

This is a combined synopsis/solicitation for commercial items, prepared in accordance with the format in FAR Subpart 12.6, as supplemented with additional information included in this notice. **This announcement constitutes the only solicitation; quotes are being requested and a written solicitation will not be issued.**

Solicitation Number 36C256-18-Q-0030 is issued as a Request for Quote (RFQ). This solicitation document and incorporated provisions and clauses are those in effect through Federal Acquisition Circular 2005-95. **Offers are due no later than Friday, October 20, 2017 by 2:00 p.m., Central Local Time (CST), New Orleans, LA.**

This solicitation is set-aside 100% for Service-Disabled Veteran-Owned Small Business concerns, under NAICS code 334510 with a small business standard of 1,250 employees or less. Eligible SDVOSB's must have an active profile/active registration in the Vendor Information Pages (i.e. VetBiz <https://www.vip.vetbiz.gov/> to be considered for a contract award from this solicitation.

TABLE OF CONTENTS

<u>SECTION A – SUPPLEMENTAL INFORMATION</u>	2
<u>SECTION B – PRICE/COST SCHEDULE AND STATEMENT OF WORK</u>	3
<u>B.1 PRICE/COST SCHEDULE & ITEM INFORMATION</u>	3
<u>B.2 STATEMENT OF WORK</u>	4
<u>SECTION C – PROVISIONS AND CLAUSES</u>	12
<u>SECTION D – ATTACHMENTS</u>	123

SECTION A – SUPPLEMENTAL INFORMATION

1. The overall purpose is to provide and install (1) Phonatory Aerodynamic System at the Southeast Louisiana Veterans Health Care System (SLVHCS) Outpatient Speech Pathology Clinic located at 2400 Canal St, New Orleans, LA 70119.
2. All work shall be completed in accordance with the Statement of Work (SOW), entitled, “Phonatory Aerodynamic System and Installation”.
3. Instructions to Offerors
 - a. --Quotes shall be submitted via email to kimberly.schneider@va.gov and Offerors must reference Solicitation 36C256-18-Q-0030 in the subject line of the email. No telephone request for information will be considered. Incomplete packages will be considered nonresponsive. All offers must be received by the closing date Friday, October 20, 2017 by 2:00 p.m.
 - b. --Solicitation Questions: The specific requirements for this solicitation are outlined in the Statement of Work. Questions concerning this solicitation shall be submitted in writing only. (Questions will not be answered or addressed via the phone). Questions shall be submitted via electronic mail (e-mail) to: kimberly.schneider@va.gov. Questions will be accepted up to 3:00 p.m. (CST), Tuesday, October 17th, 2017. All questions and answers will be published via amendment to the solicitation.
 - c. ---Amendments to Solicitation: Amendments to this solicitation shall be posted on FedBizOpps only (www.fbo.gov). It is the responsibility of the contractor to monitor this website for any amendments to this solicitation.
 - d. --Offer Acceptance Period: The minimum offer acceptance period is 90 days. Please ensure that you allow at least the stated number of calendar days for the Government to accept your offer.
 - e. --Submitting Offers: Offers must arrive at the designated location by the exact time and date as specified in this solicitation. Offers will only be received by this office via e-mail, mail (USPS, UPS, FedEx) or by hand delivery (Courier) to Kimberly Schneider, kimberly.schneider@va.gov. Transmission of offers by phone or fax to this office is NOT ACCEPTABLE and will result in such offers being rejected.
 - f. ---Specific Instructions for Acceptable Offer Submission: A company specific sales quote can be submitted. Prospective contractors shall refer to and complete the Schedule of Items to be included in their submission. If a line item in the Schedule of Items does not apply, is combined with another line item, or is already included at no cost, please make the appropriate comments and price out each line item accordingly.
 - g. ---Acceptable Offers: One single contract will be made as a result of this solicitation. For an offer to be considered for a potential contractual award the contractor must provide all CLIN items listed in this solicitation. Contract award shall be made on an ALL OR NONE BASIS by the contracting officer. Partial offers that do not address, provide, and/or quote all CLIN items shall be deemed not technically acceptable and shall be rejected. Offers must clearly indicate if brand name items are being furnished or if or equivalent, brand name or equal, alternate, or substitute products are being provided.
 - h. --Brand Name or Equal: THE BRAND NAME NOTED IN THIS SOLICITATION IS INTENDED TO BE DESCRIPTIVE AND NOT RESTRICTIVE. IF YOU PLAN TO PROVIDE OTHER THAN THE BRAND NAME ITEMS (I.E. OR EQUIVALENT/BRAND NAME OR EQUAL/ALTERNATE/SUBSTITUTE ITEMS) CITED IN THE PURCHASE DESCRIPTION, PROVIDE IN YOUR RESPONSE THE BRAND NAME AND THE CATALOG OR PART NUMBER YOU INTEND TO FURNISH AND THE SALIENT CHARACTERISTICS FOR EACH OF THE EQUIVALENT/BRAND NAME ITEMS. YOU MUST ALSO PROVIDE DOCUMENTS, SPEC SHEETS OR OTHER INFORMATION WHICH CLEARLY DESCRIBE THE ITEM(S) SO THAT IT/THEY CAN BE EVALUATED BY THE END USER. FAILURE TO PROVIDE THIS INFORMATION WILL RESULT IN YOUR OFFER NOT BEING ACCEPTED OR CONSIDERED FOR A POTENTIAL CONTRACTUAL AWARD. – SEE VAAR CLAUSE 852.211-73
 - i. ---Please provide business name, doing business as (DBA) name, mailing address, phone number, DUNS number, CAGE code and best estimated delivery time when submitting your offer in response to this solicitation.
 - j. ---Attachments – Please fill out and return the Attachment 1 – VA Medical Equipment Pre-Procurement Assessment

