SOLICITATION/CONTRACT/ORDER FOR COMMERCIAL ITEMS

OFFEROR TO COMPLETE BLOCKS 12, 17, 23, 24, & 30

1. REQUISITION NUMBER

PAGE 1 OF 81

2. CONTRACT NO.

3. AWARD/ EFFECTIVE DATE

4. ORDER NUMBER

5. SOLICITATION NUMBER: 75F40126R00020

6. SOLICITATION ISSUE DATE: 06/11/2026

7. FOR SOLICITATION INFORMATION CALL:

a. NAME: SHENEIL GREEN

b. TELEPHONE NUMBER (No collect calls): 301-796-0675

8. OFFER DUE DATE/LOCAL TIME: 07/10/2026 1200 ET

9. ISSUED BY CODE DAP

DHHS/FDA/OAGS/DAP
11601 Landsdown St.
13th Floor
North Bethesda MD 20852

10. THIS ACQUISITION IS ☒ UNRESTRICTED OR ☐ SET ASIDE: % FOR:

☐ SMALL BUSINESS
☐ HUBZONE SMALL BUSINESS
☐ SERVICE-DISABLED VETERAN-OWNED SMALL BUSINESS (SDVOSB)
☐ WOMEN-OWNED SMALL BUSINESS (WOSB)
☐ ECONOMICALLY DISADVANTAGED WOMEN-OWNED SMALL BUSINESS (EDWOSB)
☐ 8(A)

NORTH AMERICAN INDUSTRY CLASSIFICATION STANDARD (NAICS): 541690

SIZE STANDARD: $19

11. DELIVERY FOR FREE ON BOARD (FOB) DESTINATION UNLESS BLOCK IS MARKED
☒ SEE SCHEDULE

12. DISCOUNT TERMS

13a. THIS CONTRACT IS A RATED ORDER UNDER THE DEFENSE PRIORITIES AND ALLOCATIONS SYSTEM - DPAS (15 CFR 700)
☐

13b. RATING

14. METHOD OF SOLICITATION
☐ REQUEST FOR QUOTE (RFQ) ☐ INVITATION FOR BID (IFB) ☒ REQUEST FOR PROPOSAL (RFP)

15. DELIVER TO CODE DHHS/FDA/OAGS

OAGS/DAP/FSB

16. ADMINISTERED BY CODE DAP

DHHS/FDA/OAGS/DAP
11601 Landsdown St.
13th Floor
North Bethesda MD 20852

17a. CONTRACTOR/ OFFEROR CODE FACILITY CODE

TELEPHONE NO.

☐ 17b. CHECK IF REMITTANCE IS DIFFERENT AND PUT SUCH ADDRESS IN OFFER

18a. PAYMENT WILL BE MADE BY CODE

18b. SUBMIT INVOICES TO ADDRESS SHOWN IN BLOCK 18a UNLESS BLOCK BELOW IS CHECKED ☐ SEE ADDENDUM

19. ITEM NO.	20. SCHEDULE OF SUPPLIES/SERVICES	21. QUANTITY	22. UNIT	23. UNIT PRICE	24. AMOUNT
	This requirement supports FDA's Office of Occupational Safety and Health (OOSH) in providing Occupational Safety, Industrial Hygiene, Safety Engineering, Information Support, and Training services (OSIST) for the agency's Environmental and Occupational Safety and Health (EOSH) program. The Standard Form 1449 represents the contract line-item number (CLIN) structure for this Indefinite Delivery Indefinite Quantity (IDIQ) *(Use Reverse and/or Attach Additional Sheets as Necessary)*				

25. ACCOUNTING AND APPROPRIATION DATA

26. TOTAL AWARD AMOUNT *(For Government Use Only)*

☒ 27a. SOLICITATION INCORPORATES BY REFERENCE (FEDERAL ACQUISITION REGULATION) FAR 52.212-1, 52.212-4. FAR 52.212-3 AND 52.212-5 ARE ATTACHED. ADDENDA ☒ ARE ☐ ARE NOT ATTACHED.

☐ 27b. CONTRACT/PURCHASE ORDER INCORPORATES BY REFERENCE FAR 52.212-4. FAR 52.212-5 IS ATTACHED. ADDENDA ☐ ARE ☐ ARE NOT ATTACHED.

☒ 28. CONTRACTOR IS REQUIRED TO SIGN THIS DOCUMENT AND RETURN 1 COPIES TO ISSUING OFFICE. CONTRACTOR AGREES TO FURNISH AND DELIVER ALL ITEMS SET FORTH OR OTHERWISE IDENTIFIED ABOVE AND ON ANY ADDITIONAL SHEETS SUBJECT TO THE TERMS AND CONDITIONS SPECIFIED.

☐ 29. AWARD OF CONTRACT: REFERENCE _____ OFFER DATED _____. YOUR OFFER ON SOLICITATION (BLOCK 5), INCLUDING ANY ADDITIONS OR CHANGES WHICH ARE SET FORTH HEREIN, IS ACCEPTED AS TO ITEMS:

30a. SIGNATURE OF OFFEROR/CONTRACTOR

31a. UNITED STATES OF AMERICA *(SIGNATURE OF CONTRACTING OFFICER)*

30b. NAME AND TITLE OF SIGNER *(Type or print)*

30c. DATE SIGNED

31b. NAME OF CONTRACTING OFFICER *(Type or print)*: LINDA M. FINAN

31c. DATE SIGNED

19. ITEM NO.	20. SCHEDULE OF SUPPLIES/SERVICES	21. QUANTITY	22. UNIT	23. UNIT PRICE	24. AMOUNT
	contract. This IDIQ will have a single five (5) year ordering period. The dates shown in the solicitation are estimated and may change based upon final date of contract award. Individual task orders issued under this IDIQ under this IDIQ may be firm-fixed-price, time-and-materials, labor-hour, or a combination thereof, as specified in each task order. Period of Performance: 08/17/2026 to 08/15/2031				
1	Occupational Safety, Industrial Hygiene, Safety Engineering, Information Support, and Training (OSIST) support services.				

32a. QUANTITY IN COLUMN 21 HAS BEEN

☐ RECEIVED ☐ INSPECTED ☐ ACCEPTED, AND CONFORMS TO THE CONTRACT, EXCEPT AS NOTED: _____

32b. SIGNATURE OF AUTHORIZED GOVERNMENT REPRESENTATIVE	32c. DATE	32d. PRINTED NAME AND TITLE OF AUTHORIZED GOVERNMENT REPRESENTATIVE

32e. MAILING ADDRESS OF AUTHORIZED GOVERNMENT REPRESENTATIVE	32f. TELEPHONE NUMBER OF AUTHORIZED GOVERNMENT REPRESENTATIVE
	32g. E-MAIL OF AUTHORIZED GOVERNMENT REPRESENTATIVE

33. SHIP NUMBER	34. VOUCHER NUMBER	35. AMOUNT VERIFIED CORRECT FOR	36. PAYMENT	37. CHECK NUMBER
☐ PARTIAL ☐ FINAL			☐ COMPLETE ☐ PARTIAL ☐ FINAL	

38. S/R ACCOUNT NUMBER	39. S/R VOUCHER NUMBER	40. PAID BY

41a. I CERTIFY THIS ACCOUNT IS CORRECT AND PROPER FOR PAYMENT		42a. RECEIVED BY *(Print)*	
41b. SIGNATURE AND TITLE OF CERTIFYING OFFICER	41c. DATE	42b. RECEIVED AT *(Location)*	
		42c. DATE REC'D *(YY/MM/DD)*	42d. TOTAL CONTAINERS

SECTION A - SOLICITATION/CONTRACT FORM (SF-1449)

This solicitation uses Standard Form 1449 (SF-1449), Solicitation/Contract/Order for Commercial Products and Commercial Services.

SAM.gov Registration Conflict Statement:

By submission of an offer, the Offeror acknowledges the requirement that a prospective awardee must be registered in the System for Award Management (SAM) database prior to award, during performance, and through final payment of any contract resulting from this solicitation.

SECTION B - SUPPLIES OR SERVICES AND PRICES/COSTS

B.1 Contract Pricing

The Standard Form 1449 represents the contract line-item number (CLIN) structure for this Indefinite Delivery Indefinite Quantity (IDIQ) contract. Individual task orders issued under this IDIQ may be firm-fixed-price, time-and-materials, labor-hour, or a combination thereof, as specified in each task order.

The negotiated hourly rates, services, profit, overhead, and general and administrative as reflected in the U.S. Food and Drug Administration's Occupational Safety, Industrial Hygiene, Information Systems, and Training (OSIST) Pricing Structure will be incorporated into the award.

B.1.1 Labor Rates

The Contractor's proposed labor rates, as set forth in Attachment C3 (Price Workbook, Tab 1), shall serve as fully-burdened ceiling rates for labor hour and time-and-materials task orders issued under this IDIQ. These rates include all direct labor, indirect costs, overhead, general and administrative expenses, and profit.

Rate Escalation: Offerors shall propose labor rates in Attachment C3 by ordering period (Year 1, Year 2, Year 3, Year 4, Year 5). Rates may escalate between ordering periods but remain fixed within each ordering period. Once proposed and accepted, these rates become the ceiling rates for that ordering period and apply to all labor hour and time-and-materials task orders issued during that period.

B.1.2 Equipment Recertification and Decontamination Rates

The Contractor's equipment recertification and decontamination rates, as set forth in Attachment C3 (Price_Workbook, Tab 2), are incorporated into this contract and shall serve as fully burdened ceiling rates for annual equipment recertification and associated decontamination services performed under this IDIQ.

These rates include all direct and indirect costs required to perform the services, including labor, supervision, tools, minor materials, documentation, calibration of test instruments, travel (unless otherwise specified at the task order level), overhead, general and administrative expenses, and profit.

Rate Structure: Rates are established as fixed unit rates by equipment category, service type, and ordering period (Year 1 through Year 5), as specified in Attachment C3.

Two primary rate groupings apply:

a. Annual Equipment Recertification Rates: Rates represent the total cost to perform required inspection, testing, verification, and documentation necessary to maintain compliance with applicable standards and certification requirements on an annual basis.

b. Decontamination Service Rates: Rates represent the total cost to perform equipment, room, or laboratory decontamination services (e.g., VHP or equivalent methods), including setup, execution, monitoring, and documentation of decontamination effectiveness.

Scope of Rates

Included:

- Annual certification testing, inspection, and verification
- Documentation, reporting, and certification records
- Calibration of testing instruments
- Minor adjustments necessary to achieve compliance
- Decontamination services, including:
    - Equipment and laboratory decontamination
    - Placement and analysis of biological/chemical indicators
    - Documentation of decontamination results.

Excluded:

- Major repairs, system replacement, or capital upgrades
- Replacement parts or consumables exceeding task order thresholds
- Corrective actions requiring significant engineering modification.

Excluded items shall be addressed at the task order level (e.g., Other Direct Costs (ODCs) or separate CLINs).

Rate Applicability: These rates apply to labor-hour (LH) and time-and-materials (T&M) task orders requiring recertification and/or decontamination services.

For firm-fixed-price (FFP) task orders, these services shall be included in the total fixed price unless separately priced in the task order.

Rate Escalation: Rates are fixed within each ordering period and may escalate only between ordering periods as specified in Attachment C3. Rates established for an ordering period are ceiling rates for that period.

Adjustments: No adjustments to these rates are permitted during an ordering period unless expressly authorized elsewhere in the contract.

B.2 Task Order Pricing

Task orders issued under this IDIQ contract may use different pricing arrangements as specified in each task order:

(a) Firm-Fixed-Price (FFP): Fixed total price for specified scope of work
(b) Time-and-Materials (T&M): Ceiling hourly rates × actual hours worked
(c) Labor-Hour (LH): Ceiling hourly rates × actual hours worked
(d) Unit Pricing: Fixed unit rates × actual quantities delivered
(e) Combination: A task order may combine multiple pricing types

The Contractor's proposed ceiling labor and service rate (for T&M and LH work) are incorporated in Attachment C3 and shall apply to all task orders requiring labor-hour or time-and-materials pricing.

These ceiling rates may not be exceeded without a contract modification approved by the Contracting Officer.

B.3 Minimum Guarantee and Maximum Dollar Ceiling (Master Contract)

The guaranteed minimum amount to be ordered under the contract is the obligated base period of the first task order. The contract maximum is **$14,500,000** inclusive of all ordering periods.

B.4 Funding

Funds for the services provided will be obligated at the task order level as they become available. Each order will specify the amount presently available for payment by the Government and allotted to the contract line items included.

Except as required by other provisions of this IDIQ and the associated Task Orders, specifically citing and stated to be an exception to this term—

The Government is not obligated to reimburse the Contractor for costs incurred in excess of the total amount allotted by the Government to the Task Order(s); and

The Contractor is not obligated to continue performance under the contract (including actions under the Termination clause) or otherwise incur costs in excess of the amount then allotted to the Task Order(s) by the Government.

The Government may de-obligate funds as long as funds are still available in the task order for Contractor's continuing performance.

B.5 Ordering

Any supplies and services to be furnished under the contract shall be ordered by issuance of task orders by the Contracting Officer. Such orders may be issued from date of award until expiration of the contract.

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

A task order is considered "issued" when distributed via email to the Contractor's email address.

B.6 Applicable Labor Categories and Contractor Furnished Property/Services

B.6.1 Labor Categories
The labor categories, equipment certification and repair rates, and associated fully burdened hourly rates in Attachment C3 shall be used by the Contractor to develop task order pricing proposals and to invoice for time-and-materials and labor-hour task orders.

B.6.2 Contractor-Furnished Property and Services
Unless a task order specifically identifies items as Government-furnished, the Contractor shall

provide all property, equipment, tools, materials, supplies, and services required for performance at no additional cost to the Government.

B.7 Wage Determination Price Adjustments

Service Contract Labor Standards (SCLS) are not applicable to this contract. Accordingly, FAR 52.222-43, *Fair Labor Standards Act and Service Contract Labor Standards—Price Adjustment (Multiple Year and Option Contracts)*, does not apply, and no price adjustments based on Department of Labor wage determinations shall be authorized.

SECTION C - DESCRIPTION/SPECIFICATIONS/WORK STATEMENT

C.1 IDIQ Performance Work Statement (PWS)

The Performance Work Statement (PWS) for this Indefinite-Delivery/Indefinite-Quantity (IDIQ) contract is provided as Attachment C1 – OSIST IDIQ PWS.

The IDIQ PWS establishes the enterprise-level scope, performance standards, and integrated service requirements for Occupational Safety, Policy, and Laboratory Quality Support services to be performed across FDA headquarters and nationwide laboratory and field facilities.

The IDIQ PWS defines the overarching framework for all work performed under this contract, including:

- Program objectives supporting the FDA Occupational Safety and Health (OSH) mission
- IDIQ-level program management and governance requirements
- Task Areas, including:
    - Program and Order Management
    - Transition Services
    - Occupational Safety, Policy, and Laboratory Quality Support
    - Primary Barrier Equipment Maintenance and Certification
    - Industrial Hygiene Support Services
    - Information and Data Systems Support
    - Training Development and Management
- Enterprise-wide performance requirements and service expectations
- Deliverables and reporting requirements (e.g., Monthly Status Reports, technical reports, certification documentation)
- Quality control and quality assurance requirements
- Applicable regulatory, safety, and technical standards (e.g., OSHA, ANSI/ASSP Z10, NSF/ANSI 49, ISO, BMBL)

All task orders issued under this IDIQ shall be within the general scope and task areas defined in the IDIQ PWS.

C.2 Task Order Performance Work Statements (TO PWS)

Work under this IDIQ shall be ordered through the issuance of individual task orders. Each task order shall include a Task Order Performance Work Statement (TO PWS) that defines the specific scope, technical requirements, deliverables, performance standards, and place of performance applicable to that order.

Task Order 1 – CBER BSL-3 Annual Re-Verification

Attachment R1 provides the Performance Work Statement for Task Order 1 – CBER BSL-3 Annual Re-Verification and Decontamination Services.

Task Order 1 includes, but is not limited to:

- BSL-3 laboratory re-verification and certification support
- Primary barrier equipment evaluation and certification validation
- Heating, Ventilation, and Air Conditioning (HVAC) airflow and pressure differential testing, including failure scenario testing
- Vaporized hydrogen peroxide (VHP) decontamination services
- Biosafety compliance assessments aligned with CDC, NIH, USDA/APHIS, and applicable federal standards
- Deficiency identification, corrective action evaluation, and reporting
- Preparation of draft and final verification reports and certification documentation

Additional Task Orders

Future task orders may encompass any of the task areas defined in the IDIQ PWS, including but not limited to:

- Occupational safety and laboratory quality support services
- Primary barrier equipment maintenance, repair, and certification
- Industrial hygiene assessments and program support
- Information and data management system support
- Training development and delivery
- Policy, compliance, and programmatic support services

Task orders may be issued with varying levels of scope definition and may include firm-fixed-price, labor-hour, time-and-materials, or hybrid pricing arrangements, as specified in each task order.

C.3 Relationship Between IDIQ PWS and Task Order PWSs

The IDIQ PWS (Attachment C1) establishes the overall scope, framework, and performance requirements for this contract.

Task Order PWSs establish the specific requirements and performance obligations for individual task orders.

In the event of a conflict between the IDIQ PWS and a Task Order PWS:

- The Task Order PWS shall govern the specific task order; however,
- The IDIQ PWS shall govern overall contract scope and requirements, unless otherwise determined by the Contracting Officer.

