

STATEMENT OF WORK

STAT Referral Testing for the Gainesville facility

I. SCOPE OF PROCUREMENT

- a. The North Florida/South Georgia Veterans Health System (NF/SG VHA), Gainesville facility, has an ongoing need to obtain STAT referral testing services provided by a registered and/or licensed entity. It is VA's intention to solicit proposal in accordance with all terms, conditions, provisions, specifications, and schedules of this solicitation and award a firm fixed price requirements contract.
- b. Contractors shall provide in accordance with the specifications outlined below for the Malcom Randall VA Medical Center and Pathology and Laboratory Medicine Service located in Gainesville, Florida, starting the period October 1st, 2019.
- c. Services provided to Malcom Randall VA Medical Center Pathology & Laboratory Medicine Service under the resultant contract shall include the transportation of clinical laboratory specimens to the Contractor's laboratory(s), the performance of analytical testing as defined by the Contractor's reference test manual, the reporting of analytical test results and consultative services as required to assimilate the full scope of its laboratory operations to the Malcom Randall VA Medical Center Pathology and Laboratory Medicine Service.
- d. All requirements and provisions defined in the specifications of this solicitation will apply to any laboratory (i.e. branch, division, sub-contractor, etc.) performing reference testing on behalf of the Contractor.

II. LICENSURES:

- a. Only fully licensed/accredited laboratories actively engaged in providing the specific services and laboratory testing outlined in this solicitation will be considered. The reference laboratory must be licensed/accredited by the College of American Pathologists, the Nuclear Regulatory Commission, Center for Disease Control, Medicare and/ or other state regulatory agencies as mandated by federal and state statutes. In addition, the laboratory must be certified as meeting the requirements of the Clinical Laboratory Improvement Act of 1988 and comply with the National Standards to Protect the Privacy of Personal Health Information in accordance with Health Insurance Portability and Accountability Account of 1996 (HIPAA).

III. QUALITY

- a. The Government reserves the right to physically inspect the reference laboratory(s) prior to a contract award and at any time during the award period to insure the reference laboratory's compliance with accreditation and quality assurance practices and requirements.
- b. In addition, the reference laboratory shall provide the following documentation with their offer and on an annual basis in accordance with the Office of Inspector General (OIG) Combined Assessment Program (CAP) and Joint Commission for the Accreditation of Healthcare Organizations (JCAHO) requirements:
 - i. Professional Staff Curricula Vitae
 - ii. Technical Staff Competency Skills Assessment

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- iii. Proficiency Exam Participation
- iv. Proficiency Exam Exception Reports for the past two years
- v. Description of Performance Improvement (Quality Assurance) Program
- vi. Current year performance improvement monitors that include and not limited to demonstration of number of lost specimens, number of cancelled specimens, delays in turnaround times, and courier route delays/cancellations
- vii. Other Quality Assurance Monitors as defined by North Florida/South Georgia Veterans Health System Pathology and Laboratory Medicine Service

IV. TEST MENU:

- a. The tests listed below are required to be processed within an acceptable turnaround time of no more than 3 hours from the moment the service is requested.
- b. The testing shall include:
 - i. Methotrexate
 - ii. Tacrolimus (FK506)
 - iii. Mixing Studies (PT/PTT)
 - iv. Factor VIII (8)
 - v. Cyclosporine
 - vi. Thrombin Time
 - vii. Sirolimus
 - viii. Factor IX (9)

V. GENERAL REQUIREMENTS:

- a. Contractor shall supply Malcom Randall VA Medical Center Pathology & Laboratory Medicine Service facility with its commercial laboratory reference test manual to ensure that the collection and storage of specimens are in accordance with Contractor's requirements.
- b. Contractor shall provide all materials necessary to collect and preserve specimens that are destined to the commercial reference laboratory for stat testing. These materials include those items that are dictated by and in compliance with the collection requirements of the commercial reference laboratory.
- c. Contractor shall be responsible for storing specimens in such a manner to insure the integrity of the specimen.
- d. Contractor shall provide transportation of primarily biomedical materials that include patient specimens, originating from the Government facilities and destined to the contracted commercial reference laboratory. These items are classified as Hazard Materials Class 6, Division 6.2 and are defined in 49 CFR Part 173.134 as those materials that contain or could contain etiologic agents. Transportation shall be done in such a manner that the safety and integrity of the biomedical material is maintained.
- e. Emergency transportation services shall be available 24 hours per day, seven (7) days per week including Government holidays. The estimated number of emergency transportations per month is around fifteen (15).
- f. Response time for emergency transportation services shall be within 30 minutes from the time the service is requested by the Pathology and Laboratory Medicine Service staff

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within Gainesville, Florida. Emergency response time refers only to the transportation of the specimen(s) and does not include the time for test performance.

- g. Stat transportation services shall occur as requested seven days a week and twenty-four hours a day from the VA Gainesville facility located in 1601 SW Archer Road Gainesville, Florida. The Reference Lab will provide a phone number that should be available 24/7.
- h. Contractor shall provide all necessary supplies for biomedical materials to be transported from the originating facility to the Contractor's laboratory. These supplies shall include, but may not be limited to:
 - i. Shipping and packaging containers. Packing material must be capable of maintaining temperature requirements for specimens until they reach the Contractor's laboratory.
 - ii. Required labels and packaging materials for shipping specimens via courier that are infectious, or etiologic agents, in accordance with appropriate requirements of 42 CFR Part 72, 49 CFR Parts 171 and 173, and the Dangerous Goods Regulations of the International Air Transport Association (IATA) consistent with current regulatory updates.
 - iii. Test request forms preprinted with the appropriate Shipping Section details and account information if required.
 - iv. Printer and printer supplies including paper, labels, and toner/ ink cartridges, in sufficient quantities to perform work under this contract.