SECTION B – PRICE/COST SCHEDULE AND STATEMENT OF WORK

B.1 PRICE/COST SCHEDULE & ITEM INFORMATION

ITEM NUM	DESCRIPTION OF SUPPLIES/SERVICES	QTY	UNIT	UNIT PRICE	AMOUNT
0001	Phonatory Aerodynamic System Brand Name or Equal to KayPentax PN 6600-1 See SOW 2.5.1 Note Brand Name/PN Quoting _____	1.0	EA	_____	_____
0002	Flowhead Brand Name or Equal to KayPentax PN 6600 See SOW 2.5.2 Note Brand Name/PN Quoting _____	1.0	EA	_____	_____
0003	Adult Face Mask Brand Name or Equal to KayPentax PN 6602 See SOW 2.5.3 Note Brand Name/PN Quoting _____	1.0	EA	_____	_____
0004	Cardboard Tubes Brand Name or Equal to KayPentax PN 6610 See SOW 2.5.4 Note Brand Name/PN Quoting _____	1.0	CASE	_____	_____
0005	Intraoral Tubes Brand Name or Equal to KayPentax PN 6611 See SOW 2.5.5 Note Brand Name/PN Quoting _____	1.0	BX	_____	_____
0006	Screening Tubes Brand Name or Equal to KayPentax PN 6612 See SOW 2.5.6 Note Brand Name/PN Quoting _____	1.0	BX	_____	_____
0007	Airflow Head-Mask Couplers Brand Name or Equal to KayPentax PN 6613 See SOW 2.5.7 Note Brand Name/PN Quoting _____	1.0	BX	_____	_____
0008	Small Adult Mask Brand Name or Equal to KayPentax PN 1111-1872 See SOW 2.5.8 Note Brand Name/PN Quoting _____	1.0	BX	_____	_____
0009	Medium Adult Mask Brand Name or Equal to KayPentax PN 1111-1640 See SOW 2.5.9 Note Brand Name/PN Quoting _____	1.0	BX	_____	_____
0010	Large Adult Mask Brand Name or Equal to KayPentax PN 1111-1641 See SOW 2.5.10 Note Brand Name/PN Quoting _____	1.0	BX	_____	_____
0011	INSTALLATION/TRAINING	1.0	JB	_____	_____
				GRAND TOTAL	_____

B.2 STATEMENT OF WORK

Phonatory Aerodynamic System and Installation
Southeast Louisiana Veterans Health Care System
New Orleans, LA
09/05/2017

1. PURPOSE

1.1 The overall purpose is to provide and install (1) Phonatory Aerodynamic System at the Southeast Louisiana Veterans Health Care System (SLVHCS) Outpatient Speech Pathology Clinic located at 2400 Canal St, New Orleans, LA 70119.

2. SCOPE

2.1 The Contractor shall provide, transport, install, and test all listed equipment. All products must meet all salient characteristics defined in this section.

2.2 All equipment and installation must meet manufacturers and VA specifications.

2.3 The Contractor shall furnish all supplies, equipment, facilities and services required for delivery and installation of the supplies and equipment.

2.4 The Contractor is responsible for any missing parts and components not included to carry out the installation.

2.5 SALIENT CHARACTERISTICS

2.5.1 Phonatory Aerodynamics System

BRAND NAME OR EQUIVALENT TO: KayPentax/ Part No. 6600-1

Specifications/Salient Characteristics:

Medical device that is utilized to measure airflow, pressure and other parameters related to speech and voice production.

