SOLICITATION/CONTRACT/ORDER FOR COMMERCIAL ITEMS

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

1. REQUISITION NUMBER

PAGE 1 OF 76

2. CONTRACT NO.

3. AWARD/ EFFECTIVE DATE

4. ORDER NUMBER

5. SOLICITATION NUMBER: 75F40126R00051

6. SOLICITATION ISSUE DATE: 06/15/2026

7. FOR SOLICITATION INFORMATION CALL:

a. NAME: WARREN DUTTER

b. TELEPHONE NUMBER (No collect calls): 301-796-2486

8. OFFER DUE DATE/LOCAL TIME: 07/15/2026 1400 CT

9. ISSUED BY CODE HFT-323

FDA/OO/OFBA/OAGS/DAP
OAGS - Field Operations Branch
3900 NCTR ROAD
JEFFERSON AR 72079

10. THIS ACQUISITION IS ☐ UNRESTRICTED OR ☒ SET ASIDE: 100.00 % 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): 561210

SIZE STANDARD: $47

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 NCTR

NCTR
3900 NCTR ROAD
JEFFERSON AR 72079

16. ADMINISTERED BY CODE HFT-323

FDA/OO/OFBA/OAGS/DAP
OAGS - Field Operations Branch
3900 NCTR ROAD
JEFFERSON AR 72079

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

Food and Drug Administration
Vendor Payments, OFS FDA
10903 New Hampshire Avenue
Bldg 32, Rm 2162, Mail Hub 2145
Silver Spring, MD 20993-0002

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
1	National Center for Toxicological Research (NCTR) On-site Facility Operations and Maintenance (O&M) Support Services as outlined herein and in the provided Attachments.				

(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)*: NICHOLAS E. SARTAIN

31c. DATE SIGNED

19. ITEM NO.	20. SCHEDULE OF SUPPLIES/SERVICES	21. QUANTITY	22. UNIT	23. UNIT PRICE	24. AMOUNT

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

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PART I- THE SCHEDULE
SECTION B- SUPPLIES OR SERVICES AND PRICES/COSTS

B-1 Purpose

The Food and Drug Administration (FDA), National Center for Toxicological Research (NCTR) requires on-site facility Operations and Maintenance (O&M) support services to perform a full range of operational and maintenance support including Work Order (WO)/Indefinite Delivery Indefinite Quantity (IDIQ) work services.

The services include, but are not limited to, operations and maintenance of all campus utility systems; craft shop support services; operation and maintenance of utility plants and equipment; maintenance of all process and non-process equipment; maintenance, alteration and repair of buildings and structures; pest control and grounds maintenance; janitorial and housekeeping services; and cafeteria food service operation. **Attachment 1- Performance Work Statement (PWS)**

B-2 Contract Type and Ordering Structure

The Government intends to award a hybrid contract consisting of Firm-Fixed-Price (FFP) requirements for routine O&M services and an Indefinite Delivery Indefinite Quantity (IDIQ) component for additional work. Task Orders issued under the IDIQ may be Firm-Fixed-Price (FFP), Time-and-Materials (T&M), or Labor-Hour (LH), as specified in each Task Order.

The Contractor shall propose fully burdened ceiling labor rates for all labor categories applicable to IDIQ Task Orders. These rates shall include direct labor, indirect costs, overhead, G&A, and profit. Ceiling rates shall not be exceeded without a formal contract modification.

Offerors shall propose labor rates for each contract year. Rates may escalate between periods but shall remain fixed within each period.

B-3 Schedule of Items

Phase-In

CLIN	Description	Total Price
1	PHASE-IN PERIOD (20 days) (9/1/2026 to 9/20/2026)	

Base Period and Option Pricing

CLIN	Description	Annual Price
2	Base Period of Performance (9/21/2026 to 9/20/2027), Fixed-Price in accordance with requirements identified in PWS	
3	Base Period of Performance (9/21/2026 to 9/20/2027), Incidental Expenses (NTE $5,000): Reimbursement for reasonable and allowable incidental costs (e.g., minor equipment replacement, minor emergency purchases) necessary for contract performance. Contractor shall submit itemized monthly invoices with supporting documentation. Total reimbursement shall not exceed $5,000 without prior Contracting Officer approval.	$5,000.00
4	Option Period 1 (9/21/2027 to 9/20/2028): Same as Item 2 description	
5	Option Period 1 (9/21/2027 to 9/20/2028), Incidental Expenses (NTE $5,000): Reimbursement for reasonable and allowable incidental costs (e.g., minor equipment replacement, minor emergency purchases) necessary for contract performance. Contractor shall submit itemized monthly invoices with supporting documentation. Total reimbursement shall not exceed $5,000 without prior Contracting Officer approval.	$5,000.00
6	Option Period 2 (9/21/2028 to 9/20/2029): Same as Item 2 description	
7	Option Period 2 (9/21/2028 to 9/20/2029), Incidental Expenses (NTE $5,000): Reimbursement for reasonable and allowable incidental costs (e.g., minor equipment replacement, minor emergency purchases) necessary for contract performance. Contractor shall submit itemized monthly invoices with supporting documentation. Total reimbursement shall not exceed $5,000 without prior Contracting Officer approval.	$5,000.00
8	Option Period 3 (9/21/2029 to 9/20/2030),: Same as Item 2 description	
9	Option Period 3 (9/21/2029 to 9/20/2030), Incidental Expenses (NTE $5,000): Reimbursement for reasonable and allowable incidental costs (e.g., minor equipment replacement, minor	

	emergency purchases) necessary for contract performance. Contractor shall submit itemized monthly invoices with supporting documentation. Total reimbursement shall not exceed $5,000 without prior Contracting Officer approval.	$5,000.00
10	Option Period 4 (9/21/2030 to 9/20/2031): Same as Item 2 description	
11	Option Period 4 (9/21/2030 to 9/20/2031), Incidental Expenses (NTE $5,000): Reimbursement for reasonable and allowable incidental costs (e.g., minor equipment replacement, minor emergency purchases) necessary for contract performance. Contractor shall submit itemized monthly invoices with supporting documentation. Total reimbursement shall not exceed $5,000 without prior Contracting Officer approval.	$5,000.00
TOTAL PRICE (CLINs 1-11)		

Indefinite Delivery/Indefinite Quantity Work

A. Individual Task Orders shall not exceed five (5) years in total duration, inclusive of options.

B. Additional Work Task Orders-Indefinite Delivery/Indefinite Quantity Work
The Government will issue Task Orders (TO) in accordance with the terms of the contract.

C. Tables 1 through 5 below are for evaluation purposes only.
The fixed hourly rates shall include all direct labor cost, indirect labor cost, general and administrative cost and profit or fee.

1. <u>ESTIMATED INDEFINITE QUANTITY WORK-TASK ORDERS Base Year Ordering Period (9/21/2026 to 9/20/2027),</u>

Labor Category	Est. Labor Hours	Fully Burdened Hourly Rate (to be negotiated)	TOTAL ESTIMATED AMOUNT
Electrician	100	$	$

	Grounds Maintenance Laborer	100	$	$
	HVAC Mechanic	100	$	$
	Instrument Mechanic	100	$	$
	Laborer	100	$	$
	Lead Craftsman III	100	$	$
	Lead Craftsman II	100	$	$
	Lead Craftsman I	100	$	$
	Maintenance Mechanic	100	$	$
	Maintenance Trades Helper	100	$	$
	Material Coordinator	100	$	$
	Millwright	100	$	$
	Plumber/Pipefitter	100	$	$
	Sheet Metal Worker	100	$	$
	Tractor Operator	100	$	$
	Total Estimated Hours	**1,500**		
	Total Estimates		**Total Est. Amount**	

2. <u>SCHEDULE OF INDEFINITE QUANTITY WORK- TASK ORDERS Year 1 Ordering Period (9/21/2027 to 9/20/2028),</u>

	Labor Category	Est. Labor Hours	Fully Burdened Hourly Rate (to be negotiated)	TOTAL ESTIMATED AMOUNT
	Electrician	100	$	$

	Grounds Maintenance Laborer	100	$	$
	HVAC Mechanic	100	$	$
	Instrument Mechanic	100	$	$
	Laborer	100	$	$
	Lead Craftsman III	100	$	$
	Lead Craftsman II	100	$	$
	Lead Craftsman I	100	$	$
	Maintenance Mechanic	100	$	$
	Maintenance Trades Helper	100	$	$
	Material Coordinator	100	$	$
	Millwright	100	$	$
	Plumber/Pipefitter	100	$	$
	Sheet Metal Worker	100	$	$
	Tractor Operator	100	$	$
	Total Estimated Hours	**1,500**		
	Total Estimates		**Total Est. Amount**	

3. **SCHEDULE OF INDEFINITE QUANITITY WORK- TASK ORDERS Year 2 Ordering Period (9/21/2028 to 9/20/2029),**

	Labor Category	Est. Labor Hours	Fully Burdened Hourly Rate (to be negotiated)	TOTAL ESTIMATED AMOUNT
	Electrician	100	$	$
	Grounds Maintenance Laborer	100	$	$
	HVAC Mechanic	100	$	$
	Instrument Mechanic	100	$	$
	Laborer	100	$	$
	Lead Craftsman III	100	$	$
	Lead Craftsman II	100	$	$
	Lead Craftsman I	100	$	$
	Maintenance Mechanic	100	$	$
	Maintenance Trades Helper	100	$	$
	Material Coordinator	100	$	$
	Millwright	100	$	$
	Plumber/Pipefitter	100	$	$
	Sheet Metal Worker	100	$	$
	Tractor Operator	100	$	$
	Total Estimated Hours	**1,500**		
	Total Estimates		**Total Est. Amount**	

4. SCHEDULE OF INDEFINITE QUANTITY WORK-TASK ORDERS Year 3 Ordering Period (9/21/2029 to 9/20/2030),

Labor Category	Est. Labor Hours	Fully Burdened Hourly Rate (to be negotiated)	TOTAL ESTIMATED AMOUNT
Electrician	100	$	$
Grounds Maintenance Laborer	100	$	$
HVAC Mechanic	100	$	$
Instrument Mechanic	100	$	$
Laborer	100	$	$
Lead Craftsman III	100	$	$
Lead Craftsman II	100	$	$
Lead Craftsman I	100	$	$
Maintenance Mechanic	100	$	$
Maintenance Trades Helper	100	$	$
Material Coordinator	100	$	$
Millwright	100	$	$
Plumber/Pipefitter	100	$	$
Sheet Metal Worker	100	$	$
Tractor Operator	100	$	$
Total Estimated Hours	**1,500**		
Total Estimates		**Total Est. Amount**	

