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SECTION B - CONTINUATION OF SF 1449 BLOCKS

B.1 CONTRACT ADMINISTRATION DATA

1. Contract Administration: All contract administration matters will be handled by the following individuals:

a. CONTRACTOR:

b. GOVERNMENT: Contracting Officer 36C248 Moneque Rodriguez

Department of Veterans Affairs

Network Contracting Office 8 (NCO 8)

10,000 Bay Pines Blvd

Bay Pines FL 33744

2. CONTRACTOR REMITTANCE ADDRESS: All payments by the Government to the contractor will be made in accordance with:

☒ 52.232-33, Payment by Electronic Funds Transfer—System For Award Management, or

☐ 52.232-36, Payment by Third Party

3. INVOICES: Invoices shall be submitted in arrears:

a. Quarterly ☐

b. Semi-Annually ☐

c. Other ☒ Upon Delivery and Government Acceptance

4. GOVERNMENT INVOICE ADDRESS: All Invoices from the contractor shall be submitted electronically in accordance with VAAR Clause 852.232-72 Electronic Submission of Payment Requests.

ACKNOWLEDGMENT OF AMENDMENTS: The offeror acknowledges receipt of amendments to the Solicitation numbered and dated as follows:

AMENDMENT NO	DATE

B.2 STATEMENT OF WORK

Dated: September 08, 2026

TITLE: Chemistry Cost Per Reportable Result (CPRR) Agreement with Automation System

1. Purpose

This Statement of Work (SOW) defines the scope, objectives, deliverables, responsibilities, pricing structure, and implementation requirements for the provision of Chemistry Cost Per Reportable Result (CPRR) services, including an automation system, at the Bay Pines VA Healthcare System. Under the CPRR pricing methodology, the contractor shall provide the equipment, reagents, consumables, maintenance, service, and other required support specified in this SOW at the established price per reportable result.

The purpose of this fixed price indefinite delivery indefinite quantity (IDIQ) contract is to provide comprehensive chemistry laboratory testing services through a Cost Per Reportable Result (CPRR) pricing model that includes chemistry analyzers, automation systems, reagents, consumables, maintenance, middleware, interfaces, training, and operational support. The contract is intended to improve laboratory efficiency, standardize operational costs, enhance patient safety, reduce downtime, and support timely and accurate reporting of chemistry test results within the VA electronic health record environment.

2. Background

Bay Pines VA Healthcare System requires a fully integrated chemistry laboratory solution under a Cost Per Reportable Result (CPRR) pricing model. The solution shall be capable of interfacing with existing Veterans Health Administration (VHA) systems, laboratory analyzers, and associated clinical information systems.

The Chemistry CPRR solution, including the automation system, shall support:

- Automated chemistry laboratory result processing
- Instrument connectivity and interface management
- Workflow standardization
- Quality assurance and quality control tracking
- Data integrity and audit compliance

- Reduction in manual intervention and transcription errors
- Improved turnaround time for laboratory results
- Regulatory and VA policy compliance

The system will integrate into the existing VA information technology environment while maintaining cybersecurity, privacy, and interoperability standards.

3. Scope of Work

3.1 The Contractor shall provide all labor, supervision, materials, equipment, software, transportation, installation, configuration, validation, maintenance, and support required to provide a fully operational integrated chemistry and immunochemistry laboratory automation solution.

3.2 The solution shall include:

- Clinical Chemistry analyzers integrated with Immunochemistry analyzers
- Total Laboratory Automation (TLA) track system
- Middleware and data management systems
- Reagents, calibrators, controls, supplies, and consumables
- Hardware, software, and operating system support
- Installation and system validation
- Preventive maintenance and repair services
- End-user and administrator training
- Technical and applications support

3.3 All work shall comply with:

- Food and Drug Administration (FDA) requirements
 - College of American Pathologists (CAP) standards
 - Clinical Laboratory Improvement Act (CLIA) requirements
 - VA policies and cybersecurity requirements
 - Manufacturer specifications
 - Applicable Federal, State, and local regulations
-

4. Place of Performance

4.1. Services and equipment will be provided at the following locations:

- **C.W. Bill Young VA Medical Center (CWBYVAMC)**
10,000 Bay Pines Blvd
Bld.100 – Room 2B-110
Bay Pines, FL 33744

- **Lee County VA Healthcare Center (LCHCC)**

2489 Diplomat Parkway East

Room 1B-106

Cape Coral, FL 33909

NOTE: Additional performance locations may be added during the contract ordering period only through a bilateral contract modification executed by the Contracting Officer and the Contractor. Any such modification shall address, as applicable, changes to estimated quantities, CPRR unit pricing, equipment and automation requirements, implementation and transition requirements, and the IDIQ contract maximum. No additional location shall be added, and no performance at an additional location shall commence, without an executed bilateral contract modification.

5. REQUIRED TEST MENU (referred to as Attachment A):

Refer to Attachment A for a list of tests and estimated usage by the laboratory. Test menu requirement may be met by using alternate FDA approved reagents adapted to the proposed analytical solution for no more than 5 tests. Annual test volumes provided with this contract are based upon prior history and are not a guaranteed minimum. New tests within the scope of the contract may be added to the test menu. The Contractor shall provide all reagents and materials required for test validation, with associated costs included in the applicable CPRR unit price. Tests outside the existing scope or established pricing shall require a bilateral contract modification.

The Contractor shall perform specimen integrity checks/indices on all applicable specimens, with associated costs included in the CPRR unit price.

If, at any time during the contract period, the Contractor is unable to perform a test included in the contract and the Government is required to obtain that test from another source, the Contractor shall reimburse the Government for all additional costs incurred for the referral testing, including any associated processing and shipping costs.

Note: Volumes listed are estimated workload based on historical data and are not guaranteed minimums.

Note: All bolded and italicized are considered STAT (immediate) tests

CPRR / Assay Description	Combined Estimated Annual Quantity	Unit	CWBYVAMC Estimated Annual Volume	LCHCC Estimated Annual Volume
<i>Acetaminophen</i>	53	EA	53	0
Adrenocorticotrophic hormone (ACTH)	500	EA	500	0
<i>Albumin</i>	147,930	EA	122,817	25,113
<i>Alk Phos (ALP)</i>	146,097	EA	121,026	25,071
Alpha-1 Antitrypsin	746	EA	746	0
Alpha -2 Macroglobulin	100	EA	100	0
Alpha-fetoprotein	2,849	EA	2,849	0

ALT, Activated	158,678	EA	131,165	27,513
Amikacin	109	EA	109	0
Ammonia	881	EA	725	156
Amphetamines	21,678	EA	19,298	2,380
Amylase	1,675	EA	1,508	167
Anti-cyclic citrullinated peptide (Anti-CCP)	598	EA	598	0
Apolipoprotein A-1	150	EA	150	0
Apolipoprotein B	200	EA	200	0
AST, Activated	160,312	EA	130,332	29,980
Barbituates	21,678	EA	19,298	2,380
Benzodiazepines	21,678	EA	19,298	2,380
Beta2microglobulin	146	EA	146	0
B-HCG	2,571	EA	2,550	21
B-Hydroxyburate	2,405	EA	2,405	0
Bilirubin, Direct	2,965	EA	2,253	712
Bilirubin, Total	146,107	EA	121,040	25,067
NT-pro BNP	5,120	EA	4,740	380
BUN	196,081	EA	163,467	32,614
Buprenorphine	21,678	EA	19,298	2,380
C3	698	EA	698	0
C4	698	EA	698	0
CA 125	44	EA	44	0
CA 19-9	570	EA	570	0
Calcium	183,486	EA	153,496	29,990
Cannabinoids	21,678	EA	19,298	2,380
Carbamazepine	126	EA	111	15
CEA	420	EA	376	44
Ceruloplasmin	698	EA	698	0
Chloride	183,524	EA	153,445	30,079
Cholesterol	150,756	EA	80,232	70,524
CK-MB	163	EA	163	0
CO2	183,433	EA	153,452	29,981
Cocaine	21,678	EA	19,298	2,380
Cortisol	1,514	EA	1,279	235
Creatine Kinase (CK)	9,416	EA	8,890	526
Creatinine, Enzymatic	248,462	EA	176,929	71,533
CRP (including wrCRP and/or hsCRP)	8,106	EA	7,061	1,045
Cyclosporin	56	EA	56	0
Cystatin-C	14,876	EA	13,376	1,500
DHEA-S	121	EA	121	0
Digoxin	286	EA	286	0
Erythropoietin (EPO)	1,067	EA	1,067	0
Estradiol	1,436	EA	1,436	0
Ethanol (Blood)	6,096	EA	3,716	2,380
Ethanol (Urine)	21,679	EA	19,299	2,380
Fentanyl	21,679	EA	19,299	2,380
Ferritin	11,948	EA	9,676	2,272
Folate	12,277	EA	8,660	3,617
Follicle stimulating hormone	1,573	EA	1,194	379
Free PSA	1,900	EA	1,413	487

Free T3	1,031	EA	1,031	0
FreeT4	16,570	EA	14,196	2,374
Gentamicin	10	EA	10	0
GGT	1,227	EA	1,227	0
Glucose	184,316	EA	154,280	30,036
Haptoglobin	631	EA	631	0
HbA1C	59,684	EA	44,256	15,428
HDL	107,083	EA	80,199	26,884
Hep A antibody Total	2,667	EA	2,667	0
Hep A IgM	1,630	EA	1,630	0
Hep B core IgM	3,156	EA	3,156	0
Hep B core Total	3,112	EA	3,112	0
Hep B surface Antibody	3,449	EA	3,449	0
Hep B surface Antigen	3,661	EA	3,661	0
Hep B surface Antigen Confirmatory	55	EA	55	0
Hep C Antibody	7,832	EA	7,832	0
HIV (4th or 5th Generation)	7,335	EA	7,335	0
Homocysteine	230	EA	190	40
HSV-1 IgG	684	EA	684	0
HSV-2 IgG	684	EA	684	0
IgA	1,193	EA	1,127	66
IgG	880	EA	809	71
IgM	869	EA	801	68
Insulin	200	EA	200	0
Insulin like growth factor 1	240	EA	240	0
Phosphorus	10,362	EA	9,573	789
IPTH	5,031	EA	4,013	1,018
Iron	12,179	EA	10,107	2,072
UIBC	12,108	EA	10,106	2,002
Lactate	5,251	EA	5,161	90
LDH	1,029	EA	1,029	0
LDL, Direct	96,137	EA	80,036	16,101
Lipase	4,077	EA	3,892	185
Lipoprotein a	500	EA	500	0
Lithium	604	EA	498	106
Luteinizing hormone	1,567	EA	1,194	373
Magnesium	34,775	EA	31,436	3,339
Methadone	21,679	EA	19,299	2,380
Methotrexate	36	EA	36	0
Microalbumin	30,370	EA	24,471	5,899
Myoglobin	32	EA	32	0
Opiates	21,679	EA	19,299	2,380
Oxycodone	21,679	EA	19,299	2,380
Phenobarbital	11	EA	9	2
Phenytoin	86	EA	86	0
PO4	29,425	EA	28,295	1,130
Potassium	184,447	EA	154,293	30,154
Prealbumin	391	EA	364	27
Procalcitonin	6,339	EA	6,339	0
Progesterone	1,536	EA	1,536	0

Prolactin	1,373	EA	1,045	328
Protein (Blood & Urine)	153,847	EA	128,211	25,636
Protein (CSF)	1,923	EA	1,625	298
PSA free	1,080	EA	921	159
PSA	50,931	EA	41,549	9,382
Rheumatoid Factor	1,065	EA	1,033	32
Salicylate	1,630	EA	1,630	0
SARS-CoV-2 - IgG	120	EA	120	0
SARS-CoV-2S (spike)	120	EA	120	0
Sex Hormone Binding Globulin (SHBG)	491	EA	355	136
Sodium	185,592	EA	155,498	30,094
T3, Free	1,357	EA	1,031	326
T3, Total	1,162	EA	967	195
T4, Free	16,925	EA	14,196	2,729
T4, Total	15,392	EA	13,707	1,685
Tacrolimus	731	EA	731	0
Theophylline	15	EA	15	0
Thyroglobulin	382	EA	382	0
Thyroglobulin Ab	690	EA	690	0
Thyroid peroxidase Ab	549	EA	549	0
Tobramycin	24	EA	24	0
Testosterone, Free (Calculated)	6,484	EA	5,330	1,154
Testosterone, Total	6,557	EA	5,247	1,310
Tramadol	19,306	EA	16,363	2,943
Transferrin	12,203	EA	10,127	2,076
Triglyceride	51,185	EA	42,125	9,060
Troponin, High-Sensitivity	11,213	EA	11,188	25
TSH	77,780	EA	63,644	14,136
Uric Acid	15,780	EA	13,241	2,539
Valproic Acid	806	EA	686	120
Vancomycin	1,646	EA	1,646	0
Vitamin B12	47,146	EA	37,387	9,759
Vitamin D (25-OH)	52,579	EA	43,977	8,602

6. Requirements

6.1 General Requirements

- **The contractor is required to furnish all of the following to all locations defined within the contract (as a single price, CPRR):**
 - Instrumentation hardware and software to include but not limited to analyzers, automation track system, operating system, printers, monitor screens, Uninterruptible Power Supply (UPS), etc.
 - All Reagents, Calibrators, and Quality Control materials.
 - All consumables and user-defined replacement parts necessary to operate the contractor's equipment, including secondary, aliquot tubes.

- Upgrades to and maintenance of hardware and software necessary to fulfill the test requirements and allow for continuous operation.
- On- and Off-site training for end users and key operators.
- Delivery and installation of equipment at no additional charge as well as removal of test system and return shipping costs at end of contract.
- Equipment and assay installation and full validation of system hardware and software as well as assay performance studies (to include but not limited to assay correlations to existing instrumentation, carryover, linearity, dilution validation, precision, accuracy, reference range studies, and normal range studies).
- Complete system software verification, including initial rule build and validation, including but not limited to routing rules and auto-verification for the entire defined test menu. This applies to the initial test menu and any new assays added via modification of the contract throughout the life of the contract.
- Support for the modification to vendor-owned automation track system's software-with the addition of or modification to 3rd-party connections.
- Standard Operating Procedures (SOP) for all assays, maintenance tasks, and equipment operation shall be provided by the vendor.

6.2 CPRR pricing shall be based on the collective annual test volume for all testing locations (same price regardless of test location).

6.3 The VA Healthcare Network facilities will only pay for the patient test results reported to the patient's medical record. There shall be no minimum monthly charge.

6.4 CPRR shall be based on a tiered volume with additional savings as testing volume increases. Failure to adequately charge for estimated cost on volume as disclosed will not incur additional charges. Inflated reagent estimates if not consumed will not be charged.

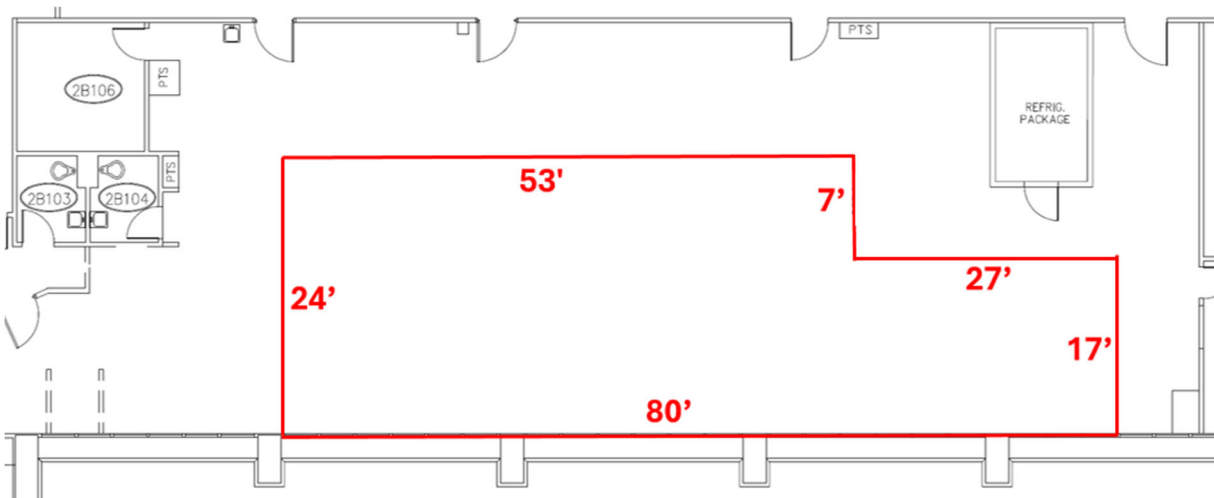
- Annual test volumes provided are based upon historical reported result data and are not guaranteed a minimum.
- New tests may be added as requested via contract modification as baseline cost per test (CPT) or reduced pricing on the cost per reportable result (CPRR) without instrumentation hardware and software or service costs added.
- All reagents for instrument verification and test method validation, per College of American Pathologists (CAP) and VA guidelines, are to be supplied by the contractor at no additional cost to the government.
- If at any time during the contract period, testing for the defined test menu is not available on this list, the Contractor shall provide, or reimburse the government, any additional costs associated with the procurement of another source of

satisfactory test performance (i.e. reference laboratory, alternate testing instrument, etc.).

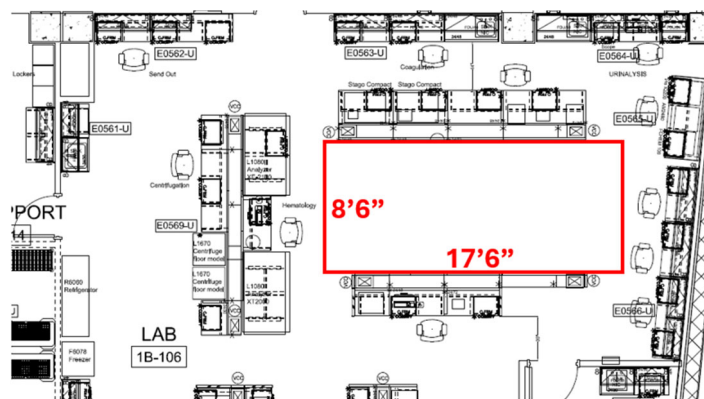
6.5 Space Allocations per Facility:

The proposed solution must fit within the allocated space using existing drains (all locations). The proposed automation solution shall be designed to support future expansion and integration without requiring significant modification to the laboratory footprint or core automation infrastructure.

- C.W. Bill Young VA Medical Center (allocated space must also include the Sysmex XN 9100 with 2- XN10, 2-XN20, 1-SP50, 1-BT50, and 1 DI60 TLA)



- Lee County VA Healthcare Center



7. Instrumentation Requirements

7.1 Integrated Chemistry-Immunochemistry System Requirements

- System shall have automation and front-loading capabilities.
- System shall prioritize automation. Site(s) with an automation line shall have both chemistry and immunoassay systems integrated and connected to the

automation line. Site(s) without an automation line shall have chemistry and immunoassay systems connected and integrated.