- Capable of providing both graphic and quantitative summaries
- Must provide an integrated system
- Capable of providing step by step protocol prompts
- At a minimum capable of performing the following protocols
 - Vital Capacity
 - Air Pressure Screening
 - Comfortable Sustained Phonation
 - Voicing Efficiency
 - Intraoral pressure
 - Laryngeal resistance
 - Speech Analysis
- Must include a one liter calibration syringe
- Capable of pre-and post-treatment comparisons of airflow, intraoral pressure as well as vocal efficiency imaging and acoustic data
- Must include an integrated microphone with at a minimum the following specifications
 - Log gain capability of at-least 120 dB SPL
 - Gain selection of at-least 27
 - Accuracy of 2dB SPL @ 104 dB SPL
- Must include a compatible power cord
- Must be capable of utilizing a 110 volt outlet

2.5.2 Flowhead

BRAND NAME OR EQUIVALENT TO: KayPentax/ Part No. 6601

Specifications/Salient Characteristics:

- Must be compatible to line item 2.5.1
- Must be able to be utilized to measure the volume that is passed through the face mask

2.5.3 Adult Face Mask

BRAND NAME OR EQUIVALENT TO: KayPentax/ Part No. 6602

Specifications/Salient Characteristics:

- Must be compatible with line item 2.5.1
- Must allow the patient to place face into mask to perform required testing

2.5.4 Cardboard Tubes

BRAND NAME OR EQUIVALENT TO: KayPentax/ Part No. 6610

Specifications/Salient Characteristics:

- Must be compatible with line item 2.5.1

2.5.5 Intraoral Tubes

BRAND NAME OR EQUIVALENT TO: KayPentax/ Part No. 6611

Specifications/Salient Characteristics:

- Disposable tubes utilized to measure intraoral pressure
- Must be compatible with line item 2.5.1

2.5.6 Screening Tubes

BRAND NAME OR EQUIVALENT TO: KayPentax/ Part No. 6612

Specifications/Salient Characteristics:

- Must be compatible with line item 2.5.1
- Must be able to be utilized to conduct speech screenings
- Disposable

2.5.7 Airflow Head-Mask Couplers

BRAND NAME OR EQUIVALENT TO: KayPentax/ Part No. 6613

Specifications/Salient Characteristics:

- Must be compatible with line item 2.5.1
- Must be able to capture an accurate measurement of a patient's respiratory volume up to the sub-glottal pressure

2.5.8 Small Adult Mask

BRAND NAME OR EQUIVALENT TO: KayPentax/ Part No. 1111-1872

Specifications/Salient Characteristics:

- Must be compatible with line item 2.5.1
- Must allow the patient to place face into mask to perform required testing
- Size small

2.5.9 Medium Adult Mask

BRAND NAME OR EQUIVALENT TO: KayPentax/ Part No. 1111-1640

Specifications/Salient Characteristics:

- Must be compatible with line item 2.5.1
- Must allow the patient to place face into mask to perform required testing
- Size medium

2.5.10 Large Adult Mask

BRAND NAME OR EQUIVALENT TO: KayPentax/ Part No. 1111-1641

Specifications/Salient Characteristics:

- Must be compatible with line item 2.5.1
- Must allow the patient to place face into mask to perform required testing
- Size large

2.5.11 Installation/ Training

Specifications/Salient Characteristics:

Vendor must provide installation services as well as training for all components.

2.6 DELIVERY AND INSTALLATION

2.6.1 DELIVERY

2.6.1.1 Contractor shall deliver all equipment to the Southeast Louisiana Veterans Health Care System (SLVHCS) Central Energy Plant building 2400 Canal St, New Orleans, LA 70119 on **November 20, 2017**.

2.6.1.2 Deliver materials to job in manufacturer's original sealed containers with brand name marked thereon.

2.6.1.3 Package to prevent damage or deterioration during shipment, handling, storage and installation. Maintain protective covering in place and in good repair until removal is necessary.

2.6.1.4 Deliver specified items only when the site is ready for installation work to proceed.

2.6.1.5 Store products in dry condition inside enclosed facilities.

2.6.1.6 Any government requested delayed delivery up to 90 days after initial award delivery date, shall be at no additional cost to the Government.

2.6.1.7 Delivery and Installation will be coordinated through the COR.

2.6.2 INSTALLATION

2.6.2.1 All equipment shall be installed in accordance with the manufactures recommendations.

2.6.2.2 Install all equipment to manufacturer's specifications maintaining Federal, and Local safety standards

2.6.2.3 Installation must be completed by **November 28, 2017**. All work shall be completed between 9:30 a.m. and 4:30 p.m. Monday – Friday. All federal holidays, excluded. Federal holidays are available at the [Federal Holiday OPM Site](#).