5. **SCHEDULE OF INDEFINITE QUANTITY WORK-TASK ORDERS YEAR 4 Ordering Period (9/21/2030 to 9/20/2031),**

Labor Category	Est. Labor Hours	Fully Burdened Hourly Rate (to be negotiated)	TOTAL ESTIMATED AMOUNT
Electrician	100	$	$
Grounds Maintenance Laborer	100	$	$
HVAC Mechanic	100	$	$
Instrument Mechanic	100	$	$
Laborer	100	$	$
Lead Craftsman III	100	$	$
Lead Craftsman II	100	$	$
Lead Craftsman I	100	$	$
Maintenance Mechanic	100	$	$
Maintenance Trades Helper	100	$	$
Material Coordinator	100	$	$
Millwright	100	$	$
Plumber/Pipefitter	100	$	$
Sheet Metal Worker	100	$	$
Tractor Operator	100	$	$
Total Estimated Hours	**1,500**		
Total Estimates		**Total Est. Amount**	

Minimum and Maximum Quantities for IDIQ portion

The contract's guaranteed minimum is the firm-fixed-price tasks for the base period (line item 2) of the contract. The contract's estimated maximum IDIQ- Task Order amount, inclusive of the five (5) year ordering period is $5,000,000.00. The estimated maximum anticipated under this contract is not intended to imply that it is an estimate of the total services that will be required. The maximum amount in no way guarantees that the volume of purchases through this IDIQ will be higher or lower than the said estimate over the term of the IDIQ.

Total Estimated Contract Price/Costs (Phase-In Period, Base Year and Four Option Periods)

A	**Total Price CLINs 1-11**	**$**
B	**Estimated Task Orders – Indefinite Quantity/Indefinite Delivery Work Base and all Ordering Periods**	**$**
	ESTIMATED GRAND TOTAL (A+B)	**$**

SECTION C- DESCRIPTION/SPECIFICATONS/STATEMENT OF WORK

C-1 Scope of Work

The Food and Drug Administration (FDA), National Center for Toxicological Research (NCTR) requires on-site facility Operations and Maintenance (O&M) support services to perform a full range of operational and maintenance support including Work Order (WO)/Indefinite Delivery Indefinite Quantity (IDIQ) work services.

The services include, but are not limited to, operations and maintenance of all campus utility systems; craft shop support services; operation and maintenance of utility plants and equipment; maintenance of all process and non-process equipment; maintenance, alteration and repair of buildings and structures; pest control and grounds maintenance; janitorial and housekeeping services; and cafeteria food service operation.

Independently and not as an agent of the Government, the Contractor shall furnish the necessary personnel, materials, services, facilities, and otherwise do all things necessary for or incident to the performance of the work set forth herein and in Attachment 1- Performance Work Statement (PWS).

In the event of a conflict between the base PWS and a Task Order PWS, the Task Order PWS shall take precedence for that specific requirement unless otherwise directed by the Contracting Officer.

Government Furnished Property and Facilities:

The Government will provide the following property and facilities under this contract. The Contractor is responsible for accountability and security of all Government-owned property and facilities for which it is entrusted. The Contractor is also responsible for maintaining all Government-owned property and facilities in a clean, serviceable condition. Except for reasonable wear and tear and property consumed in the performance of this contract, the Contractor assumes the risk of and is responsible for any loss or damage to Government property.

A. **Facilities**. The facilities listed in Appendix XII in the PWS, will be furnished for Contractor use. The operation, maintenance, and repair of these facilities are included with the PWS. Repairs necessitated by Contractor misuse or negligence will be accomplished by the Contractor at his expense. Alterations made for the benefit of the Contractor must have prior approval of the Contracting Officer and may or may not, at the discretion of the Contracting Officer, be paid for by the Government.

B. **Equipment**. Pursuant to the "Government Property" FAR Clause 52.245-1 in the Contract, the Government will furnish the items listed in Appendix VII in the PWS. The maintenance of equipment is included within the PWS.

1. In addition to the applicable Government Property clause, the Contractor shall comply with the provisions of DHHS Publication "Contractor's Guide for Control of Government Property", which is incorporated by reference, regarding both Government furnished property and direct purchase of equipment by the Contractor.

2. The warranty provisions on all equipment, component parts, and accessories shall be safeguarded during the full duration of the warranty period by complying with all manufacturers' requirements regarding maintenance manufacturer warranty obligations.

3. The equipment operating manuals and suppliers catalogs presently maintained by the incumbent Contractor will be turned over to the successor Contractor during the phase-in period. A joint inventory shall be taken of the equipment operating manuals; the Contractor shall identify to the COR those operating manuals that are missing. At the expiration of the contract, a joint inventory shall again be taken and the Contractor shall replace any lost or destroyed manuals. All files, records, manuals, and worksheets turned over to the Contractor during the contract shall remain or becomes the property of the Government and shall be returned to the government at the expiration of this contract. The Government will have the right to inspect or copy any files, records, maps, worksheets, or any other technical material during this contract.

4. The cost for repairs and replacement of Government furnished equipment due to Contractor misuse or negligence will be chargeable to the Contractor.

C. **Joint Inventory of Non-Expendable Property.** Prior to start of the performance period, the Contractor shall conduct a joint inventory with the Government and acknowledge receipt of all non-expendable property provided by the Government. The Contractor and the COR or his designee shall jointly determine the working condition of all equipment. Items of equipment not in working order and any discrepancies found beyond normal wear and tear shall be noted. The Contractor and the COR will certify to the accuracy of the joint inventory with any/all discrepancies noted. All applicable items found, that are not included in Appendix VII in the PWS will be reported to the COR and the Contractor shall provide an updated Appendix VII as equipment is added/removed throughout the performance of the contract.

(1) The Contractor and the COR or his designee shall conduct an annual joint inventory on non-expendable property. This inventory shall be documented as described in sub-paragraph C, above.

(2) A joint inventory of non-expendable property shall be conducted upon completion of this contract and shall be documented as described in sub-paragraph C, above.

D. The Contractor shall take control and manage an existing Government owned stock store of spare parts, maintenance-related supplies and materials located at JLC. This stock will service as the Contractor's initials source of supply for performance.

E. **Utilities.** The Government will furnish electricity, natural gas, fuel oil, steam, water, telephone, and sewer as necessary to ensure Contractor compliance with the PWS. Use of utilities is restricted to that which is specifically needed for contract performance.

F. **Government Vehicles.** Contractor personnel will operate a limited number of Government furnished automotive, materials handling, and miscellaneous equipment while performing work under the contract, reference Section 1.2.7 of the PWS and appendices thereto, as identified in Section D - List of Attachments to this contract. Gasoline and diesel fuel for Government owned vehicles will be provided; however, gasoline and diesel fuel for Contractor owned vehicles will NOT be provided. The Contractor shall ensure that all operators are properly qualified and licensed to the equipment assigned to them in accordance Federal regulations and requirements. Operators shall be trained to exercise due care while operating equipment and, to minimize equipment maintenance cost, shall execute appropriate pre-operation and operational checks of equipment as required by Federal standards. Corporate markings

are not permitted on Government furnished equipment. Operators are prohibited from the use of tobacco products in Government vehicles.

G. **Forms and Publications.** The Government will furnish all required Government forms and Government publications to the Contractor, as the Contractor requires them. Publications include written Center policies, FDA Staff Manual Guides, Federal regulations and Federal Register issuances.

H. **Protective Clothing - Restricted Areas.** The Government will furnish protective clothing to Contractor employees required to enter restricted areas. These items include but are not limited to: sterile clothing, shoes, head covering, gloves, respiratory protection, and personnel hoods. Protective Clothing shall be returned after exiting form restricted areas. Damage caused by Contractor misuse or negligence will be charged to the Contractor.

I. **Tools.** The Government will provide an adequate quantity of quality hand tools, small power tools, and minor instrumentation that is normally considered a "tool box" item for the individual craftsman. The Contractor shall be responsible for ensuring the individual craftsmen are equipped to accomplish their normal duties. Any tools on site at the Jefferson Laboratory Complex and under the control of the Contractor must be inventoried and must not be **REMOVED** from the premises. The Contractor must return old broken tools for replacement. Reports of lost tools shall be submitted to the COR before re-issuance of new tools.

J. **Restricted Use of Government Facilities and Property.** The Contractor is advised that Government-owned facilities, property, and utilities shall only be used in the performance of official duties required by this contract. No Government-owned facilities, property, and utilities may be used for private benefit at any time.

SECTION D- PACKAGING AND MARKING

D-1 Preparation of Delivery

All material to be delivered hereunder shall be afforded the degree of packing (preservation and packing) required to prevent deterioration and damages due to hazards of shipment, handling and storage. Best commercial practice will be accepted.

D-2 Prohibited Packaging Materials

The use of asbestos, excelsior, newspaper or shredded paper (all types including waxed paper, computer and similar hygroscopic or non-neutral material) is prohibited. In addition, loose fill polystyrene is prohibited for shipboard use.

SECTION E- INSPECTION AND ACCEPTANCE

E-1 Inspection and Acceptance

The Contracting Officer's Representative (COR), a duly authorized representative of the CO, shall monitor the Contractor's performance, evaluate the quality of services and perform the final inspection and acceptance of all deliverables. Unless otherwise requested, deliverables shall be sent to the COR specified herein.

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).

The Contractor shall be responsible for any countermeasures or corrective action, within the scope of this contract, which may be required by the CO as a result of such inspection.

E-2 - Quality Assurance

The Government will monitor the Contractor's performance under this contract. As a minimum the Government will inspect the services using the Contractor's Quality Control Plan as a guide. The Government retains the right to perform unscheduled inspections, as it deems necessary. Furthermore, the Government retains all rights provided by the FAR Clause entitled "Inspection of Services – Fixed Price" or any other inspection clause which may be specified elsewhere in the PWS or contract, and the FAR clause entitled "Default (Fixed-Price Supply and Services)."