Any inconsistencies or ambiguities shall be resolved by the Contracting Officer through written clarification or contract modification.

SECTION D – PACKAGING AND MARKING

Not applicable. Services are being acquired under this contract.

SECTION E – INSPECTION AND ACCEPTANCE

E.1 Inspection and Acceptance

Services performed under this contract are subject to inspection and acceptance by the Government in accordance with FAR 52.246-4, Inspection of Services—Fixed-Price, and FAR 52.246-6, Inspection—Time-and-Material and Labor-Hour (as applicable based on task order type).

All services shall be performed in accordance with the requirements specified in the IDIQ Performance Work Statement (Attachment C1) and individual Task Order Performance Work Statements.

Performance Requirements Summary (PRS):

Individual task orders will include a Performance Requirements Summary (PRS) that establishes: - Specific performance objectives and standards for that task order - Acceptable Quality Levels (AQLs) for measurable performance metrics - Surveillance methods the Government will use to monitor performance - Consequences for not meeting performance standards.

The PRS is incorporated into each task order and serves as the basis for the Government's quality assurance surveillance.

E.2 Contracting Officer's Representative (COR)

A Contracting Officer's Representative (COR) will be designated in writing for technical monitoring and acceptance of services. The COR will: - Monitor Contractor performance against PRS requirements - Conduct quality assurance surveillance as specified in the task order PRS - Accept or reject deliverables and services - Document performance issues and recommend corrective actions.

The COR does not have authority to modify contract terms, pricing, or scope.

E.3 Acceptance

Services will be accepted when the COR determines that: - All work has been performed in accordance with contract requirements - Performance meets or exceeds the standards specified in the task order PRS - All deliverables have been submitted and approved - Any deficiencies have been corrected to the Government's satisfaction.

Acceptance may be on a deliverable-by-deliverable basis, monthly basis, or upon completion of the entire task order as specified in the individual task order.

SECTION F – DELIVERIES OR PERFORMANCE

F.1 Period of Performance

F.1.1 IDIQ Contract Ordering Period

The ordering period for this IDIQ contract is five (5) years from the date of contract award. During this ordering period, the Contracting Officer may issue task orders for services within the scope of this contract.

The ordering period represents the period during which task orders may be issued, not the period during which task orders must be completed.

For purposes of this contract, “date of contract award” means the date the Contracting Officer signs the SF 1449 contract document in Block 27c (Award).

F.1.2 Task Order Performance Periods

Individual task order periods of performance will be specified in each task order and are subject to the following constraint:

No individual task order (inclusive of all option periods for that task order) may exceed five (5) years in duration from the date of task order issuance.

Task orders may be issued at any time during the IDIQ ordering period and may continue performance after the ordering period expires, provided the task order performance period does not exceed five (5) years from task order issuance.

F.1.3 Contract Expiration

Upon expiration of the five-year IDIQ ordering period, no new task orders may be issued. However, task orders issued prior to expiration shall continue in accordance with their specified performance periods.

F.2 Place of Performance

F.2.1 Primary Place of Performance

The primary place of performance for services under this IDIQ contract is:

FDA Headquarters – White Oak Federal Research Center
10903 New Hampshire Avenue
Silver Spring, MD 20993

F.2.2 Additional Locations

Individual task orders may specify additional or alternative performance locations within the Washington DC metropolitan area or at other FDA nation-wide facilities as required. Refer to Attachment C2 for OSIST locations.

F.2.3 Contractor Personnel Access

Contractor personnel requiring access to FDA facilities must comply with all security, badging, and credentialing requirements specified in Section H.1 and in individual task orders.

SECTION G - CONTRACT ADMINISTRATION DATA

G.1 Contracting Officer

The Contracting Officer for this contract is:

L. Maria Finan
Contracting Officer
U.S. Food and Drug Administration
Email: Linda.Finan@fda.hhs.gov

The Contracting Officer is the only person authorized to: - Modify contract terms, scope, or pricing - Issue task orders under this IDIQ - Make commitments or expenditures of Government funds - Approve Key Personnel substitutions or changes.

G.2 Contract Specialist

The Contract Specialist for this contract is:

Sheneil Green
Contract Specialist
U.S. Food and Drug Administration
Email: Sheneil.Green@fda.hhs.gov

The Contract Specialist assists with contract administration but does not have authority to modify contract terms or obligate Government funds.

G.3 Contractor Points of Contact

The Contractor shall designate and provide contact information for the following positions within five (5) business days of contract award:

(a) Primary Contract Administrator: Individual authorized to receive official correspondence, task orders, and modifications from the Contracting Officer
(b) Program Manager: Key Personnel position responsible for overall contract performance and coordination with the COR
(c) Alternate Contacts: Individual authorized to act in the absence of the Primary Contract Administrator and Program Manager.

Contact information shall include: name, title, phone number, email address, and mailing address.

G.4 Contracting Officer’s Representative (COR)

A Contracting Officer’s Representative (COR) will be designated in writing in accordance with RFO FAR Part 1. The COR is responsible for technical monitoring of the Contractor’s performance. The COR does not have authority to change contract terms or prices.

COR Designation and Communication:

The Contracting Officer will designate the COR in the contract award.

The COR serves as the primary day-to-day technical point of contact for contract performance.

COR Authority Limitations: The COR does NOT have authority to: - Modify contract terms, pricing, or period of performance - Issue task orders - Approve changes that affect contract cost or scope - Make commitments that obligate Government funds beyond existing task orders.

G.5 Government Property

The Government will not provide property or equipment to the Contractor except as specifically identified in individual task orders.

G.6 Invoice Submission

FDA Electronic Invoicing and Payment Requirements - Invoice Processing Platform (IPP) (JAN 2022)

a. All Invoice submissions for goods and or services must be made electronically through the U.S. Department of Treasury's Invoice Processing Platform System (IPP). http://www.ipp.gov/vendors/index.htm

b. Invoice Submission for Payment means any request for contract financing payment or invoice payment by the Contractor. To constitute a proper invoice, the payment request must comply with the requirements identified in FAR 32.905(b), "Content of Invoices" and the applicable Payment clause included in this contract, or the clause 52.212-4 Contract Terms and Conditions - Commercial Items included in commercial items contracts. The IPP website address is: https://www.ipp.gov

c.

1. The Agency will enroll the Contractors new to IPP. The Contractor must follow the IPP registration email instructions for enrollment to register the Collector Account for submitting invoice requests for payment. The Contractor Government Business Point of Contact (as listed in SAM) will receive Registration email from the Federal Reserve Bank of St. Louis (FRBSTL) within 3 - 5 business days of the contract award for new contracts or date of modification for existing contracts.
2. Registration emails are sent via email from ipp.noreply@mail.eroc.twai.gov. Contractor assistance with enrollment can be obtained by contacting the IPP Production Helpdesk via email to IPPCustomerSupport@fiscal.treasury.gov or phone (866) 973-3131.
3. The Contractor POC will receive two emails from IPP Customer Support, the first email contains the initial administrative IPP User ID. The second email, sent within 24 hours of receipt of the first email, contains a temporary password. You must log in with the temporary password within 30 days.
4. If your company is already registered to use IPP, you will not be required to re-register.
5. If the Contractor is unable to comply with the requirement to use IPP for submitting invoices for payment as authorized by HHSAR 332.7002, a written request must be submitted to the Contracting Officer to explain the circumstances that require the authorization of alternate payment procedures.

d. Invoices that include time and materials or labor hours Line Items must include supporting documentation to (1) substantiate the number of labor hours invoiced for each labor category, and (2) substantiate material costs incurred (when applicable).

e. Invoices that include cost-reimbursement Line Items must be submitted in a format showing expenditures for that month, as well as contract cumulative amounts. At a minimum the following cost information shall be included, in addition to supporting documentation to substantiate costs incurred.

1. Direct Labor - include all persons, listing the person's name, title, number of hours worked, hourly rate, the total cost per person and a total amount for this category;
2. Indirect Costs (i.e., Fringe Benefits, Overhead, General and Administrative, Other Indirects)- show rate, base and total amount;
3. Consultants (if applicable) - include the name, number of days or hours worked, daily or hourly rate, and a total amount per consultant;
4. Travel - include for each airplane or train trip taken the name of the traveler, date of travel, destination, the transportation costs including ground transportation shown separately and the per diem costs. Other travel costs shall also be listed;
5. Subcontractors (if applicable) - include, for each subcontractor, the same data as required for the prime Contractor;
6. Other Direct Costs - include a listing of all other direct charges to the contract, i.e., office supplies, telephone, duplication, postage; and
7. Fee - amount as allowable in accordance with the Schedule and FAR 52.216-8 if applicable.

f. Contractor is required to attach an invoice log addendum to each invoice which shall include, at a minimum, the following information for contract administration and reconciliation purposes:

(1) list of all invoices submitted to date under the subject award, including the following:

(i.) invoice number, amount, & date submitted
(ii.) corresponding payment amount & date received

(2) total amount of all payments received to date under the subject contract or order
(3) and, for definitized contracts or orders only, total estimated amounts yet to be invoiced for the current, active period of performance.

g. Payment of invoices will be made based upon acceptance by the Government of the entire task or the tangible product deliverable(s) invoiced. Payments shall be based on the Government certifying that satisfactory services were provided, and the Contractor has certified that labor charges are accurate.

h. If the services are rejected for failure to conform to the technical requirements of the Delivery Order, or any other contractually legitimate reason, the Contractor shall not be paid, or shall be paid an amount negotiated by the CO.

i. Payment to the Contractor will not be made for temporary work stoppage due to circumstances beyond the control of U.S. Food and Drug Administration such as acts of God, inclement weather, power outages, and results thereof, or temporary closings of facilities at which Contractor personnel are performing. This may, however, be justification for excusable delays.

j. The Contractor agrees that the submission of an invoice to the Government for payment is a certification that the services for which the Government is being billed, have been delivered in accordance with the hours shown on the invoices, and the services are of the quality required for timely and successful completion of the effort.

k. Questions regarding invoice payments that cannot be resolved by the IPP Helpdesk should be directed to the FDA Employee Resource and Information Center (ERIC) Helpdesk at 301-827-ERIC (3742) or toll-free 866-807-ERIC (3742); or, by email at ERIC@fda.hhs.gov. Refer to the Call-in menu options and follow the phone prompts to dial the option that corresponds to the service that's needed. All ERIC Service Now Tickets will either be responded to or resolved within 48 hours (2 business days) of being received. When emailing, please be sure to include the contract number, invoice number and date of invoice, as well as your name, phone number, and a detailed description of the issue.

G.7 Notification Requirements

The Contractor shall provide written notification to the Contracting Officer and COR for the following events:

(a) Key Personnel Changes: At least 30 calendar days advance notice for planned changes; 24 hours for emergency changes (per Section H.3)
(b) Change in Business Structure: Within 30 days of any merger, acquisition, sale, change of name, change in ownership, or change in business structure
(c) Financial Difficulties: Immediate notification of any bankruptcy filing, receivership, or financial condition that may impact contract performance
(d) Subcontractor Changes: At least 15 days advance notice of any changes to major subcontractors identified in the proposal
(e) Safety or Security Incidents: Immediate notification of any serious safety incidents, security breaches, or events that may impact Government personnel or property

Performance Issues: Immediate notification of any circumstances that may prevent the Contractor from meeting performance requirements or deadlines.

SECTION H - SPECIAL CONTRACT REQUIREMENTS

H.1 Security and Background Investigation Requirements

All Contractor personnel requiring access to FDA facilities must undergo background investigations.

Background investigations will be conducted by the Defense Counterintelligence and Security Agency (DCSA) in accordance with FDA Security Clearance Standards (See Attachment C4).

The Risk Designation for this contract is **Tier 1**

H.2 Information Security Requirements

The Contractor shall comply with all FDA information security requirements, NIST cybersecurity framework, Federal Information Processing Standard (FIPS) and FDA IT security policies and procedures - Incident reporting requirements as referenced below.

H.2.1 FDA Information Security and/or Physical Access Security (May 2022)

1. Baseline Security Requirements
    a. Applicability. The requirements herein apply whether the entire contract or modification (hereafter "contract"), or portion thereof, includes either or both of the following:

        i. Access (Physical or Logical) to Government Information: A Contractor (and/or any subcontractor) will have or will be given the ability to have, routine physical (entry) or logical (electronic) access to government information.
        ii. Operate a Federal System Containing Information: A Contractor (and/or any subcontractor) will operate a federal system and information technology containing data that supports the FDA mission. In addition to the Federal Acquisition Regulation (FAR) Subpart 2.1 definition of "information technology" (IT), the term as used in this section 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.

    b. Safeguarding Information and Information Systems. All government information and information systems must be protected in accordance with FDA policies and level of risk. At a minimum, the Contractor (and/or any subcontractor) must:

        i. Protect the:
            - Confidentiality, which means preserving authorized restrictions on access and disclosure, based on the security terms found in this contract, including means for protecting personal privacy and proprietary information;

- Integrity, which means guarding against improper information modification or destruction, and ensuring information non-repudiation and authenticity; and
- Availability, which means ensuring timely and reliable access to and use of information.

ii. Categorize all information owned and/or collected/managed on behalf of FDA and information systems that store, process, and/or transmit FDA information in accordance with FIPS 199 and National Institute of Standards and Technology (NIST) Special Publication (SP) 800-60, Volume II: *Appendices to Guide for Mapping Types of Information and Information Systems to Security Categories.* Based on information provided by the System/Data Owner, ISSO, privacy representative, or other POC, the impact level for each Security Objective (Confidentiality, Integrity, and Availability) and the Overall Impact Level, which is the highest watermark of the three factors of the information or information system are the following:

- Confidentiality: [**X**] Low [ ] Moderate [ ] High
- Integrity: [ ] Low [**X**] Moderate [ ] High
- Availability: [**X**] Low [ ] Moderate [ ] High
- Overall Impact Level: [ ] Low [**X**] Moderate [ ] High

iii. Based on the agreed-upon level of impact, implement the necessary safeguards to protect all information systems and information collected and/or managed on behalf of FDA regardless of location or purpose.

iv. Report any discovered or unanticipated threats or hazards by either the agency or contractor, or if existing safeguards have ceased to function immediately after discovery, within one (1) hour or less, to the government representative(s). This includes notifying the FDA Cybersecurity and Infrastructure Operations Coordination Center (CIOCC) within one (1) hour of discovery/detection in the event of a cybersecurity or privacy incident.

v. Adopt and implement all applicable policies, procedures, controls, and standards required by the FDA Information Security Program to ensure the confidentiality, integrity, and availability of government information and government information systems for which the Contractor is responsible under this contract or to which the Contractor may otherwise have access under this contract. Obtain the FDA Information Security Program security requirements, outlined in the FDA Information Security and Privacy Protection (IS2P) policy, by contacting the CO/COR or emailing your ISSO.

c. Privacy Act. Comply with the Privacy Act requirements (when applicable), and tailored FAR and HHSAR clauses as needed.

d. Privacy Compliance. Comply with the E-Government Act of 2002, NIST SP 800-53, and applicable FDA privacy policies and complete all the requirements below:

i. Per the Office of Management and Budget (OMB) Circular A-130, Personally Identifiable Information (PII), is "information that can be used to distinguish or trace an individual's identity, either alone or when combined with other information that is linked or linkable to a specific individual." Examples of PII include, but are not limited to the following: Social Security number, date and place of birth, mother's maiden name, biometric records, etc.

ii. Based on information provided by the ISSO, System/Data Owner, or other security or privacy representative, it has been determined that this solicitation/contract involves:

[ ] No PII [**X**] PII

iii. The Contractor must support the agency with conducting a Privacy Threshold Analysis (PTA) for the information system and/or information handled under this contract to determine whether or not a full Privacy Impact Assessment (PIA) needs to be completed.

