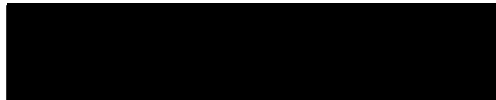


STATEMENT OF WORK (SOW)



CLINITEK Status Connect System



Phoenix Veterans Administration Health Care System

650 E. Indian School Road

Phoenix, AZ 85012

Transaction Number: (



POC:



Pathology & Laboratory Medicine Department (P&LMD)

1.0 Scope of Work:

Pathology & Laboratory Medicine's (P&LMD) Ancillary Testing section is requesting (15) Clinitek Status Connect Systems which will be utilized at (11) existing on-site clinics and CBOC's within PVAHCS and at two (2) new off-site locations (SW Clinic & Primary Care Annex swing space) expected to open in 2016. Two (2) of (15) analyzers are being requested as dedicated backups, which may also be placed at future new sites.

The Clinitek Status Connect System is a semi-automated point-of-care analyzer designed to provide biochemical urinalysis results within (60) seconds. The Clinitek Status Connect System, paired with the Telcor QML HL7 interface (separate contract), will allow patient results to be auto-electronically transmitted into the VistA Lab Package. This new upgraded analyzer/interface system will replace (11) existing, eight (8) year old, non-interfaced Clinitek Status Analyzers requiring manual entry of results into the Lab Package.

The supply acquisition does not involve connection of contractor-owned IT devices to the VA internal network, therefore the C&A requirements do not apply and a security accreditation package is not required.

APPENDIX B

VA ACQUISITION REGULATION SOLICITATION PROVISION AND CONTRACT CLAUSE

NOTE: This clause will undergo official rule making by the Office of Acquisitions and Logistics. The below language will be submitted for public review through the *Federal Register*. The final wording of the clause may be changed from what is outlined below based on public review and comment. Once approved, the final language in the clause can be obtained from the Office of Acquisitions and Logistics Programs and Policy.

1. SUBPART 839.2 – INFORMATION AND INFORMATION TECHNOLOGY SECURITY REQUIREMENTS

839.201 Contract clause for Information and Information Technology Security:

a. Due to the threat of data breach, compromise or loss of information that resides on either VA-owned or contractor-owned systems, and to comply with Federal laws and regulations, VA has developed an Information and Information Technology Security clause to be used when VA sensitive information is accessed, used, stored, generated, transmitted, or exchanged by and between VA and a contractor, subcontractor or a third party in any format (e.g., paper, microfiche, electronic or magnetic portable media).

b. In solicitations and contracts where VA Sensitive Information or Information Technology will be accessed or utilized, the CO shall insert the clause found at 852.273-75, Security Requirements for Unclassified Information Technology Resources.

2. 852.273-75 - SECURITY REQUIREMENTS FOR UNCLASSIFIED INFORMATION

TECHNOLOGY RESOURCES (INTERIM- OCTOBER 2008)

As prescribed in 839.201, insert the following clause:

The contractor, their personnel, and their subcontractors shall be subject to the Federal laws, regulations, standards, and VA Directives and Handbooks regarding information and information system security as delineated in this contract.

APPENDIX B

VA INFORMATION AND INFORMATION SYSTEM SECURITY/PRIVACY LANGUAGE FOR INCLUSION INTO CONTRACTS, AS APPROPRIATE

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.

2. ACCESS TO VA INFORMATION AND VA INFORMATION SYSTEMS

a. 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.

b. 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.

c. 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.

d. 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.

e. 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.

3. VA INFORMATION CUSTODIAL LANGUAGE

a. 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).

b. 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.

c. 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.

d. 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.

e. 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.

f. 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.

g. 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.

h. 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.

i. 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.

j. 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.

k. 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.

l. 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.

4. INFORMATION SYSTEM DESIGN AND DEVELOPMENT

a. Information systems that are designed or developed for or on behalf of VA at non-VA facilities shall comply with all VA directives developed in accordance with FISMA, HIPAA, NIST, and related VA security and privacy control requirements for Federal information systems. This includes standards for the protection of electronic PHI, outlined in 45 C.F.R.