VI. SPECIMEN TESTING REQUIREMENTS:

- a. The Contractor and/or subcontractor shall provide the full range of clinical diagnostic testing capabilities to execute all required tests as annotated in Section IV(4) (approximately 47 tests per month). Contractor shall make available the following test information:
 - i. Requisition form requirements
 - ii. Alphabetized test name list
 - iii. Test order code
 - iv. Specimen collection and preservation requirements
 - v. Test method employed (indicate if testing performed in duplicate) and interpretations
 - vi. Test reference intervals adjusted for age, sex or race, when required
 - vii. Test specific sensitivity, specificity and interferences, when required
 - viii. Result code
 - ix. Test critical values, if any
 - x. Policy for critical value notification
 - xi. CPT coding
 - xii. Test turnaround times (minimum and maximum times indicated); where the turnaround time is defined as the time between pick-up of specimen by the Contractor and receipt of results by a Government facility.
 - xiii. Schedule of test performance (specific days of week indicated)

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- xiv. Location of test performance by test name (i.e. name of primary laboratory, name of separate branch/division of primary lab, name and address of secondary (sub-contracted) laboratory must be cited)
- b. Contractor shall notify the Contracting Officer of any test information modifications no later than two weeks prior to the implementation date of the test change.
- c. Any new test(s) not listed in Section IV (4) must be added to the contract through modification by the Contracting Officer (CORs and Government facility representatives do not have this authority) prior to specimen being tested.
- d. All reference laboratory testing shall be executed in accordance with standard industry practices. It is preferred that test methods are FDA approved. Any non-FDA approved method being performed shall have a disclaimer and documented validation plan. Upon request, the validation plan and validation results shall be made available to the COR or designee.
- e. The Contractor shall ensure the accurate and timely performance (defined in Section VI.a.xii) of laboratory testing services on the biomedical materials.

VII. REPORTING OF RESULTS:

- a. The results of testing shall be reported within the prescribed turnaround times provided by the Contractor as part of the test information (defined in Section VI.a.xii).
- b. A report of laboratory testing results must be issued either as a printed final copy or through the host to host electronic transmission of the test results. Electronic delivery of reports by computer interface connection is normally the required method of receipt. However, in unusual circumstances where electronic delivery is not possible, the Contractor shall deliver the reports without an additional charge by expedited overnight courier shipping, mailing and/or transportation services by hand within 24 hours, or by telephone facsimile to a protected machine identified to the Contractor by the VA. Delivery by electronic mail i.e. MS Outlook, etc. is prohibited.
- c. Specifications outlining the requirements of this computer interface including computer hardware, maintenance and supply requirements are defined in Section Telecommunication Requirements below.
- d. Each test report shall, at minimum, include the following information:
 - i. Patient's full name
 - ii. Patient's identification number, e.g. social security number (SSN)
 - iii. Physician's name (if supplied)
 - iv. Government laboratory accession number (if supplied)
 - v. Submitting facility name
 - vi. Submitting facility account number
 - vii. Patient's location (clinic/ward) (if supplied)
 - viii. Test(s) ordered
 - ix. Date/time of specimen collection (when available)
 - x. Date/time test completed
 - xi. Test result
 - xii. Reference intervals (adjusted for age, sex or race, when appropriate)
 - xiii. Toxic and therapeutic ranges, if applicable

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- xiv. Flagged abnormal results
 - xv. Reference laboratory accession number
 - xvi. Name and address of testing laboratory
 - xvii. Any other information the laboratory has that may indicate a questionable validity of test results.
 - xviii. Specimen inadequacy shall be reported with documentation supporting its unsuitability for testing.
- e. Test results determined by the contractor to be critical, shall be communicated by telephone to a designated Government contact person(s) at the originating Government laboratory facility upon verification of the critical test result. The telephonic report shall be followed by an electronic transmission.

VIII. CUSTOMER SERVICE:

- a. Contractor shall provide customer service that is accessible by toll-free telephone service 24 hours per day, 7 days per week to assist Government staff for tracking and resolving related issues/problems that may arise in the performance under this contract.
- b. Upon award, the Contractor shall provide the name(s) and telephone number(s) of contractor employees who will address the following customer services throughout the contract performance period:
 - i. Telephone Inquiries – Telephone inquiries are divided into four major categories with additional subcategories defining the type of inquiry and the Government’s minimum time expectation for meeting this service.
 - ii. Specimen Collection
 - 1. Routine inquiries, questions and clarifications regarding collection requirements shall be addressed at the time of the initial call.
 - 2. Esoteric inquiries, questions and clarifications regarding collection requirements that require further research shall be addressed within ½ hour of the initial call.
 - iii. Testing
 - 1. Inquiries regarding the status of pending orders shall be addressed at the time of the initial call.
 - 2. Esoteric inquiries when information is requested regarding methodology, correlation, interferences, reflex tests, etc. shall be addressed within two hours of the initial call.
 - iv. Technical Expertise
 - 1. Test utilization inquiries where information is required as to the most appropriate test to be ordered shall be addressed within two business hours of initial call.
 - 2. Result interpretation inquiries shall be addressed within four business hours of initial call.
 - 3. Consultative services where information is required regarding the clinical significance of tests shall be addressed within twenty-four business hours of the initial call.