- Be space efficient and can be installed within the existing floor space square footage with proper egress for safety. The equipment proposed must accommodate workflow to ensure easy access to other parts/departments of the laboratory
 - Relocated equipment within the laboratory space must stay within the same room.
 - “Affixed equipment” means equipment affixed or anchored to real property or requiring dismantlement for relocation.
- Secondary or backup analyzer(s) provided must be manufactured by the same Contractor receiving the award and use(s) the same reagents and test methodology for each test performed to allow for standardized test builds.
 - Using third-party analyzer(s) to meet test menu requirements is not acceptable.
 - Using third-party equipment for automation is acceptable.
 - Third party open channel assay on contractors’ solution is acceptable.
- Contractor shall maintain an adequate replacement part inventory locally to minimize downtime associated with transporting parts to analyzer’s site. An adequate inventory would include parts that are known/could need to be changed frequently and should be kept either on-site or locally in a storage facility. Sufficient parts for routine maintenance to be kept onsite.
- If the integrated system requires a water system outside the Government-maintained water system, the Contractor to install and maintain an appropriately sized water system for the duration of the contract at the Contractor’s expense. The water system is to provide an acceptable quality and quantity of water to the analyzers according to the required specifications.
- Each analyzer should include an Uninterruptible Power Supply (UPS) with replacement when necessary.
- System shall be capable of handling primary tube sampling from collection tubes of various sizes and from various manufacturers.
- System shall be capable of sampling from tubes of various types, i.e. flat-bottom, round-bottom, sample cups, pour-off cups, false-bottom tubes, and tube inserts.
- System shall have ability to continuously load patient samples, reagents, quality control and/or calibrator materials during operation.
- System shall have ability to repeat and reflex test, auto-rerun and auto-dilute without user intervention.
- System shall have accurate capacity for monitoring reagent usage, maintain/store sufficient on-board supplies/reagents for 24 hours of patient testing on the combined platform, and provide reagent inventory upon request, in real time.

- System shall have RFID technology for rapid on-board reagent placement and tracking
- System shall have bidirectional interface capabilities.
- System shall have ability to perform serum indices, defined as the qualitative assessment of lipemia, icterus, and hemolysis.
- System shall have ability to detect fibrin or clots and short samples during sample aspiration.
- System shall have no requirement for sample pre-treatment.
- System shall have ability to generate Critical and/or abnormal result flags.
- System shall have ability to lock out/suppress reagent packs if there are QC failures.
- System shall have the capability to add/adapt commercially available reagents not produced by the Contractor.
- System shall have minimal carryover risk. Contract shall be responsible for completing carryover studies at installation and meeting CLIA guidelines for acceptable results.
- Calibration requirement frequency for all tests not to exceed once per 24 hours per instrument.
- Quality control testing requirement frequency for all tests not to exceed once per 24 hours per instrument.
- 95% of reagents shall be ready-to-use.

7.2 Chemistry Instrumentation Requirements

- Provide clinical chemistry analyzer(s) with sufficient capacity and throughput to meet the volume demands as defined in the Test Menu Attachment A – Volume Estimates and Individual Test Pricing.
Throughput criteria:
 - At CWBYVAMC: minimum of 1000 tests per hour per instrument
 - At LCHCC: minimum of 450 tests per hour per instrument
- Provide chemistry analyzers with standardized assay testing methodology to facilitate optimal workload distribution and backup capacities as specified in the equipment list.
- Shall have a minimum of 60 chemistry reagent test slots per instrument for CWY and 40 for Lee County.
- STAT Chemistry test results shall be available in 15 minutes from the time loaded on the analyzer to when results are available to maintain or improve current turn-around-time (TAT).

7.3 Immunochemistry Instrumentation Requirements

- Provide immunochemistry analyzer(s) with sufficient capacity and throughput to meet the volume demands as defined in the Test Menu (Attachment A – Volume Estimates and Individual Test Pricing).
Throughput criteria:

- At CWBYVAMC: minimum of 250 tests per hour per instrument
- At LCHCC: minimum of 100 tests per hour per instrument
- Provide immunochemistry analyzers with standardized assay testing methodology to facilitate optimal workload distribution and backup capacities as specified in the equipment list.
- Analyzer shall have ability to aspirate the sample and release the tube, so additional tests can be run without delays.
- Cardiac STAT immunoassay incubation times shall not to exceed 10 minutes to meet chest pain center accreditation requirements and maintain or improve current turnaround time (TAT).
- Routine immunoassay incubation times not to exceed 30 minutes to maintain or improve current TAT.
- Analyzer shall have proven solution to mitigate carryover.
- A Troponin test which meets the International Federation of Clinical Chemistry and Laboratory Medicine (IFCC) definition of high sensitivity.
- High/Ultra-sensitive reagent-based assay shall be utilized to alleviate interferences
- State carryover claim and design solutions to mitigate carryover.
- Analyzer shall have ability to duplicate repeat infectious disease testing without operator intervention.

7.4 Power for Chemistry and Immunochemistry Instrumentation

- Individual components require no more than 50 amps, 110V or 220V. It is acceptable for peripheral equipment such as the monitor, computer, and printer, to be plugged into separate outlets or UPS.
- Installed within the existing power capability that exists for each laboratory, regarding both emergency and normal power.

7.5 Automation Requirements:

- Must provide evidence that the proposed solution can meet the space requirements. The CWBYVAMC automation system shall include an FDA-cleared interface to the Sysmex-9100 system.
- Shall have capacity to add automation connectivity for future requirements during the term of the delivery order/s. Any additions will be negotiated and require the signature of the CO and delivery order/s contract holder.
- Shall have capability to establish a remote connection for the purpose of instrument troubleshooting, software updates, and generating test volumes for invoice purposes.
- System Manager — receives specimen and records time, directs the scheduling, routing, and tracking of specimen carriers on the conveyor system from loading to final disposition. The information system component of this automation system shall be able to communicate with Lab Information System (LIS) for ordering information to be sent from LIS to the

System manager and shall include but not be limited to: order code or name, tube type, accession number, container ID, and receipt date and time.

- Non-linear configuration of conveyor system for transportation of specimens to analyzers for optimal space utilization in lab and minimal disruption of current workflow and space. Pre/post analytical processors shall fit within currently allocated space.
- Sorter/Outlet station — sorts specimen tubes/aliquots into appropriate racks/targets based on the tests to be done (includes off-line instrument, reference lab or manual procedure by preselected rules) and archives specimens. Automated delivery and organization of specimens to outlet station based on bar-coded information.
- Refrigerator storage —
 - Minimum storage capacity of 20,000 specimens
 - Maximum heights not to exceed 95 inches
 - Support automated specimen disposal rules
 - Support specimens by defined criteria for disciplines not connected to the track, including specimens being sent to the reference laboratory.
- CWBYVAMC shall have a minimum of two (2) automation centrifuges capable of handling different tube sizes simultaneously and have adjustable time and RPM settings. Centrifuges shall have ability to produce sufficient separation of serum or plasma from its cellular constituents.
 - Process at least 350 tubes per hour
 - Automated placement of specimens into and removal from centrifuges with minimum loading and unloading times for maximum productivity.
- CWBYVAMC shall have an aliquoter for offline testing/sendouts.
- Ability to make barcode-labeled aliquot tubes that mirror the primary tube labeling for offline processing.
- Shall have the decapper/recapper/sealer system in an enclosed environment to prevent distribution of bio-hazardous aerosols.
- Decapper shall have the ability to remove different cap types, e.g. systems own caps, hemogard, screw caps, and rubber stoppers. This is necessary to maintain employee safety by reducing the exposure to body fluids and maintain workflow and turnaround time.
- Automation system shall have the ability to process 99% all of chemistry specimens, including whole blood and urine through the automation system.
- Contractor shall provide and install a suitable compressed air system sufficient for the automation system if needed.

7.6 System Data Management Requirements:

- A bi-directional bar-coded computer interface system compatible with the current VA LIS. The fully operational interface (both hardware and software) shall be immediately available for implementation to the VA computerized hospital information system CPRS/VistA.

- Capability to establish a remote connection for the purpose of instrument troubleshooting, reagent management, software updates, and delivering test volumes for invoice generation.
- Have ISA/MOU/ERA established with the VA OI&T (Office of Information and Technology) to allow for the implementation of remote diagnostics connectivity. All connectivity hardware and installation to be provided by the Contractor.
- Minimum of 25 thin client middleware licenses for Bay Pines VAHCS laboratories.
- Software management features with capability to prepare data for auto validation prior to host transmission.
- Sufficient data storage for 2 years of workload data and immediate access to more than 5,000 patient records per day, including instrument identification (houses PHI and PII).
- All equipment shall be compatible or have the ability to act as a pass-through to Data Innovations Instrument Manager (DI) for auto verification of patient results.
- Ability to manage rules for optimal specimen handling with ability to send automated comments to patient host records.
- Ability to perform repeat testing or add-on testing through Data Management system.
- Compatible with external Government Contractor software Unity Real Time Quality Control (QC) program.
- Updates to Data Management software are provided at no additional charge when they become available.
- Provide license(s) and hardware if needed for Data Innovations or other middleware at no additional charge to the VA.
- All software and software licenses, interfaces, and hardware (e.g. servers, printers, monitors, UPS, etc.) shall be included with cost of hardware required disclosed for removal if needed.
 - The contractor is responsible for complete system software verification, including initial rule build and validation, at installation and anytime new assays added via modification of contract throughout the life of the contract.
 - The contractor is responsible for assisting the Government with automation track operating system modifications (e.g. routing rules) when 3rd party connection is added/modified. The Government agrees to assume the cost of connection license for any Government-owned/contracted equipment at the Government's request.

7.7 Additional Requirements

- The contractor must provide all monitors (minimum 32") for the contractor's data management system/automation track system as applicable.
- The system shall include documents providing information on:
 - Electrical specifications
 - Water consumption specifications
 - Heat output specifications
 - Noise level specifications

- The system must have the ability to print patient test results / quality control results on a paper non-network connected printer in the event of a complete hospital network outage.
 - The contractor must provide all printers, including all components for printer functionality and printing (excluding paper)
 - The analyzer system must have the capability to produce a chartable patient report, including the following mandatory characteristics:
 - Facility Name
 - Facility Address
 - Facility Laboratory Medical Director
 - Laboratory CLIA Number
 - Test Result
 - Test Normal Reference Range
 - Test Unit of Measure
 - Test Critical Values / Flags

7.8 Upgrades / Replacement of Equipment within the TLA System

Request for upgrades or replacement hardware/software, due to workload increase, excessive instrumentation failures will be evaluated as needed or at least annually with communication to the Contractor for modification of the contract. A high incidence of such problems with any equipment/analyzer or assay within the test menu supplied may indicate probable non-compliance with the terms of this contract and will entitle the government to its replacement with other analyzer(s) that can produce the required criteria of this contract satisfactorily.

- “Downtime” is defined as any time the equipment is not available for patient testing due to malfunction, unacceptable quality control, software system errors, or hardware failures. This includes time used for end-user troubleshooting, conversations with technical support or on-site engineer repair/support.
- Standard acceptable performance for the life of the contract is defined as a period of 30 consecutive calendar days by operating in conformation with the contractor's technical specification without prolonged downtime (>4 hours) per instance more than 3 times within 30 days, or more than 10 instances of downtime (of any length of time) within 30 days. In the event the equipment or an assay does not meet the standard acceptable performance for 30 consecutive days, the Government will notify the contractor of the ongoing unacceptable performance, and the performance will be monitored for an addition 90 consecutive days. If after 120 calendar days from the initial date of unacceptability, the vendor does not resolve the performance concerns to meet the Government's expectations, the Government, through the Contracting Officer, may request a replacement of the equipment / assay or terminate the order upon mutual agreement.
- Removal of the existing instrument by the contractor shall be performed within 30 days following the acceptance of replacement equipment without additional charge to the government.

- Enhancements to the contractor's equipment shall be delivered to the government site and installed by the contractor within 60 days of their issuance or date of first commercial availability.
- The Contractor shall provide all upgrades to the equipment hardware and operating system software without additional charge to the Government.

7.9 Adding New Analyzers to the Total Lab Automation System

Additional laboratory equipment or analyzers may be connected to the Total Laboratory Automation (TLA) system through a bilateral contract modification. The modification shall establish, as applicable, any additional requirements, pricing, and implementation responsibilities. Following execution of the modification, the Contractor shall provide the technical support and application specialist(s) necessary for installation, connection, and validation of the additional equipment or analyzers.

Validation of the TLA system shall be performed in accordance with Government-defined guidelines and acceptance criteria. The Contracting Officer's Representative (COR) shall review all installation and validation documentation for technical acceptance.

Enhancements or upgrades to Contractor-provided equipment that are necessary to maintain the required functionality and performance of the TLA system shall be delivered and installed by the Contractor within 60 days. The costs of such enhancements or upgrades shall be included in the established CPRR pricing.

7.10 Adding New Assays to the Existing Analyzers

Additional assays may be added to the existing test menu through a bilateral contract modification. The modification shall establish, as applicable, any additional requirements, CPRR pricing, and implementation responsibilities. Following execution of the modification, the Contractor shall install and validate the assay in accordance with Section 6, General Requirements for a CPRR Contract. The assay shall be available for Government acceptance within 30 days after execution of the modification.

8. Installation/Implementation

8.1 PHASE-IN/PHASE OUT REQUIREMENT - Due to the time required to implement the requirements of this contract, including equipment installation, system integration, validation, training, and transition activities, a phase-in/phase-out period is required to ensure continuity of laboratory operations and prevent disruption to patient care.

8.2 Phase-in requirements: The implementation of the requirements described in this solicitation shall be completed no later than 180 days or based on the mutually agreed upon timeline by the Contractor and Government after award. This timeline

is based on a reasonable attempt of the Contractor to complete all of the necessary implementation requirements within the stated timeframe. Contractor shall not be penalized for implementation timelines that extend beyond the 120-day timeframe, if the extension is through no fault of the Contractor and is a result of delays due to the Government (i.e., construction/ remodeling of facilities). Upon award, the transition period for the awarded Contractor to have all equipment and peripherals installed and operational shall be 90 days from the date of award through 120 days or based on the mutually agreed-upon timeline by the Contractor and VA. This requirement includes the implementation of auto verification and the transmission of QC data to an external real-time QC service. During this same period, all initial training of VA personnel in the operation and maintenance of said award shall also be completed with exceptions due to delays at the fault of the Government.

- The new Contractor must be able to coordinate with the laboratory and install the new equipment while the current Contractor's equipment is still in operation in order to prevent any lapse of service for laboratory testing.
- At the end of 120 days from award of the Contract, the awarded Contractor has full and sole responsibility for services under the awarded delivery order/s.

8.3 Phase-out Requirements: During the phase-out period, the incumbent contractor shall be fully responsible for all work performed under this Statement of Work (SOW). Up to 180 calendar day phase out period may be required. The incumbent contractor shall cooperate fully to permit an orderly changeover of laboratory workload. The incumbent contractor shall allow the new contractor and government personnel access on a non-interference basis, to observe the day-to-day operations and to become familiar with the work requirements and procedures.

8.4 Within one week from the date of award, the CO, CORs and the Contractor will hold a kickoff meeting to discuss implementation.

8.5 Acceptance and Performance: This paragraph establishes a standard of quality performance that is to be met before any equipment listed on the delivery order/s is accepted by the Government. This also includes replacement, substitute machines and machines that are added or field modified after a system has demonstrated successful performance. The acceptance period begins on the installation date. Acceptance will occur once the analyzers/equipment have met the standard performance for a period of 30 consecutive calendar days by operating in conformance with the Contractor's technical specification or as proposed in the contract at an effectiveness level of 90% or more.

8.6 Start-Up Reagents: The Contractor provides all reagents, calibrators, controls, consumable items, disposable items, parts, accessories, and any other items included on the list of supplies defined in the contract and required to establish instruments for operation for performance of acceptance testing. The Contractor performs, to the satisfaction of the Government, all validation studies including precision, method comparison with current analyzer, accuracy (recovery), linearity

(reportable range), calibration verification, carryover studies, verification of reference interval, dilution validations, and determination of sensitivity and specificity at no cost to the Government.

- 8.7** In the event that equipment does not meet the standard of performance during the initial 30 consecutive calendar days, the standard of performance tests continues on a day-by-day basis until the standard of performance is met for a total of 30 consecutive days.
- 8.8** If the equipment fails to meet the standard of performance after 90 calendar days from the installation date, the Government may request a replacement or terminate the delivery order/s. (The Contractor will receive revenue for tests reported during the 90-day acceptance period.).
- 8.9** Operational use time for performance testing for a system is defined as the accumulated time during which the machine is in actual use. System failure downtime is the period of time when any analyzer in the system is inoperable due to equipment failure. Downtime for each incident starts from the time the Government makes a bona fide attempt to contact the Contractor's designated representative at the prearranged contact point until the system or analyzer(s) is returned to the Government in proper operating condition.
- 8.10** During the performance period for a system, a minimum of 100 hours of operational use time with productive or simulated work required begins as a basis for computation of the effectiveness level. However, in computing the effectiveness level, the actual number of operational use hours will be used when in excess of the minimum of 100 hours.
- 8.11** The Government will maintain daily records to satisfy the requirements of this paragraph and notifies the Contractor in writing of the date of the first day of the successful period of operation. Operations use time and downtime will be measured in hours and whole minutes.
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9. Service and Maintenance

Contractor provides equipment repair and preventative maintenance on all primary and back-up instrumentation and any incremental support equipment, e.g. water system, covered under the delivery order/s award, and UPS.

- 9.1 Maintenance plan:** Contractor provides manufacturer's daily, weekly, monthly, quarterly and periodic maintenance plan, outlining time required for hands on and automated tasks.
- 9.2 Support Services:** Contractor provides telephone assistance 24-hours/day, 365 days per year with a call back response of 1 hour. Following determination that

service is required, technical on-site support provided under the terms of the contract and provided for emergency repairs 365 days per year within twenty-four (24) hours of the time of notification of the malfunction for medical center lab(s) - CWBYVAMC lab. For Community Based Outpatient Clinic (CBOC) lab(s) – LCHCC lab, during normal operating hours, within twenty-four (24) hours of the time of notification of the malfunction. If both primary and backup analyzers are not able to perform a test listed as STAT, Contractor shall have defined, approved contingency plan(s) to ensure continuation of testing. Contractor provides maintenance (labor and parts) to keep the equipment in good operating condition and subject to security regulations. The Government will provide the Contractor access to the equipment to perform maintenance service according to the maintenance and service terms.