SECTION F- DELIVERIES OR PERFORMANCE

F-1 General

The Contractor shall prepare, maintain, and submit all reports, plans, and data specified in this Section in accordance with the Performance Work Statement (PWS). All deliverables shall be submitted electronically unless otherwise directed by the Contracting Officer (CO) or Contracting Officer's Representative (COR).

Failure to submit required reports or deliverables in accordance with the schedules established in this Section may constitute defective performance and may result in remedies as provided elsewhere in the contract.

F-2 Reports and Deliverables

F-2.1 Initial / Phase-In Deliverables

The Contractor shall submit the following reports and plans during the phase-in period or prior to commencement of performance:

Deliverable	Due Date	Recipient
Quality Control Plan	Within 30 calendar days after contract award	COR
Safety and Health Plan	Prior to commencement of work	COR
Emergency Procedures Plan	Prior to commencement of work	COR
Strike Contingency Plan	Within 60 calendar days after contract award	COR
Operating Plans / Standard Operating Procedures (SOPs)	Prior to start of performance	COR
Pest Control Plan	Within 30 calendar days after contract award	COR
Grounds Maintenance Plan	Within 10 calendar days after contract effective date	COR
Stock Store Operation Plan	Prior to end of phase-in period	COR
Subcontracted Services Listing	Prior to end of phase-in period	COR / CO
Required Insurance Documentation	Prior to commencement of work	CO
Personnel Security Clearance Submissions	Prior to site access	CO / COR

F-2.2 Monthly Reports

The Contractor shall submit the following reports on a monthly basis:

Report	Due Date	Recipient
Monthly Status Report	By the 10th calendar day of the following month	COR / CO
Operations Data Report	Within 7 calendar days after end of reporting period	COR
Sewage Discharge Report (Pine Bluff Arsenal)	On or about the 25th of each month	COR & PBA

Monthly Status Report – Required Content

At a minimum, the Monthly Status Report shall consolidate and include:

- Preventive Maintenance performance and backlog status
- Generator operational data
- Fire alarm system status
- Fuel oil inventory

- Water treatment and gas/oil system status
- Safety activity and incidents
- Quality Control results
- Staffing updates
- Subcontractor activity
- Any other reporting required by the PWS

The report shall provide a concise performance summary organized by PWS performance area and shall focus on measurable results, trends, exceptions, and corrective actions. The report shall not simply consist of raw work order exports or activity logs. The first page of the Monthly Status Report shall include a one-page performance dashboard showing the key monthly metrics, including PM completion percentage, RMR completion percentage within required timeframes, number of overdue RMRs, number of open corrective actions, QC pass/fail rate, repeat deficiencies, safety incidents, and major operational issues. Each metric shall show the current month result and prior month result, when available, so the Government can identify trends and recurring performance issues.

At a minimum, the Monthly Status Report shall include:

- Preventive Maintenance performance, including the number of PMs scheduled, completed on time, completed late, missed, deferred, and overdue, and the monthly PM completion percentage.
- Routine Maintenance Request performance, including the number of RMRs received, completed, open, overdue, deferred, and cancelled.
- RMR completion-time metrics, including average completion time, median completion time, longest completion time, and percentage completed within the applicable priority or required completion timeframe.
- Aging summary for open RMRs, grouped by priority, trade/shop, and age category.
- Explanation of overdue, deferred, repeat, mission-impacting, or safety-related RMRs, including current status, reason for delay, and expected completion date.
- Quality Control results, including the number of QC inspections performed, number passed, number failed, number requiring rework, number of repeat deficiencies, corrective actions taken, and open corrective actions.
- Summary of recurring deficiencies, repeat work orders, missed performance standards, and actions taken to prevent recurrence.
- Status of major open issues affecting facility operations, safety, utility systems, research support, or mission continuity.
- Generator operational data, fire alarm system status, fuel oil inventory, water treatment and gas/oil system status, safety activity and incidents, staffing updates, subcontractor activity, and any other reporting required by the PWS, summarized by exception, performance impact, or required metric.

Detailed work-order data, including individual RMR numbers, receipt dates, completion dates, trade/shop assignment, and closeout notes, shall be maintained in the Government-furnished work management system. The Service Provider shall provide detailed work-order data as an attachment or upon request by the COR or Contracting Officer.

The Quality Control portion of the report shall identify the work sampled or inspected in enough detail to allow Government verification, but individual QC checklists or inspection records are not required in the body of the Monthly Status Report unless requested by the COR or Contracting Officer.

Stand-alone monthly operational reports are not required unless specifically directed by the COR for regulatory or third-party submission purposes.

F-2.3 Bi-Weekly Reports

Report	Due Date	Recipient
Bi-Weekly Performance Report (out-of-service equipment, system status, backlog aging, estimated return-to-service dates)	At bi-weekly performance meeting	COR
Performance Evaluation Meeting Minutes	Within 3 business days after meeting	COR / CO

F-2.4 Quarterly Reports

Report	Due Date	Recipient
Quarterly Safety and Accident Report	Within 15 calendar days after end of quarter	CO

F-2.5 Annual Reports

Report	Due Date	Recipient
Inventory of Government-Furnished Property	Annually (award anniversary ±30 days)	COR / CO
Stock Store Physical Inventory	Annually	COR
USDA-Designated Bio-Based Product Report (if applicable)	Annually	COR / CO
Cafeteria Customer Satisfaction Survey	Annually	COR

F-2.6 As-Needed Reports

The Contractor shall submit the following reports when requested or when conditions warrant:

Report	Trigger
Special Reports	As requested by COR or CO
Quality Control Records	Upon request
Equipment Addition / Deletion Documentation	Upon equipment change

Report	Trigger
Preventive Maintenance Schedule Updates	As approved by COR
Corrective Action Documentation for Defective Performance	Upon occurrence

F-2.7 Key Personnel and Certification Deliverables

F-2.7.1 Initial Submission

The Contractor shall submit a **Key Personnel and Certifications Package** to the Contracting Officer's Representative (COR) **within ten (10) calendar days after contract award**.

F-2.7.2 Statement of Compliance

The Contractor shall submit a signed statement certifying that:

- All personnel performing work under this contract meet the qualification, licensing, and certification requirements of the PWS; and
- All required licenses and certifications are current and will be maintained for the duration of contract performance.

F-2.7.3 Updates and Maintenance

The Contractor shall maintain the accuracy of the Key Personnel and Certifications Package and submit updates as follows:

- **Annual Update:**
  An updated package shall be submitted **annually**, within **thirty (30) calendar days of the contract award anniversary date**.
- **Staffing Change Update:**
  An updated submission shall be provided **within fifteen (15) calendar days of any staffing change**, including replacement, addition, or removal of key or licensed personnel, or changes to certification status.

F-2.7.4 Government Review

All submissions under this section are subject to review by the COR. Acceptance does not relieve the Contractor of responsibility for ensuring personnel remain properly qualified and certified at all times. Failure to comply with this section may constitute **defective performance**.

F-3 Review and Acceptance

All reports and deliverables submitted under this Section are subject to review and acceptance by the COR. Acceptance of any report does not relieve the Contractor of responsibility for meeting contract requirements.

F-4 Order of Precedence (Reports and Deliverables)

In the event of any inconsistency between this Section and other sections of the contract or attachments (including the PWS or appendices), **this Section F shall govern** with respect to reports, deliverables, and submission schedules.

SECTION G- CONTRACT ADMINISTRATION DATA

G-1 Government Personnel

Notwithstanding the Contractor's responsibility for total management during the performance of this contract, administration of this contract shall require maximum coordination between the Government and the Contractor. The following individuals shall be the Government's points of contact during performance of the contract:

G-2 Contracting Officer (CO)

The Contracting Officer is the only person with authority to act as agent of the Government under this contract. Only the Contracting Officer has authority to: (1) direct or negotiate any changes in the contract; (2) modify or extend the period of performance; (3) change the delivery schedule; (4) authorize reimbursement to the Contractor for any costs incurred during the performance of this contract; or (5) otherwise change any terms and conditions of this contract.

The Contracting Officer for this contract is Nick Sartain.

G-3 Contract Specialist (CS)

All communications pertaining to contractual and/or administrative matters under the contract shall be addressed to the CS at the following email address:

Name: Warren Dutter
Email: warren.dutter@fda.hhs.gov
Phone: (870) 543-7577

G-4 Contracting Officer Representative (COR)

The following COR will represent the Government for the purpose of this contract: (To be provided at contract award).

Name:
Email Address:
Phone:

(a) Performance of the work under this contract shall be subject to the technical direction of the COR identified above, or a representative designated in writing. The term "technical direction" includes, without limitation, direction to the contractor that directs or redirects the labor effort, shifts the work between work areas or locations, fills in details and otherwise services to ensure that tasks outlined in the work statement are accomplished satisfactorily.

(b) Technical direction must be within the scope of the specification(s)/work statement.

The COR does not have the authority to issue any technical direction that:

(1) Constitutes a change of assignment of additional work outside the specification(s) / PWS;

(2) Constitutes a change as defined in the contract clause entitled "Changes";

(3) In any manner causes an increase or decrease in the total contract price, or the time required for contract performance;

(4) Changes any of the terms, conditions, or specification(s)/work statement of the contract.

(5) Interferes with the contractor's right to perform under the terms and conditions of the contract; or

(6) Directs, supervises or otherwise controls the actions of the contractor's employees.

(c) Technical directions may be oral or in writing. The COR shall confirm oral direction in writing within five work days, with a copy to the CO.

(d) The Contractor shall proceed promptly with the performance resulting from the technical directions issued by the COR. If, in the opinion of the contractor, any direction of the COR, or his/her designee, falls within the limitations in (b), above, the contractor shall immediately notify the CO no later than the beginning of the next Government work day.

(e) Failure of the contractor and the CO to agree that technical direction is within the scope of the contract shall be subject to the terms of the clause entitled "Disputes."

The type of actions within the purview of the COR's authority is to assure that the Contractor performs the technical requirements of the contract, and to notify both the Contractor and the CO of any deficiencies observed. A letter of designation shall be issued to both the COR and the Contractor at the time of the contract award setting forth, in full, the responsibilities and limitations of the COR.