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4. Account follow-up
 - a. Information general in nature yet specific to the account, e.g. test pricing, equipment repair, supply ordering, etc. shall be addressed within four hours of the initial call.
 - c. The Contractor shall notify the originating laboratory by telephone of specimens cancelled due to unacceptability for reasons relating to volume, specimen container, identification, loss of specimen, etc.
 - d. The Government will place orders for specimen collection and transportation supplies by telephone or through written or electronic methods or as mutually agreed in the negotiation process.

IX. CONSULTATIVE SERVICES/UTILIZATION REPORTS:

- a. Contractor shall prove consultative services that are consistent with the services offered to other contracted customers without compensation. These services may include consultations by laboratory professionals or experienced physicians on test or methodology selection or test result interpretation.
- b. Contractor shall provide a statistical analysis of the Government facilities' workload testing volumes to assist in the monitoring of ordering trends and utilization patterns and will make recommendations to the facilities on mechanisms to reduce their costs.
- c. Contractor shall provide a monthly listing of any tests listed in Section IV that are no longer performed by contractor and shall be removed from Section IV. This listing shall include, at a minimum, test name and/or test ordering code.

X. DATA MANAGEMENT SYSTEM:

- a. Contractor shall provide to the Government all necessary laboratory test parameters (parameters are required for each test contained in a panel) to insure accurate test result transmission between the Government and the Contractor's database. Required test parameters include:
 - i. Ordering code
 - ii. LOINC code
 - iii. CPT code
 - iv. Interface code
 - v. Test cost
 - vi. Reference ranges
 - vii. Units of measurement
 - viii. Test result interpretation or interpretive remarks, if appropriate
 - ix. Testing site (if not performed at the vendor's main laboratory facility)
 - x. Test methodology
 - xi. Specimen types
 - xii. Specimen collection and handling requirements

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- xiii. Indication whether test is a panel/profile test, list of tests included
- b. The parameters for all tests in the Contractor's database shall be kept current and be available to the Government site throughout the performance period of the contract. Updates to the test parameter information must be provided to the Gainesville VA facility Laboratory Information Manager (LIM) no less than 2 weeks prior to the implementation of any changes. The Contractor shall provide telephone access to a Contractor's technical representative to respond to any question(s) regarding the laboratory test parameter information.

XI. SPECIAL CONTRACT REQUIREMENTS:

- a. Services
 - i. The services specified herein may be changed by written modification to this contract. The VA Contracting Officer will prepare the modification (reference FAR clause 52.212-4(c), Changes) and, prior to becoming effective, shall be signed by both parties. Only the Contracting Officer is authorized to make commitments or issue changes that affect price, quantity, or quality of performance of this contract. In the event the Contractor effects any such change at the direction of any person other than the Contracting Officer, the change shall be considered unauthorized and no adjustment will be made in the contract price to cover any increase in costs incurred as a result thereof.
 - ii. This is a non-personal services contract as defined in FAR 37.101. There is no employer-employee relationship between the Government and the contractor or the contractor's employee(s). Contractor personnel are not subject to the supervision and control of a Government officer or employee. Rather, contractor personnel perform their duties in accordance with the Performance Work Statement. Supervisory functions such as hiring, firing, directing, and counseling of contractor personnel are not performed by the Government. The healthcare provider who furnishes services under this contract is subject to Government technical oversight of the services. The Government retains the right to reject services for contractual non-performance.
 - iii. The Government may evaluate the quality of professional and administrative services provided, but retains no control over the medical, professional aspects of services rendered.
 - iv. Contractor is required to maintain medical liability insurance for the duration of this contract. Medical Liability insurance must cover the provider(s) for services in all states where services are rendered by the provider. Contractor must indemnify the Government for any liability producing act or omission by the contractor, its employees and agents occurring during contract performance.
 - v. Contractor shall, in writing, keep the Contracting Officer informed of any unusual circumstances in conjunction with the contract.
 - vi. Contractor shall not, under any circumstances, furnish reports directly to patients.

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XII. FEDERAL HOLIDAYS:

- a. Contractor is required to provide transportation of specimens on federal holidays if requested. The 10 holidays observed by the Federal Government are: New Year's Day (January 1st), Martin Luther King's Birthday (3rd Monday in January), Presidents' Day (3rd Monday in February), Memorial Day (last Monday in May), Independence Day (July 4th), Labor Day (1st Monday in September), Columbus Day (2nd Monday in October), Veterans Day (November 11), Thanksgiving Day (4th Thursday in November), Christmas Day (December 25th) and any other day specifically declared by the President of the United States to be a national holiday.
- b. When one of the above designated legal holidays falls on a Sunday, the following Monday will be observed as a legal holiday. When a legal holiday falls on a Saturday, the preceding Friday is observed as a holiday by U.S. Government agencies.

