



**SIMPLIFIED ACQUISITION PROCEDURES (SAP) PERFORMANCE
WORK STATEMENT (PWS)**

**DEPARTMENT OF VETERANS AFFAIRS
Office of Information & Technology
Enterprise Program Management Office**

FDA Compliance Audit of Sustainment of Blood Bank Maintenance Project

**Date: May 7, 2018
TAC-18-49554
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1.0 DESCRIPTION OF SERVICES

Services are for an audit of the Sustainment of Blood Bank Maintenance Project Quality System used to create and support medical device software thereby meeting Food and Drug Administration Title 21 CFR Part 11, 803, 806, 820, and 821 regulations. The Contractor conducting the service must be a Certified Auditor with the International Register of Certificated Auditors (IRCA) or a Certified Quality Auditor with American Society for Quality (ASQ). The audit will include a desk audit of documentation and a site visit of two to three days for additional review, interviews, and discussion. The preferred audit window is June 11, 2018 to June 29, 2018 but must complete no later than July 13, 2018. A report summarizing the findings and recommendations is a required work product.

2.0 APPLICABLE DOCUMENTS

Documents referenced or germane to this Performance Work Statement (PWS) are listed below. In the performance of the tasks associated with this PWS, the Contractor shall comply with the following:

1. 5 U.S.C. § 552a, as amended, "The Privacy Act of 1974"
2. 42 U.S.C. § 2000d "Title VI of the Civil Rights Act of 1964"
3. VA Directive 0710, "Personnel Suitability and Security Program," June 4, 2010, <http://www1.va.gov/vapubs/>
4. VA Handbook 0710, "Personnel Suitability and Security Program", September 10, 2004, <http://www1.va.gov/vapubs/>
5. VA Handbook 6500.6, "Contract Security," March 12, 2010
6. OMB Memorandum M-07-16, "Safeguarding Against and Responding to the Breach of Personally Identifiable Information," May 22, 2007
7. Clinger-Cohen Act of 1996, 40 U.S.C. §11101 and §11103

3.0 PERFORMANCE DETAILS

3.1 PERFORMANCE PERIOD

The preferred audit window is June 11, 2018 to June 29, 2018 but the audit must be complete no later than July 13, 2018. The period of performance includes a desk audit, site visit, and submission of an audit report. Any work at the Government site shall not take place on Federal holidays or weekends unless directed by the Contracting Officer (CO).

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3.2 PLACE OF PERFORMANCE

Tasks under this PWS shall be performed in VA Facilities located at the Government location, Hines Office of Information Field Office (OIFO), Hines, IL 60141. Work may be performed at remote locations with prior approval of the Contracting Officer's Representative (COR).

4.0 SPECIFIC TASKS AND DELIVERABLES

The Contractor conducting the service must be a Certified Auditor with the International Register of Certificated Auditors (IRCA) or a Certified Quality Auditor with American Society for Quality (ASQ). The Contractor shall perform the following:

- Conduct an audit of a software medical device manufacture for compliance with applicable Food and Drug Administration Title 21 CFR Part 11, 803, 806, 820, and 821 regulations.
- Review each element of the FDA regulated Quality System (QS) used by the Sustainment of Blood Bank Maintenance Project to create and support the VistA Blood Establishment Computer Software (VBECS) medical device.
- Comment on its effectiveness, adequacy, and regulatory compliance of the project QS. The contractor will point out any non-compliance and recommend strategies to bring the project into compliance.
- Review available records and confirm the information they contain through interviews, observations, and requests for additional information. Quality System records that may be reviewed for objective evidence include:
 - Prior internal and external audit findings.
 - Management reviews.
 - Corrective action documentation.
 - Change control documentation.
 - IOPs and policies.
 - Organizational charts.
 - Team roles and responsibilities.
- Review materials being audited, methods used and findings identified with assigned team members daily.
- Hold a summation conference, detailing audit findings, with the Project Manager (PM), appropriate Sustainment of Blood Bank Maintenance Project team members and the Compliance Officer when appropriate.
- Present a written preliminary report of audit findings to the PM or designee at the completion of the audit.

Within ten working days of the end of the audit, the Contractor shall forward a final internal audit report with supporting documentation to the PM.