G-5 Contractor Personnel

HHSAR 352.237-75 Key Personnel (December 2015)

The key personnel specified in this contract are considered to be essential to work performance. At least 30 calendar days prior to diverting any of the specified individuals to other programs or contracts (or as soon as possible, if an individual must be replaced, for example, as a result of leaving the employ of the Contractor), the Contractor shall notify the CO and shall submit comprehensive justification for the diversion or replacement request (including proposed substitutions for key personnel) to permit evaluation by the Government of the impact on performance under this contract. The Contractor shall not divert or otherwise replace any key personnel without the written consent of the CO. The Government may modify the contract to add or delete key personnel at the request of the contractor or Government.

The Key Personnel positions are identified below.

Title
On-site Contract Manager
Operations Manager
Quality Control Manager
Utilities Manager
EMCS Manager
Safety Manager
Food Services Manager
Electrician Lead
Grounds Maintenance Lead
HVAC Mechanic Lead
Instrument Mechanic Lead
Lead Craftsman III
Lead Craftsman II
Lead Craftsman I
Maintenance Mechanic Lead
Material Coordinator Lead
Millwright Lead
Plumber/Pipefitter Lead
Sheet Metal Lead

For Key Personnel positions evaluated under Section M, the position descriptions and minimum qualifications proposed in the Contractor's awarded proposal and accepted by the Government are material contract requirements. The Contractor shall staff each such position with an individual who meets or exceeds the awarded minimum qualifications for that position, unless otherwise approved in writing by the Contracting Officer.
(End of clause)

Pursuant to Performance Work Statement Section 1.9 the Contractor shall provide the following.

A. The Contractor shall submit evidence to the Administrative Contracting Officer (ACO) that personnel meet the qualifications (Ref. PWS Section 1.9) for their respective tasks under this contract and have or have applied for the proper certification(s) and license(s) required by the State of Arkansas or other authorities. This information shall be provided to the ACO at the beginning of the performance period and shall be updated annually thereafter for the life of the contract. A temporary license may be substituted during the first ninety-days of performance. However, at least one operator in each utility plant must be fully licensed and responsible for oversight not later than the start of the performance period. Where 24-hour services are required, a fully licensed operator must be present, i.e., in the utility plants. The Contractor shall bear the cost of obtaining all necessary certifications and licenses (to include training and other related costs).
B. All boiler plant operators and their immediate supervisor(s) must possess a current Arkansas Boiler Operator License for high pressure steam. All water treatment plant operators and their immediate supervisor(s) must possess a current Grade B operator license as outlined in ACT 333 of the State of Arkansas code.
C. The Contractor has the ultimate responsibility and authority to hire personnel to accomplish the work called for in the PWS. The ACO, however, retains the right to determine whether the personnel hired by the Contractor possess the requisite qualification.
D. The Government is authorized to restrict employment under the contract of any Contractor employee, or prospective Contractor employee, who is identified by the Contracting Officer as a potential threat to the health, safety, security, general well-being, or operational mission of the Center or it population. The Contractor shall not employ any person who is an employee of the Government if the employment of that person would create a conflict of interest.
E. The Government shall not exercise any supervision or control over the Contractor's employees performing services under this contract. Such Contractor employees shall be accountable not to the Government, but solely to the Contractor, who in turn shall be accountable to the Government.

G-6 Reporting Matters Involving Fraud, Waste, and Abuse

Anyone who becomes aware of the existence or apparent existence of fraud, waste and abuse in FDA funded programs is encouraged to report such matters to the HHS Inspector General's Office in writing or on the Inspector General's Hotline. The toll free number is 1-800-HHS-TIPS (1-800-447-8477). All telephone calls will be handled confidentially. The email address is HHStips@oig.hhs.gov and the mailing address is:

Office of Inspector General
Department of Health and Human Services
Attn: HOTLINE
330 Independence Avenue, S.W.
Washington, D.C. 20201

Information regarding procedural matters is contained on the HHS/OIG website at: http://oig.hhs.gov/fraud/

G-7 Contractor Performance Evaluation (s)

In accordance with **Federal Acquisition Regulation (FAR RFO) 42.11**, FDA will complete annual and final contractor performance evaluations. Annual evaluations will be prepared to coincide with the anniversary date of the contract. Additional interim performance evaluations may be prepared at Contracting Officer discretion, as necessary. Final performance evaluations will be completed upon contract expiration.

FDA will utilize the Contractor Performance Assessment Reporting System (CPARS) in order to execute annual and final contractor performance evaluations. CPARS is a secure Internet website located at https://www.cpars.gov/. FDA will register the contractor in CPARS upon receipt of the name and email address of two (2) individuals who will be responsible for serving as the Contractor's primary and alternate CPARS contacts. Once FDA registers the contractor in CPARS, the Contractor will receive an automated CPARS email message which contains User IDs and instructions for creating a password.

Once a performance evaluation is issued, the Contractor's primary and alternate CPARS contact will receive an email instructing them to logon to CPARS in order to review the performance evaluation. The Contractor has 14 days from the date of performance evaluation issuance in which to review the evaluation. If the Contractor is in agreement with the performance evaluation outcome, the evaluation becomes final. Should the Contractor be in disagreement with the performance evaluation outcome, rebuttal comments must be submitted via the CPARS within 14 days from date the evaluation was issued by the FDA. Any disagreement between the Contracting Officer and the Contractor will be referred to a contracting official one level above the Contracting Officer, whose decision will be final.

Copies of each performance evaluation and contractor responses, if any, will be retained as part of the official contract file and will be used to support future award decisions. Evaluations will also be stored for a 3-year period in the Contractor Performance Assessment Reporting System (CPARS) at www.cpars.gov.

Contractors may obtain CPARS training material and register for on-line training at https://www.cpars.gov/. There is no fee for registration or use of the CPARS.

G-8 Delegation of Authority

The Administrative Contracting Officer (ACO) Warren Dutter is hereby designated by the Procuring Contracting Officer (PCO) to act as the authorized Government agent that oversees Contractor performance in accordance with the terms and conditions of the contract.

SECTION H- SPECIAL CONTRACT REQUIREMENT

H-1 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.

- 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;
- Indirect Costs (i.e., Fringe Benefits, Overhead, General and Administrative, Other Indirects)- show rate, base and total amount;
- Consultants (if applicable) - include the name, number of days or hours worked, daily or hourly rate, and a total amount per consultant;
- 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;
- Subcontractors (if applicable) - include, for each subcontractor, the same data as required for the prime Contractor;
- Other Direct Costs - include a listing of all other direct charges to the contract, i.e., office supplies, telephone, duplication, postage; and
- 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:

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

(1) invoice number, amount, & date submitted
(2) corresponding payment amount & date received

(b) total amount of all payments received to date under the subject contract or order

(c) 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 task 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.

Notice Regarding the Use of Macros in Submitted Documents

Be advised that FDA does not accept documents which contain the use of macros. ***When submitting documents via email, DO NOT include .exe, .mso, or any other executable file types that could potentially trigger email security protections (i.e. email blocks, quarantine).*** Document submissions required throughout the award period(s) shall not have macro enabled functionality and any document delivered having that functionality will be deemed delinquent, if not corrected prior to the due date.

H-2 Tobacco Free Facilities

In accordance with Department of Health and Human Services (HHS) policy, the Contractor and its staff are prohibited from using tobacco products of any kind (e.g., cigarettes, cigars, pipes, and smokeless tobacco) while on any HHS property, including use in personal or company vehicles operated by Contractor employees while on an HHS property. This policy also applies to all subcontracts awarded under the contract or order. The term ‘‘HHS properties’’ includes all properties owned, controlled and/or leased by HHS when totally occupied by HHS, including all indoor and outdoor areas of such properties. Where HHS only partially occupies such properties, it includes all HHS-occupied interior space. Where HHS leases space in a multi-occupant building or complex, the tobacco-free HHS policy will apply to the maximum area permitted by law and compliance with the provisions of any current lease agreements. The Contractor shall ensure that each of its employees and any subcontractor staff is made aware of, understand, and comply with this policy.

H-3 HHSAR 352.223-70 Safety and Health. (DEC 2015)

(a) To help ensure the protection of the life and health of all persons, and to help prevent damage to property, the Contractor shall comply with all Federal, State, and local laws and regulations applicable to the work being performed under this contract. These laws are implemented or

enforced by the Environmental Protection Agency, Occupational Safety and Health Administration (OSHA) and other regulatory/enforcement agencies at the Federal, State, and local levels.

(1) In addition, the Contractor shall comply with the following regulations when developing and implementing health and safety operating procedures and practices for both personnel and facilities involving the use or handling of hazardous materials and the conduct of research, development, or test projects:

(i) 29 CFR 1910.1030, Bloodborne pathogens; 29 CFR 1910.1450, Occupational exposure to hazardous chemicals in laboratories; and other applicable occupational health and safety standards issued by OSHA and included in 29 CFR part 1910. These regulations are available at https://www.osha.gov/.

(ii) Nuclear Regulatory Commission Standards and Regulations, pursuant to the Energy Reorganization Act of 1974 (42 U.S.C. 5801 et seq.). The Contractor may obtain copies from the U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001.

(2) The following Government guidelines are recommended for developing and implementing health and safety operating procedures and practices for both personnel and facilities:

(i) Biosafety in Microbiological and Biomedical Laboratories, CDC. This publication is available at

http://www.cdc.gov/biosafety/publications/index.htm.

(ii) Prudent Practices for Safety in Laboratories (1995), National Research Council, National Academy Press, 500 Fifth Street NW., Lockbox 285, Washington, DC 20055 (ISBN 0–309–05229–7). This publication is available at http://www.nap.edu/catalog/4911/prudentpractices-in-the-laboratory-handling-anddisposal-of-chemicals.

(b) Further, the Contractor shall take or cause to be taken additional safety measures with the Contracting Officer's Representative or other appropriate officials, determines to be reasonably necessary. If compliance with these additional safety measures results in an increase or decrease in the cost or time required for performance of any part of work under this contract, the Contracting Officer will make an equitable adjustment in accordance with the applicable ''Changes'' clause set forth in this contract.