XIII. QUALIFICATIONS/REQUIREMENTS OF LABORATORY & CONTRACTOR PERSONNEL:

- a. Laboratory
 - i. Offeror must have at least three years of experience in providing laboratory testing services and must have at least one-year experience in transporting biomedical materials.
 - ii. Offerors, including subcontractor(s), must continuously hold a Certificate of Compliance or Certificate of Accreditation from the Centers for Medicare & Medicaid Services as meeting the requirements of the Clinical Laboratory Improvement Amendments of 1988 or must demonstrate accreditation by a regulatory agency(s) with deemed status from the Centers for Medicare & Medicaid Services, e.g. The College of American Pathologists, and/or other state regulatory agencies, as appropriate, and as mandated by federal and state statutes. The reference laboratory (ies) must maintain valid certifications during the entire performance period of this contract.
 - iii. Copies of all relevant permits/licenses and certifications inclusive of any sanctions current or pending throughout the United States of America must be supplied in response to this solicitation. In addition, as these documents are reissued or re-awarded, the awarded Contractor must supply a copy to the Contracting Officer's Representative assigned to each Government facility. The above documents must also be supplied for each reference laboratory that is a subcontractor of the primary Contractor.
 - iv. Contractor must notify immediately the Contracting Officer's Representative (COR) at each of the Government facilities in writing, upon its loss of any required certification, accreditation or licensure.
 - v. Contractor shall maintain safety and health standards consistent with the requirements set forth by the Occupational, Health, and Safety Administration (OSHA), and the Center for Disease Control (CDC) and Prevention.
- b. Personnel

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- i. Contractor shall ensure all testing and supervisory personnel at all contractor-owned, affiliate, or subcontracted laboratories assigned to work under this contract meet and maintain the applicable personnel qualifications set forth under the Clinical Laboratory Improvement Amendments (CLIA) of 1988 regulations, the College of American Pathology (CAP) accreditation standards, or other accrediting organizations' and State standards.
- ii. Contractor shall ensure its employees have the ability to perform the applicable duties consistent with their license and certification.
- iii. Personnel assigned by the contractor to perform the services covered by this contract shall be proficient in written and spoken English (38 USC 7402).
- iv. Any new requirements for mandatory education and/or competency reassessment, which occur during the contract period, must be completed by the individual contractor employee(s) within VA established timeframes.
- v. Contractor couriers entering any Government facility must be attired in a contractor-issued uniform that bears the name of the Contractor 's company. In addition, the Contractor representative shall prominently display a contractor-issued identification badge

XIV. HHS/OIG

- a. To ensure that the individuals providing services under the contract have not engaged in fraud or abuse regarding Sections 1128 and 1128A of the Social Security Act regarding federal health care programs, the contractor is required to check the Health and Human Services - Office of Inspector General (HHS/OIG), List of Excluded Individuals/Entities on the OIG Website (www.hhs.gov/oig) for each person providing services under this contract. The listed parties and entities may not receive Federal Health Care program payments due to fraud and/or abuse of the Medicare and Medicaid programs. During the performance of this contract the contractor is prohibited from using any individual or business listed on the List of Excluded Individuals/Entities. Any healthcare provider or entity that employ or enter into contracts with excluded individuals or entities may have a Civil Monetary Penalty (CMP) imposed against them. By signing this offer, the Contractor certifies that all persons or entities listed in the contractor's proposal have been compared against the OIG list and are NOT listed as of the date the offer was signed.

XV. RECORD KEEPING CONTRACTOR:

- a. Contractor must establish a record keeping system of all tests performed.
- b. Medical Records
 - i. Clinical or other medical records (ie. test results) of VA veteran patients treated by Contractor under this contract are owned by the VA. If requested, test results will be mailed to the VA at no additional cost. Mail shall be sent in accordance with VA Directive 6609, Mailing of Sensitive Personal Information. Contractor may obtain a copy of VA Directive 6609 at the following website: <http://www1.va.gov/vhapublications/index.cfm>. If a subpoena or court order is received for the production of a medical record/test result, the contractor shall notify the Contracting Officer that a subpoena or court order was received.

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XVI. CONFIDENTIALITY OF PATIENT RECORDS:

- a. The Contractor is a VA contractor and will assist in the provision of health care to patients seeking such care from or through VA. As such, the Contractor is considered as being part of the Department health care activity. Contractor is considered to be a VA contractor for purposes of the Privacy Act, Title 5 U.S.C. 552a. Further, for the purpose of VA records access and patient confidentiality, Contractor is considered to be a VA contractor for the following provisions: Title 38 U.S.C. 5701, 5705, and 7332. Therefore, Contractor may have access, as would other appropriate components of VA, to patient medical records including patient treatment records pertaining to drug and alcohol abuse, HIV, and sickle cell anemia, to the extent necessary to perform its contractual responsibilities. However, like other components of the Department, and notwithstanding any other provisions of the sharing agreement, the Contractor is restricted from making disclosures of VA records, or information contained in such records, to which it may have access, except to the extent that explicit disclosure authority from VA has been received. The Contractor is subject to the same penalties and liabilities for unauthorized disclosures of such records as VA.
- b. The records referred to above shall be and remain the property of VA and shall not be removed or transferred from VA except in accordance with U.S.C.551a (Privacy Act), 38 U.S.C. 5701 (Confidentiality of claimants records), 5 U.S.C. 552 (FOIA), 38 U.S.C. 5705 (Confidentiality of Medical Quality Assurance Records) 38 U.S.C. 7332 (Confidentiality of certain medical records) and federal laws, rules and regulations. Subject to applicable federal confidentiality or privacy laws, the Contractor, or their designated representatives, and designated representatives of federal regulatory agencies having jurisdiction over Contractor, may have access to VA 's records, at VA's place of business on request during normal business hours, to inspect and review and make copies of such records.