- 9.3 Incident/ Service Reports:** Contractor to furnish a malfunction report on the instrument upon completion of each repair call. The report includes, at a minimum, the following: (a) date and time notified; (b) date and time of arrival; (c) serial number, type and model number(s) of equipment; (d) time spent for repair; (e) description of malfunction and repair; and (f) proof of repair that includes documentation of quality control being performed and within range, as applicable. Contractor shall notify the lab supervisor/management if repair is significant enough to require calibration and/or validation following the repair. Contractor shall perform all calibration and/or validation as applicable for the instrument to be ready for patient testing.
- 9.4 Daily maintenance:** Instrumentation requires minimal hands-on daily maintenance.
- 9.5 Preventative Maintenance:** Contractor shall provide regular, scheduled maintenance coordinated with the lab supervisor/management to assure the continued reliable operation of the equipment. These preventive maintenance visits are of a frequency that conforms to the manufacturer's operation and maintenance instructions for the supported equipment.
- 9.6 Emergency Repair:** Emergency repairs to be performed after notification that the equipment is inoperative. Contractor shall provide the Government with a designated point of contact and shall make arrangements to enable its maintenance representative to receive such notification. Contractor shall perform emergency repair service within 24 hours of time of notification of the malfunction. Contractor shall provide all parts and labor needed to repair the malfunction. Travel, per diem and other expenses associated with the repair shall be borne by the Contractor.
- 9.7 Maintenance Support:** Service repair person locally based within the geographical area.

- 9.8 Maintenance Credit for Equipment Malfunction:** If a machine remains inoperative due to a malfunction through no fault or negligence of the Government for more than 24 hours, the Contractor shall be assessed damages at the rate of 1/30 of the preceding average three-month CPRR billings times the total number of days certified as downtime with each incident starts from the time the user makes a bona fide attempt to contact the Contractor's designated representative at the prearranged contact point until the machine is returned to good operating order less any non-contracted maintenance (emergency repairs) days.
- 9.9 Replacement of Laboratory Equipment:** During the contract period, should the repair record of any laboratory equipment reflect a downtime of 10% or more of the normal working days in one calendar month, a determination will be made by the representative of the Government to replace the initial laboratory equipment with new equipment. The responsibility of maintaining the equipment furnished in good condition shall be solely that of the Contractor.
- 9.10 Failure Mean Time Disclosure:** Contractor states the failure mean time (between failure and mean time to repair) for each piece of equipment offered. Contractor shall provide redundant systems to eliminate need of emergency backup equipment.
- 9.11 Upgrades or Replacement:** Request for instrumentation upgrades or replacement, due to workload increase, menu changes, technological upgrades, excessive instrumentation failures/malfunctions, breakdowns, or service calls, will be evaluated as needed/annually with communication to the Contractor for modification of the contract. A high incidence of problems with any equipment/analyzer supplied may indicate probable non-compliance with the terms of this contract and will entitle the facility/clinic to its replacement with another analyzer(s) that can produce the required criteria of this contract satisfactorily to the user. Removal of instrument by the Contractor performed within 60 days after request.
- 9.12 FDA Approved Instruments and Methods:** Only instruments which are FDA approved will be considered and shall be operational and interface with VA Laboratory Computer systems and upgrades. Test methods shall be FDA approved with limited recalls due to product failures. This shall be a "turn-key" system.
- 9.13 Operator Procedure Manuals:** One Operator's manual along with CLSI compliant procedures shall be furnished for each instrument model supplied per site.

10. Service and Technical Support

The Contractor shall provide full service on-site technical support for all vendor-owned equipment, including the automation track system, to keep the equipment in good operating condition and subject to security regulations.

On-Site Support Coverage:

- CWBYVAMC
 - Twenty-four (24) hours per day
 - Seven (7) days per week
 - Including Federal holidays
 - LCHCC
 - Monday through Friday
 - Eight (8) hours per day
 - 8:00 AM to 4:00 PM
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11. Requirements While Working at the Facilities

- The Contractor's employees approved by the COR will wear visible identification at all times while on the premises of the facilities within the NCO. Identification will include but not be limited to a company identification card, including the company name, employee name, title, and a photograph of the employee. Contractor employees will maintain a professional appearance commensurate to their industry.
- It is the responsibility of the Contractor to park in the appropriate designated parking areas. Information on parking is available from the VA Police Section. This will not invalidate or make reimbursement for parking violations of the Contractor under any conditions.
- Any interior or exterior doors that are unlocked to gain access are to be kept locked during the performance of work unless it results in the creation of a safety hazard. In those instances, the Contractor is responsible to take necessary actions to maintain the same level of security prior to gaining access/performing work. Should any other devices need to be unlocked like an entry gate, those devices will be locked immediately upon entry or exit. At no time will the Contractor allow any person into a locked area or loan keys/access cards to another person. Contractor may be held in default for failure to comply with this requirement and subject the Contractor and its employees to contractual and other legal remedies.
- Contractor personnel are required to check into the facility Police & Security office at each visit to pick up a "Contractor" badge prior to contacting the COR. The Contractor's staff will also be required to sign in and out each day at a designated location determined by the COR. Some sites may require contractor staff to register in a Contractor's system.
- Smoking is prohibited inside any buildings at the facilities.
- Possession of weapons is prohibited. Enclosed containers, including tool kits, are subject to search. Violations of VA regulations may result in citation answerable in the United States (Federal) District Court, not a local district, state, or municipal court.

- The Contractor will not allow his/her employees, including Subcontractors' employees, to open desk drawers, cabinets, or to use office equipment, including the use of non-pay telephones for any purpose other than a local emergency call. The Contractor is responsible to provide all necessary equipment, tools, parts, and materials to perform the work. The Government is not obligated to provide any equipment, tools, parts, and materials to assist the Contractor in performing the work.
- Contractor personnel will follow all local infection control measures.

12. Ownership of Equipment

Title to the equipment remains with the Contractor. All accessories (unused consumables, etc.) furnished by the Contractor will accompany the equipment when returned to the Contractor. The Contractor, upon expiration of order/s, at termination and/or replacement of equipment, will remove the equipment at the expense of the Contractor. The Contractor will disconnect the analyzer (gas, water, air, etc.) and will be responsible for all packing and shipping required to remove the analyzer. The hard drive will remain at the VA.

13. Equipment Removal

Following the expiration of this contract, the Contractor will remove all equipment within 30 days after notification of the completion of new Contractor's equipment installation including cross over studies and approval for use for patient testing.

14. DELIVERY, PERFORMANCE, INSPECTION AND ACCEPTANCE:

14.1 General:

- The Contractor is responsible for performing all inspections and tests necessary to substantiate that the equipment, supplies and services furnished under the contract conform to contract requirements. The Government has the right to test all services ordered under the contract at all times and places throughout the term of the contract Government testing and inspection will not unduly delay any Contractor work being performed nor will it create a defect in services covered by this contract.
- The Government reserves the right to thoroughly inspect and investigate the contractor and manufacturer business reputations and other qualifications, and to reject any bid, irrespective of price, that shall be administratively determined lacking in any of the essentials necessary to assure acceptable standards of performance.
- Returned goods: The Government is responsible for inspecting all products shipped hereunder and will give the Contractor written notice of rejection within thirty (30) calendar days following receipt or installation by the contractor.
- Standard and Acceptance of performance shall begin on the installation date. It shall end on the earlier date of when a certificate of acceptance has been signed or the equipment has met the standard of performance for a period of 30 consecutive calendar days by operating in conformation with the contractor's technical specification or as quoted in any contract at an effectiveness level of

90% or more. In the event the equipment does not meet the standard of performance during the initial 30 consecutive calendar days, the standard of performance test shall continue on a day-by-day basis until the standard of performance is met for a total of 30 consecutive days. If the equipment fails to meet the standard of performance after 90 calendar days from the installation date, the user may, at his/her option, request a replacement or terminate the order upon mutual agreement.

- Operational use time for performance testing for a system is defined as the accumulated time during which the machine is in actual use. System failure downtime is that period of time when any machine in the system is inoperable due to equipment failure. Downtime for each incident shall start from the time the Government makes a bona fide attempt to contact the contractor's designated representative at the prearranged contact point until the system or machine(s) is returned to the government in proper operating condition.
- During the performance period for a system, a minimum of 100 hours of operational use time with productive or simulated work will be required as a basis for computation of the effectiveness level. However, in computing the effectiveness level, the actual number of operational use hours shall be used when in excess of the minimum of 100 hours. The government shall maintain appropriate daily records to satisfy the requirements of this paragraph and shall notify the contractor in writing of the date of the first day of the successful performance period. Operations use time and downtime shall be measured in hours and whole minutes.
- Government's Responsibility: The user will perform daily and weekly routine operation maintenance and cleaning as required in the manufacturer's operation and maintenance instructions. The user shall maintain appropriate daily records to satisfy the requirements of this paragraph.

14.2 Equipment:

- The contractor is required to provide new state-of the art equipment. Previously used or discontinued models are not acceptable.
- Acceptance will normally be consummated upon delivery and, when applicable, installation and completion of personnel training.
- The Government reserves the right to request a ninety (90) day test and evaluation of all pieces of equipment prior to placing a delivery order under the contract. If the test and evaluation is not successful as determined by the CO and COR, the Government will not be required to continue with placing a delivery order under this contract, and no default or penalty will accrue.
- The contractor shall be responsible for installation, which consists of in-house delivery, positioning and mounting of all equipment listed on the delivery order and connections of all equipment and interconnecting wiring and cabling if applicable. Upon receipt of notice to proceed with installation, it shall be the contractor's responsibility to inform the Contracting Officer of any problems which may be anticipated in connection with installation or which will affect optimum performance once installation is completed. In the event that progress of the installation is interrupted through no fault of the contractor, the

continuous installation referenced in the preceding paragraphs may be terminated until such time as the cause of delay has been eliminated, and then shall be resumed within 24 hours after the contractor has been notified that work may again proceed.

- Upon completion of installation the equipment will be turned over to the hospital for use. Final acceptance of the equipment and installation will be based upon an inspection and test to be performed within ten (10) calendar days from date of installation. If equipment passes inspection or if acceptance inspection is not conducted within ten (10) calendar days from installation, the Government shall accept installation with guarantee date commencing ten calendar days after installation.
- The contractor will provide all operational upgrades to the equipment hardware and operating system software that materially affects the performance of the equipment, without additional charge to the government. These enhancements to the contractor's equipment shall be delivered to the government site and installed by the contractor within 60 days of their issuance or date of first commercial availability.

14.3 Reagents/Supplies/Consumables:

- The Government shall require the delivery of reagents/supplies/consumables for all services required under this contract. The Contractor shall deliver reagents/supplies/consumables, shipping cost included, as needed.
- The Contractor will assure that all reagents/supplies/consumables provided/ordered for use on their equipment will be of the quality necessary to produce a quality result. The reagent quality must be high enough to satisfy proficiency testing standards of the College of American Pathologists (CAP) and The Joint Commission.
- In the event that the reagents/supplies/consumables are found to be defective and unsuitable for use with the contractor's equipment or the Contractor has failed to comply with the requirements herein, the Contractor is required to deliver the supplies within 24 hours of receipt of the verbal order for priority delivery from the government activity. This will be done at no cost to the Government and in sufficient quantity as required to allow operation of the Contractor's equipment for one week (under normal government test load volume).
- The Contractor is required to provide a continuously stocked inventory of reagents, calibrators, troubleshooting controls, required consumable supplies including all routinely replaced parts, disposables and any other materials required to properly perform tests on the equipment. Unexpected changes in methodology or technology will be at the expense of the Contractor. The Government representative will request reagents, supplies, and consumables per the contract to ensure that each site is furnished with sufficient consumable supplies to produce a volume of tests for that month. Separate deliveries of products will be shipped to each testing site, as applicable. Failure to reserve / ship adequate inventory as requested will result in default by the Contractor.

- Alert and Notification of all technical advisory recalls and/or alerts, prior to or simultaneously with field alerts should be forwarded to Contracting Officer Representative (COR), Laboratory Supervisor and the Laboratory Manager.
 - If additional requests for emergency supply delivery are required by the Government, the Contractor shall honor them until the arrival of the routine supplies are delivered.
 - All deliveries (routine and emergent) of reagents, supplies, consumables must be delivered directly to the laboratory at the expense of the Contractor.
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15. TRAINING:

15.1 Key-operator Training Program: The contractor, without additional charge to the Government, shall provide training off-site for at least one (1) key operator per instrument module installed, one (1) training slot for middleware training, and at least two (2) key operators for the automation track system at the time of installation of the Contractor's equipment. In addition, the Contractor shall provide supplemental operating training to (2) two government personnel, without additional charge to the government, upon installation of an upgrade in equipment hardware or operating system software connected with the operation of an instrument already furnished. The Contractor shall also provide two (2) additional off-site training slots per year throughout the life of the contract.

15.2 Training of Operating Personnel: The contractor shall provide the services of a qualified technical person for each lab site, at the time of equipment installation and at such time designated by Contracting Officer (CO) or Contracting Officer's Representative (COR) to on-site orientation and training to designated personnel in: operation and care of equipment; techniques and procedures recommended by manufacturer to achieve maximum dependable, efficient, and economical utilization of equipment. This training shall include actual demonstration and operation of the equipment including any adjustments or other actions which may be undertaken by operating personnel in the event of failure of equipment, provided that such adjustment or action will in no way jeopardize the Government's rights under contract guarantee clause. This training shall include at least (2) two-day at CWBYVAMC and at least (1) one-day at LCHCC, on-site all-day training session, upon installation and acceptance of equipment and later, for refresher training.

16. REGULATORY REQUIREMENTS: If the product(s) included in this solicitation are considered medical devices by the US Food and Drug Administration, the manufacturer shall be in compliance with the Food, Drug and Cosmetic Act, as amended, and regulations promulgated there under.

17. TECHNICAL INDUSTRY STANDARDS: The Contractor certifies that all applicable equipment offered under this contract shall conform to all common industry standards.

18. MANUFACTURED PRODUCTS: Materials furnished shall be of the current productions of manufacturers regularly engaged in manufacture of such items. Approval by Contracting Officer is required of deviation from products and manufacturers as shown in the schedule of items. Shelf-life of all consumables shall be at least ONE YEAR from shipping date unless FDA requires different expiration date.

19. REFERENCE SPECIFICATIONS AND PUBLICATIONS: Where an item is required to conform to certain requirements, conformance shall be evidenced by seal, label, stamp, or approval listing from such agency, or by a certified test report from an independent testing laboratory acceptable to the Government, that the item has been tested and conforms to requirements of referenced agency.

20. RECALLS: If at any time during the term of the contract, the FDA or the Contractor, or subcontractor initiates an item recall or FDA withdraws its approval to manufacture an item, the contractor will issue a notice to indicate the complete item description and identification of the recall with necessary instructions for return for credit or replacement.

21. CONTRACT ADMINISTRATION DATA: The Contracting Officer is the only person authorized to approve changes or modify any of the requirements under this contract. The Contractor shall communicate with the Contracting Officer on all matters pertaining to contract administration. Only the Contracting Officer is authorized to make commitments or issue changes, which will 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 to have been made without authority and no adjustment will be made in contract price to cover any increase in costs incurred as a result thereof.

22. RECORDS MANAGEMENT OBLIGATIONS

22.1 Applicability: This clause applies to all Contractors whose employees create, work with, or otherwise handle Federal records, as defined in Section B, regardless of the medium in which the record exists.

22.2 Definitions:

- “Federal record” as defined in 44 U.S.C. § 3301, includes all recorded information, regardless of form or characteristics, made or received by a Federal agency under Federal law or in connection with the transaction of public business and preserved or appropriate for preservation by that agency or its legitimate successor as evidence of the organization, functions, policies, decisions, procedures, operations, or other activities of the United States Government or because of the informational value of data in them.
- The term Federal record:
 - includes the Hospital Network records.
 - does not include personal materials.
 - applies to records created, received, or maintained by Contractors pursuant to their network contract.
 - may include deliverables and documentation associated with deliverables.

22.3 Requirements:

- Contractor shall comply with all applicable records management laws and regulations, as well as National Archives and Records Administration (NARA) records policies, including but not limited to the Federal Records Act (44 U.S.C. chs. 21, 29, 31, 33), NARA regulations at 36 CFR Chapter XII Subchapter B, and those policies associated with the safeguarding of records covered by the Privacy Act of 1974 (5 U.S.C. 552a). These policies include the preservation of all records, regardless of form or characteristics, mode of transmission, or state of completion.
- In accordance with 36 CFR 1222.32, all data created for Government use and delivered to, or falling under the legal control of, the Government are Federal records subject to the provisions of 44 U.S.C. chapters 21, 29, 31, and 33, the Freedom of Information Act (FOIA) (5 U.S.C. 552), as amended, and the Privacy Act of 1974 (5 U.S.C. 552a), as amended and must be managed and scheduled for disposition only as permitted by statute or regulation.
- In accordance with 36 CFR 1222.32, Contractor shall maintain all records created for Government use or created in the course of performing the contract and/or delivered to, or under the legal control of the Government and must be managed in accordance with Federal law. Electronic records and associated metadata must be accompanied by sufficient technical documentation to permit understanding and use of the records and data.
- The Hospital Network and its contractors are responsible for preventing the alienation or unauthorized destruction of records, including all forms of mutilation. Records may not be removed from the legal custody of the Hospital Network or destroyed except for in accordance with the provisions of the agency records schedules and with the written concurrence of the Head of the Contracting Activity. Willful and unlawful destruction, damage or alienation of Federal records is subject to the fines and penalties imposed by 18 U.S.C. 2701. In the event of any unlawful or accidental removal, defacing, alteration, or destruction of records, Contractor must report to the Hospital Network. The agency must report promptly to NARA in accordance with 36 CFR 1230.
- The Contractor shall immediately notify the appropriate Contracting Officer upon discovery of any inadvertent or unauthorized disclosures of information, data, documentary materials, records or equipment. Disclosure of non-public information is limited to authorized personnel with a need-to-know as described in the contract. The Contractor shall ensure that the appropriate personnel, administrative, technical, and physical safeguards are established to ensure the security and confidentiality of this information, data, documentary material, records and/or equipment is properly protected. The Contractor shall not remove material from Government facilities or systems, or facilities or systems operated or maintained on the Government's behalf, without the express written permission of the Head of the Contracting Activity. When information, data, documentary material, records and/or equipment is no longer required, it shall be returned to the Hospital Network control or the Contractor must hold it until otherwise directed. Items returned to the Government shall be hand carried, mailed, emailed, or securely electronically transmitted to the Contracting Officer or address prescribed in the contract.

Destruction of records is EXPRESSLY PROHIBITED unless in accordance with Paragraph (4).

- The 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, contracts. The Contractor (and any sub-contractor) is required to abide by Government and the Hospital Network guidance for protecting sensitive, proprietary information, classified, and controlled unclassified information.
- The Contractor shall only use Government IT equipment for purposes specifically tied to or authorized by the contract and in accordance with the Hospital Network policy.
- The Contractor shall not create or maintain any records containing any non-public the Hospital Network information that are not specifically tied to or authorized by the contract.
- The 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 from public disclosure by an exemption to the Freedom of Information Act.
- The Hospital Network owns the rights to all data and records produced as part of this contract. All deliverables under the contract are the property of the U.S. Government for which the Hospital Network shall have unlimited rights to use, dispose of, or disclose such data contained therein as it determines to be in the public interest. Any Contractor rights in the data or deliverables must be identified as required by FAR 52.227-11 through FAR 52.227-20.
- Training. All Contractor employees assigned to this contract who create, work with, or otherwise handle records are required to take [Agency]-provided records management training. The Contractor is responsible for confirming training has been completed according to agency policies, including initial training and any annual or refresher training.