Part 164, Subpart C, information and system security categorization level designations in accordance with FIPS 199 and FIPS 200 with implementation of all baseline security controls commensurate with the FIPS 199 system security categorization (reference Appendix D of VA Handbook 6500, *VA Information Security Program*). During the development cycle a Privacy Impact Assessment (PIA) must be completed, provided to the COTR, and approved by the VA Privacy Service in accordance with Directive 6507, *VA Privacy Impact Assessment*.

b. The contractor/subcontractor shall certify to the COTR that applications are fully functional and operate correctly as intended on systems using the VA Federal Desktop Core Configuration (FDCC), and the common security configuration guidelines provided by NIST or the VA. This includes Internet Explorer 7 configured to operate on Windows XP and Vista (in Protected Mode on Vista) and future versions, as required.

c. The standard installation, operation, maintenance, updating, and patching of software shall not alter the configuration settings from the VA approved and FDCC configuration. Information technology staff must also use the Windows Installer Service for installation to the default "program files" directory and silently install and uninstall.

d. Applications designed for normal end users shall run in the standard user context without elevated system administration privileges.

e. The security controls must be designed, developed, approved by VA, and implemented in accordance with the provisions of VA security system development life cycle as outlined in NIST Special Publication 800-37, *Guide for Applying the Risk Management Framework to Federal Information Systems*, VA Handbook 6500, *Information Security Program* and VA Handbook 6500.5, *Incorporating Security and Privacy in System Development Lifecycle*.

f. The contractor/subcontractor is required to design, develop, or operate a System of Records Notice (SOR) on individuals to accomplish an agency function subject to the Privacy Act of 1974, (as amended), Public Law 93-579, December 31, 1974 (5 U.S.C. 552a) and applicable agency regulations. Violation of the Privacy Act may involve the imposition of criminal and civil penalties.

g. The contractor/subcontractor agrees to:

(1) Comply with the Privacy Act of 1974 (the Act) and the agency rules and regulations issued under the Act in the design, development, or operation of any system of records on individuals to accomplish an agency function when the contract specifically identifies:

(a) The Systems of Records (SOR); and

(b) The design, development, or operation work that the contractor/subcontractor is to perform;

(2) Include the Privacy Act notification contained in this contract in every solicitation and resulting subcontract and in every subcontract awarded without a solicitation, when the work statement in the proposed subcontract requires the redesign, development, or operation of a SOR on individuals that is subject to the Privacy Act; and

(3) Include this Privacy Act clause, including this subparagraph (3), in all subcontracts awarded under this contract which requires the design, development, or operation of such a SOR.

h. In the event of violations of the Act, a civil action may be brought against the agency involved when the violation concerns the design, development, or operation of a SOR on individuals to accomplish an agency function, and criminal penalties may be imposed upon the officers or employees of the agency when the violation concerns the operation of a SOR on individuals to accomplish an agency function. For purposes of the Act, when the contract is for the operation of a SOR on individuals to accomplish an agency function, the contractor/subcontractor is considered to be an employee of the agency.

(1) "Operation of a System of Records" means performance of any of the activities associated with maintaining the SOR, including the collection, use, maintenance, and dissemination of records.

(2) "Record" means any item, collection, or grouping of information about an individual that is maintained by an agency, including, but not limited to, education, financial transactions, medical history, and criminal or employment history and contains the person's name, or identifying number, symbol, or any other identifying particular assigned to the individual, such as a fingerprint or voiceprint, or a photograph.

(3) "System of Records" means a group of any records under the control of any agency from which information is retrieved by the name of the individual or by some identifying number, symbol, or other identifying particular assigned to the individual.

i. The vendor shall ensure the security of all procured or developed systems and technologies, including their subcomponents (hereinafter referred to as "Systems"), throughout the life of this contract and any extension, warranty, or maintenance periods. This includes, but is not limited to workarounds, patches, hotfixes, upgrades, and any physical components (hereafter referred to as Security Fixes) which may be necessary to fix all security vulnerabilities published or known to the vendor anywhere in the Systems, including Operating Systems and firmware. The vendor shall ensure that Security Fixes shall not negatively impact the Systems.

j. The vendor shall notify VA within 24 hours of the discovery or disclosure of successful exploits of the vulnerability which can compromise the security of the Systems (including the confidentiality or integrity of its data and operations, or the availability of the system). Such issues shall be remediated as quickly as is practical, but in no event longer than _____ days.

k. When the Security Fixes involve installing third party patches (such as Microsoft OS patches or Adobe Acrobat), the vendor will provide written notice to the VA that the patch has been validated as not affecting the Systems within 10 working days. When the vendor is responsible for operations or maintenance of the Systems, they shall apply the Security Fixes within _____ days.

I. All other vulnerabilities shall be remediated as specified in this paragraph in a timely manner based on risk, but within 60 days of discovery or disclosure. Exceptions to this paragraph (e.g. for the convenience of VA) shall only be granted with approval of the contracting officer and the VA Assistant Secretary for Office of Information and Technology.