- If the results of the PTA show that a full PIA is needed, the Contractor must support the agency with completing a PIA for the system or information after completion of the PTA and in accordance with HHS and FDA policy and OMB M- 03-22, *Guidance for Implementing the Privacy Provisions of the E-Government Act of 2002*. The PTA/PIA must be completed and approved prior to active use and/or collection or processing of PII and is a prerequisite to agency issuance of an authorization to operate (ATO).
- The Contractor must support the agency in reviewing the PIA at least every *three years* throughout the system development lifecycle (SDLC)/information lifecycle, or when determined by the agency that a review is required based on a major change to the system, or when new types of PII are collected that introduces new or increased privacy risks, whichever comes first.

e. Controlled Unclassified Information (CUI). Executive Order 13556 defines CUI as "information that laws, regulations, or Government-wide policies require to have safeguarding or dissemination controls, excluding classified information." The Contractor (and/or any subcontractor) must comply with *Executive Order 13556, Controlled Unclassified Information, (implemented at 3 CFR,* part 2002*)* when handling CUI. 32 C.F.R. 2002.4(aa) As implemented the term "*handling"* refers to "…any use of CUI, including but not limited to marking, safeguarding, transporting, disseminating, re-using, and disposing of the information." 81 Fed. Reg. 63323. The requirements below apply only to nonfederal systems that process, store, or transmit CUI, or that provide security protection for such components. All sensitive

information that has been identified as CUI by a regulation or statute, handled by this solicitation/contract, must be:

i. Marked appropriately;
ii. Disclosed to authorized personnel on a Need-To-Know basis;
iii. Protected in accordance with NIST SP 800-53, *Security and Privacy Controls for Information Systems and Organizations* applicable baseline if handled by a contractor system operated on behalf of the agency, or NIST SP 800-171, *Protecting Controlled Unclassified Information in Nonfederal Information Systems and Organizations* if handled by internal Contractor system; and

iv. Returned to FDA control, destroyed when no longer needed, or held until otherwise directed. Information and/or data must be disposed of in accordance with NIST SP 800- 88*, Guidelines for Media Sanitization*.

f. Protection of Sensitive Information. For security purposes, information is *or* may be sensitive because it requires security to protect its confidentiality, integrity, and/or availability. The Contractor (and/or any subcontractor) must protect all government information that is or may be sensitive by securing it with a solution that is validated with current FIPS 140 validation certificate from the NIST CMVP.
g. Government Furnished Equipment (GFE) for Foreign Travel. FDA personnel are prohibited from taking GFE when participating in personal, unofficial travel to foreign countries. FDA personnel are strictly prohibited from teleworking using GFE in foreign countries. FDA personnel must also request loaner GFE from the FDA Foreign Travel program for official travel to any foreign country. Please see the FDA IS2P, *Appendix T Government Furnished Equipment for Foreign Travel*.
h. Confidentiality and Nondisclosure of Information. Any information provided to the contractor (and/or any subcontractor) by FDA or collected by the contractor on behalf of FDA must be used only for the purpose of carrying out the provisions of this contract and must not be disclosed or made known in any manner to any persons except as may be necessary in the performance of the contract. The Contractor assumes responsibility for protection of the confidentiality of Government records and must ensure that all work performed by its employees and subcontractors must be under the supervision of the Contractor. Each Contractor employee or any of its subcontractors to whom any FDA records may be made available or disclosed must be notified in writing by the Contractor that information disclosed to such employee or subcontractor can be used only for that purpose and to the extent authorized herein.

   The confidentiality, integrity, and availability of such information must be protected in accordance with HHS and FDA policies. Unauthorized disclosure of information will be subject to the HHS and FDA sanction policies and/or governed by the following laws and regulations:

   i. 18 U.S.C. 641 (Criminal Code: Public Money, Property or Records);

ii. 18 U.S.C. 1905 (Criminal Code: Disclosure of Confidential Information); an
iii. 44 U.S.C. Chapter 35, Subchapter I (Paperwork Reduction Act).

i. Internet Protocol Version 6 (IPv6). All procurements using Internet Protocol must comply with OMB Memorandum M-05-22, *Transition Planning for Internet Protocol Version 6 (IPv6)*.
j. Information and Communications Technology (ICT). ICT products and services from prohibited entities/sources must not be used/acquired in compliance with Public Law 115-232, Section 889 Parts A and B, FAR 4.21, FAR 52.204.23, FAR 52.204.24, and FAR 52.204.25. The contractor (and/or any subcontractor) must notify the government if they identify prohibited ICT products and/or services are used during the contract performance.
k. Government Websites. All new and existing public-facing government websites must be securely configured with Hypertext Transfer Protocol Secure (HTTPS) using the most recent version of Transport Layer Security (TLS). In addition, HTTPS must enable HTTP Strict Transport Security (HSTS) to instruct compliant browsers to assume HTTPS at all times to reduce the number of insecure redirects and protect against attacks that attempt to downgrade connections to plain HTTP. For internal-facing websites, HTTPS is not required, but it is highly recommended. Consult the *HHS Policy for Internet and Email Security* for additional information.
l. Contract Documentation. The Contractor must use provided templates, policies, forms, and other agency documents to comply with contract deliverables as appropriate.
m. Standard for Encryption. The Contractor (and/or any subcontractor) must:
    i. Comply with the *HHS Standard for Encryption of Computing Devices and Information* to prevent unauthorized access to government information.
    ii. Encrypt all sensitive federal data and information (i.e., PII, protected health information [PHI], proprietary information, etc.) in transit (i.e., email, network connections, etc.) and at rest (i.e., servers, storage devices, mobile devices, backup media, etc.) with an encryption solution that is validated with current FIPS 140 validation certificates from the NIST CMVP.
    iii. Secure all devices (i.e.: desktops, laptops, mobile devices, etc.) that store and process government information and ensure devices meet HHS and FDA-specific encryption standard requirements. Maintain a complete and current inventory of all laptop computers, desktop computers, and other mobile devices and portable media that store or process sensitive government information (including PII).
    iv. Verify that the encryption solutions in use have been validated under the Cryptographic Module Validation Program to confirm compliance with current FIPS 140 validation certificates from the NIST CMVP. The Contractor must provide a written copy of the validation documentation to the COR.

v. Use the Key Management system on the HHS personal identification verification (PIV) card or establish and use a key recovery mechanism to ensure the ability for authorized personnel to encrypt/decrypt information and recover encryption keys http://csrc.nist.gov/publications/. Encryption keys must be provided to the COR upon request and at the conclusion of the contract.

n. Contractor Non-Disclosure Agreement (NDA). Each Contractor (and/or any subcontractor) employee having access to non-public government information under this contract must complete the FDA non-disclosure agreement (3398 Form)*]*, as applicable. Contractors (and/or subcontractors) must submit a copy of each signed and witnessed NDA to the Contracting Officer (CO) and/or CO Representative (COR) prior to performing any work under this acquisition.

2. Training Requirements

a. Mandatory Training for All Contractor Staff. All Contractor (and/or any subcontractor) employees assigned to work on this contract must complete the applicable FDA information security awareness, privacy, and records management training (provided upon contract award) before performing any work under this contract. Thereafter, the employees must complete FDA information security awareness, privacy, and records management training at least *annually*, during the life of this contract. All provided training must be compliant with HHS training policies.
b. Role-based Training. All Contractor (and/or any subcontractor) employees with significant security responsibilities (as determined by the program manager) must complete role-based training *annually* commensurate with their role and responsibilities in accordance with HHS and FDA policy.
c. Training Records. The Contractor (and/or any subcontractor) must maintain training records for all its employees working under this contract in accordance with HHS and FDA policy. A copy of the training records must be provided to the CO and/or COR within *30 days* after contract award and *annually* thereafter or upon request.

3. Rules of Behavior

a. The Contractor (and/or any subcontractor) must ensure that all employees performing on the contract comply with the *HHS Information Technology General Rules of Behavior*, *HHS Rules of Behavior for Privileged Users*, and FDA policies and standards.
b. All Contractor employees performing on the contract must read and adhere to the Rules of Behavior before accessing Agency data or other information, systems, and/or networks that store/process government information, initially at the beginning of the contract and at least *annually* thereafter, which may be done as part of annual FDA Information Security Awareness Training. If the training is provided by the contractor, the signed ROB must be provided as a separate deliverable to the CO and/or COR per defined timelines above.

4. Incident Response

a. The Contractor (and/or any subcontractor) must respond to all alerts/Indicators of Compromise (IOCs) provided by HHS Computer Security Incident Response Center (CSIRC)/FDA CIOCC/Incident Response Team teams within 24 hours, whether the response is positive or negative.

   FISMA defines an incident as "an occurrence that (1) actually or imminently jeopardizes, without lawful authority, the integrity, confidentiality, or availability of information or an information system; or (2) constitutes a violation or imminent threat of violation of law, security policies, security procedures, or acceptable use policies. In accordance with OMB M-17-12, *Preparing for and Responding to a Breach of Personally Identifiable Information (PII)*, an incident is "an occurrence that (1) actually or imminently jeopardizes, without lawful authority, the integrity, confidentiality, or availability of information or an information system; or (2) constitutes a violation or imminent threat of violation of law, security policies, security procedures, or acceptable use policies" and a privacy breach is "the loss of control, compromise, unauthorized disclosure, unauthorized acquisition, or any similar occurrence where (1) a person other than an authorized user accesses or potentially accesses personally identifiable information or (2) an authorized user accesses or potentially accesses personally identifiable information for an other than authorized purpose." For additional information on the HHS breach response process, please see the FDA IS2P Appendix F: Incident Response and the *HHS Policy and Plan for Preparing for and Responding to a Breach of Personally Identifiable Information (PII)*."

b. In the event of a suspected or confirmed incident or breach, the Contractor (and/or any subcontractor) must:

   i. Protect all sensitive information, including any PII created, stored, or transmitted in the performance of this contract, with encryption solution that is validated with current FIPS 140 validation certificates from the NIST CMVP.
   ii. NOT notify affected individuals unless so instructed by the Contracting Officer or designated representative. If so, instructed by the Contracting Officer or representative, the Contractor must send FDA approved notifications to affected individuals as directed by FDA's SOP.
   iii. Report all suspected and confirmed information security and privacy incidents and breaches to the FDA CIOCC, COR, CO, FDA SOP (or his or her designee), and other stakeholders, including breaches involving PII, in any medium or form, including paper, oral, or electronic, as soon as possible and without unreasonable delay, no later than one (1) hour, and consistent with the applicable FDA and HHS policy and procedures, NIST standards and guidelines, as well as US-CERT notification guidelines. The types of information required in an incident report must include at a minimum: company and point of contact information, contact information, impact

classifications/threat vector, and the type of information compromised. In addition, the Contractor must:

- Cooperate and exchange any information, as determined by the Agency, necessary to effectively manage or mitigate a suspected or confirmed breach;

- Not include any sensitive information in the subject or body of any reporting e- mail; and
- Encrypt sensitive information in attachments to email, media, etc.

iv. Comply with OMB M-17-12, *Preparing for and Responding to a Breach of Personally Identifiable Information,* and HHS and FDA breach response policies when handling PII breaches.

v. Provide full access and cooperate on all activities as determined by the Government to ensure an effective incident response, including providing all requested images, log files, and event information to facilitate rapid resolution of sensitive information incidents. This may involve disconnecting the system processing, storing, or transmitting the sensitive information from the Internet or other networks or applying additional security controls. This may also involve physical access to contractor facilities during a breach/incident investigation on demand.

5. Position Sensitivity Designations

All Contractor (and/or any subcontractor) employees must obtain a background investigation commensurate with their position sensitivity designation that complies with Parts 1400 and 731 of Title 5, Code of Federal Regulations (CFR). The following position sensitivity designation levels apply to this solicitation/contract (e.g. tier 1, 2, or 4): Tier 1

6. Homeland Security Presidential Directive (HSPD)-12

The Contractor (and/or any subcontractor) and its employees must comply with Homeland Security Presidential Directive (HSPD)-12, *Policy for a Common Identification Standard for Federal Employees and Contractors*; OMB M-05-24; OMB M-19-17; FIPS 201, *Personal Identity Verification (PIV) of Federal Employees and Contractors*; HHS HSPD-12 policy; and *Executive Order 13467, Part 1 §1.2.*

7. Roster

The Contractor (and/or any subcontractor) must submit a roster by name, position, e-mail address, phone number and responsibility, of all staff working under this acquisition where the Contractor will develop, have the ability to access, or host and/or maintain a government information system(s). The roster must be submitted to the COR and/or CO per the COR or CO's direction. Any revisions to the roster as a result of staffing changes must be submitted

within a timeline as directed by the COR and/or CO. The COR will notify the Contractor of the appropriate level of investigation required for each staff member.

If the employee is filling a new position, the Contractor must provide a position description, and the Government will determine the appropriate suitability level.

8. Contract Initiation and Expiration
   a. General Security Requirements. The Contractor (and/or any subcontractor) must comply with information security and privacy requirements, Enterprise Performance Life Cycle (EPLC) processes, HHS Enterprise Architecture requirements to ensure information is appropriately protected from initiation to expiration of the contract. All information systems development or enhancement tasks supported by the contractor must follow the FDA EPLC framework and methodology in accordance with the FDA EPLC Project documentation, located here: http://sharepoint.fda.gov/orgs/DelMgmtSupport/IntakeProc/EPLCv2/SitePages/v2/EPLCHome.aspx and in accordance with the HHS Contract Closeout Guide (2012).
   b. System Documentation. Contractors (and/or any subcontractors) must follow and adhere to HHS System Development Life Cycle requirements, at a minimum, for system development and provide system documentation at designated intervals (specifically, at the expiration of the contract) within the EPLC that require artifact review and approval.
   c. Sanitization of Government Files and Information. As part of contract closeout and at expiration of the contract, the Contractor (and/or any subcontractor) must provide all required documentation in accordance with SMGs published by FDA's Office of Acquisitions and Grant Services (OAGS) *to* the CO and/or COR to certify that, at the government's direction, all electronic and paper records are appropriately disposed of and all devices and media are sanitized in accordance with NIST SP 800-88, *Guidelines for Media Sanitization*.
   d. Notification. The Contractor (and/or any subcontractor) must notify the CO and/or COR and system ISSO as soon as it is known that a contract employee will stop working under this contract.
   e. Contractor Responsibilities upon Physical Completion of the Contract. The contractor (and/or any subcontractors) must return all government information and IT resources (i.e., government information in non-government-owned systems, media, and backup systems) acquired during the term of this contract to the CO and/or COR. Additionally, the Contractor must provide a certification that all government information has been properly sanitized and purged from Contractor-owned systems, including backup systems and media used during contract performance, in accordance with HHS and FDA policies.
   f. The Contractor (and/or any subcontractor) must perform and document the actions identified in the FDA eDepart system http://inside.fda.gov:9003/EmployeeResources/NewEmployee/eDepartDepartureSystem/default.htm as soon as it is known that a contract an employee will terminate work under this contract. The Contractor (and/or any subcontractor) shall coordinate with the COR via email, copying the Contract Specialist, to ensure that the appropriate person

performs and documents the actions identified in the FDA eDepart system. All documentation must be available to the CO and/or COR upon request.

9. Records Management and Retention
   a. The Contractor (and/or any subcontractor) must maintain all information in accordance with Executive Order 13556 -- Controlled Unclassified Information, National Archives and Records Administration (NARA) records retention policies and schedules and *HHS Policy for Records Management* and HHS and FDA policies and must not dispose of any records unless authorized by HHSFDA.
   b. In the event that a contractor (and/or any subcontractor) accidentally disposes of or destroys a record without proper authorization, he/she must document and report the incident in accordance with HHS and FDA policies.
10. High Value Asset (HVA)

    If a system is identified as HVA,[24] the contractor must comply with the FDA IS2P Appendix AB: High Value Asset (HVA) Program, the HHS Policy for the High Value Asset (HVA) Program, and the DHS HVA Control Overlay[25] in addition to the above requirements.

H.3 Key Personnel

The following position is designated as Key Personnel for this IDIQ contract and orders:

Program Manager

Other positions may be identified as Key at task order level. Minimum qualifications for each position are specified in Attachment C1 (OSIST IDIQ PWS), Section 5.3.

Key Personnel Employment Status:

All Key Personnel must be direct employees of the prime contractor and under the prime contractor's direct supervision and control. Subcontractor employees may not serve in Key Personnel positions.

Rationale: Key Personnel are critical to contract success and must be under the prime contractor's direct employment control to ensure availability, performance, and continuity throughout the 5-year contract period.

Key Personnel Replacement Procedures:

Key Personnel are specific individuals identified by name whose qualifications, experience, and performance are considered essential to successful contract performance. The Contractor shall not remove, replace, or reassign Key Personnel without prior written approval from the Contracting Officer.

Planned Replacements: Submit written request at least 30 calendar days prior to proposed change. Include reason for change and complete qualifications of proposed replacement.

Emergency Replacements: Notify Contracting Officer within 24 hours. Submit qualifications for permanent replacement within 15 calendar days.

The Contracting Officer will review proposed replacements and may approve or disapprove based on qualifications. Proposed replacements must meet or exceed the minimum qualifications specified in the IDIQ or corresponding PWS.

H.4 Insurance Requirements

The Contractor shall maintain insurance coverage as required by RFO FAR 28.