2.6.2.4 If there is an operational conflict with installation, night or weekend installation may be required. Government will provide a 72 hours' notice of change of installation hours.

2.6.2.5 The contractor shall coordinate all deliveries, staging areas, installations, and parking arrangements with the COR.

2.6.2.6 The Contractor shall remove all related shipping debris and cleanup any construction associated with delivery and installation of the specified items. Contractor shall remove all packaging from the SLVHCS premises. The Contractor shall be responsible for any damage to the building that occurs due to Contractor error or neglect.

2.7 SITE CONDITIONS

2.7.1 There shall be no smoking, eating, or drinking inside the hospital at any time.

3. INSPECTION AND ACCEPTANCE:

3.1 The Contractor shall conduct a joint inspection with the COR upon delivery of equipment.

3.2 Contractor shall provide dates of completion of punch list items and replacement parts and/or short ship items from the manufacturer(s).

3.3 The COR shall ensure all work is completed satisfactorily prior to acceptance. Disputes shall be resolved by the Contracting Officer.

4. DELIVERABLES

4.1 Operation and Maintenance Manuals

4.1.1 Binders - Quantity (2) each for items 2.5.1-2.5.10

4.1.2 Digital Copies- Quantity (1) each for items 2.5.1-2.5.10

4.2 Deliver compilation of all manufacturer recommended maintenance schedule and operation materials packaged in binder(s) to COR upon completion of installation.

5. TRAINING:

5.1 Contractor shall provide On-site training of the equipment to the Users. Scheduling of operator training shall be coordinated with the SLVHCS COR after installation is complete.

5.2 The contractor shall provide a training program to the Biomedical Engineering technicians and in-house clinical personnel. Technical training must provide Biomedical Engineering with the tools and knowledge to fully operate and maintain the system.

6. PROTECTION OF PROPERTY

- 6.1 Contractor shall protect all items from damage. The Contractor shall take precaution against damage to the building(s), grounds and furnishings. The Contractor shall repair or replace any items related to building(s) or grounds damaged accidentally or on purpose due to actions by the Contractor.
- 6.2 The Contractor shall perform an inspection of the building(s) and grounds with the COR prior to commencing work. To insure that the Contractor shall be able to repair or replace any items, components, building(s) or grounds damaged due to negligence and/or actions taken by the Contractor. The source of all repairs beyond simple surface cleaning is the facility construction contractor (or appropriate subcontractor), so that building warranty is maintained. Concurrence from the VA Facilities Management POC and COR is required before the Contractor may perform any significant repair work. In all cases, repairs shall utilize materials of the same quality, size, texture, grade, and color to match adjacent existing work.
- 6.3 The Contractor shall be responsible for security of the areas in which the work is being performed prior to completion.
- 6.4 Contractor shall provide floor protection while working in all VA facilities. All material handling equipment shall have rubber wheels.

7. SECURITY REQUIREMENTS

7.1 GENERAL Contractors, contractor personnel, subcontractors, and subcontractor personnel shall be subject to the same Federal laws, regulations, standards, and VA Directives and Handbooks as VA and VA personnel regarding information and information system security.

7.2 ACCESS TO VA INFORMATION AND VA INFORMATION SYSTEMS

7.2.1 A contractor/subcontractor shall request logical (technical) or physical access to VA information and VA information systems for their employees, subcontractors, and affiliates only to the extent necessary to perform the services specified in the contract, agreement, or task order.

7.2.2 All contractors, subcontractors, and third-party servicers and associates working with VA information are subject to the same investigative requirements as those of VA appointees or employees who have access to the same types of information. The level and process of background security investigations for contractors must be in accordance with VA Directive and Handbook 0710, *Personnel Suitability and Security Program*. The Office for Operations, Security, and Preparedness is responsible for these policies and procedures.

7.2.3 Contract personnel who require access to national security programs must have a valid security clearance. National Industrial Security Program (NISP) was established by Executive Order 12829 to ensure that cleared U.S. defense industry contract personnel safeguard the classified information in their possession while performing work on contracts, programs, bids, or research and development efforts. The Department of Veterans Affairs does not have a Memorandum of Agreement with Defense Security Service (DSS). Verification of a Security Clearance must be processed through the Special Security Officer located in the Planning and National Security Service within the Office of Operations, Security, and Preparedness.

7.2.4 Custom software development and outsourced operations must be located in the U.S. to the maximum extent practical. If such services are proposed to be performed abroad and are not disallowed by other VA policy or mandates, the contractor/subcontractor must state where all non-U.S. services are provided and detail a security plan, deemed to be acceptable by VA, specifically to address mitigation of the resulting problems of communication, control, data protection, and so forth. Location within the U.S. may be an evaluation factor.