XVII. HIPAA Compliance:

- a. Contractor must adhere to the provisions of Public Law 104-191, Health Insurance Portability and Accountability Act (HIPAA) of 1996 and the National Standards to Protect the Privacy and Security of Protected Health Information (PHI). As required by HIPAA, the Department of Health and Human Services (HHS) has promulgated rules governing the security and use and disclosure of protected health information by covered entities, including the Department of Veterans Affairs (VA). The VA has recognized Diagnostic Laboratory Facilities as healthcare providers and that the PHI is being disclosed and/or used for treatment. Therefore, no BAA is required for Reference Laboratory Services.

XVIII. CONTRACT PERFORMANCE MONITORING:

- a. Contractor's employee(s) shall report to the Laboratory Central Processing area, upon arrival at the VA for specimen pickup.
- b. Monitoring of contractor's performance shall be demonstrated through clinical and administrative record reviews. COR will be responsible for verifying contract compliance. Contracting Officer's Representative(s) (COR) will designate appropriate VA

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personnel to monitor services through one or a combination of the following mechanisms:

- i. Departments being served will monitor Contractor performance to ensure that services called for in the contract have been received by VA in a timely manner. Any incidents of Contractor noncompliance as evidenced by the monitoring procedures will be forwarded immediately to the Contracting Officer.
 - ii. Documentation of services performed will be reviewed prior to certifying payment. The COR will perform periodic spot checks and document with the using service to ensure records monitoring. VA will pay only for services actually provided, and in strict accordance with the Price Schedule agreed in the Contract monitoring, and recordkeeping procedures will be sufficient to ensure proper payment and allow audit verification that services were provided.
- c. Departments being served, through the COR(s), will provide a written statement annually to the Contracting Officer to include a summary of Contractor actions and a statement that all requirements of the contract have been fulfilled as agreed. This summary evaluation will be submitted 45 days prior to expiration of contract (and/or prior to election of option year renewals, if applicable).

XIX. QUALITY ASSURANCE MONITORING:

- a. Contractor shall maintain a Quality Assurance Program related to Reference Laboratory services covered under this contract.
- b. Contractor shall also participate in a joint quality assurance surveillance program (QASP) with the Government facilities. This program must minimally address the quality aspects representative to the testing process, i.e. pre-analytical, analytical and post-analytical variables and include a description of monitoring and evaluation activities. There must be a mutually agreed upon procedure for responding to issues, problems and/or concerns identified by the Government with details as to whom and in what timeframe the matters will be reconciled. The issues that may need to be addressed may be general in nature or specific to an incident or event. The contractor will meet or communicate with the Gainesville facility/VISN 8 staff for process review and improvement of contract performance on an as needed basis.
- c. Copies of licensure/certifications are also required to be submitted upon request by the VA.
- d. Quality factors that VA may consider when monitoring quality of care may include, but are not limited to: patient medical records, security/privacy, adverse event reporting, turn-around times, timeliness to customer service requests, missed/delayed routes, etc.
- e. These monitoring procedures and disincentives for contractor's failure in meeting these tasks are further illustrated in the following Performance Requirements Summary Matrix:

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PERFORMANCE OBJECTIVE TASK	PERFORMANCE STANDARD	ACCEPTABLE (MINIMAL) QUALITY LEVEL (AQL) 1	MONITORING METHOD	DISINCENTIVES²
Ensure the safety and integrity of specimens	No loss or destruction of specimens	100% of the time	Contractor reporting; Government inquiries.	\$100 will be deducted for each specimen that is lost or destroyed.
Testing services will be performed in accordance with the defined turnaround times (TAT)	Results will be reported within the TAT agreed in this contract for each test	90% of the time.	100% inspection of tests selected per quarter	5% of the cost of each test result reported late may be deducted from the monthly invoice.
Emergency Response Time is within the required timeframes	Contractor responds within 30 minutes	100% of the time	100% Direct Observation	\$100 will be deducted from the invoice for not responding within the required timeframes.

XX. Required Registration with Contractor Performance Assessment System (CPARS)

- a. As prescribed in Federal Acquisition Regulation (FAR) Part 42.15, the Department of Veterans Affairs (VA) evaluates contractor past performance on all contracts that exceed the thresholds outlined in FAR Part 42.15, and shares those evaluations with other Federal Government contract specialists and procurement officials through the Past Performance Information Retrieval System (PPIRS). The FAR requires that the contractor be provided an opportunity to comment on past performance evaluations prior to the posting of each report. To fulfill this requirement VA uses an online database, the Contractor Performance Assessment Reporting System (CPARS). The CPARS database information is uploaded to the Past Performance Information Retrieval System (PPIRS) database, which is available to all Federal agencies.

¹ AQL's of 100% are based on the fact that all circumstances outside of the contractor's control have been accounted for in the performance work statement. For instance, loss or destruction of specimens and missed routes are "justified" in the case of *force majeure* events and therefore are not included in determining the contractor's acceptable quality level of performance. If the contractor believes there are excusable circumstances, the contractor shall inform the Contracting Officer.

² The disincentives above are based on VA's internal costs incurred when certain performance requirements are not met. Lost or destroyed specimens will require additional medical procedures and delayed health care, the costs of which exceed the disincentive amount.