SECTION I – CONTRACT CLAUSES

I.1 Incorporation by Reference

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://acquisition.gov

https://acquisition.gov/far-overhaul

https://acquisition.gov/hhsar

(End of clause)

I.2 Federal Acquisition Regulation (FAR) Clauses

1.2.1 RFO FAR Clauses Incorporated by Reference

Clause No.	Title	Date
52.212-4	Terms and Conditions—Commercial Products and Commercial Services	Nov 2025
52.212-4 Alt I	Terms and Conditions—Commercial Products and Commercial Services, Alternate I (T&M/LH)	Nov 2025
Clause/ No.	**Title**	**Date**
52.203-6 w/Alt I	Restrictions on Subcontractor Sales to the Government	Nov 2021
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	Nov 2025
52.204-10	Reporting Executive Compensation and First Tier Subcontract Awards	Nov 2025
52.204-13	System for Award Management—Maintenance	Nov 2025

52.204-15	Service Contract Reporting Requirements for Indefinite-Delivery Contracts	Nov 2025
52.204-19	Incorporation by Reference of Representations and Certifications	Dec 2014
52.209-6	Protecting the Government's Interest When Subcontracting with Contractors Debarred, Suspended, or Proposed for Debarment	Nov 2025
52.209-9	Updates of Publicly Available Information Regarding Responsibility Matters	Nov 2025
52.209-10	Prohibition on Contracting with Inverted Domestic Corporations	Nov 2025
52.215-8	Order of Precedence – Uniform Contract Format	Nov 2025
52.219-8	Utilization of Small Business Concerns	Apr 2026
52.219-9 w/Alt II	Small Business Subcontracting Plan, with Alternate II	Apr 2026
52.219-14	Limitations on Subcontracting	Nov 2025
52.219-16	Liquidated Damages—Subcontracting Plan	Nov 2025
52.222-3	Convict Labor	Nov 2025
52.222-35	Equal Opportunity for Veterans	Nov 2025
52.222-36	Equal Opportunity for Workers with Disabilities	Nov 2025
52.222-37	Employment Reports on Veterans	Nov 2025
52.222-40	Notification of Employee Rights Under the National Labor Relations Act	Dec 2010
52.222-50	Combating Trafficking in Persons	Nov 2025
52.222-54	Employment Eligibility Verification	Nov 2025
52.222-90	Addressing DEI Discrimination by Federal Contractors	Apr 2026
52.223-11	Ozone-Depleting Substances and High Global Warming Potential Hydrofluorocarbons	Nov 2025
52.223-12	Maintenance, Service, Repair, or Disposal of Refrigeration Equipment and Air Conditioners	Nov 2025
52.223-23	Sustainable Products and Services	Nov 2025
52.224-3	Privacy Training (or with Alt I)	Nov 2025

52.225-1	Buy American—Supplies (or with Alt I)	Nov 2025
52.226-8	Encouraging Contractor Policies to Ban Text Messaging While Driving	May 2024
52.227-14	Rights in Data – General	May 2014
52.229-12	Tax on Certain Foreign Procurements	Feb 2021
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	Nov 2025
52.233-4	Applicable Law for Breach of Contract Claim	Nov 2025
52.240-91	Security Prohibitions and Exclusions (or with Alt I)	Nov 2025
52.240-93	Basic Safeguarding of Covered Contractor Information Systems	Nov 2025
52.245-1	Government Property	Sept 2021
52.245-9	Use and Charges	April 2012
52.246-4	Inspection of Services – Fixed Price	Aug 1996
52.246-6	Inspection of Services – Time and Materials and Labor-Hour	May 2001

I.2.2 RFO FAR Clauses Provided in Full Text

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 the date of award through the expiration of the contract ordering period specified in Section F.1.

(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.

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 **$2,500**, 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 **$14,500,000**;
(2) Any order for a combination of items in excess of **$14,500,000**; or
(3) A series of orders from the same ordering office within **60** 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 service.

52.216-22 INDEFINITE QUANTITY (Deviation Nov 2025)

(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 *five years after expiration of the contract ordering period.*

I.3 Health and Human Services Acquisition Regulation (HHSAR) Clauses

1.3.1 HHSAR Clauses Incorporated by Reference

HHSAR 352.203-70 Anti-Lobbying (Dec 2015)

HHSAR 352.223-70 Safety and Health (Dec 2015)

HHSAR 352.237-75 Key Personnel (Dec 2015)

1.3.2 HHSAR Clauses Provided in Full Text

HHSAR 352.204-71 Information and Information Systems Security (Feb 2024) (DEV)

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

Breach means the loss of control, compromise, unauthorized disclosure, unauthorized acquisition, or any similar occurrence where—

(1) A person other than an authorized user accesses or potentially accesses personally identifiable information, or

(2) An authorized user accesses personally identifiable information for an other than authorized purpose.

*Business associate (*see 45 CFR 160.103*),* except as provided in paragraph (2) of this definition, business associate means, with respect to a covered entity, a person who -

(1) On behalf of such covered entity or of an organized health care arrangement (as defined in this clause) in which the covered entity participates, but other than in the capacity of a member of the workforce of such covered entity or arrangement, creates, receives, maintains, or transmits protected health information for a function or activity regulated by this contract or agreement, including claims processing or administration, data analysis, processing or administration, utilization review, quality assurance, patient safety activities listed at 42 CFR 3.20, billing, benefit management, practice management, and repricing; or

(2) Provides, other than in the capacity of a member of the workforce of such covered entity, legal, actuarial, accounting, consulting, data aggregation (as defined in 45 CFR section

164.501), management, administrative, accreditation, or financial services to or for such covered entity, or to or for an organized health care arrangement in which the covered entity participates, where the provision of the service involves the disclosure of protected health information from such covered entity or arrangement, or from another business associate of such covered entity or arrangement, to the person.

(3) A covered entity may be a business associate of another covered entity.

(4) *Business associate* includes the following:

(i) A Health Information Organization, E-prescribing Gateway, or other person that provides data transmission services with respect to protected health information to a covered entity and that requires access on a routine basis to such protected health information.

(ii) A person that offers a personal health record to one or more individuals on behalf of a covered entity.

(iii) A subcontractor that creates, receives, maintains, or transmits protected health information on behalf of the business associate.

(5) *Business associate* does not include:

(i) A health care provider, with respect to disclosures by a covered entity to the health care provider concerning the treatment of the individual.

(ii) A plan sponsor, with respect to disclosures by a group health plan (or by a health insurance issuer or HMO with respect to a group health plan) to the plan sponsor, to the extent that the requirements of 45 CFR 164.504(f) apply and are met.

(iii) A government agency, with respect to determining eligibility for, or enrollment in, a government health plan that provides public benefits and is administered by another government agency, or collecting protected health information for such purposes, to the extent such activities are authorized by law.

(iv) A covered entity participating in an organized health care arrangement that performs a function or activity as described by paragraph (1)(i) of this definition for or on behalf of such organized health care arrangement, or that provides a service as described in paragraph (1)(ii) of this definition to or for such organized health care arrangement by virtue of such activities or services.

Business associate agreement means the agreement, or other arrangement, as dictated by the HIPAA Privacy Rule (45 CFR 160), between an HHS covered entity and a business associate, which must be entered into in addition to the underlying contract for services and

before any disclosure (see 45 CFR 160.103) of PHI can be made to the business associate, in order for the business associate to perform certain functions or activities on behalf of an HHS entity.

Controlled unclassified information (CUI) means information that laws, regulations, or Government-wide policies require to have safeguarding or dissemination controls, excluding classified information.

Healthcare component means a component or combination of components of a hybrid entity designated by the hybrid entity in accordance with 45 CFR 164.105(a)(2)(iii)(D) (see 45 CFR 164.103). The Secretary of HHS has designated HHS as a covered entity (further designated as a "hybrid entity"), and has also designated four HHS divisions as healthcare components under HIPAA, including —

(1) The Centers for Medicare and Medicaid Services (CMS), insofar as it operates the fee-for-service Medicare program;

(2) The Program Support Center (PSC), Division of Commissioned Personnel, insofar as it operates a health plan for Commissioned Corps officers;

(3) The World Trade Center (WTC) Health Program; and,

(4) The Indian Health Service (IHS), insofar as it operates a health plan and a program providing healthcare that uses electronic transactions.

HHS Information Technology General Rules of Behavior means a set of HHS rules that describes the responsibilities and expected behavior of users of HHS information or information systems.

HHS sensitive information means all HHS data, on any storage media or in any form or format, which requires confidentiality, integrity, and availability protection due to the risk of harm that could result to interests of HHS, other agencies or entities, or individuals from inadvertent or deliberate disclosure, alteration, or destruction of the information. The term includes—

(1) Information where the improper use or disclosure could adversely affect the ability of HHS to accomplish its mission, *i.e.*, HHS proprietary information;

(2) Records about individuals requiring protection under laws and regulations such as the E-Government Act, Privacy Act and the HIPAA Privacy Rule, or based on a data use agreement or a promise or assurance of confidentiality; and

(3) Information that would be exempt from disclosure if requested under the

Freedom of Information Act. Examples of HHS sensitive information include—

(i) Individually-identifiable medical, benefits, and personnel information;

(ii) Financial, budgetary, research, quality assurance, confidential commercial, critical infrastructure, security-sensitive, procurement-sensitive, investigatory, and law enforcement information;

(iii) Controlled unclassified information;

(iv) Information that would be confidential and privileged in litigation such as information protected by the deliberative process privilege, attorney work-product privilege, and the attorney-client privilege; and

(v) Other information which, if released, could result in a violation of law or agreement, could cause harm or unfairness to any individual or group, or could adversely affect the national interest or the conduct of Federal programs.

HIPAA Rules means the Privacy, Security, Breach Notification, and Enforcement Rules at 45 CFR Part 160 and part 164.

Incident means an occurrence that (A) actually or imminently jeopardizes, without lawful authority, the integrity, confidentiality, or availability of information systems; or (B) constitutes a violation or imminent threat of violation of law, security policies, security procedures, or acceptable policies.

Information system means a discrete set of information resources organized for the collection, processing, maintenance, use, sharing, dissemination, or disposition of information.

Information system s*ecurity plan* means a formal document that provides an overview of the security requirements for an information system or an information security program and describes the security controls in place or planned for meeting those requirements.

Information technology (see FAR 2.101) also means Information and Communication Technology (ICT).

Information technology-related contracts means those contracts that include services (including support services), and related resources for information technology.

Organized health care arrangement (see 45 CFR 160.103) means:

(1) A clinically integrated care setting in which individuals typically receive health care from more than one health care provider;

(2) An organized system of health care in which more than one covered entity participates and in which the participating covered entities:

(i) Hold themselves out to the public as participating in a joint arrangement; and

(ii) Participate in joint activities that include at least one of the following:

(A) Utilization review, in which health care decisions by participating covered entities are reviewed by other participating covered entities or by a third party on their behalf;

(B) Quality assessment and improvement activities, in which treatment provided by participating covered entities is assessed by other participating covered entities or by a third party on their behalf; or

(C) Payment activities, if the financial risk for delivering health care is shared, in part or in whole, by participating covered entities through the joint arrangement and if protected health information created or received by a covered entity is reviewed by other participating covered entities or by a third party on their behalf for the purpose of administering the sharing of financial risk.

(3) A group health plan and a health insurance issuer or HMO with respect to such group health plan, but only with respect to protected health information created or received by such health insurance issuer or HMO that relates to individuals who are or who have been participants or beneficiaries in such group health plan;

(4) A group health plan and one or more other group health plans each of which are maintained by the same plan sponsor; or

(5) The group health plans described in paragraph (4) of this definition and health insurance issuers or HMOs with respect to such group health plans, but only with respect to protected health information created or received by such health insurance issuers or HMOs that relates to individuals who are or have been participants or beneficiaries in any of such group health plans.

Privacy officer means the HHS official(s) with responsibility for implementing and oversight of privacy related policies and practices that impact a given HHS acquisition.

(b) *General*. Contractors, subcontractors, their employees, third-parties, and business associates with access to HHS information, information systems, or information technology (IT) or providing and accessing IT-related goods and services, shall adhere to the HHS

Cybersecurity Program and the directives and handbooks, complete HHS security training prior to accessing HHS information (including HHS sensitive information and information systems security and privacy) and on an annual basis thereafter, as well as those set forth in the contract specifications, statement of work, or performance work statement. These include, but are not limited to, HHS *Personnel Security and Suitability Program*, which establishes HHS procedures, responsibilities, and processes for complying with current Federal law, Executive Orders, policies, regulations, standards, and guidance for protecting HHS information, information systems (see 302.101, Definitions) security and privacy, and adhering to personnel security requirements when accessing HHS information or information systems.

(c) *Access to HHS information and HHS information systems*.

(1) Contractors are limited in their request for logical or physical access to HHS information or HHS information systems for their employees, subcontractors, third parties and business associates to the extent necessary to perform the services or provide the goods as specified in the contracts, agreements, task, delivery, or purchase orders.

(2) All Contractors, subcontractors, third parties, and business associates working with HHS information are subject to the same investigative requirements as those of HHS appointees or employees who have access to the same types of information. The level and process of background security investigations for Contractors to access HHS information and HHS information systems shall be in accordance with HHS *Personnel Security and Suitability Program*.

(3) Contractors, subcontractors, third parties, and business associates who require access to national security programs must have a valid security clearance.

(4) The Contractor (and/or any subcontractor) must comply with *Executive Order 13556, Controlled Unclassified Information, (implemented at 3 CFR,* part 2002*)* when handling CUI. 32 C.F.R. 2002.4(aa) As implemented the term "*handling"* refers to "…any use of CUI, including but not limited to marking, safeguarding, transporting, disseminating, re-using, and disposing of the information." 81 Fed. Reg. 63323. The requirements below apply only to nonfederal systems that process, store, or transmit CUI, or that provide security protection for such components. All sensitive information that has been identified as CUI by a regulation or statute, handled by this solicitation/contract, must be –

(i) Marked appropriately;

(ii) Disclosed to authorized personnel on a need-to-know basis;

(iii) Protected in accordance with NIST SP 800-53, *Security and Privacy Controls for Information Systems and Organizations* applicable baseline if handled by a Contractor system operated on behalf of the agency, or NIST SP 800-171, *Protecting Controlled Unclassified*

Information in Nonfederal Information Systems and Organizations if handled by internal Contractor system; and

(iv) Returned to HHS control, destroyed when no longer needed, or held until otherwise directed. Information and/or data must be disposed of in accordance with NIST SP 800-88*, Guidelines for Media Sanitization*.

(5) *HIPAA business associate agreements*. Under the HIPAA Privacy and Security Rules (see 45 CFR 164), pursuant to 45 CFR 164.502(e)(1), a covered entity may disclose protected health information to a business associate and may allow a business associate to create, receive, maintain, or transmit protected health information on its behalf, if the covered entity obtains satisfactory assurance that the business associate will appropriately safeguard the information. A covered entity is not required to obtain such satisfactory assurances from a business associate that is a subcontractor of a covered entity's business associate. Additionally, a business associate may disclose protected health information to a business associate that is a subcontractor and may allow the subcontractor to create, receive, maintain, or transmit protected health information on its behalf, if the business associate obtains satisfactory assurances, in accordance with 45 CFR 164.504(e)(1)(i), that the subcontractor will appropriately safeguard the information. The satisfactory assurances required by 45 CFR 45 CFR 164.504(e)(1) of this section shall be documented through a written contract or other written agreement or arrangement with the business associate that meets the applicable requirements of 45 CFR 164.504(e). The contracts shall also include breach reporting policies and procedures for suspected or confirmed breaches of protected health information. The contract shall impose a duty to cooperate with the healthcare component and/or HHS breach investigation and response and must require all subcontractors to comply with the same HIPAA Rules requirements as a condition of receiving government data.

(i) *Contractors or entities required to execute business associate agreements for contracts and other agreements become HHS business associates.* Business associate agreements are issued by HHS or may be issued by other HHS programs in support of HHS. The HIPAA Privacy Rule requires HHS to execute compliant business associate agreements with persons or entities that create, receive, maintain, or transmit HHS PHI or that will store, generate, access, exchange, process, or utilize such PHI in order to perform certain activities, functions or services to, for, or on behalf of HHS. There may be other HHS components or staff offices which also provide certain services and support to HHS and must receive PHI in order to do so. If these components award contracts or enter into other agreements, purchase/delivery orders, modifications and issue governmentwide purchase card transactions to help in the delivery of these services to HHS, they will also fall within the requirement to obtain a satisfactory assurance from these contractors by executing a business associate agreements.

(ii) *Business associate agreement flow down to subcontractors.* A prime contractor required to execute a business associate agreement shall also obtain a satisfactory assurance, in the form of a business associate agreement, of its subcontractors who will also create, receive,

maintain, or transmit PHI or that will store, generate, access, exchange, process, or utilize such PHI will comply with HIPAA Rules requirements to the same degree as the Contractor. A contractor employing a subcontractor who creates, receives, maintains, or transmits PHI or that will store, generate, access, exchange, process, or utilize such PHI under a contract or agreement is required to execute a business associate agreement with each of its subcontractors which also obligates the subcontractor (*i.e.*, also a business associate) to provide the same protections and safeguards and agree to the same disclosure restrictions to PHI that is required of the covered entity and the prime contractor.

(d) *Contractor operations required to be in United States*. Custom software development and outsourced operations must be located in the U.S. to the maximum extent practicable. If such services are proposed to be performed outside the continental United States, and are not otherwise disallowed by other Federal law, regulations or policy, or other HHS policy or other mandates as stated in the contract, specifications, statement of work or performance work statement (including applicable business associate agreements), the Contractor/subcontractor must state in its proposal where all non-U.S. services are provided. At a minimum, the Contractor/subcontractor must include a detailed Information System Security Plan, for review and approval by the Contracting Officer, specifically to address mitigation of the resulting problems of communication, control, and data protection.

(e) *Roster of employees.* Contractors and subcontractors shall provide a roster containing the name, position, e-mail address, phone number, and responsibilities of each employee, including subcontractors, performing work under the contract to develop, have the ability to access, or host and/or maintain a government information system(s). The roster must be submitted to Contracting Officer within **30 calendar** days stated number of days from the effective date of the contract. Revisions to the roster as a result of staffing changes must be submitted within the number of days of the change provided by the Contracting Officer. The Contracting Officer, or the Contracting Officer's Representative (COR), will notify the Contractor of the appropriate level of investigation required for each staff member based on the information provided on the roster. If an employee is filling a new position, the Contractor must provide a position description and the Government will determine the appropriate suitability level.

(f) *Contractor/subcontractor employee reassignment and termination notification*. Contractors and subcontractors shall provide written notification to the Contracting Officer and COR immediately, and not later than four (4) hours, when an employee working on an HHS information system or with access to HHS information is reassigned or leaves the Contractor or subcontractor's employment on the cognizant HHS contract. The Contracting Officer and COR must also be notified immediately by the Contractor or subcontractor prior to an unfriendly termination.