5. INFORMATION SYSTEM HOSTING, OPERATION, MAINTENANCE, OR USE

a. For information systems that are hosted, operated, maintained, or used on behalf of VA at non-VA facilities, contractors/subcontractors are fully responsible and accountable for ensuring compliance with all HIPAA, Privacy Act, FISMA, NIST, FIPS, and VA security and privacy directives and handbooks. This includes conducting compliant risk assessments, routine vulnerability scanning, system patching and change management procedures, and the completion of an acceptable contingency plan for each system. The contractor's security control procedures must be equivalent, to those procedures used to secure VA systems. A Privacy Impact Assessment (PIA) must also be provided to the COTR and approved by VA Privacy Service prior to operational approval. All external Internet connections to VA's network involving VA information must be reviewed and approved by VA prior to implementation.

b. Adequate security controls for collecting, processing, transmitting, and storing of Personally Identifiable Information (PII), as determined by the VA Privacy Service, must be in place, tested, and approved by VA prior to hosting, operation, maintenance, or use of the information system, or systems by or on behalf of VA. These security controls are to be assessed and stated within the PIA and if these controls are determined not to be in place, or inadequate, a Plan of Action and Milestones (POA&M) must be submitted and approved prior to the collection of PII.

c. Outsourcing (contractor facility, contractor equipment or contractor staff) of systems or network operations, telecommunications services, or other managed services requires certification and accreditation (authorization) (C&A) of the contractor's systems in accordance with VA Handbook 6500.3, *Certification and Accreditation* and/or the VA OCS Certification Program Office. Government-owned (government facility or government equipment) contractor-operated systems, third party or business partner networks require memorandums of understanding and interconnection agreements (MOU-ISA) which detail what data types are shared, who has access, and the appropriate level of security controls for all systems connected to VA networks.

d. The contractor/subcontractor's system must adhere to all FISMA, FIPS, and NIST standards related to the annual FISMA security controls assessment and review and update the PIA. Any deficiencies noted during this assessment must be provided to the VA contracting officer and the ISO for entry into VA's POA&M management process. The contractor/subcontractor must use VA's POA&M process to document planned remedial actions to address any deficiencies in information security policies, procedures, and practices, and the completion of those activities. Security deficiencies must be corrected within the timeframes approved by the government. Contractor/subcontractor procedures are subject to periodic, unannounced assessments by VA officials, including the VA Office of Inspector General. The physical security aspects associated with contractor/subcontractor activities must also be subject to such assessments. If major changes to the system occur that may

affect the privacy or security of the data or the system, the C&A of the system may need to be reviewed, retested and re-authorized per VA Handbook 6500.3. This may require reviewing and updating all of the documentation (PIA, System Security Plan, Contingency Plan). The Certification Program Office can provide guidance on whether a new C&A would be necessary.

e. The contractor/subcontractor must conduct an annual self assessment on all systems and outsourced services as required. Both hard copy and electronic copies of the assessment must be provided to the COTR. The government reserves the right to conduct such an assessment using government personnel or another contractor/subcontractor. The contractor/subcontractor must take appropriate and timely action (this can be specified in the contract) to correct or mitigate any weaknesses discovered during such testing, generally at no additional cost.

f. VA prohibits the installation and use of personally-owned or contractor/subcontractor-owned equipment or software on VA's network. If non-VA owned equipment must be used to fulfill the requirements of a contract, it must be stated in the service agreement, SOW or contract. All of the security controls required for government furnished equipment (GFE) must be utilized in approved other equipment (OE) and must be funded by the owner of the equipment. All remote systems must be equipped with, and use, a VA-approved antivirus (AV) software and a personal (host-based or enclave based) firewall that is configured with a VA-approved configuration. Software must be kept current, including all critical updates and patches. Owners of approved OE are responsible for providing and maintaining the anti-viral software and the firewall on the non-VA owned OE.

g. All electronic storage media used on non-VA leased or non-VA owned IT equipment that is used to store, process, or access VA information must be handled in adherence with VA Handbook 6500.1, *Electronic Media Sanitization* upon: (i) completion or termination of the contract or (ii) disposal or return of the IT equipment by the contractor/subcontractor or any person acting on behalf of the contractor/subcontractor, whichever is earlier. Media (hard drives, optical disks, CDs, back-up tapes, etc.) used by the contractors/subcontractors that contain VA information must be returned to the VA for sanitization or destruction or the contractor/subcontractor must self-certify that the media has been disposed of per 6500.1 requirements. This must be completed within 30 days of termination of the contract.

h. 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.