7.2.5 The contractor or subcontractor must notify the Contracting Officer immediately when an employee working on a VA system or with access to VA information is reassigned or leaves the contractor or subcontractor's employ. The Contracting Officer must also be notified immediately by the contractor or subcontractor prior to an unfriendly termination.

7.3 VA INFORMATION CUSTODIAL LANGUAGE

7.3.1 Information made available to the contractor or subcontractor by VA for the performance or administration of this contract or information developed by the contractor/subcontractor in performance or administration of the contract shall be used only for those purposes and shall not be used in any other way without the prior written agreement of the VA. This clause expressly limits the contractor/subcontractor's rights to use data as described in Rights in Data - General, FAR 52.227-14(d) (1).

7.3.2 VA information should not be co-mingled, if possible, with any other data on the contractors/subcontractor's information systems or media storage systems in order to ensure VA requirements related to data protection and media sanitization can be met. If co-mingling must be allowed to meet the requirements of the business need, the contractor must ensure that VA's information is returned to the VA or destroyed in accordance with VA's sanitization requirements. VA reserves the right to conduct on site inspections of contractor and subcontractor IT resources to ensure data security controls, separation of data and job duties, and destruction/media sanitization procedures are in compliance with VA directive requirements.

7.3.3 Prior to termination or completion of this contract, contractor/subcontractor must not destroy information received from VA, or gathered/created by the contractor in the course of performing this contract without prior written approval by the VA. Any data destruction done on behalf of VA by a contractor/subcontractor must be done in accordance with National Archives and Records Administration (NARA) requirements as outlined in VA Directive 6300, *Records and Information Management* and its Handbook 6300.1 *Records Management Procedures*, applicable VA Records Control Schedules, and VA Handbook 6500.1, *Electronic Media Sanitization*. Self-certification by the contractor that the data destruction requirements above have been met must be sent to the VA Contracting Officer within 30 days of termination of the contract.

7.3.4 The contractor/subcontractor must receive, gather, store, back up, maintain, use, disclose and dispose of VA information only in compliance with the terms of the contract and applicable Federal and VA information confidentiality and security laws, regulations and policies. If Federal or VA information confidentiality and security laws, regulations and policies become applicable to the VA information or information systems after execution of the contract, or if NIST issues or updates applicable FIPS or Special Publications (SP) after execution of this contract, the parties agree to negotiate in good faith to implement the information confidentiality and security laws, regulations and policies in this contract.

7.3.5 The contractor/subcontractor shall not make copies of VA information except as authorized and necessary to perform the terms of the agreement or to preserve electronic information stored on contractor/subcontractor electronic storage media for restoration in case any electronic equipment or data used by the contractor/subcontractor needs to be restored to an operating state. If copies are made for restoration purposes, after the restoration is complete, the copies must be appropriately destroyed.

7.3.6 If VA determines that the contractor has violated any of the information confidentiality, privacy, and security provisions of the contract, it shall be sufficient grounds for VA to withhold payment to the contractor or third party or terminate the contract for default or terminate for cause under Federal Acquisition Regulation (FAR) part 12.

7.3.7 If a VHA contract is terminated for cause, the associated BAA must also be terminated and appropriate actions taken in accordance with VHA Handbook 1600.01, *Business Associate Agreements*. Absent an agreement to use or disclose protected health information, there is no business associate relationship.

7.3.8 The contractor/subcontractor must store, transport, or transmit VA sensitive information in an encrypted form, using VA-approved encryption tools that are, at a minimum, FIPS 140-2 validated.

7.3.9 The contractor/subcontractor's firewall and Web services security controls, if applicable, shall meet or exceed VA's minimum requirements. VA Configuration Guidelines are available upon request.

7.3.10 Except for uses and disclosures of VA information authorized by this contract for performance of the contract, the contractor/subcontractor may use and disclose VA information only in two other situations: (i) in response to a qualifying order of a court of competent jurisdiction, or (ii) with VA's prior written approval. The contractor/subcontractor must refer all requests for, demands for production of, or inquiries about, VA information and information systems to the VA contracting officer for response.

7.3.11 Notwithstanding the provision above, the contractor/subcontractor shall not release VA records protected by Title 38 U.S.C. 5705, confidentiality of medical quality assurance records and/or Title 38 U.S.C. 7332, confidentiality of certain health records pertaining to drug addiction, sickle cell anemia, alcoholism or alcohol abuse, or infection with human immunodeficiency virus. If the contractor/subcontractor is in receipt of a court order or other requests for the above mentioned information, that contractor/subcontractor shall immediately refer such court orders or other requests to the VA contracting officer for response.