(g) *Non-disclosure agreement*. The Contractor and subcontractors shall submit completed non-disclosure agreements, as provided by the Contracting Officer, for each

employee having access to non-public government information under this contract. The non-disclosure agreements shall be submitted to the Contracting Officer prior to the performance of work.

(h) *HHS information custodial requirements*. (1) *Release, publication, and use of data*. Information made available to a Contractor or subcontractor by HHS for the performance or administration of a contract or information developed by the Contractor/subcontractor in performance or administration of a contract shall be used only for the stated contract purpose and shall not be used in any other way without HHS prior written approval. This clause expressly limits the Contractor's/subcontractor's rights to use data as described in 52.227-14, Rights in Data—General, paragraph (d).

(2) *Media sanitization*. HHS information shall not be co-mingled with any other data on the Contractors/subcontractor's information systems or media storage systems in order to ensure federal and HHS requirements related to data protection, information segregation, classification requirements, and media sanitization can be met (see HHS Cybersecurity Program). HHS reserves the right to conduct scheduled or unscheduled on-site inspections, assessments, or audits of Contractor and subcontractor IT resources, information systems and assets to ensure data security and privacy controls, separation of data and job duties, and destruction/media sanitization procedures are in compliance with Federal and HHS requirements. The Contractor and subcontractor will provide all necessary access and support to HHS and/or GAO staff during periodic control assessments or audits.

(3) *Data retention, destruction and contractor self-certification*. The Contactor and its subcontractors are responsible for collecting and destroying any HHS data provided, created, or stored under the terms of this contract, to a point where HHS data or materials are no longer readable or reconstructable to any degree, in accordance with NIST SP 800-88*, Guidelines for Media Sanitization*, or subsequent directive. Prior to termination or completion of this contract, the Contractor/subcontractor must provide its plan for destruction or return of all HHS data in its possession accordance with contract requirements or Contracting Officer instructions for disposition, including compliance with National Institute of Standards and Technology (NIST) SP 800-88, Guidelines for Media Sanitization, for the purposes of media sanitization on all IT equipment. The Contractor must certify in writing to the Contracting Officer within 30 days of termination of the contract that the data destruction requirements in this paragraph have been met.

(4) *Return of HHS data and information*. When information, data, documentary material, records and/or equipment is no longer required, it shall be returned to the HHS (as stipulated by the Contracting Officer or the COR) or the Contractor/subcontractor must hold it until otherwise directed. Items returned will be hand carried, securely mailed, emailed, or securely electronically transmitted to the Contracting Officer or to the address as provided in the contract or by the assigned COR, and/or accompanying business associate agreement. Depending on the method of return, Contractor/subcontractor must store, transport, or transmit

HHS sensitive information, when permitted by the contract using HHS-approved encryption tools that are, at a minimum, validated under Federal Information Processing Standards (FIPS) 140-3 (or its successor). If mailed, Contractor/subcontractor must send via a trackable method (USPS, UPS, Federal Express, etc.) and immediately provide the Contracting Officer with the tracking information. No information, data, documentary material, records or equipment will be destroyed unless done in accordance with the terms of this contract and the HHS Agency Records Control Schedules (2019).

(5) *Use of HHS data and information*. The Contractor/subcontractor must receive, gather, store, back up, maintain, use, disclose and dispose of HHS information only in compliance with the terms of the contract and applicable Federal and HHS information confidentiality and security laws, regulations, and policies. If Federal or HHS information confidentiality and security laws, regulations, and policies become applicable to the HHS information or information systems after execution of the contract, or if the 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 for this contract as a result of any updates, if required.

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

(7) *Violation of information custodial requirements*. If HHS determines that the Contractor has violated any of HHS information confidentiality, privacy, or security provisions, it shall be sufficient grounds for HHS to withhold payment to the Contractor or third-party or terminate the contract for default in accordance with FAR part 49 or terminate for cause in accordance with FAR 12.403.

(8) *Encryption*. The Contractor/subcontractor must store, transport, or transmit HHS sensitive information, when permitted by the contract, using cryptography, HHS encryption policies, and HHS-approved encryption tools that are, at a minimum, validated under FIPS 140-3 (or its successor).

(9) *Firewall and web services security controls*. The Contractor/subcontractor's firewall and Web services security controls, if applicable, shall meet or exceed HHS minimum requirements. HHS Configuration Standards Guidelines are available upon request.

(10) *Disclosure of HHS data and information*. Except for uses and disclosures of HHS information authorized in a cognizant contract for performance of the contract, the Contractor/subcontractor may use and disclose HHS information only in two other situations: (i)

subject to paragraph 10 of this section, in response to a court order from a court of competent jurisdiction, or (ii) with HHS prior written approval. The Contractor/subcontractor must refer all requests for, demands for production of, or inquiries about, HHS information and information systems to the Contracting Officer for response. If the Contractor/subcontractor is in receipt of a court order or other request or believes it has a legal requirement to disclose HHS information, that Contractor/subcontractor shall immediately refer such court order or other request to the Contracting Officer for response. If the Contractor or subcontractor discloses information on behalf of HHS, the Contractor and/or subcontractor must maintain an accounting of disclosures. Accounting of Disclosures documentation maintained by the Contractor/subcontractor will include the name of the individual to whom the information pertains, the date of each disclosure, the nature or description of the information disclosed, a brief statement of the purpose of each disclosure or, in lieu of such statement, a copy of a written request for a disclosure, and the name and address of the person or agency to whom the disclosure was made. The Contractor/subcontractor will provide its Accounting of Disclosures upon request and within 15 calendar days to the assigned COR and Privacy Officer. Accounting of disclosures should be provided electronically via encrypted email to the COR and designated HHS facility Privacy Officer as provided in the contract, business associate agreement, or by the Contracting Officer. If providing the Accounting of disclosures electronically cannot be done securely, the Contractor/subcontractor will provide copies via trackable methods (UPS, USPS, Federal Express, etc.) immediately, providing the designated COR and Privacy Officer with the tracking information.

(11) *Compliance with privacy statutes and applicable regulations*. The Contractor/subcontractor shall not disclose HHS information protected by any of HHS privacy statutes or applicable regulations including, but not limited to, the Privacy Act of 1974 or the HIPAA Rules. If the Contractor/subcontractor is in receipt of a court order or other requests for HHS information or has questions if it can disclose information protected under the above-mentioned confidentiality statutes because it is required by law, that Contractor/subcontractor shall immediately refer such court order or other request to the Contracting Officer for response.

(i) *Compliance with identification policies*. Contractors shall comply with the Homeland Security Presidential Directive (HSPD)-12, Policy for a Common Identification Standard for Federal Employees and Contractors; OMB M-05-24; OMB M-19-17; FIPS 201, Personal Identity Verification (PIV) of Federal Employees and Contractors; HHS HSPD-12 policy; HHS Policy for Information Security and Privacy Protection (IS2P) Control Catalog, and Executive Order 13467, Part 1, section 1.2.

(j) *Report of known or suspected incident or breach*. The Contractor, subcontractor, third-party affiliate or business associate, and its employees shall notify HHS immediately via the Contracting Officer and the COR or within one (1) hour of a known or suspected incident or breach. The initial notification may first be made verbally but must be followed up in writing within one (1) hour. Report all actual or suspected incident and breach information to the

Contracting Officer and the COR as identified in the contract or as directed in the contract, within one hour of discovery or suspicion.

(1) Such issues shall be remediated as quickly as is practical, but in no event longer than **3 working days** The Contractor shall notify the Contracting Officer in writing.

(2) When the security fixes involve installing third party patched (*e.g.*, Microsoft OS patches or Adobe Acrobat), the Contractor will provide written notice to HHS that the patch has been validated as not affecting the systems within 10 working days. When the Contractor is responsible for operations or maintenance of the systems, they shall apply the security fixes within **5 working days**.

(3) All other vulnerabilities shall be remediated in a timely manner based on risk, in accordance with the timelines specified in the HHS Policy for Vulnerability Management, and the HHS Standard for Plan of Action and Milestones (POAM) Management and Reporting. Contractors shall notify the Contracting Officer, and COR within 2 business days after remediation of the identified vulnerability. Exceptions to this paragraph (e.g., for the convenience of HHS) must be requested by the Contractor through the COR and shall only be granted with approval of the Contracting Officer and the Office of the Chief Information Officer (OCIO). These exceptions will be tracked by the Contractor in concert with the Government in accordance with HHS Policy for IT Procurements–Security and Privacy Language.

(k) *Incident and breach investigation*. (1) The Contractor/ subcontractor shall immediately notify the Contracting Officer and COR for the contract of any known or suspected incident or breach (see definitions, paragraph (a)), or any other unauthorized disclosure of sensitive information, including that contained in system(s) to which the Contractor/subcontractor has access.

(2) To the extent known by the Contractor/subcontractor, the Contractor/ subcontractor's notice to HHS shall identify the information involved, an estimate of the number of potentially impacted individuals, the circumstances surrounding the incident (including to whom, how, when, and where the HHS information or assets were placed at risk or compromised), and any other information that the Contractor/subcontractor considers relevant.

(3) With respect to unsecured protected health information, the business associate is deemed to have discovered an incident as defined above when the business associate either knew, or by exercising reasonable diligence should have been known to an employee of the business associate. Upon discovery, the business associate must notify HHS of the incident immediately within one hour of discovery or suspicion as agreed to in the business associate agreement.

(4) In instances of theft or break-in or other criminal activity, the Contractor/subcontractor must concurrently report the incident to the appropriate law

enforcement entity (or entities) of jurisdiction. The Contractor, its employees, and its subcontractors and their employees shall cooperate with HHS 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 HHS in any civil litigation to recover HHS 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.

(l) *Incident and breach notification requirements*. (1) The Contractor/subcontractor shall provide notice to HHS of an incident as set forth in the incident and breach investigation section of this clause. The Contractor shall fully cooperate with HHS or third-party entity performing an independent risk analysis on behalf of HHS. Failure to cooperate may be deemed a material incident or breach and grounds for contract termination.

(2) The Contractor/subcontractor shall fully cooperate with the HHS Computer Security Incident Response Center (CSIRC), HHS Breach Response Team, Operating Divisions (OPDIVs), Staff Divisions (STAFFDIVs), other stakeholders or any Government agency conducting an analysis regarding any notice of an incident or breach, potential incident or breach, or incident which may require the Contractor to provide information to the Government or third-party performing a risk analysis for HHS, and shall address all relevant information concerning the incident or breach, including the following:

(i) Nature of the event (loss, theft, unauthorized access).

(ii) Description of the event, including:

(A) Date of occurrence.

(B) Date of incident or breach detection.

(C) Data elements involved, including any PII, such as full name, social security number, date of birth, home address, account number, disability code.

(D) Number of individuals affected or potentially affected.

(E) Names of individuals or groups affected or potentially affected.

(F) 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.

(G) Amount of time the data has been out of HHS control.

(H) The likelihood that the sensitive information will or has been compromised (made accessible to and usable by unauthorized persons).

(I) Known misuses of data containing sensitive information, if any.

(J) Assessment of the potential harm to the affected individuals.

(K) Incident or breach analysis as outlined in the HHS Breach Response Policy and Plan, as appropriate.

(L) Whether credit protection services may assist record subjects in avoiding or mitigating the results of identity theft based on the sensitive information that may have been compromised.

(M) Steps taken in response to mitigate or prevent a repetition of the incident.

(m) *Training*. (1) All Contractor employees and subcontractor employees requiring access to HHS information or HHS information systems shall complete the following before being granted access to HHS information and its systems:

(i) On an annual basis, successfully complete the HHS Privacy and Information Security Awareness and HHS Information Security Rules of Behavior training.

(ii) On an annual basis, sign and acknowledge (either manually or electronically) understanding of and responsibilities for compliance with the HHS Information Security Rules of Behavior, relating to access to HHS information and information systems.

(iii) Successfully complete any additional cyber security or privacy training, as required for HHS personnel with equivalent information system access.

(2) The Contractor shall provide to the Contracting Officer and/or the COR a copy of the training certificates and affirmation that HHS Information Security Rules of Behavior signed by each applicable employee have been completed and submitted within five (5) days of the initiation of the contract and annually thereafter, as required.

(3) Failure to complete the mandatory annual training and acknowledgement of the HHS Information Security Rules of Behavior, 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.

(n) *Subcontract flow down*. The Contractor shall include the substance of this clause, including this paragraph (k), in subcontracts, third-party agreements, and business associate agreements, of any amount and in which subcontractor employees, third-party servicers/employees, and business associates will perform functions where they will have

access to HHS information (including HHS sensitive information), information systems, information technology (IT) or providing and accessing information technology-related contract services, support services, and related resources (see HHSAR 302.101 definition of information technology-related contracts.)

HHSAR 352.204-73 Contractor Personnel Security and Agency Access (Feb 2024) (DEV)

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

Agency access means access to HHS facilities, sensitive information, information systems or other HHS resources.

Applicant means a contractor employee for whom the Contractor applies for an HHS identification card.

Contractor employee means a prime contractor and subcontractor employee who requires agency access to perform work under an HHS contract.

Identification card (or "ID card") means a government issued or accepted identification card such as a Personal Identity Verification (PIV) card, a PIV-Interoperable (PIV-I) card from an authorized PIV-1 issuer, or a non-PIV card issued by HHS, or a non-PIV card issued by another Federal agency and approved by HHS. PIV and PIV-1 cards have physical and electronic attributes that other (non-PIV) ID cards do not have.

Issuing office means the HHS entity that issues identification cards to contractor employees.

Local security servicing organization means the HHS entity that provides security services to the HHS organization sponsoring the contract.

(b) *Risk and sensitivity level designations*. For contracts requiring access to HHS facilities, sensitive information, information systems or other HHS resources, contractor employees will be required to complete background investigations, identity proofing, and government identification card application procedures to determine suitability for access. HHS will assign a risk and sensitivity level designation to the overall contract and/or to contractor employee positions by category, group or individual. The risk and sensitivity level designations will be the basis for determining the level of personnel security processing required for contractor employees. The position sensitivity designation levels that apply will be identified in the contract. The following risk and sensitivity level designations and associated level of processing are required, and each level includes the prior levels—

1. Low risk level: National Agency Check with Written Inquiries (NACI);

2. Moderate risk level: Minimum Background Investigation (MBI); and

3. High risk level: Background Investigation.

(c) *Security clearances.* Contractor employees may also be required to obtain security clearances (*i.e.*, Confidential, Secret, or Top Secret). National Security work designated "special sensitive," "critical sensitive," or "non-critical sensitive," will determine the level of clearance required for contractor employees. Personnel security clearances for national security contracts in HHS will be processed according to the HHS Personnel Security and Suitability Program, HHS Instruction 731-1, and the Department of Defense National Industrial Security Program Operating Manual (NISPOM).

(d) *Pre-screening of contractor employees*. The Contractor must pre-screen individuals designated for employment under any HHS contract by verifying minimal suitability requirements to ensure that only candidates that appear to meet such requirements are considered for contract employment, and to mitigate the burden on the Government of conducting background investigations on objectionable applicants. The Contractor must exercise due diligence in pre-screening all employees prior to submission to HHS for agency access. HHS may decline to grant agency access to a contractor employee for reasons including, but not limited to—

(1) Conviction of a felony, a crime of violence, or a misdemeanor involving moral turpitude;

(2) Falsification of information entered on forms or of other documents submitted;

(3) Improper conduct including criminal, infamous, dishonest, immoral, or notoriously disgraceful conduct or other conduct adverse to the Government regardless of whether the conduct is directly related to the contract; and

(4) Any behavior judged to pose a potential threat to HHS facilities, sensitive information, information systems or other resources.

(e) *Citizenship status*. The Contractor must monitor a non-citizen’s continued authorization for employment in the United States. The Contractor must provide documentation to the Contracting Officer or the Contracting Officer's Representative (COR) during the background investigation process that validates that the E-Verify requirement has been met for each contractor employee.

(f) *Background investigation and adjudication*. A contractor employee must have a favorable adjudication of background investigation before HHS will issue an ID card to the contractor employee granting access to HHS facilities, sensitive information, information systems or other HHS resources. HHS may accept favorable adjudications of background investigations from other Federal agencies when applicants have held PIV cards issued by those agencies with no break in service. HHS may also accept PIV-I (Interoperable) cards issued by an authorized PIV-

1 issuer as evidence of identity. A favorable adjudication does not preclude HHS from initiating a new investigation when deemed necessary. At a minimum, the FBI National Criminal History Check (fingerprint check) must be favorably completed before an HHS identification card can be issued. Each Contractor must use the Office of Personnel Management's (OPM) e-QIP system, or successor system identified by HHS, to complete any required investigative forms. Instructions for obtaining fingerprints will be provided by the COR or Contracting Officer. The HHS Assistant Secretary for Administration, Program Support Center (PSC), or authorized HHS designee, is responsible for adjudicating the suitability of contractor employees.

(g) *Agency access denied*. Upon contract award, HHS will initiate the agency access procedure for all contractor employees requiring access to HHS facilities, sensitive information, controlled unclassified information, information systems, and other HHS resources for contract performance. HHS may deny agency access to any individual about whom an adverse suitability determination is made. Failure to submit the required security information or to truthfully answer all questions shall constitute grounds for denial of access. The Contractor must not provide agency access to contractor employees until the COR or Contracting Officer provides notice of approval, which is authorized only by the PSC, or authorized HHS designee. Where a proposed contractor employee is denied agency access by the Government or, if for any reason a proposed application is withdrawn by the Contractor during the agency access process, the additional costs and administrative burden for conducting additional background investigations caused by a lack of effective pre-screening or planning on the part of the Contractor may be considered as part of the Contractor's overall performance evaluation.