4.1 REPORTING REQUIREMENTS

The Contractor shall provide the Contracting Officer's Representative (COR) with a daily report when on site during the audit. At the conclusion of the audit the Contractor shall

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hold a summation meeting and provide a preliminary report of the audit findings. A final report of the audit findings is required within ten working days from the end of the onsite audit and shall include any non-conformances found with a reference to the FDA regulation.

Deliverable:

A. Final Audit Finding Report

5.0 GENERAL REQUIREMENTS

5.1 ENTERPRISE AND IT FRAMEWORK

5.1.1 ONE-VA TECHNICAL REFERENCE MODEL

Not applicable.

5.1.2 FEDERAL IDENTITY, CREDENTIAL, AND ACCESS MANAGEMENT (FICAM)

Not applicable.

5.1.3 INTERNET PROTOCOL VERSION 6 (IPV6)

Not applicable.

5.1.4 TRUSTED INTERNET CONNECTION (TIC)

Not applicable.

5.1.5 STANDARD COMPUTER CONFIGURATION

Not applicable.

5.1.6 VETERAN FOCUSED INTEGRATION PROCESS (VIP)

Not applicable.

5.1.7 PROCESS ASSETT LIBRARY (PAL)

Not applicable.

5.2 SECURITY AND PRIVACY REQUIREMENTS

The work defined in this PWS for an audit of the Sustainment of Blood Bank Maintenance Quality System does not release or carry a risk of exposure to any secure information.

5.2.1 CONTRACTOR PERSONNEL SECURITY REQUIREMENTS

Not applicable.

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5.3 METHOD AND DISTRIBUTION OF DELIVERABLES

The Contractor shall deliver documentation in electronic format, unless otherwise directed in Section B of the solicitation/contract. Acceptable electronic media include: MS Word 2000/2003/2007/2010, MS Excel 2000/2003/2007/2010, MS PowerPoint 2000/2003/2007/2010, MS Project 2000/2003/2007/2010, MS Access 2000/2003/2007/2010, MS Visio 2000/2002/2003/2007/2010, AutoCAD 2002/2004/2007/2010, and Adobe Postscript Data Format (PDF).

5.4 PERFORMANCE METRICS

The table below defines the Performance Standards and Acceptable Performance Levels for Objectives associated with this effort.

Performance Objective	Performance Standard	Acceptable Levels of Performance
A. Technical / Quality of Product or Service	<ol style="list-style-type: none">1. Demonstrates understanding of requirements2. Efficient and effective in meeting requirements3. Meets technical needs and mission requirements4. Provides quality services/products	Satisfactory or higher
B. Project Milestones and Schedule	<ol style="list-style-type: none">1. Established milestones and project dates are met2. Products completed, reviewed, delivered in accordance with the established schedule3. Notifies customer in advance of potential problems	Satisfactory or higher

The COR will utilize a Quality Assurance Surveillance Plan (QASP) throughout the life of the contract to ensure that the Contractor is performing the services required by this PWS in an acceptable level of performance. The Government reserves the right to alter or change the surveillance methods in the QASP at its own discretion. A SAP Performance Based Service Assessment will be used by the COR in accordance with the QASP to assess Contractor performance.

5.5 FACILITY/RESOURCE PROVISIONS

The Government will provide office space, telephone service and system access when authorized contract staff work at a Government location as required in order to

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accomplish the Tasks associated with this PWS. All procedural guides, reference materials, and program documentation for the project and other Government applications will also be provided on an as-needed basis.

The Contractor shall request other Government documentation deemed pertinent to the work accomplishment directly from the Government officials with whom the Contractor has contact. The Contractor shall consider the COR as the final source for needed Government documentation when the Contractor fails to secure the documents by other means. The Contractor is expected to use common knowledge and resourcefulness in securing all other reference materials, standard industry publications, and related materials that are pertinent to the work.

VA may provide remote access to VA specific systems/network in accordance with VA Handbook 6500, which requires the use of a VA approved method to connect external equipment/systems to VA's network. Citrix Access Gateway (CAG) is the current and only VA approved method for remote access users when using or manipulating VA information for official VA Business. VA permits CAG remote access through approved Personally Owned Equipment (POE) and Other Equipment (OE) provided the equipment meets all applicable 6500 Handbook requirements for POE/OE. All of the security controls required for Government furnished equipment (GFE) must be utilized in approved POE or OE. The Contractor shall provide proof to the COR for review and approval that their POE or OE meets the VA Handbook 6500 requirements and VA Handbook 6500.6 Appendix C, herein incorporated as Addendum B, before use. CAG authorized users shall not be permitted to copy, print or save any VA information accessed via CAG at any time. VA prohibits remote access to VA's network from non-North Atlantic Treaty Organization (NATO) countries. The exception to this are countries where VA has approved operations established (e.g. Philippines and South Korea). Exceptions are determined by the COR in coordination with the Information Security Officer (ISO) and Privacy Officer (PO).