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- b. Each contractor whose contract award is estimated to exceed the thresholds outlined in FAR Part 42.15 is required to provide to the contracting officer contact information for the contractor's representative with their response to the solicitation. The contractor is responsible to notify the contracting officer of any change to the contractor's representative during the contract performance period. Contractor's representative contact information consists of a name and email address.
- c. The Government will register the contract within thirty days after contract award. For contracts with a period of one year or less, the contracting officer will perform a single evaluation when the contract is complete. For contracts exceeding one year, the contracting officer will evaluate the contractor's performance annually. Intermediate reports will be filed each year until the last year of the contract, when the final report will be completed. Each report shall be forwarded in CPARS to the contractor's designated representative for comment. The contractor's representative will have thirty days to submit any comments and return the report to the VA contracting officer. Failure by the contractor to respond within those thirty days will result in the Government's evaluation being placed on file in PPIRS without contractor's comments.

XXI. CONTRACT SECURITY REQUIREMENTS

XXII. General

- a. 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.
- b. Contractor Personnel Security Requirements
 - i. Failure to comply with the contractor personnel security requirements may result in termination of the contract for default.
 - ii. Contractor shall certify that all its employees and subcontractor employees having access to VA sensitive information (ie. laboratory technicians, administrative personnel) during the performance of this contract have successfully passed a contractor employee background check.
 - iii. All contractor employees who require access to the Department of Veterans Affairs' computer systems for system connectivity shall be the subject of a VA background investigation. The VA obtains the Background Investigation through the Electronic Questionnaires for Investigations Process (e-QIP). Upon receiving a request for the investigation from the Contracting Officer, the contractor's employee will be initiated into e-QIP for the Background Investigation followed by an e-mail with instructions to log into e-QIP. Contractor employee shall complete all application requirements within 14 days or receipt of e-QIP email. A contractor's employee shall not commence working at VA under contract until the Contracting Officer receives notification from the VA Office of Security and Law Enforcement that the contract employee's application was received

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complete. A favorable adjudication from the VA Office of Security and Law Enforcement must be received in order for a contractor employee to continue contract performance. This requirement is also applicable to all subcontractor personnel.

- c. Position Sensitivity - The position sensitivity has been designated as Low Risk.
 - i. Background Investigation - The level of background investigation commensurate with the required level of access is National Agency Check with Written Inquiries.
- d. Contractor Responsibilities
 - i. The contractor shall bear the expense of obtaining background investigations. If the Office of Personnel Management (OPM) conducts the investigation, the contractor shall reimburse VA within 30 days. If timely payment is not made within 30 days from date of bill for collection, then VA shall deduct the cost incurred from the contractor's 1st month's invoice(s) for services rendered.
 - ii. It is imperative for the contractor to provide, at the request of VA, a listing of contractor personnel performing services under the contract in order for the background investigation process to commence. This list will include name (first, middle, last) social security number; date of birth; city, state, and country of birth.
 - iii. The contractor or their employees shall submit a complete background investigation packet through the Electronic Questionnaires for Investigations Process (e-QIP). Additional guidance and information will be provided through e-mail from the VA Office of Security and Law Enforcement.
- e. The following required forms must be submitted through the e-QIP system to the VA Office of Security and Law Enforcement before contract performance begins:
 - i. e-QIP Signature Pages (two) (print, sign and submit)
 - ii. Optional Form 306, Declaration for Federal Employment
- f. Electronic Fingerprint Form (FD 258) or electronic fingerprints
- g. Fingerprinting is required with the background investigation. Fingerprinting can be done at the local VA Facility. The Electronic Fingerprint Verification Form must be submitted with the above required forms.
 - i. The contractor shall inform the contract employee that when filling out the application, that there should be no gaps in employment history. Any gaps in employment history may result in OPM rejecting the documentation for investigation and delay contract performance.
 - ii. The contractor, when notified of an unfavorable determination by the Government, shall withdraw the employee from consideration from working under the contract, and at the request of the VA, submit another employee for consideration.
 - iii. The contractor may utilize a private investigating agency if such agency possesses an OPM and Defense Security Service certification. A Cage Code number must be provided to the VA Office of Security and Law Enforcement. VA Office of Security and Law Enforcement will verify the information and

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advise the contracting officer whether contractor's access to the computer systems can be authorized.

- iv. All contractor employees and subcontractors are required to complete VA's Privacy training annually. All Contractor employees and subcontractors requiring access to VA computer network are required to complete Cyber Security training courses annually either on-line or hard copy. Documented proof must be provided to the Contracting Officer.
- h. The contractor will notify the COR immediately when their employee(s) no longer require access to VA computer systems.
- i. Government Responsibilities
 - i. The contracting officer will request the contractor employee's background investigation by the Office of Security and Law Enforcement.
 - ii. The Office of Security and Law Enforcement will notify the contractor with instructions for the contractor's employees, coordinate the background investigations, and notify the contracting officer and contractor of the results of the investigations.
 - iii. The VA facility will pay for requested investigations in advance. A bill for collection will be sent to the contractor to reimburse the VA facility. The contractor will reimburse the VA facility within 30 days. If timely payment is not made within 30 days from date of bill for collection, then VA shall deduct the cost incurred from the contractors 1st month's invoice(s) for services rendered.
 - iv. The current fees associated with background investigations are \$125.00 each for low level investigation, \$809.00 each for medium level investigation, and \$3,189.00 each for high level investigation.
- j. REQUIREMENTS FOR REMOTE ACCESS

The contractor may be allowed remote access to VA computer systems in the performance of the contract. VA has stringent policies and procedures covering remote computer access therefore, the following responsibilities are outlined below.