(c) The Contractor shall maintain an accurate record of, and promptly report to the Contracting Officer, all accidents or incidents resulting in the exposure of persons to toxic substances, hazardous materials or hazardous operations; the injury or death of any person; or damage to property incidental to work performed under the contract resulting from toxic or hazardous materials and resulting in any or all violations for which the Contractor has been cited by any Federal, State or local regulatory/enforcement agency. The report citing all accidents or incidents resulting in the exposure of persons to toxic substances, hazardous materials or hazardous operations; the injury or death of any person; or damage to property incidental to work performed under the contract

resulting from toxic or hazardous materials and resulting in any or all violations for which the Contractor has been cited shall include a copy of the notice of violation and the findings of any inquiry or inspection, and an analysis addressing the impact these violations may have on the work remaining to be performed. The report shall also state the required action(s), if any, to be taken to correct any violation(s) noted by the Federal, State, or local regulatory/ enforcement agency and the time frame allowed by the agency to accomplish the necessary corrective action.

(d) If the Contractor fails or refuses to comply with the Federal, State or local regulatory/enforcement agency's directive(s) regarding any violation(s) and prescribed corrective action(s), the Contracting Officer may issue an order stopping all or part of the work until satisfactory corrective action (as approved by the Federal, State, or local regulatory/enforcement agencies) has been taken and documented to the Contracting Officer. No part of the time lost due to any such stop work order shall form the basis for a request for extension or costs or damages by the Contractor.

(e) The Contractor shall insert the substance of this clause in each subcontract involving toxic substances, hazardous materials, or hazardous operations. The Contractor is responsible for the compliance of its subcontractors with the provisions of this clause.

(End of clause)

H-4 Ordering Against IDIQ Additional Work Task Order Portion of the Contract

In addition to the Ordering Clause in Section I the following ordering information/instruction is provided. IDIQ work is defined as work that is not part of the routine work for operations and maintenance support for the Jefferson Lab Complex, but comes within the scope of the contract. Specific work will be defined as required by the JLC in accordance with the performance work statement attached to this contract.

The Contractor shall prepare and submit a task order proposal addressing all areas of the requirement. The Contractor shall submit the task order proposal within the time period specified in the Request for Task Order Proposal (RFTOP) and adhere to the ceiling rates established in the contract. Ceiling rate discounts may always be proposed. Other direct costs shall be clearly identified, explained, and substantiated. Proposals shall include: (1) a schedule of performance; (2) a staffing plan including estimated manhours by labor category per task area; (3) subcontractors solicited and quotes received. No separate payment will be made to the contractor for the cost to prepare, submit and/or negotiate a task order proposal. The Government will evaluate task order proposals as specified in the individual RFTOP on a best value basis. The government reserves the right to insert anticipated travel by utilizing Other Direct Costs (ODC).

1.Prior to starting any work, the Contractor shall submit a proposal outlining the work to be done to the ACO, including a tentative start date and indicating the number of days to complete the work. The proposal shall also identify the methods, equipment and material to be used and the number of hours and wage rate per craft, using the fully burdened rates previously negotiated under Section B, to complete the work. ACO approval is required prior to performing any additional task order work.

2.If any other direct prices (for example, materials) are involved in performance of this work, they shall be priced out separately when submitting proposals to the ACO. If work is of such urgency that it cannot be awarded and negotiated in a timely manner, the contractor shall notify the ACO immediately.

3.Additional Work Task Orders may be issued by the Government during the ordering period from the date of contract award and the period of any option periods exercised or Contract extensions. Any order issued during the effective period of this contract and not completed within that period shall be completed by the Contractor within the time period specified in the task order. Orders may be issued by mail, fax or electronic methods.

4.The effective period for delivery of orders under this contract begins on the date of contract award and ends on the date following the date of final payment under this contract.

5.The contractor shall invoice once an approved task order is accepted by the Government and shall include the work order number and task order number.

6. Authorized Ordering Activities: The following activity(ies) or individual(s) is/are designated as Ordering Officers under this contract:

   i. Any Contracting Officer of the U.S. Food and Drug Administration-Office of Acquisitions and Grants Services (OAGS); subject to the limitations contained in their respective contracting officer warrants (SF 1402, Certificate of Appointment).

   ii. Others as authorized in writing by the Contracting Officer.

7. Content of Order: Each task order placed under this contract shall include the following minimum information:

   i. The contract number, task order number, and date of order.

   ii. Description of the service to be provided.

   iii. Applicable accounting and appropriation data, and special invoicing instructions where applicable.

Additional Information can include:

iv. Item number and description, quantity and unit price.

v. Cost and hours (as negotiated), extended amounts, fee (if applicable,) total estimated amount, and reporting requirements.

vi. Delivery or performance date.

vii. Place of delivery or performance (including consignee). Packaging, packing, and shipping instructions, if any.

viii. Such other terms and conditions as may be pertinent and peculiar to the particular tasks thereby ordered.

ix. Individual orders will reflect the requirement of particular circumstances as applicable. Urgent orders will cite peculiar terms and requirements.

8. Pricing of Orders: The Contractor warrants that the prices charged under this contract shall not exceed the costs charged by the Contractor to its most favored customers for like items or services under comparable conditions.

9. All task orders issued hereunder are subject to the terms and conditions of this contract. This contract shall control in the event of conflict with any task order. Task orders may contain option clauses.

H-5 Phase-In/Phase-Out

A. Contractor Phase-In – During the Contractor twenty (20) day phase-in the Contractor shall receive work requests, prepare estimates, receive delivery orders, order material and prepare work schedules for Indefinite Quantity work where the actual performance will begin after the start date. The incumbent Contractor shall continue to plan, schedule, and perform, Indefinite Quantity type work requests received up through contract expiration. The successor Contractor, however, shall be prepared to take over and complete all work requests in progress at the beginning of the contract performance period. The successor Contractor shall also prepare estimates for the remaining portion of Indefinite Quantity work begun but not completed by the incumbent. Upon award, the Contractor shall begin phase-in execution in accordance with the approved phase-in plan.

B. Incumbent Phase-Out - The phase-in of incoming Contractor forces many occur in conjunction with a phase-out of incumbent employees. The Contractor shall not assume that incumbent employees will be able to guide, direct, or specifically orientate each incoming Contractor employee. The in-coming Contractor shall cooperate with the incumbent during the phase-in period.

H-6 Continuity of Service Implementation

The Contractor is expected to meet full performance requirements from the stated date of the contract. The Contractor shall provide sufficient experienced personnel during the phase-in period to ensure that the services specified by this contract are maintained at the required level of proficiency. FAR Clause 52.237-3 "Continuity of Services" in Section I, applies to the phase-out period of this contract.

H-7 Collective Bargaining Agreement

The Contractor shall provide the Contracting Officer with copies of any collective bargaining agreement(s), and amendments thereto, which arise during the course of this contract and that apply to Contractor employees working under this contract.

H-8 Required Insurance

The Clause 52.228-5, Insurance-Work on a Government Installation, is supplemented to require the following minimum amount of insurance:

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

B. General liability. Bodily injury liability insurance coverage written on the comprehensive form of policy of at least $500,000 per occurrence is required.

C. Automobile liability. The Contractor shall provide automobile liability insurance written on the comprehensive form of policy. The policy shall provide for bodily injury and property damage liability covering the operation of all automobiles used in connection with performing the contract. Policies covering automobiles operating in the United States, its possessions, and Puerto Rico shall provide coverage of at least $200,000 per person and $500,000 per occurrence for bodily injury and $20,000 per occurrence for property damage. The amount of liability coverage on other policies shall be commensurate with any legal requirements of the locality and sufficient to meet normal and customary claims.

H-9 General Conditions (Construction at Jefferson Labs Campus)

A. <u>General</u>

Contractors (including sub-contractors), their officials, employees, and all other persons visiting or conducting business at any Food and Drug Administration facility or construction site in connection with contract work shall conform to these requirements. The Prime Contractor shall be responsible for the enforcement of these requirements by its sub-contractors.

Before work is started, the Contractor shall furnish to the Contracting Officer and COR, the name of the principal responsible official for the contract plus at least one alternate, with their home addresses and phone numbers, who may be contracted in case of emergencies occurring outside the regular hours of work. Similar information shall be furnished concerning all sub-contractors.

B. Non-Interruption of Government Activities

Interruption or interference with conduct of Government business in other business in other building areas outside the contract area, or damage to existing equipment or property within the contract area, will not be permitted. To protect Government property and to isolate its work, the Contractor shall provide, at no additional expense to the Government, drop cloths, plastic film draping, taping, barriers, weatherproof closures and/or coverings, and temporary dust-proof enclosures and partitions, etc. Temporary dust-proof enclosures and partitions shall be provided whenever demolition or construction operation will produce dust or dirt which would be spread by tracking or air currents beyond the immediate area of work. Such enclosures shall be erected structurally sound, and shall be maintained dust proof so as to keep surrounding areas clean and free of dust. Where practical, dust-producing activities shall be kept dampened with water, so as to reduce the generation of dust.

Temporary dust-proof enclosures will always be required to separate sterile or germ-free areas from the Contractors work areas. Materials shall be conveyed inside buildings using Contractor-provided equipment, in a manner that prevents damage to floors (i.e., by hand, using rubber tired vehicles, etc.). Use of FDA equipment is prohibited. The use of equipment which produces substantial noise or vibration in buildings, such as pneumatic hammers, etc., must be coordinated in advance with the COTR.

C. Utility Shutdown

Contractors shall not cut, disconnect, switch, open, or alter position of valves, or otherwise interrupt any utility systems, piping systems, electric services, etc., without prior written approval of the COR. Shutdown of any utility service which will affect service to any areas other than those in the contract area must be requested in writing a minimum of ten (10) working days in advance, and required written confirmation/approval prior to service interruption.

D. Material Delivery, Storage Areas and Debris Removal

1. Material Delivery. Contractors shall arrange for the deliveries of supplies or materials and equipment to the work site or designated storage areas via previously approved routes.

Wherever practicable, deliveries shall be made during the regular FDA working hours (unless prior approval is obtained from the Contracting Officer through the COR) and only when the Contractors Authorized Representative is available to receive them.