This remote access may provide access to VA specific software such as Veterans Health Information System and Technology Architecture (VistA), ClearQuest, PAL, Primavera, and Remedy, including appropriate seat management and user licenses, depending upon the level of access granted. The Contractor shall utilize government-provided software development and test accounts, document and requirements repositories, etc. as required for the development, storage, maintenance and delivery of products within the scope of this effort. The Contractor shall not transmit, store or otherwise maintain sensitive data or products in Contractor systems (or media) within the VA firewall IAW VA Handbook 6500.6 dated March 12, 2010. All VA sensitive information shall be protected at all times in accordance with VA Handbook 6500, local security field office System Security Plans (SSP's) and Authority to Operate (ATO)'s for all systems/LAN's accessed while performing the tasks detailed in this PWS. The Contractor shall ensure all work is performed in countries deemed not to pose a significant security risk. For detailed Security and Privacy Requirements (additional

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requirements of the contract consolidated into an addendum for easy reference) refer to
ADDENDUM A - ADDITIONAL VA REQUIREMENTS, CONSOLIDATED and
ADDENDUM B - VA INFORMATION AND INFORMATION SYSTEM
SECURITY/PRIVACY LANGUAGE.

5.6 SHIPMENT OF HARDWARE OR EQUIPMENT

Not Applicable.

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ADDENDUM A – ADDITIONAL VA REQUIREMENTS, CONSOLIDATED

Not applicable.

**ADDENDUM B – VA INFORMATION AND INFORMATION SYSTEM
SECURITY/PRIVACY LANGUAGE**

Not applicable.

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Notes to the Contracting Officer

(This section to be removed from PWS before solicitation)

TYPE OF CONTRACT - FIRM FIXED PRICE

SCHEDULE FOR DELIVERABLES

Note: Days used in the table below refer to calendar days unless otherwise stated. Deliverables with due dates falling on a weekend or holiday shall be submitted the following Government work day after the weekend or holiday.

Table with 3 columns: Task ID, Deliverable ID, Deliverable Description. Row 1: 4.1, A, Final Audit Finding Report. Due 10 working days after completion of onsite audit. Electronic submission to: VA PM, COR, CO. Inspection: destination. Acceptance: destination.

(Always Checked for Services)- VA INFORMATION AND INFORMATION SYSTEM SECURITY/PRIVACY LANGUAGE, VA HANDBOOK 6500.6, APPENDIX C. Security Requirement guidance to CO within Section B9 Training, Para. a) Sub Para. 2,

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.]

POINTS OF CONTACT

VA Program Manager:

Name: Gary Pickwood
Address: Remote Employee
Voice: (941) 479-7715
Email: gary.pickwood@va.gov

Contracting Officer’s Representative:

Name: Gary Pickwood

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Address: Remote Employee
Voice: (941) 479-7715
Email: gary.pickwood@va.gov

Contracting Officer:

Name:
Address:
Voice:
Email:

ADDITIONAL ITEMS

SPECIAL INSTRUCTIONS/REMARKS

SPECIAL CLAUSES, ETC.

(Choose Special Clause(s), etc., if applicable, by selecting the checkbox and modifying as necessary)

- OCI Clause required?
- Intellectual Property/Technical Data Rights Clause required?
- BAA required **for an OI&T Contract on behalf of VHA?**

If the answer to Question 4 of the Security Checklist is a “yes” and the Contractor will provide a service, function, or activity **to OI&T, on behalf of VHA**, then it must be determined if protected health information (PHI) is disclosed or accessed, if so, a BAA is required. (The “Decision Tree for Business Associate Agreements” can be used by the requiring activity (with help from their OI&T Privacy Officer [Garnett Best/Rita Grewal] if needed) to determine if a BAA is required, see VHA Handbook 1605.05, Business Associate Agreements, Appendix A, (http://vaww.va.gov/vhapublications/ViewPublication.asp?pub_ID=3027)).