- k. VA Responsibilities
 - i. VA will provide secure and reliable remote access to systems, applications, and information on the VA network to the contractor.
 - ii. VA will provide firewall and antiviral software with updates to the contractor.
 - iii. VA will provide security training to contractor's current employees and new employees as needed.
 - iv. After contract award, VA reserves the right to inspect contractor's facilities, installations, operations, documentation, records and databases.
- l. Contractor Responsibilities
 - i. The contractor will ensure adequate LAN/Internet, data, information, and system security in accordance with VA standard operating procedures and contract terms and conditions.
 - ii. The contractor shall install VA provided firewall and antiviral software on all networks and/or individual computers accessing VA network. The Contractor is

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responsible for the installation and testing of all required patches to ensure the security of the system.

- iii. All remote connections to VA network must be approved to use Office of Cyber and Information Security (OCIS) authorized configurations and access points. Contractor's remote access sessions through the Internet or other networks must be conducted using VA's remote access Virtual Private Network (VPN) service.
- iv. The contractor will notify the assigned Information Security Officer and Contracting Officer immediately when their employee(s) no longer require access to VA computer systems.
- v. Contractor will not publish or disclose in any manner details of any safeguards either designed or developed by the Contractor and/or subcontractors under this contract or otherwise provided by the VA without prior written approval by the Contracting Officer and the assigned Information Security Officer.
- vi. The Contractor will require that employees sign VA National Rules of Behavior and VPN Rules of Behavior, follow VA guidelines to create strong passwords, do not divulge or share access codes or passwords, safeguard all sensitive information, and follow all information security and privacy requirements.
- vii. The Contractor will notify the Contracting Officer in writing of any subcontractors performing work under this contract that will require remote access to VA computer systems. Contractors will be held responsible for their subcontractors. All subcontractors will be required to follow the same VA computer requirements as the contractor.
- viii. The Contractor will adhere to the remote access requirements, and ensure that systems are properly configured and appropriate security mechanisms and monitoring devices are up to date with best practices and technical standards.
- ix. Contractor will report any security violations, suspected or attempted violations, and any unanticipated threats or hazards immediately to the assigned Information Security Officer and the COR.

XXIII. SECURITY TRAINING

- a. Due to the increased emphasis on privacy and information security, the following special contract requirements are established and hereby made part of the contract entered into with the Department of Veterans Affairs. All contractor employees and subcontractor employees requiring access to VA information and VA information systems shall complete the following before being granted to VA information and its systems:
 - i. Privacy & Information Security Training: Contractor and their sub-contractors assigned work under the contract are required to receive annual training on patient privacy as established by HIPAA statues. Training must meet VHA's and/or the Department of Health and Human Services Standards for Privacy of Individually-identifiable health information. For contractors and sub-contractors who do not have access to VHA computer systems, this requirement is met by receiving VHA National Privacy Training, other VHA approved privacy training, or contractor furnished training that meets the requirements of the

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HHS standards. Contractor shall provide certification to the VA upon request that all employees and sub-contractor employees assigned work and/or having access to Protected Health Information have received annual training.

- ii. Rules of Behavior: Contractor personnel having access to VA systems are required to read and sign a Rules of Behavior statement, which outline rules of behavior related to VA contracts.
 - iii. Failure to complete mandatory annual training and/or 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. Information on fulfilling the training requirements as stated in paragraphs a-c can be found at the VA Talent Management System (TMS) at <https://www.tms.va.gov/plateau/user/login.jsp>. Once there, follow the steps to create an account, launch the mandatory training, and complete the content. The training will provide information regarding privacy, information security, rules of behavior, and other pertinent topics relevant to work at the VA. If any difficulty is experienced while creating an account or completing the mandatory content, contact the VA MSE Help Desk at 1.888.501.4917 or via email at VAMSEHelp@gpworldwide.com.
- b. As VA routinely reviews and updates policies and procedures covering contractor computer access, security requirements may change during the term of this contract and new policies and procedures may be implemented unilaterally during the term of this contract.

XXIV. 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. 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.

XXV. COMPUTER SECURITY

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- a. In performing this agreement, contractor shall be considered a part of VA for purposes of 5 U.S.C. §552a, 38 U.S.C. §§5701 and 7332. Contractor's employees and agents may have access to patient medical records and general files to the extent necessary to perform this contract. Notwithstanding any other provision of this agreement, contractor and/or its employees may not disclose information contained in general files and patient records and or other individually identified patient information, including information and records generated by the contractor in performance of this contract, except pursuant to explicit instructions from the VA. For the purposes of this paragraph, instruction to disclose may be provided by these officials only: Contracting Officer, Contracting Officer Technical Advisor, the Release of Information supervisor, or VA attorneys.
- b. Records created by contractor in the course of performing this agreement are the property of the VA and shall not be accessed, released, transferred, or destroyed except in accordance with applicable federal law, regulations, and policy. Access to data will be limited to the minimum necessary for performance of the contract. Contractor will take steps to ensure that access is limited to those employees who need access to the data to perform the contract. Contractor will not copy information contained in the system, either by printing to paper or by copying to another digital format, without the express permission of one of the officials listed in paragraph (b), above, except as is necessary to make single copies in the ordinary course of providing patient care. Contractor will not commingle the data from the system with information from other sources. Contractor shall report any unauthorized disclosure of VA information to the officials listed in paragraph (b).
- c. If this agreement is terminated for any reason, contractor will provide the VA with all individually-identified VA patient treatment records or other information in its possession, as well as any copies made pursuant to paragraph (c), above within seven (7) days of the termination of the agreement.
- d. Certain information available from the database and other records created by the contractor under this Contract are medical quality assurance records protected by 38 U.S.C. §5705; it's implementing regulations at 38 U.S.C. §§17.500-511; and VHA Directive 98-016,4.b.(1)(d), 4.6(2)(c) and 4.6(4). These records may be disclosed only as authorized by 38 U.S.C. §5705 and the VA regulations. Disclosure of these records in violation of §5705 is a criminal offense under 38 U.S.C. §5705(e).
- e. Contractor shall follow all VA policies regarding the retention of records. In the alternative, contractor may deliver the records to VA for retention.
- f. Any changes in the law or regulations governing the information covered by this contract during the term of this contract shall be deemed to be incorporated into this contract. Contractor shall educate its employees and subcontractors, if any, of the requirements of this section and shall advise its employees and subcontractors, if any, of