[Note: To the extent an agency requires contractors to complete records management training, the agency must provide the training to the contractor.]

23. VA INFORMATION AND INFORMATION SYSTEM SECURITY/PRIVACY LANGUAGE

23.1 Access To Va Information and VA Information Systems:

- 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.
- 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.
- 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.

- 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.
- Contractor Personnel Security Requirements:
All contractor employees who require access to the Department of Veterans Affairs' computer systems shall be the subject of a background investigation and must receive a favorable adjudication from the VA Office of Security and Law Enforcement prior to contract performance. This requirement is applicable to all subcontractor personnel requiring the same access. If the investigation is not completed prior to the start date of the contract the contractor will be responsible for the actions of those individuals that provide or perform work for the VA.

Position Sensitivity – The position sensitivity has been designated as (low) risk.

Background Investigation – The level of background investigation commensurate with the required level of access is National Agency Check (NACI) with written inquiries.

Contractor Responsibilities:

- The contractor shall bear the expense of obtaining background investigations. If the investigation is conducted by the Office of Personnel Management (OPM), the contractor shall reimburse the VA within 30 days. The web site which provides information on the cost of the security investigation is: www.opm.gov/extra/investigate – Select Federal Investigations Notices (FIN 01-01)
The contractor shall prescreen all personnel requiring access to the computer systems to ensure they maintain a U.S. citizenship and are able to read, write, speak, and understand the English language.
- The contractor will provide to the Contracting Officer prior to award the following: (1) List of names of contract personnel. (2) Social security numbers of contractor personnel. (3) Home address of contractor personnel or the contractor address. The Contracting Officer will submit the above information to the Office of Security and Law Enforcement, Washington, D.C. The Office of Security and Law Enforcement will provide the necessary investigative forms (these forms are indicated in paragraph 3.d. below) to the contractor's personnel, coordinate the background investigations with OPM and notify the Contracting Officer and contractor of the results of the investigation.
- The contractor shall submit or have their employees submit the following required forms to the VA Office of Security and Law Enforcement within 30 days of receipt:

- ✓ Standard Form 85P, Questionnaire for Public Trust Positions
- ✓ Standard Form 85P-S, Supplemental Questionnaire for Selected Positions
- ✓ FD 258, U.S. Department of Justice Fingerprint Applicant Chart
- ✓ VA Form 0710, Authority for Release of Information Form
- ✓ Optional Form 306, Declaration for Federal Employment
- ✓ Optional Form 612, Optional Application for Federal Employment
- The contractor, when notified of an unfavorable determination by the Government, shall withdraw the employee from consideration from working under the contract.
- Failure to comply with the contractor personnel security requirements may result in termination of the contract for default.

23.2 VA Information Custodial Language:

- 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).
- 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.
- 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.
- 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.

- 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.
- 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.
- If a VHA contract is terminated for cause, the associated BAA must also be terminated and appropriate actions taken in accordance with VHA Handbook 1600.1, Business Associate Agreements. Absent an agreement to use or disclose protected health information, there is no business associate relationship.
- 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.
- 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.
- 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.
- 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.
- 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 COR.

23.3 Security Incident Investigation:

- 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.
- 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.
- 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.
- 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.

23.4 Liquidated Damages for Data Breach:

- 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. However, it is the policy of the VA to forego collection of liquidated damages in the event the contractor provides payment of actual damages in an amount determined to be adequate by the agency.
- 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.

- Each risk analysis shall address all relevant information concerning the data breach, including the following:
 - Nature of the event (loss, theft, unauthorized access);
 - Description of the event, including:
 - 23.4...1 date of occurrence;
 - 23.4...2 (b)data elements involved, including any PII, such as full name, social security number, date of birth, home address, account number, disability code;
 - Number of individuals affected or potentially affected;
 - Names of individuals or groups affected or potentially affected;
 - 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;
 - Amount of time the data has been out of VA control;
 - The likelihood that the sensitive personal information will or has been compromised (made accessible to and usable by unauthorized persons);
 - Known misuses of data containing sensitive personal information, if any;
 - Assessment of the potential harm to the affected individuals;
 - Data breach analysis as outlined in 6500.2 Handbook, Management of Security and Privacy Incidents, as appropriate; and
 - 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.
- 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 for affected individual to cover the cost of providing credit protection services to affected individuals consisting of the following:
 - Notification;
 - One year of credit monitoring services consisting of automatic daily monitoring of at least 3 relevant credit bureau reports;
 - Data breach analysis;
 - Fraud resolution services, including writing dispute letters, initiating fraud alerts and credit freezes, to assist affected individuals to bring matters to resolution;
 - One year of identity theft insurance with \$20,000.00 coverage at \$0 deductible; and
 - Necessary legal expenses the subjects may incur to repair falsified or damaged credit records, histories, or financial affairs.

23.5 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-days' 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.

23.6 Training:

- All contractor employees and subcontractor employees requiring access to VA information and VA information systems shall complete VA Privacy and Information Security Awareness and Rules of Behavior Training and Privacy and HIPAA Training and HIPAA Training before being granted access to VA information and its systems.
 - Sign and acknowledge (either manually or electronically) understanding of and responsibilities for compliance with the Rules of Behavior before being granted access to VA information and its systems.
- The contractor shall provide to the contracting officer and/or the COR a copy of the training certificates and certification of signing the Rules of Behavior for each applicable employee within 1 week of the initiation of the contract and annually thereafter, as required.
- 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.

The Certification and Accreditation (C&A) requirements do not apply and a Security Accreditation Package is not required for this SOW.

***** IF APPLICABLE*****

23.7 Information System Design and Development

- 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 COR, and approved by the VA Privacy Service in accordance with Directive 6507, VA Privacy Impact Assessment.
- The contractor/subcontractor shall certify to the COR 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.

- 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.
- Applications designed for normal end users shall run in the standard user context without elevated system administration privileges.
- 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.
- 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.
- The contractor/subcontractor agrees to:
 - 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:
 - 23.7...1 The Systems of Records (SOR); and
 - 23.7...2 The design, development, or operation work that the contractor/subcontractor is to perform;
 - 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
 - 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.
- 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.

- “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.
 - “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.
 - “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.
- 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.
 - 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.
 - 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.
 - 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.

23.8 Information System Hosting, Operation, Maintenance, or Use

- 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 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.

- 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.
- 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.
- 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.
- The contractor/subcontractor must conduct an annual self-assessment on all systems and outsourced services as required. Both hard copies and electronic copies of the assessment must be provided to the COR. 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.

- 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.
 - 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.
 - 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:
 - Vendor must accept the system without the drive;
 - 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
 - VA must reimburse the company for media at a reasonable open market replacement cost at time of purchase.
 - 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;
- 23.8...1 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
- 23.8...2 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.
- 23.8...3 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.

All Contractor, Pharmaceutical Company Representative (PCR), and Healthcare Industry Representatives (HIR) will coordinate with Contracting Officer Representative for instructions, so they are in compliance with the Hospital policies listed on the facility Document Management Center share point site:

HPM NO. 90-25; HEALTHCARE VENDOR ACCESS AND COMPETENCY
 HPM NO. 132-04; SECURITY MANAGEMENT PROGRAM
 HPM NO. 132 05; HOSPITAL IDENTIFICATION PROGRAM
 HPM NO. 11-91; PHARMACEUTICAL COMPANY REPRESENTATIVES

- HIR are required to report to MSDU (Room GC-003), immediately after entering the facility. HIR will be required to sign into the monitoring system and print a badge for proper identification. . The Healthcare Industry Representatives for Nutrition and Food Services, Office of Information and Technology, and Social Work Services are included in this policy; vendors (HIR) for Pharmacy Services are to follow (HPM 11-91) policy. HIR must be sponsored by a physician, a Service Chief, or their designee, for a specified date and a specified case. HIR are not permitted in patient care areas or clinics unless a prior appointment has been made.
- Pharmaceutical Company Representative (PCR) refers to anyone acting on behalf of a pharmaceutical company or its business partners for the purpose of promoting the use of items managed under the VA formulary process. These items primarily include drugs, but to a lesser extent also include any medical supplies, nutritional supplements, and similar commodities managed under the VA formulary process.
- Sign-In: PCRs may visit VA Medical care facilities no earlier than 8:00 a.m. and stay no later than 3:30 p.m., Monday through Friday, unless they receive prior approval from both the Chief of the Service that they will be visiting and the Chief of Pharmacy. Representatives visiting the Facility must sign in at the Pharmacy Administrative Office (Located in Trailer 78) and wear a visitor's badge as well as their company's personal name badge while in the hospital.
- Vendors: Reference Hospital Memorandum Policy Number 90-25 Healthcare Vendor Access and Competency.
- Contractors and/or project managers: Will be issued a PIV/ID badge in accordance with the facility PIV Policy. Contractors will contact their assigned VA Contracting Officer Representative (COR) for coordination.
- Contract Personnel/Sub-Contractors: Contractors are responsible for the daily accountability and identification of all personnel assigned to their respective contract including sub-contractors. Contractors will identify personnel using the following procedures as appropriate.
- Construction Project contract personnel will report to the contractor for issuance of a temporary self-adhesive identification badge. This badge will be issued on a daily basis and must include the following information: Company name, project number, date and name of individual. Contractor will maintain a daily log of all personnel.

- Contract personnel not involved in an actual construction project will report to police dispatch for issuance of a numbered badge. A driver's license or photo ID will be required each day upon entering the facility, in exchange for the badge, and will be given back once the badge is returned to police dispatch. The contractor will provide Police Service with a list of names for all sub-contract personnel requiring access to the facility. It is the responsibility of the contractor to update the list as necessary.
- NPR OPC; CBOCs and Off-site Lease facilities with VA Police staffing: As above with check-in with VA Police.
- Off-site Lease facilities w/o VA Police staffing: Coordinate with COR, Administrative Officer, or Service Point of Contact.

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.

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.

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.

(END OF CLAUSE)

B.3 PRICE/COST SCHEDULE

The guaranteed minimum amount for this Indefinite-Delivery, Indefinite-Quantity (IDIQ) contract is **\$10,000.00**. The Government's obligation under this contract is limited to the guaranteed minimum amount. The maximum aggregate value of all orders issued under this contract shall not exceed **\$45,000,000.00**.

The Government does not guarantee that orders will be placed in excess of the guaranteed minimum amount. Any quantities identified in the Schedule are estimates only, provided for solicitation and planning purposes, and are based on historical usage. These estimates do not represent a guarantee that the Government will order any specific quantity beyond the guaranteed minimum. Actual ordering requirements will depend on the Government's bona fide needs during the period of performance.

ITEM INFORMATION

ITEM NUMBER	DESCRIPTION OF SUPPLIES/SERVICES	ESTIMATED QUANTITY	UNIT	UNIT PRICE	AMOUNT
0001	Clinical Chemistry and Immunochemistry Cost-Per-Reportable-Result Contract Period: Base POP Begin: 10-01-2026 POP End: 09-30-2027 PRINCIPAL NAICS CODE: 334516 - Analytical Laboratory Instrument Manufacturing PRODUCT/SERVICE CODE: 6640 - Laboratory Equipment and Supplies MANUFACTURER PART NUMBER (MPN): TBD *Period of Performance is dependent upon the date of award. Pricing Period 1. See Reagents attachment in Section D.	1.00	EA		
1001	Clinical Chemistry and Immunochemistry Cost-Per-Reportable-Result Contract Period: Base POP Begin: 10-01-2027 POP End: 09-30-2028 PRINCIPAL NAICS CODE: 334516 - Analytical Laboratory Instrument Manufacturing PRODUCT/SERVICE CODE: 6640 - Laboratory Equipment and Supplies MANUFACTURER PART NUMBER (MPN): TBD *Period of Performance is dependent upon the date of award. Pricing Period 2.	1.00	EA		

2001	1.00 EA	Clinical Chemistry and Immunochemistry Cost-Per-Reportable-Result Contract Period: Base POP Begin: 10-01-2028 POP End: 09-30-2029 PRINCIPAL NAICS CODE: 334516 - Analytical Laboratory Instrument Manufacturing PRODUCT/SERVICE CODE: 6640 - Laboratory Equipment and Supplies MANUFACTURER PART NUMBER (MPN): TBD *Period of Performance is dependent upon the date of award. Pricing Period 3.
3001	1.00 EA	Clinical Chemistry and Immunochemistry Cost-Per-Reportable-Result Contract Period: Base POP Begin: 10-01-2029 POP End: 09-30-2030 PRINCIPAL NAICS CODE: 334516 - Analytical Laboratory Instrument Manufacturing PRODUCT/SERVICE CODE: 6640 - Laboratory Equipment and Supplies MANUFACTURER PART NUMBER (MPN): TBD *Period of Performance is dependent upon the date of award. Pricing Period 4.
4001	1.00 EA	Clinical Chemistry and Immunochemistry Cost-Per-Reportable-Result Contract Period: Base POP Begin: 10-01-2030 POP End: 09-30-2031 PRINCIPAL NAICS CODE: 334516 - Analytical Laboratory Instrument Manufacturing PRODUCT/SERVICE CODE: 6640 - Laboratory Equipment and Supplies MANUFACTURER PART NUMBER (MPN): TBD *Period of Performance is dependent upon the date of award. Pricing Period 5.
GRAND TOTAL		

B.4 DELIVERY SCHEDULE

ITEM NUMBER	SHIPPING INFORMATION	QUANTITY	DELIVERY DATE
0001	SHIP TO: Department of Veterans Affairs 10000 Bay Pines Blvd Building 100 2nd Floor Lab Bay Pines, FL 33744 United States MARK FOR: Taffy White 727 398-6661,X 14681 Taffy.White@va.gov FOB: DESTINATION	1.00	To Be Determined based on PoP.
1001	SHIP TO: Department of Veterans Affairs 10000 Bay Pines Blvd Building 100 2nd Floor Lab Bay Pines, FL 33744 United States MARK FOR: Taffy White 727 398-6661,X 14681 Taffy.White@va.gov FOB: DESTINATION	1.00	To Be Determined based on PoP.
2001	SHIP TO: Department of Veterans Affairs 10000 Bay Pines Blvd Building 100 2nd Floor Lab Bay Pines, FL 33744 United States MARK FOR: Taffy White 727 398-6661,X 14681 Taffy.White@va.gov FOB: DESTINATION	1.00	To Be Determined based on PoP.
3001	SHIP TO: Department of Veterans Affairs 10000 Bay Pines Blvd Building 100 2nd Floor Lab Bay Pines, FL 33744 United States	1.00	To Be Determined based on PoP.

4001

MARK FOR: Taffy White
727 398-6661,X 14681
Taffy.White@va.gov

FOB: DESTINATION

SHIP TO: Department of Veterans
Affairs
10000 Bay Pines Blvd
Building 100 2nd Floor Lab
Bay Pines, FL 33744
United States

1.00 To Be
Determined
based on PoP.

MARK FOR: Taffy White
727 398-6661,X 14681
Taffy.White@va.gov

FOB: DESTINATION

SECTION C - CONTRACT CLAUSES

C.1 52.212-4 CONTRACT TERMS AND CONDITIONS—COMMERCIAL PRODUCTS AND COMMERCIAL SERVICES (OCT 2025) (DEVIATION)

(a) *Definitions.* The clause at Federal Acquisition Regulation (FAR) 52.202-1, Definitions, is incorporated by reference.

(b) *Inspection/Acceptance.* The Contractor shall only tender for acceptance those items that conform to the requirements of this contract. The Government reserves the right to inspect or test any supplies or services that have been tendered for acceptance. The Government may require repair or replacement of nonconforming supplies or reperformance of nonconforming services at no increase in contract price. If repair/replacement or reperformance will not correct the defects or is not possible, the Government may seek an equitable price reduction or adequate consideration for acceptance of nonconforming supplies or services. The Government must exercise its post acceptance rights—

(1) Within a reasonable time after the defect was discovered or should have been discovered; and

(2) Before any substantial change occurs in the condition of the item, unless the change is due to the defect in the item.

(c) *Assignment.* The Contractor or its assignee may assign its rights to receive payment due as a result of performance of this contract to a bank, trust company, or other financing institution, including any Federal lending agency in accordance with the Assignment of Claims Act (31 U.S.C. 3727). However, when a third party makes payment (e.g., use of the Governmentwide commercial purchase card), the Contractor may not assign its rights to receive payment under this contract.

(d) *Changes.* Changes in the terms and conditions of this contract may be made only by written agreement of the parties.

(e) *Disputes.* This contract is subject to 41 U.S.C. chapter 71, Contract Disputes. Failure of the parties to this contract to reach agreement on any request for equitable adjustment, claim, appeal or action arising under or relating to this contract shall be a dispute to be resolved in accordance with the clause FAR 52.233-1, Disputes, which is incorporated in this contract by reference. The Contractor shall proceed diligently with performance of this contract, pending final resolution of any dispute arising under the contract.

(f) *Excusable delays.* The Contractor shall be liable for default unless nonperformance is caused by an occurrence beyond the reasonable control of the Contractor and without its fault or negligence. Examples of occurrences include acts of God or the public enemy, acts of the Government in either its sovereign or contractual capacity, fires, floods, epidemics, quarantine restrictions, strikes, unusually severe weather, and delays of common carriers. When an excusable delay occurs, the Contractor shall—

(1) Notify the Contracting Officer in writing as soon as possible;

(2) Remedy the delay as quickly as possible; and

(3) Notify the Contracting Officer when the occurrence is over.

(g) *Invoice.* The Government will handle invoices according to the Prompt Payment Act (31 U.S.C. 3903) and 5 CFR part 1315. The Contractor shall submit invoices to the address designated in the contract to receive invoices. An invoice must include the information required by 5 CFR part 1315.9(b).

(h) *Patent indemnity.* The Contractor shall indemnify the Government and its officers, employees, and agents against liability, including costs, for actual or alleged direct or contributory infringement of, or inducement to infringe, any United States or foreign patent, trademark, or copyright, arising out of the performance of this contract, provided the Contractor is reasonably notified of such claims and proceedings.

(i) *Payment—*

(1) *Items accepted.* Payment shall be made for items accepted by the Government that have been delivered to the delivery destinations set forth in this contract.

(2) *Prompt payment.* The Government will make payment in accordance with the Prompt Payment Act (31 U.S.C. 3903) and prompt payment regulations at 5 CFR part 1315.

(3) *Discount.* In connection with any discount offered for early payment, time shall be computed from the date of the invoice. For the purpose of computing the discount earned, payment shall be considered to have been made on the date that appears on the payment check or the specified payment date if an electronic funds transfer payment is made.