(h) *Identification card application process*. The COR will be the HHS ID card Sponsor and point of contact for the Contractor's application for an HHS ID card. The COR shall review and approve the HHS ID card application before an ID card is issued to the applicant. An applicant may be issued either a Personal Identity Verification (PIV) card that meets the standards of Homeland Presidential Security Directive (HSPD-12), or an applicant may be issued a non-PIV card. Generally, a non-PIV card will be issued for contracts that expire in six months or less, including option periods. The COR may request the issuing office to waive the six-month eligibility requirement when it is in HHS interest for contract performance. The following applies—

(1) PIV card. The applicant must complete an HHS on-line application for a PIV card;

(2) Non-PIV card. The applicant must complete and submit a hard copy of the necessary form(s) to be provided to Contractor by COR/Sponsor) to the COR/Sponsor; and

(3) Regardless of the type of card to be issued (PIV or non-PIV), the applicant must appear in person to provide two forms of identity source documents in original form to HHS. The identity source documents must come from the list of acceptable documents included in Form F-9, OMB No. 1115-0136, Employment Eligibility Verification. At least one document must be a valid State

or Federal government-issued picture identification. For a PIV card, the applicant may be required to appear in-person a second time for enrollment and activation.

(i) *Identification card custody and control*. The Contractor is responsible for the custody and control of all forms of government identification issued by HHS to contractor employees for access to HHS facilities, sensitive information, information systems and other HHS resources. The Contractor shall:

(1) Provide a listing of personnel for whom an identification (ID) card is requested to the COR who will provide a copy of the listing to the card issuing office. This may include Contractor and subcontractor personnel. Follow issuing office directions for submittal of an application package(s).

(2) While visiting or performing work on an HHS facility, as specified by the issuing office or COR, ensure that contractor employees prominently display their ID card.

(3) Immediately notify the COR or, if the COR is unavailable, the Contracting Officer when a contractor employee's status changes and no longer requires agency access (*e.g.*, employee's transfer, completion of a project, retirement, removal from work on the contract, or termination of employment) that may affect the employee's eligibility for access to the facility, sensitive information, or resources.

(4) Promptly deliver to the issuing office: (a) all ID cards assigned to an employee who no longer requires access to the facility; and (b) all expired ID cards within five (5) days of their expiration or all cards at time of contract termination, whichever occurs first.

(5) Immediately report any lost or stolen ID cards to the issuing office and follow its instructions.

(i) The Contractor is responsible for maintaining and safeguarding the HHS ID card upon issuance to the contractor employee. The Contractor must ensure that contractor employees comply with HHS requirements concerning the renewal, loss, theft, or damage of an ID card. The Contractor must immediately notify the COR or, if the COR is unavailable, the Contracting Officer when an ID card is lost, stolen or damaged.

(ii) Failure to comply with the requirements for custody and control of HHS ID cards may result in withholding final payment or contract termination based on the potential for serious harm caused by inappropriate access to HHS facilities, sensitive information, information systems or other HHS resources.

(iii) Specific actions and activities are required in certain events—

(A) *Renewal*. A contractor employee's HHS issued ID card is valid for a maximum of three years or until the contract expiration date (including option periods), whichever occurs first. The

renewal process should begin six weeks before the PIV card expiration date. If a PIV card is not renewed before it expires, the contractor employee will be required to sign-in daily for facility access and may have limited access to information systems and other resources.

(B) *Lost/stolen*. Immediately upon detection, the Contractor or contractor employee must report a lost or stolen HHS ID card to the COR, or if the COR is unavailable, the Contracting Officer, the issuing office, or the local servicing security organization. The Contractor must submit an incident report within 48 hours, through the COR or, if the COR is unavailable, the Contracting Officer, the issuing office, or the local security servicing organization describing the circumstances of the loss or theft. The Contractor must also report a lost or stolen PIV card through the HHS on-line registration system. If the loss or theft is reported by the Contractor to the local police, a copy of the police report must be provided to the COR or Contracting Officer. From the date of notification to HHS, the Contractor must wait three days before getting a replacement ID card. During the 3-day wait period, the contractor employee must sign in daily for facility access.

(C) *Replacement*. An ID card will be replaced if it is damaged, contains incorrect data, or is lost or stolen for more than 3 days, provided there is a continuing need for agency access to perform work under the contract.

(D) *Surrender of ID cards*. Upon notification that routine access to HHS facilities, sensitive information, information systems or other HHS resources is no longer required, the Contractor must surrender the HHS issued ID card to the COR, or if the COR is unavailable, the Contracting Officer, the issuing office, or the local security servicing organization in accordance with agency procedures.

(j) *Flow down of clause*. The Contractor is required to include this clause in any subcontracts at any tier that require the subcontractor or subcontractor's employees to have access to HHS facilities, sensitive information, information systems or other resources.

HHSAR 352.208-70 Printing and Duplication (Feb 2026) (RFO DEV)

(a) Unless otherwise specified in this contract, no printing by the Contractor or any subcontractor is authorized under this contract. All printing required must be performed by the Government Printing Office except as authorized by the Contracting Officer. The Contractor must submit camera-ready copies to the Contracting Officer's Representative (COR). The terms “printing” and “duplicating/copying” are defined in the Government Printing and Binding Regulations of the Joint Committee on Printing.

(b) If necessary for performance of the contract, the Contractor may duplicate or copy less than 5,000 production units of only one page, or less than 25,000 production units in aggregate of multiple pages for the use of a department or agency. A production unit is defined as one

sheet, size 8.5 x 11 inches, one side only, and one color. The pages may not exceed a maximum image size of 10 3⁄4 by 14 1⁄4 inches. This page limit applies to each printing requirement and not for all printing requirements under the entire contract.

(c) Approval for all printing, as well as duplicating/copying in excess of the stated limits, must be obtained from the COR who will consult with the designated publishing services office and provide direction to the contractor. The cost of any unauthorized printing or duplicating/copying under this contract will be considered an unallowable cost for which the Contractor will not be reimbursed.

HHSAR 352.232-71 ELECTRONIC SUBMISSION OF PAYMENT REQUESTS (Apr 2026) (RFO DEVIATION)

(a) *Definitions.* As used in this clause –
Payment request means a bill, voucher, invoice, or request for contract financing payment with associated supporting documentation. The payment request must comply with the requirements in FAR 32.905(b) and the applicable payment clause included in this contract.
(b) *Submission instructions.* Except as provided in paragraph (c) of this clause, the Contractor must submit payment requests electronically using the Department of Treasury Invoice Processing Platform (IPP) or successor system. Information regarding IPP, including IPP Customer Support contact information, is available at www.ipp.gov or any successor site.
(c) *Alternate submission procedures.* The Contractor may submit payment requests using other than IPP only when the Contracting Officer authorizes alternate procedures in writing.
(d) *Submission of alternate payment procedures authorization.* If alternate payment procedures are authorized, the Contractor must include a copy of the Contracting Officer's written authorization with each payment request.

HHSAR 352.239-79 Information and Communication Technology Accessibility (Feb 2024) (DEV)

(a) Pursuant to Section 508 of the Rehabilitation Act of 1973 (29 U.S.C. 794d), as amended by the Workforce Investment Act of 1998, all information and communication technology (ICT) supplies, products, platforms, information, documentation, and services support developed, acquired, maintained or delivered under this contract or order must comply with the Revised 508 Standards, which are located at 36 C.F.R. 1194.1 and Appendices A, B, and C, and are available at https://www.access-board.gov/ict/. Information about Section 508 is available at https://www.hhs.gov/web/section-508/index.html.

(b) Additional Section 508 accessibility standards applicable to this contract or order may be identified in the specification, statement of work, or performance work statement. If it is determined by the Government that ICT supplies, products, platforms, information, documentation, and services support provided by the Contractor do not conform to the described accessibility standards in the contract, remediation of the supplies, products, platforms, information, documentation, or services support to the level of conformance specified in the contract will be the responsibility of the Contractor at its own expense.

(c) In the event of a modification(s) to this contract or order, which adds new ICT supplies or services or revises the type of, or specifications for, supplies, products, platforms, information, documentation, or services support, the Contracting Officer shall require that the Contractor submit a completed HHS Section 508 Accessibility Conformance Checklist (see *https://www.hhs.gov/web/section-508/accessibility-checklists/index.html*) or an Accessibility Conformance Report (ACR) (based on the Voluntary Product Accessibility Template (VPAT) see https://www.itic.org/policy/accessibility/vpat), and any other additional information necessary to assist the Government in determining that the ICT supplies or services conform to Section 508 accessibility standards. If it is determined by the Government that ICT supplies, products, platforms, information, documentation, and services support provided by the Contractor do not conform to the described accessibility standards in the contract, remediation of the supplies, products, platforms, information, documentation, or services support to the level of conformance specified in the contract will be the responsibility of the Contractor at its own expense.

(d) If this is an Indefinite-Delivery type contract, a Blanket Purchase Agreement or a Basic Ordering Agreement, the task/delivery order requests that include ICT supplies, products, platforms, information, documentation, or services support will define the specifications and accessibility standards for the order. In those cases, the Contractor shall be required to provide a completed HHS Section 508 Accessibility Conformance Checklist (see *https://www.hhs.gov/web/section-508/accessibility-checklists/index.html*) or an ACR (based on the VPAT see https://www.itic.org/policy/accessibility/vpat), and any other additional information necessary to assist the Government in determining that the ICT supplies, products, platforms, information, documentation, or services support conform to Section 508 accessibility standards. If it is determined by the Government that ICT supplies and services provided by the Contractor do not conform to the described accessibility standards in the provided documentation, remediation of the supplies, products, platforms, information, documentation, or services support to the level of conformance specified in the contract will be the responsibility of the Contractor at its own expense.

(e) The contractor shall identify to the Contracting Officer any perceived exception or exemption to Section 508 requirements.

I.4 Food and Drug Administration (FDA) Specific Requirements

FDA Electronic Invoicing and Payment Requirements

All invoices must be submitted through FDA's Invoice Processing Platform (IPP) System in accordance the procedures in Section G.6.

FDA Contractor Personnel Security Clearance Standards

Background investigations will be conducted by the Defense Counterintelligence and Security Agency (DCSA) in accordance with FDA Security Clearance Standards as outlined in H.1.

FDA Information Security Requirements

The Contractor shall comply with all applicable Information security requirements specified in Section H.2.

SECTION J - LIST OF ATTACHMENTS

The following attachments are incorporated into this solicitation and resulting contract:

Contract Attachments

The following attachments (C-series) are incorporated into the base IDIQ contract:

Attach #	Title	Description
C1	OSIST IDIQ Performance Work Statement (PWS)	Baseline requirements for OSIST services
C2	OSIST Facility Inventory (Locations and Square Footage)	Listing of OSIST facility locations and associated square footage to support proposal development, staffing, and pricing
C3	OSIST Price_Workbook	Excel pricing workbook template for offeror completion
C4	FDA Form 3398, DHS/FDA Commitment to Protect Non-Public Information Employee Agreement	Employee agreement for non-public information
C5	FDA Contractor Personnel Security Clearance Standard	Guidance and instruction for Contractor Personnel Security Clearance and badging

RFP Attachments

The following attachments (R-series) are provided for proposal preparation:

Attach #	Title	Description
R1	CBER Annual Re-Verification of BSL-3 Suites PWS	**Anticipated first task order PWS.** Offerors shall propose technical approach and pricing for this requirement.
R2	CBER BSL-3 Suite Decontamination Spaces for Decontamination and/or Reverification	Listing of CBER BSL spaces for decontamination and/or re-verification
R3	OOSH Workstream Sample PWS	Scenario Sample PWS for various services under tasks 3,4,5,6, and 7.
R4	Past Performance Questionnaire	Template for past performance references
R5	RFP Questions and Answers Template	Template for submitting solicitation questions
R6	HHS Subcontracting Plan Template	Template for submitting Subcontracting Plan (small businesses exempt)

SECTION K - REPRESENTATIONS, CERTIFICATIONS, AND OTHER STATEMENTS

K.1 Offeror Representations and Certifications Instructions

Offerors shall complete only the representations and certifications identified in this section. Where representations are maintained in the System for Award Management (SAM), the Offeror affirms that its SAM record is current, accurate, and complete as of proposal submission.

The Offeror's responses shall be consistent with its SAM registration; however, this representation is required for solicitation compliance.

K.1.1 System for Award Management

The Offeror represents that it is registered in SAM and that the registration is active and current.
☐ Yes ☐ No

K.1.2 Annual Representations and Certifications

The Offeror has completed the annual representations and certifications electronically via SAM.
☐ Yes ☐ No

K.1.3 Small Business Representation (NAICS 541690)

NAICS Code: 541690
NAICS Title: Other Scientific and Technical Consulting Services
Size Standard: $19.0 million

The Offeror represents its business size status for NAICS **541690**:
☐ Small Business (meets the $19.0M size standard)
☐ Other Than Small Business

If "Small Business" is selected, indicate all applicable categories (check all that apply):
☐ Small Disadvantaged Business (SDB)
☐ Women-Owned Small Business (WOSB)
☐ Economically Disadvantaged Women-Owned Small Business (EDWOSB)
☐ HUBZone Small Business
☐ Service-Disabled Veteran-Owned Small Business (SDVOSB)
☐ Veteran-Owned Small Business (VOSB)

Certification

The Offeror certifies that:
- Its size status for NAICS 541690 is accurate as of the date of offer; and
- Its representations are consistent with its current SAM registration.

☐ Yes ☐ No

The Government will rely on the Offeror's SAM registration for validation of size and socioeconomic status; however, this representation is required for proposal evaluation, reporting, and contract administration purposes.

52.252-1 Solicitation Provisions Incorporated by Reference (FEB 1998)

This solicitation incorporates provisions by reference, with the same force and effect as if they were given in full text. The full text may be accessed electronically at:

https://acquisition.gov

https://acquisition.gov/far-overhaul

https://acquisition.gov/hhsar

Prov. No.	Title	Date
52.204-7	System for Award Management—Registration	Nov 2025
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—Representation	Jan 2017
52.209-2	Prohibition on Contracting with Inverted Domestic Corporations-Representation	Nov 2025
52.209-5	Certification Regarding Responsibility Matters	Nov 2025
52.209-7	Information Regarding Responsibility Matters	Nov 2025
52.209-11	Representation by Corporations Regarding Delinquent Tax Liability or a Felony Conviction	Nov 2025
52.229-11	Tax on Certain Foreign Procurements—Notice and Representation	Nov 2025
52.240-90	Security Prohibitions and Exclusions—Representations and Certifications	Nov 2025

K.2 52.216-1 Type of Contract (DEVIATION Nov 2025)

The Government contemplates award of a single award, Indefinite Delivery Indefinite Quantity (IDIQ) contract with individual task orders issued as firm-fixed-price, time-and-materials, labor-hour, or a combination resulting from this solicitation.

SECTION L- INSTRUCTIONS TO OFFERORS – COMMERCIAL SERVICES (SINGLE-AWARD IDIQ)

L.1 Acquisition Overview

Clause/Prov. No.	Title	Date
52.215-1	Instructions to Offerors – Competitive Acquisition	Apr 2026
52.217-5	Evaluation of Options	Nov 2025

This acquisition is conducted in accordance with:

RFO FAR Part 12 – Acquisition of Commercial Products and Commercial Services

RFO FAR Part 15 – Contracting by Negotiation

RFO FAR Part 16.5 – Indefinite-Delivery Contracts

The Government intends to award one IDIQ contract for commercial services.

Task Order 1 (CBER Annual Re-Verification BSL-3 Suites) will be awarded at time of IDIQ award and satisfies the guaranteed minimum.

Contract Type Framework

The Government anticipates issuing task orders under this IDIQ using a combination of Firm-Fixed-Price (FFP), Time-and-Materials (T&M), and Labor-Hour (LH) contract types, depending on the nature, risk, and level of definition of the requirement at the time of task order issuance.

Due to the evolving nature of mission priorities, variable funding availability, and fluctuating workload (hereafter referred to as a “dynamic operating environment”), the Government cannot fully define all future task orders at the time of IDIQ award.

Accordingly, this solicitation is structured to evaluate the Offeror’s ability to perform effectively under varying levels of requirement definition, funding availability, and contract types.

Because certain future task orders are not fully defined at time of award, the Government will evaluate price using scenario-based pricing.

Non-price factors, when combined, are significantly more important than price.

L.2 Proposal Volumes

L.2.1 Volume 0 – Administrative

Include solicitation forms, amendments, representations/certifications, and any subcontracting/teaming agreements required under L.7. For Offerors other than small business concerns, Volume III shall include a compliant Subcontracting Plan in accordance with Section L.9.

L.2.2 Format Requirements (Narrative Volumes)

Proposals shall be prepared in accordance with the format instructions provided in this section. Failure to comply with these instructions may result in the proposal being evaluated as unacceptable or may result in portions of the proposal not being evaluated where noncompliance materially affects the Government's ability to conduct a meaningful evaluation.