7.3.12 For service that involves the storage, generating, transmitting, or exchanging of VA sensitive information but does not require C&A or an MOU-ISA for system interconnection, the contractor/subcontractor must complete a Contractor Security Control Assessment (CSCA) on a yearly basis and provide it to the COTR.

7.4 INFORMATION SYSTEM HOSTING, OPERATION, MAINTENANCE, OR USE

7.4.1 Bio-Medical devices and other equipment or systems containing media (hard drives, optical disks, etc.) with VA sensitive information must not be returned to the vendor at the end of lease, for trade-in, or other purposes. The options are:

(1) Vendor must accept the system without the drive;

(2) VA's initial medical device purchase includes a spare drive which must be installed in place of the original drive at time of turn-in; or

(3) VA must reimburse the company for media at a reasonable open market replacement cost at time of purchase.

(4) Due to the highly specialized and sometimes proprietary hardware and software associated with medical equipment/systems, if it is not possible for the VA to retain the hard drive, then;

(a) The equipment vendor must have an existing BAA if the device being traded in has sensitive information stored on it and hard drive(s) from the system are being returned physically intact; and

(b) Any fixed hard drive on the device must be non-destructively sanitized to the greatest extent possible without negatively impacting system operation. Selective clearing down to patient data folder level is recommended using VA approved and validated overwriting technologies/methods/tools. Applicable media sanitization specifications need to be pre-approved and described in the purchase order or contract.

(c) A statement needs to be signed by the Director (System Owner) that states that the drive could not be removed and that (a) and (b) controls above are in place and completed. The ISO needs to maintain the documentation.

7.5 SECURITY INCIDENT INVESTIGATION

7.5.1 The term "security incident" means an event that has, or could have, resulted in unauthorized access to, loss or damage to VA assets, or sensitive information, or an action that breaches VA security procedures. The contractor/subcontractor shall immediately notify the COTR and simultaneously, the designated ISO and Privacy Officer for the contract of any known or suspected security/privacy incidents, or any unauthorized disclosure of sensitive information, including that contained in system(s) to which the contractor/subcontractor has access.

7.5.2 To the extent known by the contractor/subcontractor, the contractor/subcontractor's notice to VA shall identify the information involved, the circumstances surrounding the incident (including to whom, how, when, and where the VA information or assets were placed at risk or compromised), and any other information that the contractor/subcontractor considers relevant.

7.5.3 With respect to unsecured protected health information, the business associate is deemed to have discovered a data breach when the business associate knew or should have known of a breach of such information. Upon discovery, the business associate must notify the covered entity of the breach. Notifications need to be made in accordance with the executed business associate agreement.

7.5.4 In instances of theft or break-in or other criminal activity, the contractor/subcontractor must concurrently report the incident to the appropriate law enforcement entity (or entities) of jurisdiction, including the VA OIG and Security and Law Enforcement. The contractor, its employees, and its subcontractors and their employees shall cooperate with VA and any law enforcement authority responsible for the investigation and prosecution of any possible criminal law violation(s) associated with any incident. The contractor/subcontractor shall cooperate with VA in any civil litigation to recover VA information, obtain monetary or other compensation from a third party for damages arising from any incident, or obtain injunctive relief against any third party arising from, or related to, the incident.

7.6 LIQUIDATED DAMAGES FOR DATA BREACH

7.6.1 Consistent with the requirements of 38 U.S.C. §5725, a contract may require access to sensitive personal information. If so, the contractor is liable to VA for liquidated damages in the event of a data breach or privacy incident involving any SPI the contractor/subcontractor processes or maintains under this contract.

7.6.2 The contractor/subcontractor shall provide notice to VA of a “security incident” as set forth in the Security Incident Investigation section above. Upon such notification, VA must secure from a non-Department entity or the VA Office of Inspector General an independent risk analysis of the data breach to determine the level of risk associated with the data breach for the potential misuse of any sensitive personal information involved in the data breach. The term 'data breach' means the loss, theft, or other unauthorized access, or any access other than that incidental to the scope of employment, to data containing sensitive personal information, in electronic or printed form, that results in the potential compromise of the confidentiality or integrity of the data. Contractor shall fully cooperate with the entity performing the risk analysis. Failure to cooperate may be deemed a material breach and grounds for contract termination.

c. Each risk analysis shall address all relevant information concerning the data breach, including the following:

- (1) Nature of the event (loss, theft, unauthorized access);
- (2) Description of the event, including:
 - (a) date of occurrence;
 - (b) data elements involved, including any PII, such as full name, social security number, date of birth, home address, account number, disability code;
- (3) Number of individuals affected or potentially affected;
- (4) Names of individuals or groups affected or potentially affected;
- (5) Ease of logical data access to the lost, stolen or improperly accessed data in light of the degree of protection for the data, e.g., unencrypted, plain text;
- (6) Amount of time the data has been out of VA control;
- (7) The likelihood that the sensitive personal information will or has been compromised (made accessible to and usable by unauthorized persons);
- (8) Known misuses of data containing sensitive personal information, if any;
- (9) Assessment of the potential harm to the affected individuals;
- (10) Data breach analysis as outlined in 6500.2 Handbook, *Management of Security and Privacy Incidents*, as appropriate; and
- (11) Whether credit protection services may assist record subjects in avoiding or mitigating the results of identity theft based on the sensitive personal information that may have been compromised.

d. Based on the determinations of the independent risk analysis, the contractor shall be responsible for paying to the VA liquidated damages in the amount of \$ _____ per affected individual to cover the cost of providing credit protection services to affected individuals consisting of the following:

- (1) Notification;
- (2) One year of credit monitoring services consisting of automatic daily monitoring of at least 3 relevant credit bureau reports;
- (3) Data breach analysis;
- (4) Fraud resolution services, including writing dispute letters, initiating fraud alerts and credit freezes, to assist affected individuals to bring matters to resolution;
- (5) One year of identity theft insurance with \$20,000.00 coverage at \$0 deductible; and
- (6) Necessary legal expenses the subjects may incur to repair falsified or damaged credit records, histories, or financial affairs.

7.7 SECURITY CONTROLS COMPLIANCE TESTING

7.7.1 On a periodic basis, VA, including the Office of Inspector General, reserves the right to evaluate any or all of the security controls and privacy practices implemented by the contractor under the clauses contained within the contract. With 10 working-day's notice, at the request of the government, the contractor must fully cooperate and assist in a government-sponsored security controls assessment at each location wherein VA information is processed or stored, or information systems are developed, operated, maintained, or used on behalf of VA, including those initiated by the Office of Inspector General. The government may conduct a security control assessment on shorter notice (to include unannounced assessments) as determined by VA in the event of a security incident or at any other time.

7.8 TRAINING

7.8.1 All contractor employees and subcontractor employees requiring access to VA information and VA information systems shall complete the following before being granted access to VA information and its systems:

(1) Sign and acknowledge (either manually or electronically) understanding of and responsibilities for compliance with the *Contractor Rules of Behavior*, Appendix E relating to access to VA information and information systems;

(2) Successfully complete the *VA Cyber Security Awareness and Rules of Behavior* training and annually complete required security training;

(3) Successfully complete the appropriate VA privacy training and annually complete required privacy training; and

(4) Successfully complete any additional cyber security or privacy training, as required for VA personnel with equivalent information system access *[to be defined by the VA program official and provided to the contracting officer for inclusion in the solicitation document – e.g., any role-based information security training required in accordance with NIST Special Publication 800-16, Information Technology Security Training Requirements.]*

7.8.2 The contractor shall provide to the contracting officer and/or the COTR a copy of the training certificates and certification of signing the Contractor Rules of Behavior for each applicable employee within 1 week of the initiation of the contract and annually thereafter, as required.

7.8.3 Failure to complete the mandatory annual training and sign the Rules of Behavior annually, within the timeframe required, is grounds for suspension or termination of all physical or electronic access privileges and removal from work on the contract until such time as the training and documents are complete.

7.9 REFERENCE (S):

7.9.1 VA Affairs Handbook 6500, Risk Management Framework for VA Information Systems – Tier 3: VA Information Security Program, 10 Mar 2015.

7.9.2 Veterans Health Administration Procurement Manual (VHA PM) – 11/3/2014.

7.9.3 VA Handbook 1901.01, Health Information Management and Health Records – 19 Mar 15.

7.9.4 VHA Handbook 1605.5, Business Associate Agreements – 22 July 2014

7.9.5 Privacy Act of 1974 (5 U.S.C. 552a).

8. WARRANTY

8.1 The contractor shall provide a one year manufacturer's warranty on all parts and labor.

8.2 The warranty shall include all travel and shipping costs associated with any warranty repair.

SECTION C – PROVISIONS AND CLAUSES

The following FAR provisions and clauses apply to this solicitation and are incorporated by reference. The solicitation document, incorporated provision and clauses are those in effect through the Federal Acquisition Circular (FAC) 2005-95, Effective January 13, 2017. It is the responsibility of the contractor to be familiar with the applicable clauses and provisions.

The full text of the provisions and clauses may be accessed electronically at the following addresses:

<http://www.acquisition.gov/far/index.html>

<http://www.va.gov/oal/library/vaar/index.asp>

This contract incorporates one or more clauses by reference, with the same force and effect as if they were given in full text. Upon request, the Contracting Officer will make their full text available.