(4) *Overpayments.* If the Contractor becomes aware of a duplicate contract financing or invoice payment or that the Government has otherwise overpaid on a contract financing or invoice payment, the Contractor shall—

(i) Remit the overpayment amount to the payment office cited in the contract along with a description of the overpayment including the—

(A) Circumstances of the overpayment (e.g., duplicate payment, erroneous payment, liquidation errors, date(s) of overpayment);

(B) Affected contract number and delivery order number, if applicable;

(C) Affected line item or subline item, if applicable;

(D) Contractor point of contact; and

(ii) Provide a copy of the remittance and supporting documentation to the Contracting Officer.

(5) *Interest.*

(i) All amounts that become payable by the Contractor to the Government under this contract shall bear simple interest from the date due until paid unless paid within 30 days of becoming due. The interest rate shall be the interest rate established by the Secretary of the

Treasury as provided in 41 U.S.C. 7109, which is applicable to the period in which the amount becomes due, as provided in (i)(6)(v) of this clause, and then at the rate applicable for each six-month period as fixed by the Secretary until the amount is paid.

(ii) The Government may issue a demand for payment to the Contractor upon finding a debt is due under the contract.

(iii) *Final decisions.* The Contracting Officer will issue a final decision as required by FAR part 33 if—

(A) The Contracting Officer and the Contractor are unable to reach agreement on the existence or amount of a debt within 30 days;

(B) The Contractor fails to liquidate a debt previously demanded by the Contracting Officer within the timeline specified in the demand for payment unless the amounts were not repaid because the Contractor has requested an installment payment agreement; or

(C) The Contractor requests a deferment of collection on a debt previously demanded by the Contracting Officer (see FAR part 32).

(iv) If a demand for payment was previously issued for the debt, the demand for payment included in the final decision shall identify the same due date as the original demand for payment.

(v) Amounts shall be due at the earliest of the following dates:

(A) The date fixed under this contract.

(B) The date of the first written demand for payment, including any demand for payment resulting from a termination for cause.

(vi) The interest charge shall be computed for the actual number of calendar days involved beginning on the due date and ending on—

(A) The date on which the designated office receives payment from the Contractor;

(B) The date of issuance of a Government check to the Contractor from which an amount otherwise payable has been withheld as a credit against the contract debt; or

(C) The date on which an amount withheld and applied to the contract debt would otherwise have become payable to the Contractor.

(vii) The interest charge made under this clause may be reduced under the procedures for interest credits prescribed in FAR part 32 in effect on the date of this contract.

(j) *Risk of loss.* Unless the contract specifically provides otherwise, risk of loss or damage to the supplies provided under this contract shall remain with the Contractor until, and shall pass to the Government upon—

(1) Delivery of the supplies to a carrier, if transportation is f.o.b. origin; or

(2) Delivery of the supplies to the Government at the destination specified in the contract, if transportation is f.o.b. destination.

(k) *Taxes.* The contract price includes all applicable Federal, State, and local taxes and duties.

(l) *Termination for the Government's convenience.* The Government reserves the right to terminate this contract, or any part hereof, for its sole convenience. In the event of such termination, the Contractor shall immediately stop all work and shall immediately cause any and all of its suppliers and subcontractors to cease work. Subject to the terms of this contract, the Contractor shall be paid a percentage of the contract price reflecting the percentage of the work performed prior to the notice of termination, plus reasonable charges the Contractor can demonstrate to the satisfaction of the Government using its standard record keeping system, have resulted from the termination. The Contractor shall not be required to comply with the cost accounting standards or contract cost principles for this purpose. This paragraph does not give the Government any right to audit the Contractor's records. The Contractor shall not be paid for any work performed or costs incurred which reasonably could have been avoided.

(m) *Termination for cause.* The Government may terminate this contract, or any part hereof, for cause in the event of any default by the Contractor, or if the Contractor fails to comply with any contract terms and conditions, or fails to provide the Government, upon request, with adequate assurances of future performance. The Government will send a cure notice to the Contractor, unless the reason for the termination is late delivery. In the event of termination for cause, the Government shall not be liable to the Contractor for any amount for supplies or services not accepted, and the Contractor shall be liable to the Government for any and all rights and remedies provided by law. If it is determined that the Government improperly terminated this contract for default, such termination shall be deemed a termination for convenience.

(n) *Title.* Unless specified elsewhere in this contract, title to items furnished under this contract shall pass to the Government upon acceptance, regardless of when or where the Government takes physical possession.

(o) *Warranty.* The Contractor warrants and implies that the items delivered under this contract are merchantable and fit for use for the particular purpose described in this contract.

(p) *Limitation of liability.* Except as otherwise provided by an express warranty, the Contractor will not be liable to the Government for consequential damages resulting from any defect or deficiencies in accepted items.

(q) *Compliance with laws unique to Government contracts.* The Contractor agrees to comply with 31 U.S.C. 1352 relating to limitations on the use of appropriated funds to influence certain Federal contracts; 40 U.S.C. chapter 37, Contract Work Hours and Safety Standards; 41 U.S.C. chapter 87, Kickbacks; 49 U.S.C. 40118, Government-financed air transportation; and 41 U.S.C. chapter 21 relating to procurement integrity.

(r) *Order of precedence.* Any inconsistencies in this solicitation or contract shall be resolved by giving precedence in the following order:

(1) The schedule of supplies/services.

(2) The Disputes, Payments, Invoice, Compliance with Laws Unique to Government Contracts, and Unauthorized Obligations paragraphs of this clause;

(3) Other contract clauses incorporated in the solicitation or contract;

(4) Addenda to this solicitation or contract,

(5) Solicitation provisions incorporated in the solicitation.

(6) Other paragraphs of this clause.

(7) Other documents, exhibits, and attachments; and

(8) The specification.

(s) *Unauthorized obligations.*

(1) Except as stated in paragraph (s)(2) of this clause, when any supply or service acquired under this contract is subject to any End User License Agreement (EULA), Terms of Service (TOS), or similar legal instrument or agreement, that includes any clause requiring the Government to indemnify the Contractor or any person or entity for damages, costs, fees, or any other loss or liability that would create an Anti-Deficiency Act violation (31 U.S.C. 1341), the following shall govern:

(i) Any such clause is unenforceable against the Government.

(ii) Neither the Government nor any Government-authorized end user shall be deemed to have agreed to such clause by virtue of it appearing in the EULA, TOS, or similar legal instrument or agreement. If the EULA, TOS, or similar legal instrument or agreement is invoked through an "I agree" click box or other comparable mechanism (e.g., "click-wrap" or "browse-wrap" agreements), execution does not bind the Government or any Government authorized end user to such clause.

(iii) Any such clause is deemed to be stricken from the EULA, TOS, or similar legal instrument or agreement.

(2) Paragraph (s)(1) of this clause does not apply to indemnification by the Government that is expressly authorized by statute and specifically authorized under applicable agency regulations and procedures.

(t) *Comptroller General examination of record.* This paragraph applies if this contract was awarded using other than sealed bid procedures and is in excess of the simplified acquisition threshold on the date of award of this contract.

(1) The Comptroller General of the United States, or an authorized representative of the Comptroller General, shall have access to and right to examine any of the Contractor's directly pertinent records involving transactions related to this contract.

(2) The Contractor shall make available at its offices, at all reasonable times, the records, materials, and other evidence for examination, audit, or reproduction, until 3 years after final payment under this contract or for any shorter period specified in FAR part 4, longer period

required by statute, or periods specified in other clauses of this contract. If this contract is completely or partially terminated, the records relating to the work terminated shall be made available for 3 years after any resulting final termination settlement. Records relating to appeals under the disputes clause or to litigation or the settlement of claims arising under or relating to this contract shall be made available until such appeals, litigation, or claims are finally resolved.

(3) As used in this clause, records include books, documents, accounting procedures and practices, and other data, regardless of type and regardless of form. This clause does not require the Contractor to create or maintain any record that the Contractor does not maintain in the ordinary course of business or pursuant to a provision of law.

(u) *Incorporation by reference.* The Contractor's representations and certifications, including those completed electronically via the System for Award Management (SAM), are incorporated by reference into the contract.

(End of Clause)

ADDENDUM to FAR 52.212-4 CONTRACT TERMS AND CONDITIONS—COMMERCIAL PRODUCTS AND COMMERCIAL SERVICES

Clauses that are incorporated by reference (by Citation Number, Title, and Date), have the same force and effect as if they were given in full text. Upon request, the Contracting Officer will make their full text available.

The following clauses are incorporated into 52.212-4 as an addendum to this contract:

C.2 52.216-18 ORDERING (AUG 2020)

(a) Any supplies and services to be furnished under this contract shall be ordered by issuance of delivery orders or task orders by the individuals or activities designated in the Schedule. Such orders may be issued from date of award through 5 years from award.

(b) All delivery orders or task orders are subject to the terms and conditions of this contract. In the event of conflict between a delivery order or task order and this contract, the contract shall control.

(c) A delivery order or task order is considered "issued" when—

(1) If sent by mail (includes transmittal by U.S. mail or private delivery service), the Government deposits the order in the mail;

(2) If sent by fax, the Government transmits the order to the Contractor's fax number; or

(3) If sent electronically, the Government either—

(i) Posts a copy of the delivery order or task order to a Government document access system, and notice is sent to the Contractor; or

(ii) Distributes the delivery order or task order via email to the Contractor's email address.

(d) Orders may be issued by methods other than those enumerated in this clause only if authorized in the contract.

(End of Clause)

C.3 52.216-19 ORDER LIMITATIONS (OCT 1995)

(a) *Minimum order.* When the Government requires supplies or services covered by this contract in an amount of less than \$15,000.00, the Government is not obligated to purchase, nor is the Contractor obligated to furnish, those supplies or services under the contract.

(b) *Maximum order.* The Contractor is not obligated to honor—

(1) Any order for a single item in excess of \$1,000.00;

(2) Any order for a combination of items in excess of \$5,000,000.00; or

(3) A series of orders from the same ordering office within 5 days that together call for quantities exceeding the limitation in paragraph (b)(1) or (2) of this section.

(c) If this is a requirements contract (i.e., includes the Requirements clause at subsection 52.216-21 of the Federal Acquisition Regulation (FAR)), the Government is not required to order a part of any one requirement from the Contractor if that requirement exceeds the maximum-order limitations in paragraph (b) of this section.

(d) Notwithstanding paragraphs (b) and (c) of this section, the Contractor shall honor any order exceeding the maximum order limitations in paragraph (b), unless that order (or orders) is returned to the ordering office within 5 days after issuance, with written notice stating the Contractor's intent not to ship the item (or items) called for and the reasons. Upon receiving this notice, the Government may acquire the supplies or services from another source.

(End of Clause)

C.4 52.216-22 INDEFINITE QUANTITY (NOV 2025) (DEVIATION)

(a) This is an indefinite-quantity contract for the supplies or services specified, and effective for the period stated, in the Schedule. The quantities of supplies and services specified in the Schedule are estimates only and are not purchased by this contract.

(b) Delivery or performance shall be made only as authorized by orders issued in accordance with the Ordering clause. The Contractor shall furnish to the Government, when and if ordered, the supplies or services specified in the Schedule up to and including the quantity designated in the Schedule as the "maximum." The Government shall order at least the quantity of supplies or services designated in the Schedule as the "minimum."

(c) Except for any limitations on quantities in the Order Limitations clause or in the Schedule, there is no limit on the number of orders that may be issued. The Government may issue orders requiring delivery to multiple destinations or performance at multiple locations.

(d) Any order issued during the ordering period of this contract and not completed within that period shall be completed by the Contractor within the time specified in the order, which may include order options to be exercised after the ordering period of this contract but before the end of the period of performance of the order. The contract shall govern the Contractor's and Government's rights and obligations with respect to that order, including options exercised, to

the same extent as if the order were completed during the contract's ordering period; provided, that the Contractor shall not be required to make any deliveries under this contract after September 30, 2031.

(End of Clause)

C.5 52.217-8 OPTION TO EXTEND SERVICES (NOV 1999)

The Government may require continued performance of any services within the limits and at the rates specified in the contract. These rates may be adjusted only as a result of revisions to prevailing labor rates provided by the Secretary of Labor. The option provision may be exercised more than once, but the total extension of performance hereunder shall not exceed 6 months. The Contracting Officer may exercise the option by written notice to the Contractor within 30 Days before expiration.

(End of Clause)

C.6 52.222-90 ADDRESSING DEI DISCRIMINATION BY FEDERAL CONTRACTORS (DEVIATION APR 2026)

(a) *Definitions.* As used in this clause—

Program participation means membership or participation in, or access or admission to: training, mentoring, or leadership development programs; educational opportunities; clubs; associations; or similar opportunities that are sponsored or established by the contractor or subcontractor.

Racially discriminatory diversity, equity, and inclusion (DEI) activities means disparate treatment based on race or ethnicity in the recruitment, employment (e.g., hiring, promotions), contracting (e.g., vendor agreements), program participation, or allocation or deployment of an entity's resources.

(b) In connection with the performance of work under this contract, the Contractor agrees as follows:

- (1) The Contractor will not engage in any racially discriminatory DEI activities;
- (2) The Contractor will furnish all information and reports, including providing access to books, records, and accounts, as required by the Contracting Officer, for purposes of ascertaining compliance with this clause;
- (3) In the event of the Contractor's or a subcontractor's noncompliance with this clause, this contract may be canceled, terminated, or suspended in whole or in part, and the Contractor or subcontractor may be declared ineligible for further Government contracts;
- (4) The Contractor will report any subcontractor's known or reasonably knowable conduct that may violate this clause to the Contracting Officer and take any appropriate remedial actions directed by the Contracting Officer; and
- (5) The Contractor will inform the Contracting Officer if a subcontractor sues the Contractor and the suit puts at issue, in any way, the validity of this clause.

(6) The Contractor recognizes that compliance with the requirements of this clause are material to the Government's payment decisions for purposes of 31 U.S.C. 3729(b)(4).

(c) The Contractor must include the substance of this clause, including this paragraph (c), in subcontracts at any tier, including those for commercial products and commercial services, except those where the place of delivery or performance is outside the United States.

(End of Clause)

C.7 52.228-5 INSURANCE—WORK ON A GOVERNMENT INSTALLATION (JAN 1997)

(a) The Contractor shall, at its own expense, provide and maintain during the entire performance of this contract, at least the kinds and minimum amounts of insurance required in the Schedule or elsewhere in the contract.

(b) Before commencing work under this contract, the Contractor shall notify the Contracting Officer in writing that the required insurance has been obtained. The policies evidencing required insurance shall contain an endorsement to the effect that any cancellation or any material change adversely affecting the Government's interest shall not be effective—

(1) For such period as the laws of the State in which this contract is to be performed prescribe; or

(2) Until 30 days after the insurer or the Contractor gives written notice to the Contracting Officer, whichever period is longer.

(c) The Contractor shall insert the substance of this clause, including this paragraph (c), in subcontracts under this contract that require work on a Government installation and shall require subcontractors to provide and maintain the insurance required in the Schedule or elsewhere in the contract. The Contractor shall maintain a copy of all subcontractors' proofs of required insurance, and shall make copies available to the Contracting Officer upon request.

(End of Clause)

C.8 SUPPLEMENTAL INSURANCE REQUIREMENTS

In accordance with FAR 28.307-2 and FAR 52.228-5, the following minimum coverage shall apply to this contract:

(a) Workers' compensation and employers liability: Contractors are required to comply with applicable Federal and State workers' compensation and occupational disease statutes. If occupational diseases are not compensable under those statutes, they shall be covered under the employer's liability section of the insurance policy, except when contract operations are so commingled with a Contractor's commercial operations that it would not be practical to require this coverage. Employer's liability coverage of at least \$100,000 is required, except in States with exclusive or monopolistic funds that do not permit workers' compensation to be written by private carriers.

(b) General Liability: \$500,000.00 per occurrences.

(c) Automobile liability: \$200,000.00 per person; \$500,000.00 per occurrence and \$20,000.00 property damage.

(d) The successful bidder must present to the Contracting Officer, prior to award, evidence of general liability insurance without any exclusionary clauses for asbestos that would void the general liability coverage.

(End of Clause)

C.9 52.240-91 SECURITY PROHIBITIONS AND EXCLUSIONS (NOV 2025) (DEVIATION)

(a) *Definitions.* As used in this clause—

American Security Drone Act-covered foreign entity means an entity included on a list that the Federal Acquisition Security Council (FASC) develops and maintains and publishes in the System for Award Management (SAM) at <https://www.sam.gov> (section 1822 of Pub. L. 118-31, 41 U.S.C. 3901 note prec.).

Backhaul means intermediate links between the core network, or backbone network, and the small subnetworks at the edge of the network (e.g., connecting cell phones/towers to the core telephone network). Backhaul can be wireless (e.g., microwave) or wired (e.g., fiber optic, coaxial cable, Ethernet).

Covered application means the social networking service TikTok or any successor application or service developed or provided by ByteDance Limited or an entity owned by ByteDance Limited.

Covered article, as defined in 41 U.S.C. 4713(k), means:

(1) Information technology, as defined in 40 U.S.C. 11101, including cloud computing services of all types;

(2) Telecommunications equipment or telecommunications service, as those terms are defined in section 3 of the Communications Act of 1934 (47 U.S.C. 153);

(3) The processing of information on a Federal or non-Federal information system, subject to the requirements of the Controlled Unclassified Information program (see 32 CFR part 2002); or

(4) Hardware, systems, devices, software, or services that include embedded or incidental information technology.

Covered foreign country means The People's Republic of China.

Covered telecommunications equipment or services means—

(1) Telecommunications equipment produced by Huawei Technologies Company or ZTE Corporation (or any subsidiary or affiliate of such entities);

(2) For the purpose of public safety, security of Government facilities, physical security surveillance of critical infrastructure, and other national security purposes, video surveillance and telecommunications equipment produced by Hytera Communications Corporation,

Hangzhou Hikvision Digital Technology Company, or Dahua Technology Company (or any subsidiary or affiliate of such entities);

(3) Telecommunications or video surveillance services provided by such entities or using such equipment; or

(4) Telecommunications or video surveillance equipment or services produced or provided by an entity that the Secretary of Defense, in consultation with the Director of National Intelligence or the Director of the Federal Bureau of Investigation, reasonably believes to be an entity owned or controlled by, or otherwise connected to, the government of a covered foreign country.

Critical technology means—

(1) Defense articles or defense services included on the United States Munitions List set forth in the International Traffic in Arms Regulations under subchapter M of chapter I of title 22, Code of Federal Regulations;

(2) Items included on the Commerce Control List set forth in Supplement No. 1 to part 774 of the Export Administration Regulations under subchapter C of chapter VII of title 15, Code of Federal Regulations, and controlled—

(i) Pursuant to multilateral regimes, including for reasons relating to national security, chemical and biological weapons proliferation, nuclear nonproliferation, or missile technology; or

(ii) For reasons relating to regional stability or surreptitious listening;

(3) Specially designed and prepared nuclear equipment, parts and components, materials, software, and technology covered by part 810 of title 10, Code of Federal Regulations (relating to assistance to foreign atomic energy activities);

(4) Nuclear facilities, equipment, and material covered by part 110 of title 10, Code of Federal Regulations (relating to export and import of nuclear equipment and material);

(5) Select agents and toxins covered by part 331 of title 7, Code of Federal Regulations, part 121 of title 9 of such Code, or part 73 of title 42 of such Code; or

(6) Emerging and foundational technologies controlled pursuant to section 1758 of the Export Control Reform Act of 2018 (50 U.S.C. 4817).