If it is determined that a BAA is required, the CO must, in eCMS, insert the BAA Document below as a “Clause” into Section D - CONTRACT DOCUMENTS, EXHIBITS, OR ATTACHMENTS of the solicitation manually by performing the following instructions:

1. Open the below embedded “VA Subcontractor BAA with OI&T” Template file, insert a brief description of the services involved in the effort within the “Scope” Section, and the VA Program Manager information in the VA Signature block at the end of the form, replacing the <RED TEXT> within the template. Once complete, save the “Business Associate Agreement” file to your computer.
2. Create a solicitation document in eCMS
3. Click on the ‘Content Manager’ link and highlight Section D, Contract Documents, Exhibits, or Attachments.

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4. Click on the “Insert” tab in the top left corner to insert an “External File” after the selected clause.
5. Upload the “Business Associate Agreement” file you saved to your computer.

The Business Associate Agreement file is the text of the eCMS VHA Clause 1605.05, tailored for the individual effort, and is essentially the Business Associate Agreement language itself, and needs to be seen by the bidders in the solicitation (if a BAA is required).



VA OI&T
Subcontractor Busine

BAA required for a Veterans Health Administration (VHA) Contract?

If the answer to Question 4 of the Security Checklist is a “yes” and the Contractor will provide a service, function, or activity **to VHA or on behalf of VHA**, then it must be determined if protected health information (PHI) is disclosed or accessed and if a BAA is required. The “Decision Tree for Business Associate Agreements” should be used by the requiring activity (with help from their Privacy Officer if needed [the VHA Privacy Service -Stephania Griffin/ Andrea Wilson can advise] to determine if a BAA is required, see VHA Handbook 1605.05, Business Associate Agreements, Appendix A, (http://vaww.va.gov/vhapublications/ViewPublication.asp?pub_ID=3027). If it is determined that a BAA is required, the CO must, in eCMS, insert the VHA clause 1605.05 into Section D - CONTRACT DOCUMENTS, EXHIBITS, OR ATTACHMENTS of the solicitation. This can be accomplished by performing the following in eCMS:

1. Insert the 1605.05 clause through the Clause Library (or by answering “Yes, access to PHI is necessary and a BAA is required,” to the Dialog Session question that asks, “Will the contractor require access to Protected Health Information to perform the functions or services required in this acquisition?”)
2. After inserting the clause, double-click on the clause and use the “Fill-in” field in the “Scope” section to add a description of the service(s) being performed.
3. In the MS Word version of your solicitation, manually input “Contractor” throughout the document where it has been blanked out. The embedded file below shows the locations of the “blanks” (showing codes from eCMS in red instead of “blanks”) to assist you in adding the missing information properly. The eCMS VHA Clause 1605.05 text is the BAA itself and needs to be seen by the bidders if a BAA is required. **Note:** The actual

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Contractor's Name will automatically populate in the appropriate sections of the BAA clause from the Data Values upon creation of the award document.



VHA 1605.05
BUSINESS ASSOCIAT

- Other _____
- Other _____

ADDITIONAL NOTES TO PREPARER

1. *Run Spell Check and Grammar Check in document for final review. Simple and easy tool to utilize and benefit from.*
2. *When listing/itemizing points, keep the outline consistent (use appropriate number or letter, versus a bullet).*
3. *If deliverables need to be submitted in draft form, timeframes must be stated. Reference example provided in the table above.*
4. *Other submissions may be required but not held to draft/comment/final submissions. For example, monthly status reports are due 5 days after the conclusion of the reporting period (end of month).*
5. *Do not put due dates in "Deliverables:" section of task, rather include timeframes/due dates in "Schedule for Deliverables" table above. Also ensure customer deliverables are detailed in the narrative of the task to include format and content requirements.*
6. *Ensure deliverables in tasks match deliverables in table.*
7. *If VIP applies, ensure deliverables are delivered in 3 month increments or less within an agile framework.*
8. *Deliverable due dates should be in terms of number of days after award or based on an event.*
9. *If for some reason the deliverable must be submitted in hard copy or on CD, be sure to specify the requirement within the line item. Also, in this case identify number of copies and mailing address.*
10. *Each deliverable line item must cite inspection and acceptance criteria; Inspection: Origin or Destination; Acceptance: Origin or Destination (most likely destination on both).*
11. *Update the Table of Contents by hitting F9.*