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any changes as they occur. On contractor's request, VA will provide trainers who can educate contractor's employees and subcontractors, if any, of their obligations under this section.

- g. Contractor shall make its internal policies and practices regarding the safeguarding of medical and/or electronic information available to federal agencies with enforcement authority over the maintenance of those records upon request.

XXVI. 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.

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- 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, any 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 CO and Lead COR.

XXVII. 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

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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 COR 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 CO and the Lead COR. The government reserves the right to conduct such an assessment using government personnel or another

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- 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:
 - i. Vendor must accept the system without the drive;
 - ii. 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
 - iii. VA must reimburse the company for media at a reasonable open market replacement cost at time of purchase.
 - i. 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;
 - j. 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
 - k. 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.

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- i. 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.

XXVIII. 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 COR 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.

XXIX. 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

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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:
 - i. Nature of the event (loss, theft, unauthorized access);
 - ii. Description of the event, including:
 - iii. date of occurrence;
 - iv. data elements involved, including any PII, such as full name, social security number, date of birth, home address, account number, disability code;
 - v. Number of individuals affected or potentially affected;
 - vi. Names of individuals or groups affected or potentially affected;
 - vii. 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;
 - viii. Amount of time the data has been out of VA control;
 - ix. The likelihood that the sensitive personal information will or has been compromised (made accessible to and usable by unauthorized persons);
 - x. Known misuses of data containing sensitive personal information, if any;
 - xi. Assessment of the potential harm to the affected individuals;
- d. Data breach analysis as outlined in 6500.2 Handbook, Management of Security and Privacy Incidents, as appropriate; and
- e. 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.
- f. 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 \$37.50 per affected individual to cover the cost of providing credit protection services to affected individuals consisting of the following:
 - i. Notification;
 - ii. One year of credit monitoring services consisting of automatic daily monitoring of at least 3 relevant credit bureau reports;
 - iii. Data breach analysis;
 - iv. Fraud resolution services, including writing dispute letters, initiating fraud alerts and credit freezes, to assist affected individuals to bring matters to resolution;
 - v. One year of identity theft insurance with \$20,000.00 coverage at \$0 deductible; and
 - vi. Necessary legal expenses the subjects may incur to repair falsified or damaged credit records, histories, or financial affairs.

XXX. SECURITY CONTROLS COMPLIANCE TESTING

- a. 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

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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.

XXXI. RECORDS MANAGEMENT

The following standard items relate to records generated in executing the contract:

- a. Citations to pertinent laws, codes and regulations such as 44 U.S.C chapters 21, 29,31 and 33; Freedom of Information Act (5 U.S.C. 552); Privacy Act (5 U.S.C. 552a); 26 CFR Part 1222 and Part 1228.
- b. Contractor shall treat all deliverables under the contract as the property of the U.S. Government for which the Government Agency shall have unlimited rights to use, dispose of , or disclose such data contained therein as it determines to be in the public interest.
- c. Contractor shall not create or maintain any records that are not specifically tied to or authorized by the contract using Government IT equipment and/or Government records.
- d. Contractor shall not retain, use, sell, or disseminate copies of any deliverable that contains information covered by the Privacy Act of 1974 or that which is generally protected by the Freedom of Information Act.
- e. Contractor shall not create or maintain any records containing any Government Agency records that are not specifically tied to or authorized by the contract.
- f. The Government Agency owns the rights to all the data/records produced as part of this contract.
- g. The Government Agency owns the rights to all electronic information (electronic data, electronic information systems, electronic databases, etc.) and all supporting documentation created as part of this contract. Contractor must deliver sufficient technical documentation with all data deliverables to permit the agency to use the data.
- h. Contractor agrees to comply with Federal and Agency records management policies, including those policies associated with the safeguarding of records covered by the Privacy Act of 1974. These policies include the preservation of all records created or received regardless of format [paper, electronic, etc] or mode of transmission [e-mail, fax, etc.] or state of completion [draft, final, etc.].

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- i. No disposition of documents will be allowed without the prior written consent of the Contracting Officer. The Agency and its contractors are responsible for preventing the alienation or unauthorized destruction of records, including all forms of mutilation. Willful and unlawful destruction, damage or alienation of Federal records is subject to fines and penalties imposed by 18 U.S.C. 2701. Records may not be removed from the legal custody of the Agency or destroyed without regard to the provisions of the agency records schedules.

- j. Contractor is required to obtain the Contracting Officer's approval prior to engaging in any contractual relationship (sub-contractor) in support of this contract requiring the disclosure of information, documentary material and/or records generated under, or relating to, this contract. The Contractor (and any sub-contractor) is required to abide by Government and Agency guidance for protecting sensitive and proprietary information.