FASC-prohibited unmanned aircraft system means an unmanned aircraft system manufactured or assembled by an American Security Drone Act—covered foreign entity.

FASCSA order means any of the following orders issued under the Federal Acquisition Supply Chain Security Act (FASCSA) requiring removing covered articles from executive agency information systems or excluding one or more named sources or named covered articles from executive agency procurement actions, as described in 41 CFR 201-1.303(d) and (e):

(1) The Secretary of Homeland Security may issue FASCSA orders that apply to civilian agencies, to the extent not covered by paragraph (2) or (3) of this definition. This type of FASCSA order may be referred to as a Department of Homeland Security (DHS) FASCSA order.

(2) The Secretary of Defense may issue FASCSA orders that apply to the Department of Defense (DoD) and national security systems other than sensitive compartmented information systems. This type of FASCSA order may be referred to as a DoD FASCSA order.

(3) The Director of National Intelligence (DNI) may issue FASCSA orders that apply to the intelligence community and sensitive compartmented information systems, to the extent not covered by paragraph (2) of this definition. This type of FASCSA order may be referred to as a DNI FASCSA order.

Information technology, as defined in 40 U.S.C. 11101(6)—

(1) Means any equipment or interconnected system or subsystem of equipment, used in the automatic acquisition, storage, analysis, evaluation, manipulation, management, movement, control, display, switching, interchange, transmission, or reception of data or information by the executive agency, if the equipment is used by the executive agency directly or is used by a contractor under a contract with the executive agency that requires the use—

(i) Of that equipment; or

(ii) Of that equipment to a significant extent in the performance of a service or the furnishing of a product;

(2) Includes computers, ancillary equipment (including imaging peripherals, input, output, and storage devices necessary for security and surveillance), peripheral equipment designed to be controlled by the central processing unit of a computer, software, firmware and similar procedures, services (including support services), and related resources; but

(3) Does not include any equipment acquired by a Federal contractor incidental to a Federal contract.

Intelligence community, as defined by 50 U.S.C. 3003(4), means the following—

(1) The Office of the Director of National Intelligence;

(2) The Central Intelligence Agency;

(3) The National Security Agency;

(4) The Defense Intelligence Agency;

(5) The National Geospatial-Intelligence Agency;

(6) The National Reconnaissance Office;

(7) Other offices within the Department of Defense for the collection of specialized national intelligence through reconnaissance programs;

(8) The intelligence elements of the Army, the Navy, the Air Force, the Marine Corps, the Coast Guard, the Federal Bureau of Investigation, the Drug Enforcement Administration, and the Department of Energy;

(9) The Bureau of Intelligence and Research of the Department of State;

(10) The Office of Intelligence and Analysis of the Department of the Treasury;

(11) The Office of Intelligence and Analysis of the Department of Homeland Security; or

(12) Such other elements of any department or agency as may be designated by the President, or designated jointly by the Director of National Intelligence and the head of the department or agency concerned, as an element of the intelligence community.

Interconnection arrangement means arrangements governing the physical connection of two or more networks to allow the use of another's network to hand off traffic where it is ultimately delivered (e.g., connecting a customer of telephone provider A to a customer of telephone company B) or sharing data and other information resources.

Kaspersky Lab-covered article means any hardware, software, or service that—

(1) Is developed or provided by a Kaspersky Lab-covered entity;

(2) Includes any hardware, software, or service developed or provided in whole or in part by a Kaspersky Lab-covered entity; or

(3) Contains components using any hardware or software developed in whole or in part by a Kaspersky Lab-covered entity.

Kaspersky Lab-covered entity means—

(1) Kaspersky Lab;

(2) Any successor entity to Kaspersky Lab, including any change in name, e.g., "Kaspersky";

(3) Any entity that controls, is controlled by, or is under common control with Kaspersky Lab; or

(4) Any entity of which Kaspersky Lab has a majority ownership.

National security system, as defined in 44 U.S.C. 3552, means any information system (including any telecommunications system) used or operated by an agency or by a contractor of an agency, or other organization on behalf of an agency—

(1) The function, operation, or use of which involves intelligence activities; involves cryptologic activities related to national security; involves command and control of military forces; involves equipment that is an integral part of a weapon or weapons system; or is critical to the direct fulfillment of military or intelligence missions, but does not include a system that is to be used for routine administrative and business applications (including payroll, finance, logistics, and personnel management applications); or

(2) Is protected at all times by procedures established for information that have been specifically authorized under criteria established by an Executive order or an Act of Congress to be kept classified in the interest of national defense or foreign policy.

Roaming means cellular communications services (e.g., voice, video, data) received from a visited network when unable to connect to the facilities of the home network either because signal coverage is too weak or because traffic is too high.

Sensitive compartmented information means classified information concerning or derived from intelligence sources, methods, or analytical processes, which is required to be handled within formal access control systems established by the Director of National Intelligence.

Sensitive compartmented information system means a national security system authorized to process or store sensitive compartmented information.

Source means a non-Federal supplier, or potential supplier, of products or services, at any tier.

Subsidiary means an entity in which more than 50 percent of the entity is owned directly by a parent corporation or through another subsidiary of a parent corporation.

Substantial or essential component means any component necessary for the proper function or performance of a piece of equipment, system, or service.

Unmanned aircraft means an aircraft that is operated without the possibility of direct human intervention from within or on the aircraft (49 U.S.C. 44801(11)).

Unmanned aircraft system means an unmanned aircraft and associated elements (including communication links and the components that control the unmanned aircraft) that are required for the operator to operate safely and efficiently in the national airspace system (49 U.S.C. 44801(12)).

(b) *Prohibitions on providing or using specific products or services in performance of contract.* Unless a waiver or exception applies, the Contractor is prohibited from providing any products or services to the Government or using in the performance of the contract any of the following:

(1) A covered application on any information technology owned or managed by the Government, or on any information technology used or provided by the Contractor under this contract, including equipment provided by the Contractor's employees (section 102 of Division R of the Consolidated Appropriations Act, 2023 (Pub. L. 117-328));

(2) A Kaspersky Lab-covered article (Section 1634 of Division A of the National Defense Authorization Act for Fiscal Year 2018 (Pub. L. 115-91));

(3) Covered telecommunications equipment or services used as a substantial or essential component of any system, or as critical technology as part of any system (paragraphs (a)(1)(A) of section 889 of the John S. McCain National Defense Authorization Act for Fiscal Year 2019 (Pub. L. 115-232)). This does not prohibit contractors from providing—

(i) A service that connects to the facilities of a third-party, such as backhaul, roaming, or interconnection arrangements; or

(ii) Telecommunications equipment that cannot route or redirect user data traffic or cannot permit visibility into any user data or packets that such equipment transmits or otherwise handles.

(c) Prohibition on unmanned aircraft systems manufactured or assembled by American Security Drone Act—covered foreign entities.

(1) Prohibition. The Contractor is prohibited from—

(i) Delivering any FASC-prohibited unmanned aircraft system, which includes unmanned aircraft (i.e., drones) and associated elements (sections 1823 and 1826 of American Security Drone Act of 2023, within the National Defense Authorization Act for Fiscal Year 2024, Pub. L. 118-31, Div. A, Title XVIII, Subtitle B, 41 U.S.C. 3901 note prec.);

(ii) On or after December 22, 2025, operating a FASC-prohibited unmanned aircraft system in the performance of the contract (section 1824 of Pub. L. 118-31); and

(iii) On or after December 22, 2025, using Federal funds to procure or operate a FASC-prohibited unmanned aircraft system (section 1825 of Pub. L. 118-31).

(2) *Procedures.* The Contractor shall search SAM for the FASC-maintained list of American Security Drone Act—covered foreign entities before proposing, or using in performance of the contract, any unmanned aircraft system. Also, the Contractor shall ensure any effort or expenditure associated with a FASC-prohibited unmanned aircraft system is consistent with a corresponding exemption, exception, or waiver determination expressly stated in the contract.

(3) *Exemptions, exceptions, and waivers.* The prohibitions in paragraph (c) of this clause do not apply where the agency has determined an exemption, exception, or waiver applies, and the contract indicates that such a determination has been made. See sections 1823 through 1825 and 1832 of Public Law 118-31 for statutory requirements pertaining to exemptions, exceptions, and waivers.

(d) *Prohibition on using or providing specific products or services or conducting certain transactions regardless of connection to contract.*

(1) *Certain telecommunications and video surveillance equipment, systems, or services.*

(i) Unless an applicable waiver has been issued by the Government, the Contractor cannot use any equipment, systems, or services that uses covered telecommunications equipment or services as a substantial or essential component of any system, or as critical technology as part of any system (paragraph (a)(1)(B) of section 889 of the John S. McCain National Defense Authorization Act for Fiscal Year 2019 (Pub. L. 115-232)).

(ii) This prohibition applies to using covered telecommunications equipment or services, regardless of whether that use is in performance of work under a Federal contract. This does not prohibit the contractor from using—

(A) A service that connects to the facilities of a third party, such as backhaul, roaming, or interconnection arrangements; or

(B) Telecommunications equipment that cannot route or redirect user data traffic or cannot permit visibility into any user data or packets that such equipment transmits or otherwise handles.

(2) *Office of Foreign Assets Control Restrictions.*

(i) Except as authorized by the Office of Foreign Assets Control (OFAC) in the Department of the Treasury, the Contractor shall not acquire, for use in the performance of this contract, any supplies or services if any proclamation, Executive order, or statute administered by OFAC, or if

OFAC's implementing regulations at 31 CFR chapter V, would prohibit such a transaction by a person subject to the jurisdiction of the United States.

(ii) Except as authorized by OFAC, most transactions involving Cuba, Iran, and Sudan are prohibited, as are most imports from Burma or North Korea, into the United States or its outlying areas.

(A) For lists of entities and individuals subject to economic sanctions, see OFAC's List of Specially Designated Nationals and Blocked Persons at <https://home.treasury.gov/policy-issues/financial-sanctions/specially-designated-nationals-and-blocked-persons-list-sdn-human-readable-lists>.

(B) For more information about these restrictions, as well as updates, see OFAC's regulations at 31 CFR chapter V and at <https://home.treasury.gov/policy-issues/office-of-foreign-assets-control-sanctions-programs-and-information>.

(C) To conduct electronic screens of potential parties to regulated transactions, see the consolidated screening list at <https://www.trade.gov/consolidated-screening-list>, which consolidates multiple export screening lists of the Departments of Commerce, State, and the Treasury.

(3) *Sudan prohibition.* The Contractor is prohibited from conducting any restricted business operations in Sudan in accordance with Accountability and Divestment Act of 2007 (Pub. L. 110-174).

(4) *Iran prohibitions.*

(i) Unless an exception applies according to paragraph (d)(4)(iii) or the Government grants a waiver, the contractor shall not engage in certain activities or transactions relating to Iran (section 6(b)(1)(A) of Iran Sanctions Act (50 U.S.C. 1701 note)).

(ii) Unless an exception applies according to paragraph (d)(4)(iii) or the Government grants a waiver, contractor shall not export certain sensitive technology to Iran, as determined by the President, and has an active exclusion in SAM (22 U.S.C. 8515).

(iii) The prohibition in paragraphs (d)(4)(i) and (d)(4)(ii) do not apply if the acquisition is subject to trade agreements and the offeror certifies that all the offered products are designated country end products or designated country construction material (see part 25).

(iv) Unless an exception applies or the Government grants a waiver, contractors are prohibited from knowingly engaging in any significant transaction (i.e., over \$15,000) with Iran's Revolutionary Guard Corps or any of its officials, agents, or affiliates, the property and interests in property of which are blocked according to the International Emergency Economic Powers Act (section 6(b)(1)(B) of Iran Sanctions Act (50 U.S.C. 1701 note)).

(e) *Governmentwide exclusion and removal orders.*

(1) Unless the Government has issued an applicable waiver, contractors shall not provide or use as part of the performance of the contract any covered article, or any products or services

produced or provided by a source, if the covered article or the source is prohibited by an applicable FASCSA order as follows:

(i) For solicitations and contracts awarded by a Department of Defense contracting office, DoD FASCSA orders apply.

(ii) For all other solicitations and contracts, DHS FASCSA orders apply.

(2) The Contractor shall search for the phrase “FASCSA order” in the System for Award Management (SAM) at <https://www.sam.gov> to locate applicable FASCSA orders.

(3) The Government may identify in the solicitation other FASCSA orders that are not in SAM, which are effective and apply to the solicitation and resulting contract.

(4) A FASCSA order issued after the date of solicitation applies to this contract only if added by an amendment to the solicitation or modification to the contract (see FAR 40.204-1(c)).

(f) *Reasonable inquiry*. The contractor shall conduct a reasonable inquiry to determine if there are any prohibited products or services. The inquiry will look at any information in the entity’s possession but does not need to include an internal or third-party audit.

(g) *Removal of prohibited products and services*. For Federal Supply Schedules, Governmentwide acquisition contracts, multi-agency contracts or any other procurement instrument intended for use by multiple agencies, upon notification from the Contracting Officer, during the performance of the contract, the Contractor shall promptly make any necessary changes or modifications to remove any product or service produced or provided by a source that this clause prohibits.

(h) *General report*.

(1) If the Contractor identifies or is notified by any source, (including a subcontractor at any tier), that any product or service provided or used (or to be provided or used) during contract performance does not comply with any prohibition in this clause, then the Contractor shall report the following information, or as much information is known, in writing to the contracting office as identified in paragraph (h)(2) within 72 hours:

(i) Contract number and order number, if applicable;

(ii) The specific prohibition the product or service is not complying with;

(iii) A description of the products or services that the Contractor identifies or has reason to suspect is prohibited (include brand; model number, such as the original equipment manufacturer (OEM) number, manufacturer part number, or wholesaler number; and item description, as applicable);

(iv) The entity that produced the product or service (include entity name, unique entity identifier, Contractor and Government Entity (CAGE) code, facilities responsible for design, fabrication, assembly, packaging, and test of the product, and whether the entity was the OEM or a distributor (provide manufacturer codes and distributor codes used for the product));

(v) Description of the functionality of the product or service and how that functionality impacts the risk to the product or service;

(vi) An explanation of any factors relevant to determining if the product or service should be permitted by an applicable exception, exemption, or waiver (if the contractor would like the Government to consider a waiver, and asks for such a waiver);

(vii) Whether alternative products or services are available that would comply with the prohibition;

(viii) If the product or service is related to item maintenance, include the following information on the item being maintained:

(A) Brand;

(B) Model number, OEM number, manufacturer part number, or wholesaler number; and

(C) Item description, as applicable.

(ix) Any readily available information about mitigation actions implemented or recommended.

(2) If a report must be submitted to a contracting office, the Contractor shall submit the report as follows:

(i) If a Department of Defense contracting office, the Contractor shall report to the website at <https://dibnet.dod.mil>.

(ii) For all other contracting offices, the Contractor shall report to the Contracting Officer.

(iii) For indefinite delivery contracts, the Contractor shall report to both the contracting office for the indefinite delivery contract and the contracting office for any affected order.

(3) If the report provided does not contain any of the information required by paragraph (h)(1) of this clause, and the contractor later discovers new information that is required by paragraph (h)(1) of this clause, then the contractor shall submit a subsequent report within 72 hours of discovering the new information.

(4) The contractor shall also report the information in paragraph (h)(1) if the contractor wishes to ask for a waiver of the requirements of a new FASCSA order being applied through modification.

(i) *New FASCSA orders report.*

(1) During contract performance, the Contractor shall review SAM at least once every three months, or as advised by the Contracting Officer, to check for covered articles subject to FASCSA order(s), or for products or services produced by a source subject to FASCSA order(s) not currently identified under paragraph (e) of this clause.

(2) If the Contractor identifies a new FASCSA order(s) that could impact their supply chain, then the Contractor shall conduct a reasonable inquiry to identify whether a covered article or product or service produced or provided by a source subject to the FASCSA order(s) was

provided to the Government or used during contract performance. The inquiry will look at any information in the entity's possession but does not need to include an internal or third-party audit.

(3) The Contractor shall submit a report to the contracting office identified in paragraph (h)(2) of this clause if the Contractor identifies, including through any notification by a subcontractor at any tier, that a covered article or product or service produced or provided by a source was provided to the Government or used during contract performance and is subject to a FASCSA order(s). For indefinite delivery contracts, the Contractor shall report to both the contracting office for the indefinite delivery contract and the contracting office for any affected order. The Contractor shall report the following information within 72 hours for each covered article or each product or service produced or provided by a source, where the covered article or source is subject to a FASCSA order:

- (i) Contract number and order number, if applicable;
- (ii) Name of the covered article or source subject to a FASCSA order;
- (iii) The specific FASCSA order the product or service does not comply with;
- (iv) The elements of (h)(1)(iii) through (ix) of this clause.

(j) Subcontracts. The Contractor shall insert the substance of this clause, including this paragraph (j) but excluding subparagraphs (d)(1) and (i)(1), in all subcontracts and other contractual instruments, including subcontracts for acquiring commercial products or commercial services.

(End of Clause)

C.10 52.240-93 BASIC SAFEGUARDING OF COVERED CONTRACTOR INFORMATION SYSTEMS (DEVIATION) (NOV 2025)

(a) Definitions. As used in this clause—

Covered contractor information system means an information system that is owned or operated by a contractor that processes, stores, or transmits Federal contract information.

Federal contract information—

(1) Means information, not intended for public release, that is provided by or generated for the Government under a contract to develop or deliver a product or service to the Government; but

(2) Does not include information provided by the Government to the public (such as on public websites) or simple transactional information (such as information necessary to process payments).

Information means any communication or representation of knowledge such as facts, data, or opinions, in any medium or form, including textual, numerical, graphic, cartographic, narrative, or audiovisual (Committee on National Security Systems Instruction (CNSSI) 4009).

Information system means a discrete set of information resources organized for the collection, processing, maintenance, use, sharing, dissemination, or disposition of information (44 U.S.C. 3502).

Safeguarding means measures or controls that are prescribed to protect information systems.

(b) Safeguarding requirements.

(1) Basic requirements. The Contractor shall safeguard its covered contractor information systems by implementing, at minimum, the following security controls:

(i) Limit information system access to authorized users, processes acting on behalf of authorized users, or devices (including other information systems).

(ii) Limit information system access to the types of transactions and functions that authorized users are permitted to execute.

(iii) Verify and control/limit connections to and use of external information systems.