FAR 52.209-5 Certification Regarding Responsibility Matters

FAR 52.211-6 Brand Name or Equal

FAR 52.212-1 Instructions to Offerors—Commercial

FAR 52.212-2 Evaluation- Commercial Items

- (a) The Government will award a contract resulting from this solicitation to the responsible offeror whose offer conforming to the solicitation will be most advantageous to the Government, price and other factors considered. The following factors shall be used to evaluate offers:

Lowest Price Technically Acceptable

FAR 52.212-3 Offeror Representations and Certifications

FAR 52.212-4 Contract Terms and Conditions

FAR 52.212-5 Contract Terms and Conditions Required To Implement Statutes Or Executive Orders—Commercial Item

Contracting Officer checked items:

52.204-10, Reporting Executive Compensation and First-Tier Subcontract Awards

52.209-6, Protecting the Government's Interest When Subcontracting with Contractors Debarred, Suspended, or Proposed for Debarment

52.219-13, Notice of Set-Aside of Orders

52.219-14, Limitations on Subcontracting

52.219-28, Post Award Small Business Program Rerepresentation

52.222-3, Convict Labor

52.222-19, Child Labor—Cooperation with Authorities and Remedies

52.222-21, Prohibition of Segregated Facilities

52.222-26, Equal Opportunity

52.222-36, Equal Opportunity for Workers with Disabilities

52.222-50, Combating Trafficking in Persons

52.223-18, Encouraging Contractor Policies to Ban Text Messaging While Driving

52.225-3 Alternate I, Buy American—Free Trade Agreements—Israeli Trade Act

52.225-13, Restrictions on Certain Foreign Purchases

52.232-33, Payment by Electronic Funds Transfer—System for Award Management

FAR 52.219-6 Notice of Total Small Business Set-Aside (Nov 2011)

FAR 52.219-8 Utilization of Small Business Concerns (Oct 2014)

FAR 52.233-3 Protest After Award (Aug 1996)

FAR 52.233-2 Service of Protest

VAAR 852.203-70 COMMERCIAL ADVERTISING

VAAR 852.211-73 BRAND NAME OR EQUAL (JAN 2008)

(Note: as used in this clause, the term "brand name" includes identification of products by make and model.)

(a) If items called for by this invitation for bids have been identified in the schedule by a "brand name or equal" description, such identification is intended to be descriptive, but not restrictive, and is to indicate the quality and characteristics of products that will be satisfactory. Bids offering "equal" products (including products of the brand name manufacturer other than the one described by brand name) will be considered for award if such products are clearly identified in the bids and are determined by the Government to meet fully the salient characteristics requirements listed in the invitation.

(b) Unless the bidder clearly indicates in the bid that the bidder is offering an "equal" product, the bid shall be considered as offering a brand name product referenced in the invitation for bids.

(c)(1) If the bidder proposes to furnish an "equal" product, the brand name, if any, of the product to be furnished shall be inserted in the space provided in the invitation for bids, or such product shall be otherwise clearly identified in the bid. The evaluation of bids and the determination as to equality of the product offered shall be the responsibility of the Government and will be based on information furnished by the bidder or identified in his/her bid as well as other information reasonably available to the purchasing activity. CAUTION TO BIDDERS. The purchasing activity is not responsible for locating or securing any information that is not identified in the bid and reasonably available to the purchasing activity. Accordingly, to insure that sufficient information is available, the bidder must furnish as a part of his/her bid all descriptive material (such as cuts, illustrations, drawings or other information) necessary for the purchasing activity to:

(i) Determine whether the product offered meets the salient characteristics requirement of the Invitation for Bids, and

(ii) Establish exactly what the bidder proposes to furnish and what the Government would be binding itself to purchase by making an award. The information furnished may include specific references to information previously furnished or to information otherwise available to the purchasing activity.

(2) If the bidder proposes to modify a product so as to make it conform to the requirements of the Invitation for Bids, he/she shall:

(i) Include in his/her bid a clear description of such proposed modifications, and

(ii) Clearly mark any descriptive material to show the proposed modifications.

(3) Modifications proposed after bid opening to make a product conform to a brand name product referenced in the Invitation for Bids will not be considered.

The clause entitled "Brand name or equal" applies only to the following line items: 0001 - 0010

(End of Clause)

VAAR 852.219-10 VA NOTICE OF TOTAL SERVICE-DISABLED VETERAN-OWNED SMALL BUSINESS SET-ASIDE

VAAR 852.232-72 ELECTRONIC SUBMISSION OF PAYMENT REQUESTS

VAAR 852.246-70 GUARANTEE

VAAR 852.246-71 INSPECTION

SECTION D – ATTACHMENTS

ATTACHMENT 1 - VA Medical Equipment Pre-Procurement Assessment