2. Storage or Materials. The Government will make space available in FDA buildings or on FDA grounds for the storage of materials and equipment. The Contractor shall, as set forth in paragraph H.1 herein, be responsible for security of their property and material from theft and vandalism. Corridors and other public areas must be kept clear at all times.
3. Debris Removal. Removed materials, which are designated in the specifications or drawings as Contractor property, or debris, shall be promptly removed from the job site and the FDA facility. Storage and/or collection of debris inside or outside buildings will not be permitted. Contractors shall remove all debris and other material with their own carts, containers, and/or refuse disposal facilities. Government facilities may not be used for this purpose. All interior areas of existing buildings shall be left clean on a daily basis. When debris must be removed from buildings outside normal FDA work hours, it must be scheduled for a designated time in advance (the same as for material deliveries).

E. Safety and Accident Prevention

1. Contractors working at FDA facilities shall be responsible for compliance with all applicable safety regulations and standards issued under the provisions of the William's/Steiger Occupational Safety and Healthy Activities (OSHA) and other applicable regulations issued by state, county, or local authorities. Any deviations from the OSHA regulations will require a variance from the OSHA authorities prior to initiating the change.
2. Contractor shall safeguard the work site and perform all operations in such manner as to insure that their employees, Government personnel, and others who may gain access to the site will not be endangered.
3. Contractors shall provide illuminated barricades, flags, warning signs, and lighting at excavations, open manholes, damaged roads, or walks, and any interior danger areas, other open or broken surfaces, resulting from the Contractors operation. Similar barriers and warning devices shall be provided by the Contractor to limit access to hazardous work areas, such as pavement-breaking operations and overhead work that requires the use of cranes, ladders, or scaffolds.
4. Explosives shall not be brought on FDA property without permission from the COR and local Fire Department Officials. Contractors shall obtain a written permit for the use of explosives at least five (5) days prior to the actual date of use. For blasting operations, the Contractor shall provide personnel, flags, signs, barricades, and other appropriate means of adequate warning.
5. Where work requires entrance into a room posted as a Restricted Area, which might present danger to Contractors personnel in the form of pathogenic, radioactive, or chemical agents, the Contractor shall request instruction from the COR as to required protective measures, and shall abide by such instructions.
6. The Prime Contractor shall be responsible for the enforcement of these safety rules by its sub-contractors. Questions concerning safety shall be submitted to the COR for clarification by the Safety Office. The Safety Office has the authority at any time to enter a Contractor construction site, in conjunction with the COR, after first contracting the Construction Foreman, for the purpose of conducting a safety survey.
7. A Contractor working on FDA Property is required to promptly report any accident suffered

by its employees to the COR who will in turn notify the Safety Office.

F. Fire Prevention

1. Contractors shall instruct their employees to immediately report any fire to the COR, even if it has been extinguished.
2. Contractors are responsible for providing and maintaining fully functioning/charged fire extinguishers at work site at all times.
3. Construction trailers, sheds or temporary storage buildings shall not be moved to, or erected on, FDA Property without written approval, including inspection by the COR and Safety Officer, as to location of the structure and method of heating and lighting. They must be located within the Contractors assigned area, are generally restricted to large projects.
4. The FDA COR and Safety Officer must approve the installation of aboveground tanks for fueling the Contractors equipment. Installation of underground tanks will not be permitted.
5. Contractors shall not make connection to or use fire hydrants, standpipe risers, fire warning, or FDA fire alarm systems without prior approval of the COR. In case of actual or anticipated emergencies, the Fire Department may discontinue the use by Contractors of water from fire hydrants or standpipe risers without advance notice.
6. Surges in water pressure frequently trip sprinkler alarm valves, and electric power switching surges affect the fire alarm system. Therefore, Contractors shall not open valves to new water lines or switch large electric loads on or off without prior notice to the FDA COR.
7. The Contractor shall obtain a Hazardous Work Permit from the FDA Safety Officer for any work involving heating, soldering, brazing, gas or electric welding, flame-cutting, tar kettles, salamanders, or other flame or heat-producing devices, both inside and outside buildings. The permit shall be conspicuously posted at the work site.
8. The Contractor shall provide fire extinguishers, fire blankets and fire watch personnel as required by the Hazardous Work Permit.
9. Accumulation of combustible waste materials and rubbish is prohibited. Such trash shall be removed promptly by the Contractor. Burning of waste material and rubbish is not permitted on the FDA Property.
10. The bulk storage of combustible and flammable building materials in corridors, cross-corridor intersections, stairwells, lobbies, and mechanical rooms is prohibited.
11. The nightly storage of oil painting materials and supplies in corridors, cross-corridor intersections, stairwells, lobbies, and mechanical rooms is prohibited. Such materials shall be kept in locked and ventilated rooms or removed from the building each night.
12. The use of equipment fueled by petroleum products (propane, gasoline, fuel oil, etc.) is prohibited unless approved by the FDA Safety Officer. If approved, storage of flammable liquids in a building will be limited to the fuel tank capacity of such equipment.

G. Security

1. Contractors shall be responsible for security of their property and material from theft and vandalism.
2. The Government does not accept responsibility for loss or damage to any property or work it has not accepted.
3. Contractors shall be responsible for excluding all but authorized persons from their work site.

4. Contractors and their employees shall immediately report any known violation of law or regulations, or the discovery of unaccountable property, either private or Government-owned, to the COR.
5. Conduct on Federal Property. Contractors are advised that operating a motor vehicle when entering upon or while on FDA property by a person under the influence of alcoholic beverages, narcotic drugs, including hallucinogens, marijuana, barbiturates, or amphetamines, is prohibited. Entering upon the property, or while on the property, under the influence of, or using, or possessing any narcotic drug is prohibited. Such prohibition shall not apply in cases where the drug has been prescribed by a physician. Entering upon the property or being on the property, under the influence of alcoholic beverages is prohibited.

H. Motor Vehicles and Parking Regulations

1. All persons driving motor vehicles on FDA property in connection with Contractor business, shall abide by the rules and regulations of this clause; those of FMR 102-74.430, Vehicular and Pedestrian Traffic; Conduct of Person and Traffic on Certain Federal Enclaves; and executive order 13513, Federal Leadership on Reducing Text Messaging While Driving, as a condition of being permitted to enter the property and as part of the contract. Only Contractor vehicles for the use of Contractor business shall be allowed to enter the NCTR campus gates and shall remain parked at the job site, i.e., not be used to drive back and forth to the cafeteria.
2. Employees of Contractors shall park only in areas designated by the Building Manager.
3. Contractors and sub-contractors shall use only truck routes designated by the COR for deliveries of material and other contract operations. Designation of truck routes shall be requested and approved before the start of construction. Contractors shall be responsible for notifying all suppliers to make deliveries via the designated routes.
4. Vehicles operated over station roads in connection with contract work shall be loaded so as to minimize spillage of dirt, gravel, and other debris. The Contractor shall remove inadvertent spillage of nails, construction materials, scrap, etc., immediately. Dirt and gravel spillages or accumulations shall be removed as soon as practicable and as satisfactory to the COR, but in every case it shall be removed no later than the end of each workday.
5. The driver of any vehicle involved in an accident on the FDA Property shall stop and render aid as required. The accident shall be reported as soon as possible in person or by telephone to the COR. Drivers of the vehicles involved shall remain until released, and shall furnish such reports of the accident as required.
6. When closing of roads or lots is necessary for a Contractor to perform work, notify the COR at least five (5) working days in advance. Once approval is granted, Contractors shall provide their own barricades and cones and block off the area.

I. Grounds, Roads, and Walkways

1. Contractors shall perform their work in such a manner as to cause minimum damage to roads, walkways, and plantings, including lawns, shrubs, and trees. Any damaged items not specifically designated in the contract specifications for demolition, removal or alteration shall be restored to original condition or replaced, as satisfactory to the Contracting Officer. Ground areas disturbed during construction shall be landscaped and planted to original

condition as promptly as possible. During the progress of the contract the Contractor shall, within the construction area, protect and maintain all plant material including lawns and temporary ground cover by mowing, spraying, watering, etc., sufficient to provide a level of maintenance conforming to that of other areas of the Property, and at no time shall weeds or undesirable grasses be allowed to seed.

2. Contractors shall not create obstruction to the flow of traffic, including temporary reduction in horizontal or vertical clearances, except in accordance with schedules and by such means satisfactory to the Building Manager.

J. Sanitation

1. Contractors shall maintain their working areas free from food debris and wrappers. Contractors shall provide covered trash containers in the number and type approved by the COR, and shall be responsible for the sanitary collection and prompt removal of trash in these containers from the FDA property.
2. The COR must approve temporary toilets used by the Contractor as to number, location, and construction. The Contractor must arrange to secure this approval.

K. Project Record Drawings

1. The Contractor shall set aside at the site one set of contract drawings to be used as Project Record Drawings (As-Builts). As-Builts shall be kept current.
2. The Contractor shall record on the Project Record Drawings all changes to show accurate as-built conditions.
3. The Contractor shall use colored pencils for notes, sketches, cross references to drawing details, etc. Pasted-on data, sketches, etc., will be accepted provided they do not cover any of the drawing data, manufacturers' name, model numbers, size, rating, etc. of equipment.
4. The COR must review and concur with all data placed on the drawings. The completed Project Record Drawings shall be given to the Contracting Officer at the conclusion of the job.

H-10 Statutory and Actual Damages

Mandatory deductions addressed in subparagraph "a" below, relate to the value of services not received for work either not performed or defectively performed. The Contractor shall additionally be liable for damages incurred by the Government as a result of the Contractor's none or defective performance. This liability may arise as a result of total or partial default or when specific contract requirements are not performed or unsatisfactorily performed.

a. Statutory Damages. When the Contractor fails to or defectively performs any requirement of this contract, whether referred to or not in the Performance Requirement Summary. When the Contracting Officer determines that such failure is the proximate cause of the JLC being in noncompliance with any Federal, State or local statute or regulation and when the JLC is assessed any fine or penalty as a result of such noncompliance, the Contractor shall be liable to the Government for the amount of any fine or penalty so assessed. Any amount determined as the Contractor's liability shall be deducted from the amounts due the Contractor.

b. Actual Damages. When the Contractor's failure to perform causes the full or partial failure of any on-going experiment or research project, the Contractor shall be liable to the Government for all cost associated with the failure. As used in this paragraph, "failure" means that progress is hindered to the extent that additional personnel or material resources must be expended to bring the program back up to the level it was prior to the incident that caused the disruption.

c. Assessment of Damages. Cost assessed will be based on the cost of fines and/or penalties assessed to the Government, and the loss of material and personnel due to the Contractor-induced errors. Proposed assessments against the Contractor will be fully documented by the Government and forwarded to the Contractor for explanation of any extenuating factors which may apply. The Contracting Officer will review the Contractor's reply and make a final determination regarding liability.