(iv) Control information posted or processed on publicly accessible information systems.

(v) Identify information system users, processes acting on behalf of users, or devices.

(vi) Authenticate (or verify) the identities of those users, processes, or devices, as a prerequisite to allowing access to organizational information systems.

(vii) Sanitize or destroy information system media containing Federal Contract Information before disposal or release for reuse.

(viii) Limit physical access to organizational information systems, equipment, and the respective operating environments to authorized individuals.

(ix) Escort visitors and monitor visitor activity; maintain audit logs of physical access; and control and manage physical access devices.

(x) Monitor, control, and protect organizational communications (i.e., information transmitted or received by organizational information systems) at the external boundaries and key internal boundaries of the information systems.

(xi) Implement subnetworks for publicly accessible system components that are physically or logically separated from internal networks.

(xii) Identify, report, and correct information and information system flaws in a timely manner.

(xiii) Provide protection from malicious code at appropriate locations within organizational information systems.

(xiv) Update malicious code protection mechanisms when new releases are available.

(xv) Perform periodic scans of the information system and real-time scans of files from external sources as files are downloaded, opened, or executed.

(2) Other requirements. This clause does not relieve the Contractor of any other specific safeguarding requirements specified by Federal departments and agencies relating to covered contractor information systems generally or other Federal safeguarding requirements for controlled unclassified information (CUI) as established by Executive Order 13556.

(c) Subcontracts. The Contractor shall include the substance of this clause, including this paragraph (c), in subcontracts under this contract (including subcontracts for the acquisition of commercial products, other than commercially available off-the-shelf items, or commercial services), in which the subcontractor may have Federal contract information residing in or transiting through its information system.

(End of Clause)

C.11 VAAR 852.247-71 DELIVERY LOCATION (OCT 2018)

Shipment of deliverable items, other than reports, shall be to:

- **C.W. Bill Young VA Medical Center (CWBYVAMC)**
10,000 Bay Pines Blvd
Bld.100 – Room 2B-110
Bay Pines, FL 33744
- **Lee County VA Healthcare Center (LCHCC)**
2489 Diplomat Parkway East
Room 1B-106
Cape Coral, FL 33909

(End of Clause)

C.12 MANDATORY WRITTEN DISCLOSURES

Mandatory written disclosures required by FAR clause 52.203-13 to the Department of Veterans Affairs, Office of Inspector General (OIG) must be made electronically through the VA OIG Hotline at <https://www.vaoig.gov/hotline/online-forms> and clicking on "FAR clause 52.203-13 Reporting." If you experience difficulty accessing the website, call the Hotline at 1-800-488-8244 for further instructions.

C.13 52.252-2 CLAUSES INCORPORATED BY REFERENCE (FEB 1998)

This contract incorporates one or more clauses by reference, with the same force and effect as if they were given in full text. Upon request, the Contracting Officer will make their full text available. Also, the full text of a clause may be accessed electronically at this/these address(es):

https://www.acquisition.gov/far-overhaul/far-part-deviation-guide/far-overhaul-part-52#FAR_52_252_2
<http://www.va.gov/oal/library/vaar/index.asp>

(End of Clause)

FAR
Number

Title

Date

52.203-6	RESTRICTIONS ON SUBCONTRACTOR SALES TO THE GOVERNMENT ALTERNATE I (NOV 2021)	JUN 2020
52.203-12	LIMITATION ON PAYMENTS TO INFLUENCE CERTAIN FEDERAL TRANSACTIONS	JUN 2020
52.203-13	CONTRACTOR CODE OF BUSINESS ETHICS AND CONDUCT	NOV 2021
52.203-17	CONTRACTOR EMPLOYEE WHISTLEBLOWER RIGHTS	NOV 2023
52.203-19	PROHIBITION ON REQUIRING CERTAIN INTERNAL CONFIDENTIALITY AGREEMENTS OR STATEMENTS	JAN 2017
52.204-9	PERSONAL IDENTITY VERIFICATION OF CONTRACTOR PERSONNEL	JAN 2011
52.204-13	SYSTEM FOR AWARD MANAGEMENT—MAINTENANCE (DEVIATION)	NOV 2025
52.209-6	PROTECTING THE GOVERNMENT'S INTEREST WHEN SUBCONTRACTING WITH CONTRACTORS DEBARRED, SUSPENDED, PROPOSED FOR DEBARMENT, OR VOLUNTARILY EXCLUDED (DEVIATION)	NOV 2025
52.209-9	UPDATES OF PUBLICLY AVAILABLE INFORMATION REGARDING RESPONSIBILITY MATTERS (DEVIATION)	NOV 2025
52.209-10	PROHIBITION ON CONTRACTING WITH INVERTED DOMESTIC CORPORATIONS (DEVIATION)	NOV 2025
52.219-4	NOTICE OF PRICE EVALUATION PREFERENCE FOR HUBZONE SMALL BUSINESS CONCERNS (DEVIATION)	NOV 2025
52.219-8	UTILIZATION OF SMALL BUSINESS CONCERNS (DEVIATION)	NOV 2025
52.219-28	POSTAWARD SMALL BUSINESS PROGRAM REREPRESENTATION (DEVIATION)	NOV 2025
52.222-3	CONVICT LABOR (DEVIATION)	NOV 2025
52.222-19	CHILD LABOR—COOPERATION WITH AUTHORITIES AND REMEDIES (DEVIATION)	MAR 2026
52.222-35	EQUAL OPPORTUNITY FOR VETERANS (DEVIATION)	NOV 2025
52.222-36	EQUAL OPPORTUNITY FOR WORKERS WITH DISABILITIES (DEVIATION)	NOV 2025
52.222-37	EMPLOYMENT REPORTS ON VETERANS (DEVIATION)	NOV 2025
52.222-40	NOTIFICATION OF EMPLOYEE RIGHTS UNDER THE NATIONAL LABOR RELATIONS ACT (DEVIATION)	NOV 2025
52.222-50	COMBATING TRAFFICKING IN PERSONS (DEVIATION)	NOV 2025
52.223-5	POLLUTION PREVENTION AND RIGHT-TO-KNOW INFORMATION	MAY 2024
52.223-23	SUSTAINABLE PRODUCTS (DEVIATION)	NOV 2025
52.224-3	PRIVACY TRAINING	JAN 2017
52.225-5	TRADE AGREEMENTS	NOV 2023
52.226-8	ENCOURAGING CONTRACTOR POLICIES TO BAN TEXT MESSAGING WHILE DRIVING	MAY 2024
52.229-3	FEDERAL, STATE, AND LOCAL TAXES (DEVIATION)	SEP 2025
52.229-12	TAX ON CERTAIN FOREIGN PROCUREMENTS	FEB 2021
52.232-18	AVAILABILITY OF FUNDS	APR 1984
52.232-33	PAYMENT BY ELECTRONIC FUNDS TRANSFER—SYSTEM FOR AWARD MANAGEMENT	OCT 2018
52.232-40	PROVIDING ACCELERATED PAYMENTS TO SMALL BUSINESS SUBCONTRACTORS	MAR 2023
52.233-3	PROTEST AFTER AWARD (DEVIATION)	NOV 2025
52.233-4	APPLICABLE LAW FOR BREACH OF CONTRACT CLAIM (DEVIATION)	NOV 2025

52.237-2	PROTECTION OF GOVERNMENT BUILDINGS, EQUIPMENT, AND VEGETATION	APR 1984
52.244-6	SUBCONTRACTS FOR COMMERCIAL PRODUCTS AND COMMERCIAL SERVICES (DEVIATION)	APR 2026
852.201-70	CONTRACTING OFFICER'S REPRESENTATIVE	DEC 2022
852.203-70	COMMERCIAL ADVERTISING	MAY 2018
852.204-70	PERSONAL IDENTITY VERIFICATION OF CONTRACTOR PERSONNEL (DEVIATION)	MAR 2026
852.204-71	INFORMATION AND INFORMATION SYSTEMS SECURITY	FEB 2023
852.211-70	EQUIPMENT OPERATION AND MAINTENANCE MANUALS	NOV 2018
852.211-72	TECHNICAL INDUSTRY STANDARDS	NOV 2018
852.212-71	GRAY MARKET AND COUNTERFEIT ITEMS	FEB 2023
852.215-70	SERVICE-DISABLED VETERAN-OWNED AND VETERAN- OWNED SMALL BUSINESS EVALUATION FACTORS (DEVIATION)	JAN 2023
852.215-71	EVALUATION FACTOR COMMITMENTS	OCT 2019
852.219-70	VA SMALL BUSINESS SUBCONTRACTING PLAN MINIMUM REQUIREMENTS (DEVIATION)	JAN 2023
852.222-71	COMPLIANCE WITH EXECUTIVE ORDER 13899 (DEVIATION) (APR 2025)	APR 2025
852.232-72	ELECTRONIC SUBMISSION OF PAYMENT REQUESTS	NOV 2018
852.239-70	SECURITY REQUIREMENTS FOR INFORMATION TECHNOLOGY RESOURCES	FEB 2023
852.239-73	INFORMATION SYSTEM HOSTING, OPERATION, MAINTENANCE, OR USE	FEB 2023
852.239-74	SECURITY CONTROLS COMPLIANCE TESTING	FEB 2023
852.239-76	INFORMATION AND COMMUNICATION TECHNOLOGY ACCESSIBILITY	FEB 2023
852.242-71	ADMINISTRATIVE CONTRACTING OFFICER	OCT 2020
852.246-71	REJECTED GOODS	OCT 2018
852.247-73	PACKING FOR DOMESTIC SHIPMENT	OCT 2018
(End of Addendum to 52.212-4)		

SECTION D - CONTRACT DOCUMENTS, EXHIBITS, OR ATTACHMENTS

Attachment 1: Reagents Attachment A.

Attachment 2: Business Associate Agreement example

SECTION E - SOLICITATION PROVISIONS

E.1 52.212-1 INSTRUCTIONS TO OFFERORS—COMMERCIAL PRODUCTS AND COMMERCIAL SERVICES (OCT 2025) (DEVIATION)

(a) *Submission of offers.* Submit signed and dated offers to the office specified in this solicitation at or before the exact time specified in this solicitation. As a minimum, offers shall include—

- (1) The solicitation number;
- (2) The name, address, telephone number of the Offeror;
- (3) The Offeror's Unique Entity Identifier (UEI) and, if applicable, Electronic Funds Transfer (EFT) indicator;
- (4) Information necessary to evaluate the factors contained in the provision at 52.212-2 or as described in the solicitation;
- (5) Responses to provisions that require Offeror completion of information, representations, and certifications (other than those collected via the System for Award Management (SAM)); and
- (6) A statement specifying the extent of agreement with all terms, conditions, and provisions included in the solicitation and any solicitation amendments.

(b) *Period for acceptance of offers.* The Offeror agrees to hold the prices in its offer firm for 60 calendar days from the date specified for receipt of offers, unless another time period is specified in an addendum to the solicitation.

(c) *Late submissions, modifications, revisions, and withdrawals of offers.*

- (1) Offerors are responsible for submitting offers and any modifications or revisions to the Government office designated in the solicitation by the time specified in the solicitation.
- (2) Any offer, modification, or revision received after the time specified for receipt of offers is "late" and will not be considered unless it is received before award is made and the Contracting Officer determines that accepting the late offer would not unduly delay the acquisition. However, a late modification of an otherwise successful offer that makes its terms more favorable to the Government will be considered at any time it is received and may be accepted.
- (3) If an emergency or unanticipated event interrupts normal Government processes so that offers cannot be received at the Government office designated for receipt of offers by the exact time specified in the solicitation, and urgent Government requirements preclude amendment of the solicitation or other notice of an extension of the closing date, the time specified for receipt of offers will be deemed to be extended to the same time of day specified in the solicitation on the first work day on which normal Government processes resume.

(4) Offerors may withdraw their offers by written notice to the Government received at any time before award.

(d) *Contract award (not applicable to Invitation for Bids)*. The Government intends to evaluate offers and award a contract without discussions with Offerors. Therefore, the Offeror's initial offer should contain the Offeror's best terms. However, the Government reserves the right to conduct discussions, if necessary. The Government may reject any or all offers if such action is in the public interest, accept other than the lowest offer, and waive informalities and minor irregularities in offers received.

(e) *Debriefings*. If a postaward debriefing is given to requesting Offerors, the Government will disclose the following information, if applicable:

(1) The agency's evaluation of the significant weak or deficient factors in the debriefed Offeror's offer.

(2) The overall evaluated cost or price and technical rating of the successful Offeror and the debriefed Offeror and past performance information on the debriefed Offeror.

(3) The overall ranking of all Offerors when any ranking was developed by the agency during source selection.

(4) A summary of the rationale for award.

(5) For acquisitions of commercial products, the make and model of the product to be delivered by the successful Offeror.

(6) Reasonable responses to relevant questions posed by the debriefed Offeror as to whether the agency followed source-selection procedures set forth in the solicitation, applicable regulations, and other applicable authorities.

(End of Provision)

E.2 ADDENDUM to FAR 52.212-1 INSTRUCTIONS TO OFFERORS— COMMERCIAL PRODUCTS AND COMMERCIAL SERVICES

Provisions that are incorporated by reference (by Citation Number, Title, and Date), have the same force and effect as if they were given in full text. Upon request, the Contracting Officer will make their full text available.

The following provisions are incorporated into 52.212-1 as an addendum to this solicitation:

The following paragraphs are added to FAR 52.212-1.

(a) General

Offerors shall submit proposals that are complete, clear, and sufficiently detailed to permit a comprehensive evaluation in accordance with the evaluation criteria identified in this solicitation. The Government intends to evaluate proposals and make award without discussions; therefore, initial proposals should contain the Offeror's best terms from both a technical and price

standpoint. The Government reserves the right to conduct discussions if determined to be in the Government's best interest.

(b) Questions Regarding the Solicitation

Offerors are encouraged to submit any questions concerning this solicitation in writing via email to **Moneque Rodriguez, Contracting Officer**, at moneque.rodriguez@va.gov no later than **September 23, 2026 at 15:00PM EST**. The subject line of the email shall state **"Questions – Solicitation No. 36C24826R0114"**.

Questions received after the stated deadline may not be considered. The Government intends to provide written responses to all timely submitted questions through an amendment to the solicitation, if required. Oral explanations or instructions provided by Government personnel before award shall not be considered binding. Only written amendments issued by the Contracting Officer are binding and may modify the terms of this solicitation.

(c) Proposal Format

Proposals shall consist of the following separate volumes:

Volume I – Technical Capability

The Technical Capability volume shall describe the proposed solution and demonstrate how it satisfies the requirements of the Statement of Need. The proposal shall address each Technical Capability subfactor in sufficient detail to permit evaluation.

At a minimum, the Technical Capability proposal shall include:

- Description of the proposed chemistry analyzers, immunochemistry analyzers, and automation system.
- Manufacturer's literature, specifications, or other documentation supporting the proposed system's capabilities.
- Throughput and performance data for all proposed equipment.
- Description of operational efficiency features, including utility requirements and environmental considerations.
- Description of automation, workflow, and third-party integration capabilities.
- Proposed laboratory design recommendations and any value-added features provided at no additional cost to the Government.
- Identification of any proposed features that exceed the minimum requirements identified in the Statement of Work.

Volume II – Past Performance

Offerors shall provide up to three (3) recent and relevant references for contracts performed for three (3) consecutive years involving chemistry automation systems of similar size, complexity, and clinical workload. Recency is defined as the past five (5) years for the purposes of this solicitation.

For each reference, provide:

- Customer name and address.
- Point of contact, telephone number, and email address.

- Contract number.
- Period of performance.
- Description of the supplies and services provided.
- Description of system size and complexity.

The Government reserves the right to obtain past performance information from any source it deems appropriate.

Volume III – Price

The Price proposal shall include completed pricing for all Contract Line Item Numbers (CLINs) and any other pricing information required by the solicitation.

Offerors shall include sufficient detail to demonstrate that pricing is complete and consistent with the proposed technical approach.

(d) Basis for Award

Award will be made using the tradeoff process described in Revolutionary FAR Overhaul (RFO) 15.103-1.

The Government will evaluate proposals under the following factors:

1. Technical Capability
2. Past Performance
3. Price

Non-price Factors 1 and 2 are significantly more important than Factor 3 – Price.

The Government may award to other than the lowest-priced Offeror if a higher-rated proposal is determined to provide benefits that justify any associated price premium.

(e) Clarifications and Discussions

The Government reserves the right to seek clarifications, establish a competitive range, conduct discussions, request proposal revisions, and make award in accordance with RFO Part 15.

(f) Award Without Discussions

The Government intends to evaluate proposals and make award without discussions. Accordingly, each initial proposal should contain the Offeror's best technical and price terms. However, the Government reserves the right to conduct discussions if determined necessary.

(g) Proposal Validity

Proposals shall remain valid for a minimum of 180 calendar days after the proposal due date.

(h) Electronic Submission

Proposals shall be submitted electronically to Moneque Rodriguez at moneque.rodriguez@va.gov in accordance with the instructions identified elsewhere in this

solicitation. Offerors are responsible for ensuring proposals are received by the date and time specified in the solicitation.

E.3 52.209-7 INFORMATION REGARDING RESPONSIBILITY MATTERS (OCT 2018)

(a) *Definitions.* As used in this provision—

"Administrative proceeding" means a non-judicial process that is adjudicatory in nature in order to make a determination of fault or liability (e.g., Securities and Exchange Commission Administrative Proceedings, Civilian Board of Contract Appeals Proceedings, and Armed Services Board of Contract Appeals Proceedings). This includes administrative proceedings at the Federal and State level but only in connection with performance of a Federal contract or grant. It does not include agency actions such as contract audits, site visits, corrective plans, or inspection of deliverables.

"Federal contracts and grants with total value greater than \$10,000,000" means—

(1) The total value of all current, active contracts and grants, including all priced options; and

(2) The total value of all current, active orders including all priced options under indefinite-delivery, indefinite-quantity, 8(a), or requirements contracts (including task and delivery and multiple-award Schedules).

"Principal" means an officer, director, owner, partner, or a person having primary management or supervisory responsibilities within a business entity (e.g., general manager; plant manager; head of a division or business segment; and similar positions).

(b) The offeror [] has [] does not have current active Federal contracts and grants with total value greater than \$10,000,000.

(c) If the offeror checked "has" in paragraph (b) of this provision, the offeror represents, by submission of this offer, that the information it has entered in the Federal Awardee Performance and Integrity Information System (FAPIS) is current, accurate, and complete as of the date of submission of this offer with regard to the following information:

(1) Whether the offeror, and/or any of its principals, has or has not, within the last five years, in connection with the award to or performance by the offeror of a Federal contract or grant, been the subject of a proceeding, at the Federal or State level that resulted in any of the following dispositions:

(i) In a criminal proceeding, a conviction.

(ii) In a civil proceeding, a finding of fault and liability that results in the payment of a monetary fine, penalty, reimbursement, restitution, or damages of \$5,000 or more.

