE equipment. This will result in limited user error and improved patient safety. If another manufacturer/model is purchased that is different from the current facility, this will affect patient care by increasing user error.

Standardization of medical equipment to improve patient safety has been held as a rational basis for contracting brand name equipment as decided in Government Accountability Office (GAO) protest B-411904, November 2015.

"In our view, the VA's rationale for standardizing medical equipment, to reduce medical errors and enhance patient safety, sets forth a reasonable basis for procuring APCs on a brand name basis under the circumstances here. The determination of the government's needs and the best method of accommodating them is primarily the responsibility of the procuring agency, since its contracting officials are most familiar with the conditions under which supplies, equipment, and services have been employed in the past and will be utilized in the future. Columbia Imaging, Inc., supra, at 2. Where, as here, a requirement relates to human safety concerns, the agency has the discretion to set its minimum needs so as to achieve not just reasonable results, but the highest possible reliability and effectiveness. McKesson Automation Sys., Inc., B-290969.2, B-290969.3, Jan. 14, 2003, 2003 CPD ¶ 24 at 8."

VA Omaha has a requirement to outfit five (5) new anesthesia machines in the new ACC. Current use is the GE Aisys CS2 which will remain in use in the main hospital alongside the ACC. All anesthesia units must interface with the GE monitoring system, GE vaporizers and the Anesthesia Record Keeping System currently in use in the main hospital and that will be installed in the ACC. The Aisys Anesthesia machine is a highly specialized system operated in conjucton with other GE systems. Since GE Healthcare is the manufacturer of the Aisys machines, this is a "Brand Name Only" requirement because GE's networking protocol is proprietary. There is no other manufacturer that can meet GE's technical specifications as it is a proprietary system. Only GE and their authorized dealers can satisfy this requirement.

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

See section 8 below for detailed efforts to ensure offers will be solicited from as many potential sources as deemed practicable.

7. <u>Determination by the CO that the Anticipated Cost to the Government will be Fair and</u> Reasonable:

Price reasonableness will be based on competition between the authorized dealers, comparison to the independent Government estimate (IGE), and/or comparison of the proposed price with prices found reasonable on previous purchases.

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

In accordance with FAR Part 10, market research has been conducted for this acquisition. The following *techniques* were used:

Medical Surgical Prime Vendor (MSPV) Contracts: A search was conducted on the National Acquisition Center's MedSurg Catalog search located at http://www.va.gov/nac/MedSurg/List for a list of nationally awarded contractors and/or prime vendor contracts. The MSPV for Omaha is Kreisers, LLC. (https://www.va.gov/opal/sac/mspvng.asp) A search using the formulary provided no results. MSPV is not an appropriate source at this time.

GSA eLibrary: https://www.gsaelibrary.gsa.gov/ElibMain/home.do. A search for the keyword "anesthesia equipment" (65 II A Medical Equipment and Supplies, sub category A-44 Anesthesia Equipment and applying the SDVOSB and VOSB filters was conducted and resulted in five (5) vendors. These vendors were contacted via email (Attachment Email – GSA). Zero (0) vendors responded. The conclusion of this effort is GSA is not an appropriate source at this time.

SDVOSB/VOSB Sources via VetBiz (VIP): In accordance with VAAR Subpart 819.7004, 819.7005, 819.7006 - https://www.vip.vetbiz.va.gov/. A search on Vetbiz.gov was conducted in an attempt to locate Service-Disabled-Veteran-Owned-Small-Business (SDVOSB) and Veteran-Owned-Small Business (VOSB) concerns utilizing NAICS code 339112 (this search provided 271 SDVOSB and 52 VOSB results). From these results, all vendors were contacted via email (Attachments Email - SDVOSB and Email - VOSB). One (1) SDVOSB, TrillaMed, LLC responded as being able to meet this requirement with GE Brand and has been identified in the table below. Two (2) SDVOSBs, The Janz Corporation (Janz) and Alliant Healthcare Products (Alliant) responded as being able to meet this requirement if an "or equal" were acceptable Janz proposed Draeger and Alliant proposed Mindray and have been identified in the table below.

FBO RFI/Sources Sought Notice: An RFI/Sources Sought Notice was published to Federal Business Opportunities (FBO) on July 31, 2019 (Attachment – S03 - FBO – 36A77619Q0179). One (1) Large Business vendor (Draeger) responded as being able to meet this requirement if an "or equal" were acceptable. This vendor has been identified on the table below.

GE Healthcare: GE Healthcare was contacted via email asking if they had authorized distributors. GE Healthcare Inc. stated they have authorized distributors. These vendors have been identified in the table below (1 duplicate from VIP) (Attachment – GE – Authorized Distributors).

Vendor	DUNS	Socioeconomic	GE Brand

		Category	Name
TrillaMed, LLC	828126321	SDVOSB	Yes
Alko Enterprises, LLC	181118738	SDVOSB	Yes
Jaken Medical	068665699	8a	Yes
Draeger, Inc	044549434	Other than Small	No
The Janz Corporation	103534595	SDVOSB	No
Alliant Healthcare			
Products	121170653	SDVOSB	No
GE Healthcare Inc	053046579	Other than Small	OEM

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

GE Anesthesia Machines requires certified technicians with an agreement or certification from the original manufacturer to work on the equipment. The facility would have to fund two (2) service contracts to maintain another manufacturer costing an additional dollars a year to maintain.

The anesthesia machines must be compatible with the existing GE monitoring systems and must be capable of interfacing with GE's proprietary protocol network currently in operation at the facility. GE Healthcare holds all proprietary rights to the design and manufacture of the Aisys Anesthesia System. Additionally, deviation from this system would incur additional service and maintenance costs than what is currently projected.

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

TrillaMed, LLC – SDVOSB

Alko Enterprises, LLC – SDVOSB

Jaken Medical – 8a

Draeger – Other Than Small – cannot meet GE Healthcare brand name

Tha Janz Coporation – SDVOSB – cannot meet GE Healthcare brand name

Alliant Healthcare Products – SDVOSB– cannot meet GE Healthcare brand name

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:

The Omaha is standardized to the GE brand and anesthesia machines, and the GE Aisys Gas Module is compatible with all current machines and support/maintenance contracts. Acuiring another brand would create substantial duplication of costs as a result of incompatibility issues, the requirement to purchase multiple brand machine support/maintenance costs, and the costs resulting from having to train all affected employees on multiple brands of equipment. This could also potentially lead to patient safety concerns if employees have to work with multiple brands of devices in emergency situations.

12. <u>Requirements Certification</u>: 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.

Omaha VA Medical Center

13. Approvals in accordance with the **VHAPM Part 806.3 OFOC SOP**:

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

Program Contracting Activity Central

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

Program Contracting Activity Central