H-11 Lost and Found Property

When any item is found that appears to have been lost and/or abandoned the Contractor shall secure the item and report the finding to the COR.

A. Any item of personal (individual) property or currency either lost or found shall be reported to the COR.
B. Any lost or abandoned property, by an employee, on a Federal installation is considered to belong to the Government. However, upon request by the owner, lost or abandoned property will be returned when adequate proof is presented.
C. The Government is not responsible for lost or stolen property, including currency.

H-12 Government Rights to Data

The Government will acquire the right to use, duplicate, or disclose in any manner and for any purpose, and have or permit others to do so, all data required to be delivered under any contract resulting from this solicitation.

H-13 Applicable Wage Rate Decision

The Secretary of Labor has made a determination of the minimum prevailing wage rates which are to be paid to classes of labor to be employed on this project. The decision number and date with minimum rates for this project are shown as Attachments J-5 and J-6 in Section J.

H-14 Organizational Conflict of Interest

(a) *Purpose.* The purpose of this clause is to ensure that the contractor and its subcontractors:

(1) Are not biased because of their financial, contractual, organizational, or other interests which relate to the work under this contract, and

(2) Do not obtain any unfair competitive advantage over other parties by virtue of their performance of this contract.

(b) *Scope.* This clause applies to performance or participation by the contractor, its parents, affiliates, divisions and subsidiaries, and successors in interest (hereinafter collectively referred to as "contractor") in the performance of this contract as a prime contractor, subcontractor, co-sponsor, joint venturer, consultant, or in any similar capacity.

(c) *Warrant and Disclosure.* The warrant and disclosure requirements apply to both the contractor and all subcontractors. The contractor warrants that, to the best of the contractor's knowledge and belief, there are no relevant facts or circumstances which would give rise to an organizational conflict of interest, as defined in FAR Subpart 9.5, and that the contractor has disclosed all relevant information regarding any actual or potential conflict. The contractor agrees it shall make an immediate and full disclosure, in writing, to the Contracting Officer of any potential or actual organizational conflict of interest or the existence of any facts that may cause a reasonably prudent person to question the contractor's impartiality because of the appearance or existence of bias or an unfair competitive advantage. Such disclosure shall include a description of the actions the contractor has taken or proposes to take in order to avoid, neutralize, or mitigate any resulting conflict of interest.

(d) *Remedies.* The Contracting Officer may terminate this contract for convenience, in whole or in part, if the Contracting Officer deems such termination necessary to avoid, neutralize or mitigate an actual or apparent organizational conflict of interest. If the contractor fails to disclose facts pertaining to the existence of a potential or actual organizational conflict of interest or misrepresents relevant information to the Contracting Officer, the Government may terminate the contract for default, suspend or debar the contractor from Government contracting, or pursue such other remedies as may be permitted by law or this contract.

(e) *Subcontracts.* The contractor shall include a clause substantially similar to this clause, including paragraphs (f) and (g), in any subcontract or consultant agreement.

(f) *Prime Contractor Responsibilities.*– The contractor shall determine in writing whether the interests disclosed present an actual, or significant potential for, an organizational conflict of interest. The contractor shall identify and avoid, neutralize, or mitigate any subcontractor organizational conflict prior to award of the contract to the satisfaction of the Contracting Officer. If the subcontractor's organizational conflict cannot be avoided, neutralized, or mitigated, the contractor must obtain the written approval of the Contracting Officer prior to entering into the subcontract. If the contractor becomes aware of a subcontractor's potential or actual organizational conflict of interest after contract award, the contractor agrees that the Contractor may be required to eliminate the subcontractor from its team, at the contractor's own risk. The contractor shall obtain from its subcontractors or consultants the disclosure required in FAR Part 9.507

(g) Waiver. The contractor may seek a waiver from the Head of the Contracting Activity by submitting such waiver request to the Contracting Officer, including a full written description of the requested waiver and the reasons in support thereof.

(h) All contractor personnel involved in this requirement shall abide by the FDA Commitment to Protect Non-Public Information Agreement (See Section J Attachment J-7).

H-15 Procurements Requiring Information Security and/or Physical Access Security

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.

        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:

(i) Confidentiality: ☒Low ☐Moderate ☐High

(ii) Integrity: ☒Low ☐Moderate ☐High

(iii) Availability: ☒Low ☐Moderate ☐High

(iv) Overall Impact Level: ☒Low ☐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 tailor 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 ☒ 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.

1. 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).
2. 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:

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

18 U.S.C. 1905 (Criminal Code: Disclosure of Confidential Information); and

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.

b. 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)."

c. 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

   a. 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:

☐ Does not apply

☒ Tier 1 Low Risk, Non-Sensitive, including HSPD-12 Credentialing

☐ Tier 2 Moderate Risk Public Trust (MRPT)

☐ Tier 3 Non-Critical Sensitive, National Security, including SECRET & "L" access eligibility

☐ Tier 4 High Risk Public Trust (HRPT)

☐ Tier 5 Critical Sensitive and Special Sensitive National Security, including Top Secret, SCI, and "Q" access eligibility

6. Homeland Security Presidential Directive (HSPD)-12

    a. 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

    a. 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.
        i. 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.as px 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.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.

b. 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 Overlay25 in addition to the above requirements.

H-16 Personnel Security Clearance Requirements

1) BACKGROUND - The Office of the Assistant Secretary for Management and Budget, Department of Health and Human Services (DHHS), requires that Contractor employees (including subcontractors) who will be working in DHHS-owned or leased space and/or who will have access to DHHS equipment, and non-public privileged, proprietary, or trade secret information, must undergo a background investigation that results in a favorable determination.

   Contractor employees who will work in DHHS-owned or leased space for less than thirty (30) days are considered visitors and are exempted from background investigation requirements; and therefore, will not be issued a Personal Identity Verification (PIV) Card. These contractor employees go through visitor screening each day and must be escorted at all time while in DHHS- owned or leased space.

2) GENERAL - The Contractor must submit the following items to the Contracting Officer's Representative (COR), within five (5) business days of commencement of work under this contract:

   - A roster of contractor employee names, identifying Key Personnel and Tier designation(s);
   - Confirmation all individual employee security information has been submitted properly; and
   - "Contractor's Commitment to Protect Non-public Information Agreement" forms signed by each employee named in the roster.

   Pursuant to HSPD-12, the Contractor must advise its prospective employees about the security and background requirements stated herein.

   For any individual who does not obtain a favorable background investigation he/she must cease work on the contract immediately.

   If a Contractor employee changes job responsibilities under this contract, the Contractor must notify the COR, and the Government will make a determination whether an additional security clearance is required.

   In the event there are any proposed personnel changes in the Contractor's staffing roster previously submitted to the COR, the Contractor must submit an updated roster to the COR, along with a brief explanation for the change. In turn, the COR will initiate the procedures stated herein to ensure any new contractor employees obtain a PIV card in a timely manner – prior to that individual commencing work under the contract.

Note: If the proposed personnel change is for a position designated Key Personnel under the contract, a complete justification – along with a resume or curriculum vitae – must be submitted to the Contracting Officer and COR for review and approval. If approved, the Contracting Officer will execute a Contract Modification prior to that individual commencing work under the contract.

3) BACKGROUND INVESTIGATIONS - With the exception of costs associated with fingerprinting Contractor employees outside of the FDA Personnel Security Office, the Government will conduct all required background investigations at no cost to the Contractor. The cost of fingerprinting Contractor employees at any location other than the FDA Personnel Security Office will be borne by the Contractor. Employees who hold or have previously held a Government security clearance must advise the FDA Personnel Security Staff of the details of such clearance.

   Note: Background investigations will be conducted by the Office of Personnel Management (OPM)

4) CONTRACT RISK DESIGNATION(S) - Contractor employees who will be in DHHS-owned or leased space for thirty (30) days or more must be able to obtain and shall obtain a PIV card pursuant to Homeland Security Presidential Directive-12 (HSPD-12) in order to access to DHHS-owned or leased property without an escort. (See Section 6 for details on the PIV Card process) However, in the event that work must commence before a security screening can be completed, contractor employees will be considered visitors, as described above, and allowed onto DHHS-owned or leased property, but must be escorted at all times.

   All Contractor employees who undergo a background investigation are required to log onto the Office of Personnel Management's (OPM's) Electronic Questionnaire for Investigation Processing system (e-Qip) system. The FDA Personnel Security Specialist will provide access to the e-Qip as well as guidance as to which forms will be required. The forms required vary with the position risk designations for the contract.

   All standard forms submitted to the FDA will be forwarded to the Office of Personnel Management (OPM) to initiate background investigations. The assigned FDA Personnel Security Specialist will resolve with the contractor employee any issues arising out of inaccurate or incomplete forms.

The Risk Designation(s) for this contract is/are: <u>Tier 1</u>

There are three (3) potential position risk designations, which are:

- Non-Sensitive Low Risk (Tier 1) - Positions which involve the lowest degree of adverse impact on the efficiency of the Agency. The forms set forth by the FDA Personnel Security Specialist are required for Non-Sensitive Low Risk Positions.
- Sensitive Moderate Risk (Tier 2) or Sensitive High Risk (Tier 4) - Public Trust Positions - Positions in which the incumbent's actions or inaction could diminish public confidence in the integrity, efficiency, or effectiveness of assigned Government activities, whether or not actual damage occurs.

In order to access the e-QIP system, Contractor employees must provide the appropriate FDA Personnel Security Specialist with the following information: (a) full name; (b)

position title; (c) social security number; (d) date of birth; (e) place of birth; (f) email address; and (g) phone number. This information will be provided on the e-Qip form that will be electronically sent to the employee. The FDA Personnel Security Specialist will use this information to enter each Contractor employee into the e-QIP system. Once this is done, each Contractor employee will receive an email that contains a web link to access the e-QIP system, as well as instructions and additional forms needed to initiate the background investigation.