(iii) In an administrative proceeding, a finding of fault and liability that results in—

(A) The payment of a monetary fine or penalty of \$5,000 or more; or

(B) The payment of a reimbursement, restitution, or damages in excess of \$100,000.

(iv) In a criminal, civil, or administrative proceeding, a disposition of the matter by consent or compromise with an acknowledgment of fault by the Contractor if the proceeding could have led to any of the outcomes specified in paragraphs (c)(1)(i), (c)(1)(ii), or (c)(1)(iii) of this provision.

(2) If the offeror has been involved in the last five years in any of the occurrences listed in (c)(1) of this provision, whether the offeror has provided the requested information with regard to each occurrence.

(d) The offeror shall post the information in paragraphs (c)(1)(i) through (c)(1)(iv) of this provision in FAPIIS as required through maintaining an active registration in the System for Award Management, which can be accessed via <https://www.sam.gov> (see 52.204-7).

(End of Provision)

E.4 52.216-1 TYPE OF CONTRACT (NOV 2025) (DEVIATION)

The Government contemplates award of a Firm-Fixed-Price, Indefinite Delivery Indefinite Quantity contract resulting from this solicitation.

(End of Provision)

E.5 52.219-1 SMALL BUSINESS PROGRAM REPRESENTATIONS (NOV 2025) (DEVIATION)

(a) *Definitions.* As used in this provision-

Economically disadvantaged women-owned small business (EDWOSB) concern means a small business concern that is at least 51 percent directly and unconditionally owned by, and the management and daily business operations of which are controlled by, one or more women who are citizens of the United States and who are economically disadvantaged in accordance with 13 CFR part 127, and the concern is certified by SBA or an approved third-party certifier in accordance with 13 CFR 127.300. It automatically qualifies as a women-owned small business concern eligible under the WOSB Program.

HUBZone small business concern means a small business concern that meets the requirements described in 13 CFR 126.200, is certified by the Small Business Administration (SBA) and designated by SBA as a HUBZone small business concern in the Small Business Search (SBS) (13 CFR 126.103).

Service-disabled veteran-owned small business (SDVOSB) concern eligible under the SDVOSB Program means an SDVOSB concern that is designated in the System for Award Management (SAM) as certified by the Small Business Administration (SBA) in accordance with 13 CFR 128.300.

Small business concern—

(1) Means a concern, including its affiliates, that is independently owned and operated, not dominant in its field of operation, and qualified as a small business under the criteria in 13 CFR part 121 and the size standard in paragraph (b) of this provision.

(2) *Affiliates*, as used in this definition, means business concerns, one of whom directly or indirectly controls or has the power to control the others, or a third party or parties control or have the power to control the others. In determining whether affiliation exists, consideration is given to all appropriate factors including common ownership, common management, and contractual relationships. SBA determines affiliation based on the factors set forth at 13 CFR 121.103.

Small disadvantaged business concern, means a small business concern that-

(1) Is at least 51 percent unconditionally and directly owned (as defined at 13 CFR 124.105) by one or more socially disadvantaged (as defined at 13 CFR 124.103) and economically disadvantaged (as defined at 13 CFR 124.104) individuals who are citizens of the United States, and

(2) The management and daily business operations of which are controlled (as defined at 13 CFR 124.106) by individuals who meet the criteria in paragraph (1) of this definition.

Women-owned small business (WOSB) concern eligible under the WOSB Program (in accordance with 13 CFR part 127) means a small business concern that is at least 51 percent directly and unconditionally owned by, and the management and daily business operations of which are controlled by, one or more women who are citizens of the United States, and the concern is certified by SBA or an approved third-party certifier in accordance with 13 CFR 127.300.

(b)(1) The North American Industry Classification System (NAICS) code for this acquisition is 334516.

(2) The small business size standard is 1000 Employees.

(3) The small business size standard for a concern that submits an offer, other than on a construction or service acquisition, but proposes to furnish an end item that it did not itself manufacture, process, or produce (*i.e.*, nonmanufacturer), is 500 employees, or 150 employees for information technology value-added resellers under NAICS code 541519, if the acquisition—

(i) Is set aside for small business and has a value above the simplified acquisition threshold;

(ii) Uses the HUBZone price evaluation preference regardless of dollar value, unless the offeror waives the price evaluation preference; or

(iii) Is an 8(a), HUBZone, service-disabled veteran-owned, economically disadvantaged women-owned, or women-owned small business set-aside or sole-source award regardless of dollar value.

(c) *Representations*.

(1) The offeror represents as part of its offer that—

(i) It ☐ is, ☐ is not a small business concern; or

(ii) It ☐ is, ☐ is not a small business joint venture that complies with the requirements of 13 CFR 121.103(h) and 13 CFR 125.8(a) and (b). *[The offeror shall enter the name and unique entity identifier of each party to the joint venture: _____.]*

(2) *[Complete only if the offeror represented itself as a small business concern in paragraph (c)(1) of this provision.]* The offeror represents that it ☐ is, ☐ is not, a women-owned small disadvantaged business concern.

(3) *Women-owned small business (WOSB) joint venture eligible under the WOSB Program.* The offeror represents as part of its offer that it ☐ is, ☐ is not a joint venture that complies with the requirements of 13 CFR 127.506(a) through (c). *[The offeror shall enter the name and unique entity identifier of each party to the joint venture: _____.]*

(4) *Economically disadvantaged women-owned small business (EDWOSB) joint venture.* The offeror represents as part of its offer that it ☐ is, ☐ is not a joint venture that complies with the requirements of 13 CFR 127.506(a) through (c). *[The offeror shall enter the name and unique entity identifier of each party to the joint venture: _____.]*

(5) *SDVOSB joint venture eligible under the SDVOSB Program.* *[Complete only if the offeror is certified as a SDVOSB concern.]* The offeror represents as part of its offer that it ☐ is, ☐ is not a SDVOSB joint venture eligible under the SDVOSB Program that complies with the requirements of 13 CFR 128.402. *[The offeror shall enter the name and unique entity identifier of each party to the joint venture: _____.]*

(6) *HUBZone joint venture eligible under the HUBZone Program.* *[Complete only if the offeror is a HUBZone small business concern.]* The offeror represents, as part of its offer, that it ☐ is, ☐ is not a HUBZone joint venture that complies with the requirements of 13 CFR 126.616(a) through (c). *[The offeror shall enter the name and unique entity identifier of each party to the joint venture: _____.]* Each HUBZone small business concern participating in the HUBZone joint venture must be certified as a HUBZone concern.

(d) *Notice.*

Under 15 U.S.C. 645(d), any person who misrepresents a firm's status as a business concern that is small, HUBZone small, small disadvantaged, service-disabled veteran-owned small, economically disadvantaged women-owned small, or women-owned small eligible under the WOSB Program in order to obtain a contract to be awarded under the preference programs established pursuant to section 8, 9, 15, 31, and 36 of the Small Business Act or any other provision of Federal law that specifically references section 8(d) for a definition of program eligibility, will be—

- (1) Punished by imposition of fine, imprisonment, or both;
- (2) Subject to administrative remedies, including suspension and debarment; and
- (3) Ineligible for participation in programs conducted under the authority of the Act.

(End of Provision)

E.6 52.225-6 TRADE AGREEMENTS CERTIFICATE (FEB 2021)

(a) The offeror certifies that each end product, except those listed in paragraph (b) of this provision, is a U.S.-made or designated country end product, as defined in the clause of this solicitation entitled "Trade Agreements."

(b) The offeror shall list as other end products those supplies that are not U.S.-made or designated country end products.

Other End Products

Line item No.	Country of origin

[List as necessary]

(c) The Government will evaluate offers in accordance with the policies and procedures of Part 25 of the Federal Acquisition Regulation. For line items covered by the WTO GPA, the Government will evaluate offers of U.S.-made or designated country end products without regard to the restrictions of the Buy American statute. The Government will consider for award only offers of U.S.-made or designated country end products unless the Contracting Officer determines that there are no offers for such products or that the offers for those products are insufficient to fulfill the requirements of this solicitation.

(End of Provision)

E.7 52.233-2 SERVICE OF PROTEST (SEP 2006)

Protests, as defined in section 33.101 of the Federal Acquisition Regulation, that are filed directly with an agency, and copies of any protests that are filed with the Government Accountability Office (GAO), shall be served on the Contracting Officer (addressed as follows) by obtaining written and dated acknowledgment of receipt from:

Moneque Rodriguez – Contracting Officer
Email Only: moneque.rodriguez@va.gov

(b) The copy of any protest shall be received in the office designated above within one day of filing a protest with the GAO.

(End of Provision)

E.8 VAAR 852.233-70 PROTEST CONTENT/ALTERNATIVE DISPUTE RESOLUTION (OCT 2018)

(a) Any protest filed by an interested party shall—

(1) Include the name, address, fax number, email and telephone number of the protester;

(2) Identify the solicitation and/or contract number;

(3) Include an original signed by the protester or the protester's representative and at least one copy;

(4) Set forth a detailed statement of the legal and factual grounds of the protest, including a description of resulting prejudice to the protester, and provide copies of relevant documents;

(5) Specifically request a ruling of the individual upon whom the protest is served;

(6) State the form of relief requested; and

(7) Provide all information establishing the timeliness of the protest.

(b) Failure to comply with the above may result in dismissal of the protest without further consideration.

(c) Bidders/offerors and Contracting Officers are encouraged to use alternative dispute resolution (ADR) procedures to resolve protests at any stage in the protest process. If ADR is used, the Department of Veterans Affairs will not furnish any documentation in an ADR proceeding beyond what is allowed by the Federal Acquisition Regulation.

(End of Provision)

E.9 VAAR 852.233-71 ALTERNATE PROTEST PROCEDURE (OCT 2018)

(a) As an alternative to filing a protest with the Contracting Officer, an interested party may file a protest by mail or electronically with: Executive Director, Office of Acquisition and Logistics, Risk Management and Compliance Service (003A2C), Department of Veterans Affairs, 810 Vermont Avenue NW, Washington, DC 20420 or Email: EDProtests@va.gov.

(b) The protest will not be considered if the interested party has a protest on the same or similar issue(s) pending with the Contracting Officer.

(End of Provision)

PLEASE NOTE: The correct mailing information for filing alternate protests is as follows:

Deputy Assistant Secretary for Acquisition and Logistics,
Risk Management Team, Department of Veterans Affairs
810 Vermont Avenue, N.W.
Washington, DC 20420

Or for solicitations issued by the Office of Construction and Facilities Management:

Director, Office of Construction and Facilities Management
811 Vermont Avenue, N.W.
Washington, DC 20420

E.10 52.252-1 SOLICITATION PROVISIONS INCORPORATED BY REFERENCE (FEB 1998)

This solicitation incorporates one or more solicitation provisions by reference, with the same force and effect as if they were given in full text. Upon request, the Contracting Officer will make their full text available. The offeror is cautioned that the listed provisions may include blocks that must be completed by the offeror and submitted with its quotation or offer. In lieu of submitting

the full text of those provisions, the offeror may identify the provision by paragraph identifier and provide the appropriate information with its quotation or offer. Also, the full text of a solicitation provision may be accessed electronically at this/these address(es):

https://www.acquisition.gov/far-overhaul/far-part-deviation-guide/far-overhaul-part-52#FAR_52_252_1

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

(End of Provision)

<u>FAR Number</u>	<u>Title</u>	<u>Date</u>
52.203-11	CERTIFICATION AND DISCLOSURE REGARDING PAYMENTS TO INFLUENCE CERTAIN FEDERAL TRANSACTIONS	SEP 2024
52.203-18	PROHIBITION ON CONTRACTING WITH ENTITIES THAT REQUIRE CERTAIN INTERNAL CONFIDENTIALITY AGREEMENTS OR STATEMENTS—REPRESENTATION	JAN 2017
52.204-7	SYSTEM FOR AWARD MANAGEMENT—REGISTRATION (DEVIATION)	NOV 2025
52.214-21	DESCRIPTIVE LITERATURE	APR 2002
52.225-18	PLACE OF MANUFACTURE	AUG 2018
52.229-11	TAX ON CERTAIN FOREIGN PROCUREMENTS—NOTICE AND REPRESENTATION (DEVIATION)	SEP 2025
852.239-71	INFORMATION SYSTEM SECURITY PLAN AND ACCREDITATION	FEB 2023
852.239-75	INFORMATION AND COMMUNICATION TECHNOLOGY ACCESSIBILITY NOTICE	FEB 2023

(End of Addendum to 52.212-1)

E.11 52.212-2 EVALUATION—COMMERCIAL PRODUCTS AND COMMERCIAL SERVICES (OCT 2025) (DEVIATION)

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

The Government will utilize a Best Value Trade-Off source selection process. Award may be made to an offeror other than the lowest-priced offeror when the Government determines that the evaluated benefits of a higher-priced proposal warrant the additional price.

The following factors shall be used to evaluate offers:

Factor 1 – Technical

Factor 2 – Past Performance

Factor 3 – Price

Non-price Factors 1 and 2 are significantly more important than Factor 3 – Price.

As proposals become more equal under Factors 1 and 2, Price may become a more significant consideration in the best-value trade-off.

In addition, the Government will evaluate the information submitted pursuant to VAAR 852.215-70, Service-Disabled Veteran-Owned Small Business and Veteran-Owned Small Business Evaluation Factors, in accordance with that provision.

Factor 1 – Technical Capability

The Government will evaluate the offeror's proposed technical solution to determine its ability to satisfy the requirements of the solicitation.

The Technical Factor consists of the following four (4) subfactors, which are of equal importance:

Subfactor A – System Performance

The Government will evaluate:

- Chemistry analyzer throughput.
- Immunochemistry analyzer throughput.

Higher demonstrated throughput that improves laboratory efficiency and supports projected workload may be evaluated more favorably.

Subfactor B – Operational Efficiency

The Government will evaluate:

- Water consumption.
- Heat generation.
- Noise generation.
- Utility requirements.

Solutions demonstrating lower utility consumption and reduced environmental impact may receive a more favorable evaluation.

Subfactor C – Automation and Workflow

The Government will evaluate:

- Third-party instrument integration (e.g. Sysmex XN 9100, Werfen ACL TOPS 750)
- Storage capacity and accessibility.
- STAT specimen turn around time.
- Routine immunoassay specimen turn around time.
- Calibration frequency
- Quality control frequency

Solutions providing greater automation, broader integration, and improved laboratory workflow may receive a more favorable evaluation.

Subfactor D – Laboratory Design and Value-Added Features

The Government will evaluate:

Identification of furnishings or other enhancements that are included at no additional cost to the Government.

Features that improve productivity, safety, and workflow without increasing contract price may receive a more favorable evaluation.

The following adjectival ratings will be used for Factor 1 and its subfactors:

RATING	DESCRIPTION
Outstanding	Proposal meets requirements and indicates an <i>exceptional approach</i> and understanding of the requirements. Proposal contains multiple strengths and no deficiencies. Risk of unsuccessful performance is low.
Good	Proposal meets requirements and indicates a <i>thorough approach</i> and understanding of the requirements. Proposal contains at least one strength and no deficiencies. Risk of unsuccessful performance is low to moderate.
Acceptable	Proposal meets requirements and indicates an <i>adequate approach</i> and understanding of the requirements. Proposal has no strengths or deficiencies. Risk of unsuccessful performance is no worse than moderate.
Marginal	Proposal does not clearly meet requirements and has <i>not demonstrated and adequate approach</i> and understanding of the requirements. Risk of unsuccessful performance is high.
Unsatisfactory	Proposal does not meet requirements and/or contains one or more deficiencies and is not awardable. Proposal is not awardable unless the deficiency is corrected.

Ratings will not be determined by mechanically counting strengths, weaknesses, or other findings. The evaluation team will consider the significance of the findings, associated Government benefits and risks, and the totality of the proposal under the applicable factor or subfactor.

The overall Technical Factor rating will not be determined by mathematically averaging the four subfactor ratings. The SSEB will determine the overall technical rating based on the substantive evaluation findings and the equal importance of the four Technical subfactors.

Factor 2 – Past Performance

The Government will evaluate the offeror's recent and relevant past performance to assess the Government's expectation that the offeror will successfully perform the requirements of this solicitation.

Offerors shall provide at least **three (3) recent and relevant references for contracts with at least three (3) years of service involving chemistry automation systems of similar size, complexity, and clinical workload. Recency is defined as the past five (5) years for the purposes of this solicitation.**

For each reference, the offeror shall provide:

1. Customer name and address;
2. Point of contact, telephone number, and email address;
3. Contract number;
4. Period of performance;
5. Description of the supplies and services provided; and
6. Description of system size and complexity.

The Government reserves the right to obtain past performance information from any source it deems appropriate and is not limited to the information or references provided by the offeror.

Past Performance Relevancy

The Government will consider the similarity of the offeror's past performance to the requirements of this solicitation. Past performance information may be categorized as:

- **Very Relevant**
- **Relevant**
- **Somewhat Relevant**
- **Not Relevant**

The relevancy determination will be based on the degree of similarity between the past performance effort and the current requirement, including, as applicable, size, scope, complexity, clinical workload, and the supplies and services performed.

Past Performance Rating

The Government will assign the following Past Performance ratings:

RATING	DESCRIPTION
Excellent	Based on the offerors' recent/ relevant performance record, the government has a <i>high expectation</i> the offeror will successfully perform the required effort.
Good	Based on the offerors' recent/ relevant performance record, the government has a <i>reasonable expectation</i> the offeror will successfully perform the required effort.
Satisfactory	Based on the offerors' recent/ relevant performance record, the government has a <i>moderate expectation</i> the offeror will successfully perform the required effort.
Marginal	Based on the offerors' recent/ relevant performance record, the government has a <i>low expectation</i> the offeror will successfully perform the required effort.

Unsatisfactory	Based on the offerors' recent/ relevant performance record, the government has a <i>no expectation</i> the offeror will successfully perform the required effort.
Unknown	No recent/ relevant performance record is available, or the offerors' performance record is so sparse that no meaningful confidence assessment rating can be reasonably assigned.

An offeror without a record of relevant past performance, or for whom information on past performance is not available, will not be evaluated favorably or unfavorably on past performance.

Factor 3 – Price

This factor will be evaluated by determining if price submitted is fair and reasonable in relation to the requirements of solicitation. The Government will evaluate the price by adding the total of all line-item prices. The Total Evaluated Price will be that sum. Price proposals will be evaluated to determine if the prices are:

- a. **Complete** – The proposal contains price(s) listed for all contract line-item numbers (CLIN) and all items required for the proposed solution.
- b. **Reasonableness** of an offeror's proposal is evaluated through cost or price analysis techniques as described in RFO Subpart 15.4.

(b) *Notice of award*. A written notice of award or acceptance of an offer furnished to the successful Offeror within the time for acceptance specified in the offer, shall result in a binding contract without further action by either party. Before the offer's specified expiration time, the Government may accept an offer (or part of an offer), whether or not there are negotiations after its receipt, unless a written notice of withdrawal is received before award.

(End of Provision)