Document Format

Each submission shall comply with the following:

- Page size: 8.5 x 11 inches
- Minimum text size: 11-point font (narrative text)
- Minimum text size for graphics: 9-point font
- Margins: at least 1 inch (top/bottom) and 3/4 inch (sides)
- Pages shall be numbered sequentially within each volume

Tables, charts, graphs, and figures:

- Shall be clear and legible
- Shall not exceed 8.5 x 11 inches
- Foldout pages are not permitted

Electronic Submission Requirements

Offerors shall submit proposals electronically in accordance with the instructions in this solicitation.

- Individual email submissions shall not exceed 20 MB
- If the proposal exceeds this limit, the submission shall be divided into multiple emails
- Each email subject line shall include the solicitation number and identify sequencing (e.g., "1 of X")

The electronic copy received in the Government's designated email inbox by the time specified for receipt shall constitute the official submission for purposes of determining timeliness in accordance with FAR 52.215-1.

Hard copy submissions will not be accepted.

File Format and Accessibility

- Files shall be readable using Microsoft Office or Adobe Acrobat (PDF)
- Microsoft Office documents shall not contain macros

The Government is not responsible for the inability to open, read, or process files that do not conform to these requirements.

If submitted files cannot be opened or are otherwise unreadable:

- The Contracting Officer may, at their discretion, request clarification or allow a limited opportunity for correction
- Failure to provide a readable submission may result in the proposal being evaluated as unacceptable

Virus Protection

Offerors are responsible for ensuring that all electronic submissions are virus-free.

Any submission determined to contain a virus may be rejected and not evaluated.

Marking Requirements

Offerors shall properly mark proprietary and source selection sensitive information in accordance with:

- FAR 52.215-1(e), Restriction on Disclosure and Use of Data
- FAR 3.104-4, Disclosure, Protection, and Marking of Contractor Bid or Proposal Information and Source Selection Information

Responsibility for Submission

Offerors are responsible for ensuring that proposals are submitted in sufficient time to be received by the Government by the date and time specified in the solicitation.

Offerors assume the risk of transmission delays, including those caused by system congestion or other technical issues.

Noncompliance

Failure to comply with the format requirements of this section may result in:

- The proposal being evaluated as unacceptable; and/or
- Pages exceeding stated limitations not being evaluated.

L.2.3 Volume I – Technical Proposal (80 pages maximum)

Offerors shall organize Volume I in accordance with the evaluation factors identified in Section M.

The Technical Proposal shall be structured as follows:

- **Factor 1 – Corporate Experience** (10 pages)
- **Factor 2 – Technical Approach** (30 pages)
- **Factor 3 – Management Approach** (10 pages)
- **Factor 4 – Past Performance** (30 pages)

A **Workshare Allocation Table (1 page)** shall be included and does not count toward page limits.

All pages count toward limits unless otherwise specified.

L.3 Factor 1 – Corporate Experience (10 pages)

Offerors shall demonstrate corporate experience at the Offeror team level, including the Prime Contractor and any proposed subcontractors or teaming partners.

Offerors may submit up to five (5) contracts performed within the past five (5) years.

Experience may be Prime-only, subcontractor-only, or combined.

For each contract, include:

- Customer contact information
- Period of performance
- Contract value
- Scope
- Geographic scope (identify states/regions)
- Prime or subcontractor attribution

Requirements:

- Demonstrate experience in biomedical research, laboratory, or similarly regulated environments
- Demonstrate nationwide or multi-regional performance
- Demonstrate experience covering all Task Areas 3 to 7, not partial capability

If a subcontractor is proposed to provide critical experience, that subcontractor must be assigned meaningful work and supported by a teaming agreement (if ≥25%).

L.4 Factor 2 – Technical Approach (30 pages)

L.4.1 Objective

Demonstrate a comprehensive and integrated approach to execute:

- The IDIQ PWS
- Task Order 1 (BSL-3 Suite)
- Workstream Support (Tasks 3 to 7)

L.4.2 Required Elements / Subfactors

A. Overall IDIQ Execution Strategy

Describe overall strategy for executing the IDIQ Statement of Work, including how your firm will:

- Manage multiple concurrent task orders under this single-award IDIQ;
- Scale staffing and technical resources based on funding variability and changing workload;

- Balance active task orders, including mission-critical baseline requirements, with variable and surge Workstream requirements;
- Coordinate and manage task orders performed across multiple geographic regions, including the processes, staffing structure, and communication mechanisms used to support nationwide performance
- Prioritize competing requirements without degrading performance;
- Maintain continuity of operations during workload spikes, funding shifts, or changing Government priorities.

B. Task Order 1 – BSL-3 Technical Approach

Provide methodology for containment integrity, HVAC cascade control, preventative maintenance and validation intervals, HEPA management, decontamination support, emergency response, and staffing.

Offerors shall base staffing levels, preventive maintenance frequencies, validation intervals, and ODC assumptions on the required tasks identified in Attachment R1 – CBER Annual Re-Verification of BSL-3 Suite PWS and in Attachment R2 - CBER BSL-3 Suite Decontamination Spaces for Decontamination and/or Re-Verification.

Proposals that rely on generic or unsupported assumptions, or that fail to demonstrate a clear linkage to Attachment R1 and R2, may be evaluated as presenting increased performance risk.

C. Workstream Support / Variable Technical Approach

Describe the Offeror's delivery methodology for providing Workstream Support requirements, including policy, compliance, training, Laboratory Quality Management Systems (LQMS), communications, and technical assistance, including nationwide execution capability.

The Government anticipates Workstream task orders will be issued in a dynamic operating environment characterized by evolving requirements, variable funding availability (including late fiscal year funding), and fluctuating workload.

As a result, requirements may be issued with high-level scope, rough order-of-magnitude estimates, or partially defined performance objectives, and may be refined post-award.

Accordingly, Offerors shall demonstrate an approach that supports flexible, scalable, and rapid deployment of resources across varying contract types (FFP, T&M, LH), rather than reliance on fully defined, stable requirements.

The Offeror shall address:

- The ability to rapidly mobilize and adjust staffing in response to changing requirements and funding levels;
- Scalable resource allocation and level-of-effort adjustment mechanisms;
- Processes for refining scope, staffing, and deliverables post-award while maintaining performance objectives;

- Integration of Workstream activities with ongoing IDIQ and Task Order 1 performance;
- Capability to execute across multiple geographic regions.

Proposals that assume stable, fully defined requirements or fail to demonstrate adaptability to changing scope, funding, and priorities may be evaluated as increased performance risk.

D. Risk Management

Provide key risks associated with performance of the IDIQ, along with corresponding mitigation strategies and recovery objectives at the IDIQ level. The Offeror shall describe how risks are identified, managed, and mitigated, and how performance will be recovered in the event of realized risks.

L.5 Factor 3 – Management Approach (10 pages)

Offerors shall describe an integrated management approach, including organizational structure, personnel, and execution controls.

The proposal shall address:

A. Organizational Structure & Integration

- Prime/subcontractor roles
- Reporting relationships
- Governance structure

B. Task Order Management

- Concurrent TO management
- Resource prioritization
- Nationwide coordination

C. Personnel and Staffing Approach

Offerors shall demonstrate a cohesive staffing strategy aligned with the technical approach.

At a minimum, include:

- Identification of key leadership (e.g., Program Manager)
- Roles and responsibilities
- Qualifications and relevant experience
- Alignment of personnel to Task Areas 1 to 7
- Staffing approach for TO1 and Workstreams Scenario
- Surge and contingency staffing

Program Manager Requirement:

- Resume (max 2 pages)

- Relevant certifications
- Letter of commitment/availability

D. Staffing Alignment and Workshare Consistency

- Alignment between staffing, technical approach, and pricing
- Integration of subcontractor personnel
- Consistency with Workshare Allocation Table

E. Quality Control and Performance Management

- QCP approach
- Deliverable review
- Personnel oversight

F. Continuity of Operations

- Retention strategy
- Replacement planning
- Transition continuity

G. Communication Approach

- CO/COR interface
- Internal communication
- Issue escalation

L.6 Factor 4 – Past Performance (30 pages)
Objective: Demonstrate recent, relevant past performance.
Element-Level Page Limits:
• Reference 1 (Maximum 5 pages): Description + contact info
• Reference 2 (Maximum 5 pages): Description + contact info
• Reference 3 (Maximum 5 pages): Description + contact info
• CPARS documentation (Maximum 5 pages each): If provided.

Provide up to three (3) references for contracts completed or ongoing within the past five (5) years. Subcontractor past performance only counts if tied to proposed workshare.
The offeror shall clearly identify the subcontractor's role and scope of work performed. A subcontractor/teaming agreement documentation shall also be submitted to support combined reference for consideration.

For each reference:
• Customer name, point of contact (name, title, email, phone)

• Contract number, period of performance, total value (awarded and obligated)
• Description of work performed
• Explanation of relevance to this requirement.

Note: Offerors may reuse examples from Factor 1 – Corporate Experience. CPARS documentation may be included if available. The Government will evaluate the past performance references submitted by the Offeror. Offerors may submit up to three (3) references. If fewer than three references are submitted, the Government will evaluate the references provided.

A **neutral rating** will be assigned only when the Offeror does not possess recent and relevant past performance information. An Offeror that fails to submit past performance information despite possessing relevant past performance may be evaluated based on other information available to the Government, including information obtained from Government sources.
The Government may consider past performance information obtained from sources other than those provided by the Offeror, including CPARS or other Government records.

Past Performance Questionnaire:
Offerors shall provide Attachment XX (Past Performance Questionnaire) to each past performance reference identified in their proposal. References shall complete Attachment XX and submit it directly to the following Government points of contact:

Maria Finan, Contracting Officer – Maria.Finan@fda.hhs.gov

Sheneil Green, Contract Specialist – Sheneil.Green@fda.hhs.gov

Offerors shall include the name and contact information for each reference in their proposal to enable the Government to follow up in the event a completed questionnaire is not received.

L.7 Prime Contractor Capability & Subcontracting (1 page)

Offerors shall clearly identify the roles and responsibilities of the Prime Contractor and any proposed subcontractors or teaming partners in performing the requirements of this IDIQ.

Offerors shall submit a **Workshare Allocation Table** identifying:

- The entity responsible for each major functional area or task category (Prime or subcontractor);
- Key capabilities or expertise provided by each entity; and
- The Offeror’s anticipated level of participation (as a %) by the Prime Contractor and subcontractors based on the proposed technical approach for Tasks 1 to 7.

For each proposed subcontractor or teaming partner, Offerors shall also provide the legal business name, business address, UEI, CAGE Code, and primary point of contact (name, title, phone, and email).

Because future task orders are not fully defined at the time of award, Offerors are not required to provide precise percentages of total contract value or labor hours. Instead, Offerors should describe the expected division of responsibilities and typical allocation of work between the Prime Contractor and subcontractors.

If a subcontractor or teaming partner is expected to perform a substantial portion of the work (generally 25 percent or more) based on the Offeror's proposed approach, the Offeror shall provide a signed teaming or subcontracting agreement identifying the scope of work and commitment of the subcontractor.

The Prime Contractor remains fully responsible for performance of the contract, including work performed by subcontractors.

The Workshare Allocation Table will be used to assess consistency across Corporate Experience, Technical Approach, Management Approach, and Price.

L.8 Volume II – Price Proposal

Offerors shall submit a Price Proposal consisting of the completed Government-provided Excel Price Workbook, a Staffing-to-Price Crosswalk, and a Basis of Estimate (BOE) narrative.

Price proposals shall clearly align with the Offeror's Technical Proposal and demonstrate reasonable and realistic pricing for the proposed approach.

L.8.1 Excel Price Workbook

Offerors shall complete Attachment C3 – OSIST Price_Workbook (Excel).

The workbook contains multiple tabs corresponding to the pricing elements evaluated under this solicitation. Offerors shall complete all applicable input cells and shall not alter the structure, formulas, or formatting of the workbook. The Excel workbook shall be submitted in native Excel format (.xlsx).

The workbook includes the following tabs:

IDIQ Level Pricing

Offerors shall provide fully burdened hourly labor rates for each proposed labor category for each ordering year. These rates represent the baseline pricing structure for future task orders issued under the IDIQ.

Labor categories used in scenario pricing shall be consistent with those provided in the IDIQ labor rate schedule.

Task Order 1 – BSL-3 Pricing

Offerors shall provide pricing for Task Order 1 – CBER Annual Re-Verification of BSL-3 Suites based on the proposed technical approach.

Offerors shall include:

- Labor categories
- Proposed labor hours
- IDIQ fully burdened hourly labor rates
- Any proposed Other Direct Costs (ODCs)

Staffing levels, preventive maintenance frequencies, validation intervals, and ODC assumptions shall be based on the specific tasks identified in Attachment R1. Areas requiring decontamination may vary by option year based on prior work or unanticipated needs.

Generic or unsupported assumptions may be evaluated as performance risk.

Scenario Pricing – Workstream Support

Offerors shall provide pricing for the Workstream Support scenario described in Attachment R3 – OOSH Workstream Sample PWS.

Offerors shall include:

- Proposed labor categories
- Estimated labor hours
- IDIQ fully burdened hourly labor rates
- Any applicable Other Direct Costs

Offerors shall present a single Estimated Not-to-Exceed (NTE) Rough Order of Magnitude (ROM) Value (Evaluation Scenario Only) derived from the above elements.

This estimate shall reflect the Offeror's projected cost to perform the scenario based on its proposed technical approach and will be used solely for evaluation of price reasonableness, realism, and consistency with the Technical Proposal.

The Scenario NTE ROM *does not represent a guaranteed task order*, funding commitment, or binding pricing for future work.

The Government has not provided a target price, ceiling, or funding constraint for the scenario. Offerors shall independently develop their Estimated NTE ROM.

Scenario pricing shall be consistent with the Offeror's Technical Proposal and Staffing-to-Price Crosswalk. Inconsistencies may be evaluated as performance risk.

L.8.2 Staffing-to-Price Crosswalk

Offerors shall submit a one-page Staffing-to-Price Crosswalk demonstrating alignment between the Technical Proposal and the Price Workbook.

At a minimum, the crosswalk shall include:

- Labor category
- Role described in the Technical Proposal

- Proposed staffing level (FTE or hours)
- Corresponding labor category from the Price Workbook
- Applicable pricing scenario (TO1 or Workstream)
- Reference to the Technical Proposal section where the role is described

Separate crosswalk entries shall be provided for:

- Task Order 1 (BSL-3 Suite)
- Workstream Scenario

Significant unexplained variances may be evaluated as performance risk.

L.8.3 Basis of Estimate (BOE) (5 pages)

Offerors shall provide a BOE narrative describing how proposed labor hours, labor categories, and ODCs were developed.

The BOE shall explain:

- Key assumptions used to develop labor hours
- Methodology used to determine staffing levels
- Preventive maintenance and validation assumptions for Task Order 1
- Assumptions related to nationwide execution of Workstream or similar requirements
- Any assumptions regarding surge or variable workload

For Task Order 1, the BOE shall clearly explain how assumptions were derived from Attachment R1.

For the Workstream Scenario, the BOE shall support the Estimated NTE ROM, including labor mix, level of effort, and any constraints or exclusions.

L.8.4 Price Consistency

The Price Proposal shall be consistent with the Technical Proposal.

Labor categories, staffing levels, and workshare allocations shall correspond to the labor hours and rates reflected in the Price Workbook.

Inconsistencies may be evaluated as performance risk.

L.8.5 Price Evaluation Purpose

Scenario pricing, including the Workstream Support Estimated NTE ROM, is provided for evaluation purposes only and is not intended to represent actual future task orders or establish binding pricing.

Scenario pricing provides a standardized basis for evaluating price reasonableness, realism, and alignment with the Offeror’s technical approach.

Scenario pricing does not guarantee issuance of any task order beyond the stated minimum and does not establish minimum or maximum ordering expectations.

L.9 Volume III - Subcontracting Plan Requirement

(a) Applicability: Applies to Offerors other than small business concerns. Small business Offerors are exempt.

(b) Requirement: Other-than-small business Offerors shall submit an Individual Subcontracting Plan in accordance with:

- RFO FAR Subpart 19.7
- FAR 52.219-9
- HHS Subcontracting Plan Template (Attachment R6)

Failure to submit an acceptable plan may render the proposal ineligible for award.

(c) Minimum Content: The plan shall include, at a minimum:

- Total subcontracting dollars and percentages
- Goals (dollars and %) for SB, SDB (incl. 8(a)/ANC/Tribal), WOSB, HUBZone, and SDVOSB
- Description of subcontracting opportunities
- Basis for goal development
- Program administration and oversight
- Assurances, reporting (ISR/SSR), and recordkeeping

(d) HHS Goals (FY26): Goals shall reflect maximum practicable opportunity and generally align with:

- SB 23%, SDB 5%, WOSB 5%, SDVOSB 5%, HUBZone 3%

Lower goals must be justified.

(e) Consistency: The subcontracting plan shall be consistent with the technical approach, management approach, and proposed workshare. Inconsistencies may indicate performance risk.

(f) Submission: Submit a signed plan with Volume III (Administrative) in accordance with HHS Subcontracting Plan Template. Does not count toward page limits.

(g) Flow-down: Offerors shall comply with FAR 52.219-8 and ensure required subcontracting provisions are flowed down to applicable subcontractors.

L.10 QUICK REFERENCE SUMMARY TABLE

The table below summarizes proposal volumes, evaluation factors, page limits, and key submission requirements. Offerors shall comply with the detailed instructions in this Section L.