6. SECURITY INCIDENT INVESTIGATION

a. 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.

b. 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.

c. 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.

d. 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. LIQUIDATED DAMAGES FOR DATA BREACH

a. 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.

b. 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.

8. SECURITY CONTROLS COMPLIANCE TESTING

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.



9. TRAINING

a. 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.]*

b. 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.

c. 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.

2.0 Tasks:

The Contractor shall provide all products, labor, and materials according to the SOW Specifications. The items required must meet or exceed the specifications listed below.

General Requirements; the contractor shall provide the following:

1. Specifications set forth in this proposal are minimum specifications and shall not be construed as limiting the overall quality, quantity, or performance of the equipment.
2. The contractor shall meet or exceed the minimum requirements and shall be held responsible for the performance and overall quality of the equipment during the warranty period.
3. The equipment, based upon the specifications requested, shall be CLIA waived and the newest, most current model of Clinitek Status Connect System. A refurbished system is not acceptable. The equipment should be a standard product of the manufacturer of record. The manufacturer of record is defined as a company whose main occupation is the manufacture for sale items of equipment and which:
 - a. Maintains a factory production line.
 - b. Maintains a stock of replacement parts for the item.
 - c. Maintains engineering drawings, specifications, operating manuals and maintenance manuals.
 - d. Has published and distributed descriptive literature and equipment specifications on the equipment.
4. The Clinitek Status Connect System initial system validation must be performed by the vendor/manufacture
5. The Clinitek Status Connect System vendor/manufacture will provide a specific training plan for product implementation at both the main facility and individual CBOC's, including a description of the training and time-line for its completion

2.1 System Requirements; the contractor shall provide the following:

The requested equipment shall have the following salient characteristics:

1. The Clinitek Status Connect System must support the Telcor Inc. "QML" bi-directional Ethernet HL7 interface that automatically orders the test and enters results into VISTA
2. The Clinitek Status Connect System must be able to capture errors to prevent compromised data from reaching a patient's medical record, and there must be a built-in mechanism for alerting the laboratory to deviant test results for both patient and quality control testing
3. The Clinitek Status Connect System must have capacity to report the following semi-quantitative urine tests: albumin, bilirubin, creatinine, glucose, ketone, leukocytes, nitrite, pH, protein, specific gravity, and urobilinogen.
4. The Clinitek Status Connect System must have operator and quality control lockout ability
5. The Clinitek Status Connect System must have a hand-held barcode scanner/reader for patient barcode label scan, thereby eliminating transcription error and time intensive manual entry of demographics

6. The Clinitek Status Connect System must have automatic self-calibration.

2.2 Instrument Requirements; the contractor shall provide the following:

1. The Clinitek Status Connect System shall be no larger than 11" (depth) x 7" (width) x 8" (height).
2. The Clinitek Status Connect System should weigh no more than 5 lbs.
3. The Clinitek Status Connect System should have an ambient temperature operation range 64-86°F.
4. The Clinitek Status Connect System should have a UL electrical rating 100V-240V AC.
5. The Clinitek Status Connect System should have an operating relative humidity range 18-80%.
6. Any additional costs such as industrial funding fees, special shipping and handling fees, or other usage fees must be clearly indicated in the price quote.

2.3 Supply Requirements; the contractor shall provide the following:

1. The vendor/distributor must provide, in easy-to-understand plain English, all necessary procedure manuals, troubleshooting manuals, and operator manuals.
2. All necessary accessories required for operating the Clinitek Status Connect System should be listed as an addendum in the pricing schedule.

2.4 Repair & Maintenance Services; the contractor shall provide the following:

1. The manufacturer of the instrument system should define maintenance requirements and indicate what maintenance is performed by the end-user and what maintenance is performed by the manufacturer.

2.5 Pre-Installation Assessment; the contractor shall perform the following:

1. The vendor will provide environmental requirements (heat/cool, humidity, light, etc.) and recommendations for instrument and testing material storage.
2. Technical capability:
 - a. Provide dimensions of the system (key element)
 - b. Describe any environmental impact issues that instrumentation may create (water requirements, media disposal, etc.).
 - c. Describe user friendliness.
 - d. Describe ability to trouble-shoot system.

2.6 Support Services: The contractor shall perform the following:

1. Technical support should be available Monday-Friday 8:00am to 4:30pm Arizona time and should be through one contractor (preferably the manufacturer of the instrument).

3.0 Mandatory Value-Added Characteristics:

These characteristics are mandatory, and will be considered in the best-value determination.

Value added characteristics include, but are not limited to:

1. N/A