Proposal Organization Summary

Volume	Factor	Title	Page Limit	Key Requirements
Volume 0	—	Administrative	No limit	Forms, amendments, representations, teaming agreements (if applicable)
Volume I	Factor 1	Corporate Experience	10 pages	Team-level experience; all tasks under 3 to 7; biomedical
Volume I	Factor 2	Technical Approach	30 pages	IDIQ+TO1+Workstream Scenario
Volume I	Factor 3	Management Approach	10 pages	Org + staffing + personnel + integration
Volume I	Factor 4	Past Performance	30 pages	3 references; CPARS 5 pg limit; relevance
Volume 1	—	Workshare Table	1 page	Prime/sub roles
Volume II	Factor 5	Price	No limit	Price Workbook (Excel); Crosswalk + BOE
Volume III	Factor 6	Subcontracting Plan	No limit	HHS Subkt Plan Template (small business exempt)

SECTION M - EVALUATION FACTORS FOR AWARD

Clause/Prov. No.	Title	Date
52.212-2	Evaluation – Commercial Products and Commercial Services	Nov 2025

M.1 Basis of Award

Award will be made on a best-value trade-off basis.

The Government may evaluate proposals in phases and reserves the right to eliminate an Offeror from further consideration at any stage of the evaluation process if the proposal is not among the most highly rated or if the proposal receives a confidence rating of less than High Confidence or Some Confidence under any non-price factor (Factors 1–4).

The Government will conduct a best-value tradeoff among proposals that are not rated Low Confidence under Factors 1–4.

Non-price factors, when combined, are significantly more important than price.

Any proposal rated Low Confidence under Factors 1–4 will be ineligible for award.

M.2 Evaluation Factors and Relative Importance

The Government will evaluate proposals using the following factors, listed in descending order of importance:

Factor 1 – Corporate Experience

Factor 2 – Technical Approach

Factor 3 – Management Approach

Factor 4 – Past Performance

Factor 5 – Price

Factor 6 – Subcontracting Plan (for other than small businesses concerns)

Factors 1 and 2 (Corporate Experience and Technical Approach) are equal in importance and, when combined, are *significantly more important* than any other individual factor or combination of factors. The Government will consider both factors together to assess the Offeror's overall capability, technical understanding, and likelihood of successful performance.

Factor 3 (Management Approach) and Factor 4 (Past Performance) are of equal importance and are less important than Factors 1 and 2; however, when combined, Factors 3 and 4 are more important than Price.

Factor 6 – Subcontracting Plan (for other than small businesses concerns) will be evaluated for the extent to which the Offeror demonstrates a realistic, compliant, and meaningful approach to

small business participation, consistent with FAR 19.7. This factor is less important than all other non-price factors and will not be evaluated using the confidence rating methodology in Section M.3. Instead, the Subcontracting Plan will be evaluated on an *acceptable/unacceptable basis*. A rating of Unacceptable may render the proposal ineligible for award.

Price will not be assigned a numerical weight but will be evaluated for reasonableness and consistency. In addition, the Government may perform a price realism analysis, as described in Section M.8, to assess whether proposed pricing reflects a clear understanding of the requirements and is realistic for the work to be performed. The results of any price realism analysis may be used to inform the Government's assessment of performance risk.

All non-price factors (Factors 1–4) will be evaluated using the confidence rating methodology described in Section M.3.

To support efficient evaluation, the Government may limit further consideration to those proposals that demonstrate the highest confidence ratings and lowest performance risk. Proposals receiving less than **High Confidence or Some Confidence** under any non-price factor may be excluded from further consideration.

M.3 Confidence Ratings for Technical and Past Performance

High Confidence	The Government has high confidence that the Offeror understands the requirement, proposes a sound approach, and will be successful in performing the contract with little or no Government intervention.
Some Confidence	The Government has some confidence that the Offeror understands the requirement, proposes a sound approach, and will be successful in performing the contract with some Government intervention.
Low Confidence	The Government has low confidence that the Offeror understands the requirement, proposes a sound approach, or will be successful in performing the contract even with Government intervention.
Neutral Confidence **(Past performance only)**	The Government has no basis to determine the Offeror's probability of successful performance because the Offeror has no relevant past performance or the Offeror's past performance is not available. In accordance with FAR 15.305(a)(2)(iv), the Offeror will be evaluated neither favorably nor unfavorably.

Performance Risk Framework

Performance risk is a central consideration across all non-price factors and reflects the likelihood that the Offeror can successfully perform the contract in a dynamic operating environment characterized by evolving requirements, variable funding, fluctuating workload, and mixed contract types (FFP, T&M, LH).

Assessment of performance risk is inherent in the confidence ratings assigned. Proposals demonstrating lower performance risk will be evaluated more favorably.

M.4 Factor 1 – Corporate Experience

The Government will evaluate the Offeror's demonstrated corporate experience based on up to five (5) contracts performed within the past five (5) years.

The Government will evaluate corporate experience at the Offeror team level, which includes the Prime Contractor and any proposed subcontractors, or teaming partners identified in the proposal.

The Government will evaluate:

- Similarity of scope, with strong preference for experience performed in biomedical research, laboratory, or comparable regulated scientific environments;
- Demonstrated nationwide or multi-regional performance;
- Demonstrated experience performing the full range of requirements comparable to Task Areas 3–7, rather than isolated or partial task area performance;
- Experience performing under IDIQ or multi-task order environments;
- The extent to which relevant experience is distributed across the Prime Contractor and proposed subcontractors consistent with their proposed roles and responsibilities; and
- The effectiveness of the Offeror's approach to integrating the combined experience of the team.

Experience of subcontractors and teaming partners will be considered only to the extent that such entities are proposed to perform meaningful and clearly defined portions of the requirement, as reflected in the Offeror's technical approach and workshare allocation.

Greater confidence will be assigned to proposals that demonstrate recent, relevant, and integrated experience within biomedical research or similarly regulated laboratory environments across the Offeror team, and that collectively demonstrate the capability to perform all Task Areas 3 to 7 as an integrated program.

Proposals that:

- Rely on subcontractor experience that is not aligned with proposed roles;
- Demonstrate experience limited to only one or a subset of Task Areas 3–7; or
- Lack experience in biomedical or comparable laboratory environments

may be assessed increased performance risk and receive a lower confidence rating.

M.5 Factor 2 – Technical Approach

The Government will evaluate the Offeror's ability to perform effectively in a dynamic operating environment and under varying contract types, including Firm-Fixed-Price (FFP), Time-and-Materials (T&M), and Labor-Hour (LH) task orders.

The evaluation will consider:

- Integrated IDIQ execution strategy;

- Technical depth of BSL-3 operations within biomedical or similarly regulated laboratory environments;
- Alignment of proposed staffing, preventive maintenance (PM), validation intervals, and other assumptions with Task Order 1 CBER Annual Reverification of BSL-3 Suites
- Nationwide Workstream capability; and
- Integration model and continuity protection across all Task Areas.

Performance Risk Consideration
In addition to assessing the Offeror's understanding and technical approach, the Government will evaluate the performance risk associated with the Offeror's proposed approach. Performance risk is the potential for disruption to schedule, increased cost, degradation of technical performance, or failure to meet contract requirements.

Performance risk will be assessed based on the degree to which the proposal demonstrates:

- Realistic and feasible technical and management approaches grounded in biomedical or regulated laboratory environments;
- Effective integration of concurrent requirements, including all Task Areas from 3 to 7;
- Adequate staffing, resource allocation, and operational controls; and
- The ability to perform under conditions of changing requirements, funding variability, and workload fluctuations.

Assessment of performance risk is inherent in the confidence rating assigned. Proposals that demonstrate lower performance risk will be evaluated more favorably, while proposals that present higher performance risk may result in reduced confidence.

M.5.1 Overall IDIQ Execution Strategy Evaluation

The Government will evaluate the extent to which the Offeror demonstrates a clear, feasible, and low-risk strategy for executing the IDIQ as a single-award vehicle.

Greater confidence will be assigned to proposals that demonstrate:

- A structured and repeatable prioritization framework;
- Clear resource allocation controls;
- An execution model grounded in biomedical research, laboratory safety, or similarly regulated environments;
- Protection of mission-critical requirements during surge events;
- Low performance risk under variable funding conditions;
- A structured coordination mechanism for nationwide task order execution; and
- An integrated approach to delivering all technical Task Areas 3 to 7 concurrently, rather than as isolated or siloed functions.

Proposals that lack biomedical/laboratory context, rely on ad hoc staffing adjustments, or fail to demonstrate integration across Task Areas 3 to 7 may be assessed increased performance risk.

M.5.2 Task Order 1 – BSL-3 Technical Approach Evaluation

The Government will evaluate the extent to which the Offeror demonstrates a technically sound, realistic, and low-risk approach to performing Task Order 1 (CBER Annual Re-Verification of BSL-3 Suites).

The Government will assess:

- The adequacy of the Offeror's methodology to maintain containment integrity;
- The technical approach to HVAC pressure cascade control and monitoring;
- The realism and completeness of preventive maintenance and validation intervals;
- The adequacy of HEPA filtration management and replacement strategy;
- The approach to decontamination and autoclave support;
- The clarity and feasibility of emergency response and recovery procedures;
- The sufficiency and qualifications of proposed staffing.

Grounding Requirement

The Government will specifically evaluate whether the Offeror's proposed:

- Staffing levels,
- Preventive maintenance frequencies,
- Validation intervals, and
- ODC assumptions

are logically derived from and consistent with the requirements outlined in Task Order 1 Attachment R1 (CBER BSL-3 Suite Decontamination).

Proposals relying on generic industry assumptions without clear correlation to the required tasks may be assessed increased performance risk and may receive a lower confidence rating.

Proposals that materially understate maintenance frequencies, validation requirements, or staffing needs relative to the Attachment R1 context may be evaluated as unrealistic and indicative of performance risk.

M.5.3 Workstream Support / Variable Technical Approach Evaluation

The Government will evaluate the extent to which the Offeror demonstrates a flexible, scalable, and responsive approach for delivering Workstream Support requirements (Tasks 3 to 7) in a dynamic funding and priority environment.

The Government will assess:

- The Offeror's ability to rapidly mobilize and adjust staffing in response to evolving requirements and funding availability;
- The effectiveness of proposed scalable staffing models and level-of-effort adjustment mechanisms;
- The Offeror's processes for refining scope, staffing, and deliverables post-award while maintaining schedule and performance objectives;
- The capability to execute Workstream requirements across multiple geographic regions;
- The degree to which Workstream activities are integrated with ongoing IDIQ and Task Order 1 performance without disruption.

Greater confidence will be assigned to proposals that demonstrate:

- A structured and repeatable approach to rapid resource deployment;
- Clearly defined mechanisms for scaling level of effort based on funding and priority changes;
- The ability to operate effectively under high-level or evolving task order requirements;
- Seamless integration across concurrent efforts with minimal performance risk.

Proposals that rely on rigid execution models, assume stable or fully defined requirements, or fail to demonstrate adaptability to changing scope, funding, and priorities may be assessed increased performance risk and receive a lower confidence rating.

M.5.4 Risk Management Evaluation

The Government will evaluate the Offeror's identification of key performance risks and the effectiveness of proposed mitigation strategies and recovery approaches at the IDIQ level.

The Government will assess:

- The relevance and completeness of identified risks;
- The feasibility of proposed mitigation strategies;
- The adequacy of recovery objectives and contingency planning.

Greater confidence will be assigned to proposals that demonstrate proactive and comprehensive risk identification, realistic and actionable mitigation strategies, and well-defined recovery approaches that minimize performance disruption and reduce overall performance risk.

Proposals that identify risks without meaningful mitigation strategies, propose unrealistic or unsupported recovery approaches, or fail to demonstrate integration of risk management into the overall approach may be assessed increased performance risk and may receive a lower confidence rating.

M.6 Factor 3 – Management Approach

The Government will evaluate the extent to which the Offeror demonstrates an effective and integrated management approach to support successful IDIQ performance.

The Government will assess:

- The clarity and effectiveness of the Offeror's organizational structure, including defined roles and responsibilities across the Prime Contractor and any proposed subcontractors;
- The approach to managing multiple concurrent task orders in a dynamic operating environment, including allocation and prioritization of personnel and resources;
- The qualifications, experience, and suitability of proposed personnel, including key leadership (i.e. Program Manager), to successfully manage and execute contract requirements;
- The alignment between proposed personnel, their roles and responsibilities, and the overall staffing approach, including consistency with the technical approach and workshare allocation;
- The adequacy of quality control processes, including oversight of personnel performance and deliverable quality;
- The effectiveness of Prime Contractor and subcontractor integration, including management of personnel across organizational boundaries;
- The adequacy of continuity of operations planning, including personnel retention, replacement strategies, and surge staffing capability; and
- The effectiveness of communication with Government stakeholders (CO, IDIQ COR, and Task Order COR), including communication pathways between Government and Contractor personnel.

Personnel Integration and Performance Risk Consideration

The Government will evaluate the extent to which the Offeror demonstrates a cohesive and well-integrated workforce capable of performing the full scope of the requirement. Emphasis will be placed on the Offeror's ability to:

- Provide qualified personnel across all required functional areas;
- Maintain continuity of key roles;
- Effectively integrate Prime and subcontractor personnel; and
- Ensure personnel resources are sufficient and aligned to support all Task Areas (1–7), including concurrent and geographically dispersed performance.

Greater confidence will be assigned to proposals that demonstrate:

- Highly qualified personnel aligned with clearly defined roles;
- Strong alignment between staffing, technical approach, and workshare;
- Effective management of personnel across multiple task orders and locations; and
- Low performance risk associated with staffing, integration, and continuity.

Proposals that:

- Demonstrate misalignment between personnel and the technical approach;
- Rely on unclear or unsupported staffing assumptions;
- Fail to demonstrate effective management of subcontractor personnel; or
- Present risks related to staffing continuity or personnel capability

may be assessed increased performance risk and receive a lower confidence rating.

M.7 Factor 4 – Past Performance

The Government will evaluate the Offeror's past performance to assess the probability of successful performance of the required effort.

The Government will evaluate:

- The relevance of the Offeror's past performance to the requirements of this solicitation, including similarity of scope, magnitude, and complexity;
- The quality of performance, including but not limited to schedule adherence, cost control, technical performance, and business relations; and
- The extent to which the past performance demonstrates the Offeror's ability to successfully perform requirements similar to this effort.

The Government will consider past performance information obtained from the references submitted in accordance with Section L, as well as information obtained from other sources, including CPARS and other Government records.

Past performance of proposed subcontractors may be considered to the extent that the subcontractor is proposed to perform meaningful aspects of the requirement, consistent with the Offeror's proposed approach.

A Neutral Confidence rating will be assigned when the Offeror does not have recent and relevant past performance or when such information is not available. In accordance with FAR 15.305(a)(2)(iv), a neutral rating will be evaluated neither favorably nor unfavorably.

M.8 Factor 5 – Price

The Government will evaluate the Offeror's Price Proposal for reasonableness and consistency, and for limited price realism where sufficient information is available.

The Government may perform a price realism assessment for Task Order 1 (BSL-3 Suite) and scenario pricing to evaluate whether proposed labor hours, staffing levels, and assumptions are realistic for the work described.

Price realism will not be evaluated for all potential future task orders due to the undefined nature of those requirements at the time of award.

Because future task orders are not fully defined at the time of award, the Government will assess whether the Offeror's pricing structure, labor rates, and supporting assumptions provide

a reasonable, flexible, and scalable basis for future task order pricing across FFP, T&M, and LH contract types.

Scenario pricing will be used for evaluation purposes only to assess price reasonableness and consistency across Offerors and does not represent guaranteed task orders.

Inconsistencies, unsupported assumptions, or pricing that is not aligned with the technical approach may be evaluated as performance risk.

M.9 Factor 6 - Subcontracting Plan (Other than Small Business Offerors Only)

(a) Applicability: Applies only to Offerors other than small business concerns.
(b) Evaluation Basis: The Government will evaluate the subcontracting plan for:

1. Compliance
    - Conformance with FAR Subpart 19.7, FAR 52.219-9, and HHS Subcontracting Plan Template
    - Inclusion of all required elements identified in Section L.9(c).
2. Adequacy of Goals
    - Extent to which proposed subcontracting goals reflect maximum practicable opportunity
    - Alignment with HHS subcontracting goals
    - Adequacy of rationale for any goals below targets.
3. Quality of Approach
    - Logical linkage between subcontracting opportunities and the proposed work
    - Sound methodology for establishing goals.
4. Feasibility and Consistency
    - Consistency with the Technical Approach, Management Approach, and proposed workshare
    - Realism and likelihood of successful execution.
5. Program Management
    - Adequacy of subcontracting program administration, reporting, and oversight.

(c) Evaluation Method: The subcontracting plan will be evaluated on an Acceptable / Unacceptable basis:

- Acceptable: Meets FAR requirements, demonstrates realistic and achievable goals, and reflects a credible, integrated approach
- Unacceptable: Missing, materially incomplete, inconsistent with the proposal, or fails to demonstrate a good faith effort.

(d) Award Eligibility: An Unacceptable rating will render the proposal ineligible for award, consistent with FAR requirements for submission of an acceptable subcontracting plan.
(e) Performance Risk Consideration: Deficiencies or inconsistencies in the subcontracting plan may be considered in assessing proposal risk under other evaluation factors.