A Contractor's failure to comply with the e-QIP processing guidelines will result in that Contractor's employees being denied access to FDA property until all security processing has been completed. Furthermore, any such noncompliance may detrimentally impact Contractor performance, Contractor performance evaluations, rights and remedies available at law and equity retained by the Government.

5) PERSONAL IDENTITY VERIFICATION (PIV) CARDS - All PIV Cards (and any other type of Government-issued Access Card) shall remain the property of the Federal Government. At any time, if a Contractor employee is terminated or otherwise ceases work under the contract, or no longer requires a PIV Card for contract performance purposes, the Contractor must collect the individual's PIV card and immediately notify FDA Personnel Security Staff in writing, with copies to the respective COR and Contracting Officer. The Contractor must immediately return the PIV Card(s) to the COR.

   Because PIV Cards, like other Government-issued Access Cards are Government property, Contractors and Contractor Employees are hereby placed on notice that any abuse, destruction, defacement, unauthorized transfer or withholding (i.e., failure to return to the Government) may be punishable to the greatest extent at law.

   Unauthorized possession of a PIV Card, or any other type of Government-issued Access Card, and/or willfully allowing any other person to have or to use your Access Card, is prohibited and can be criminally prosecuted under 18 U.S.C. §§ 499 and 70I, which prohibit photographing or otherwise reproducing or possessing HHS identification cards in an unauthorized manner, under penalty of fine, imprisonment, or both. Wrongdoers may also be held financially responsible for any/all civil and equitable remedies – to include, but not limited to, damages for any pecuniary loss suffered by the Government as a result of any of the above-listed actions or failure to act.

6) PIV CARD PROCESS - The COR will sponsor Contractor employees on the Form HHS 745 and HHS Smart Card Management System (SCMS) for the purpose of obtaining an FDA PIV Card. In order to obtain a PIV card, a Contractor employee must receive a favorable FBI fingerprint return and complete required security forms. The FDA Personnel Security Specialist will provide the Contractor employee(s) direction for scheduling fingerprinting appointments at the FDA location or other approved location.

   During a fingerprint appointment, each contractor employee must present two (2) forms of identification in order to receive his or her PIV Card. One form of identification must be a government-issued photo identification document. Acceptable forms of identification are listed in Appendix A, provided below. An individual who receives an unfavorable report

may appeal that finding by submitting a written request to the FDA Personnel Security Specialist.

Required background investigations may include, but are not limited to:

- Review of prior Government/military personnel records;
- Review of FBI records and fingerprint files;
- Searches of credit bureaus;
- Personal interviews; and
- Written inquiries covering the subject's background.

7) RESIDENCY REQUIREMENTS FOR FOREIGN NATIONALS - Under the requirements for Homeland Security Presidential Directive-12 (HSPD-12), OPM can complete a background investigation only for persons who have resided in the U.S. for a total of at least three (3) of the past five (5). The residency requirements apply only to foreign nationals. If any prospective foreign national contractor/subcontractor employee does not meet the residency requirements, he/she cannot qualify for a PIV Card under HSPD-12.

8) NON-PUBLIC DATA PROTECTION - The Contractor must protect the privacy of all information reported by or about Contractor employees and protect against unauthorized disclosure.

***Upon a favorable fingerprint return, the Contractor will be notified to return to the Office of Regulatory Compliance and Risk Management Office for their building pass.**

*Food and Drug Administration

Office of Regulatory Compliance and Risk Management Office

8:00 a.m. – 11:00 a.m. and 1:00 p.m. – 3:00 p.m., Central Time

3900 NCTR Road

Bldg. 50, Room 304

Jefferson, AR 72079

Please note that to receive the badge the applicant will need to provide two current forms of identity source documents in original form, one form must be a current photo. Also, if the two identity source documents bear different names, evidence of a formal name change SHALL be provided.

The identity source documents **SHALL NOT be expired or cancelled.** At least one identity source document SHALL meet the requirements of Strong evidence as specified in **[SP 800-63A]** and be one of the following forms of identification:	The second piece of evidence **MAY** be from the list above, but it **SHALL NOT** be of the same type as the primary identity source document. The second identity source document **MAY** also be one of the following:

• U.S. Passport or a U.S. Passport Card • Driver's license or ID card that **is compliant with [REAL-ID] requirements.** • Permanent Resident Card or Alien Registration Receipt Card (Form I-551) • Foreign passport • Employment Authorization Document that contains a photograph (Form I-766) • U.S. Military ID card • U.S. Military dependent's ID card • PIV Card **RLA Only** • In the case of a nonimmigrant alien authorized to work for a specific employer incident to status, a foreign passport with Form I-94 or Form I-94A bearing the same name as the passport and containing an endorsement has not yet expired and the proposed employment is not in conflict with any restrictions or limitations identified on the form. • Passport from the Federal States of Micronesia (FSM) or the Republic of the Marshall Islands (RMI) with Form I-94 or Form I-94A indicating nonimmigrant admission under the Compact of Free Association Between the US and the FSM or RMI.	• ID card issued by a federal, state, or local government agency or entity, provided that it contains a photograph. • Voter's registration card • U.S. Coast Guard Merchant Mariner Card • Certificate of U.S. Citizenship (Form N-560 or N-561) • Certificate of Naturalization (Form N-550 or N-570) • U.S. Citizen ID Card (Form I-197) • Identification Card for Use of Resident Citizen in the United States (Form I-179) • Certification of Birth Abroad or Certification of Report of Birth issued by the Department of State (Form FS-545 or Form DS-1350) • Reentry Permit (Form I-327) • Employment authorization document issued by the Department of Homeland Security (DHS) • Driver's license issued by a Canadian government entity. • Native American tribal document • U.S. Social Security Card issued by the Social Security Administration • Original or certified copy of a birth certificate issued by a state, county, municipal authority, possession, or outlying possession of the United States bearing an official seal. • Another piece of evidence that meets the requirements of Fair evidence specified in **NIST [SP 800-63A].**

Performance of work may require the contractor to have access to and use of data and information that may be considered proprietary to regulated industry, a government agency or Government contractor, or that may otherwise be of such nature that its dissemination or use would be adverse to the interest of FDA or others. The contractor agrees that contractor personnel shall not divulge or release data or information discussed in connection with the performance of the resulting contract, unless made public by FDA.

Due to the possible sensitive nature of the information discussed, contractor personnel shall be required to sign a Commitment to Protect Non-Public Information form 3398.

Contractor Conformance with Applicable Laws, Regulations, Policies and Standards - The contractor shall be responsible for knowledge of and compliance with all applicable federal information.

H-17 Non-Personal Services and Inherently Governmental Functions

Pursuant to FAR 37.1, no personal services shall be performed under this contract. Work requirements shall flow only from the Contracting Officer or the COR to the Contractor's Project Manager. No Contractor employee will be directly supervised by the Government. All employee assignments, and daily work direction, shall be given by the applicable Contractor supervisor. If the Contractor believes any Government action or communication has been given that would create a personal services relationship between the Government and any Contractor employee, the Contractor shall promptly notify the Contracting Officer of this communication or action.

Pursuant to FAR 7.5, the Contractor shall not perform any inherently governmental actions under this contract. No Contractor employee shall hold him or herself out to be a Government employee, agent, or representative. No Contractor employee shall state orally or in writing at any time that he or she is acting on behalf of the Government. In all communications in connection with this contract, Contractor employees shall identify themselves as Contractor employees and specify the name of the company for which they work. In all communications with other Government Contractors in connection with this contract, the Contractor employee shall state that they have no authority to in any way change this contract and that if the other Contractor believes this communication to be a direction to change their contract, they shall notify the Contracting Officer for that contract and not carry out the direction until a clarification has been issued by the Contracting Officer.

The Contractor shall insure that all of its employees working on this contract are informed of the substance of this article. Nothing in this article shall limit the Government’s rights in any way under the other provisions of this contract, including those related to the Government’s right to inspect and accept the services to be performed under this contract. The substance of this article shall be included in all subcontracts at any tier.

H-18 Environmental Requirements

In the performance of services under this contract, the contractor shall design supply specifications, when available at a reasonable price, which meet Recommended Recovered Materials Content Levels as identified in the EPA Comprehensive Procurement Guideline, are comprised of the minimum biobased content requirements under the USDA Biopreferred program, or are certified by ENERGY STAR or designated by FEMP as energy efficient products.

PART II CONTRACT CLAUSES

SECTION I- CONTRACT CLAUSES

I-1 52.252-2 Clauses Incorporated by Reference. (FEB 1998)

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

https://www.acquisition.gov/far-overhaul and https://www.hhs.gov/grants/contracts/contract-policies-regulations/hhsar/index.html

FAR NUMBER	TITLE	
52.203-6 Alt I	Restrictions on Subcontractor Sales to the Government, Alternate I	Jun 2020 Alt 1 NOV 2021
52.203-13	Contractor Code of Business Ethics and Conduct	NOV 2021
52.203-17	Contractor Employee Whistleblower Rights	NOV 2023
52.203-19	Prohibition on Requiring Certain Internal Confidentiality Agreements or Statements	JAN 2017
52.204-9	Personal Identity Verification of Contractor Personnel	JAN 2011
52.204-13	System for Award Management Maintenance	(Deviation) RFO AUG 2025
52.204-15	Service Contract Reporting Requirements for Indefinite-Delivery Contracts. (Deviation)	(Deviation) RFO NOV 2025
52.208-9	Contractor Use of Mandatory Sources of Supply or Services	(Deviation) RFO AUG 2025
52.209-6	Protecting the Government's Interest When Subcontracting With Contractors Debarred, Suspended, Proposed for Debarment, or Voluntarily Excluded	(DEVIATION) RFO NOV 2025
52.209-9	Updates of Publicly Available Information Regarding Responsibility Matters	(DEVIATION) RFO NOV 2025
52.209-10	Prohibition on Contracting with Inverted Domestic Corporations	(Deviation) RFO NOV 2025
52.212-4	Contract Terms and Conditions-Commercial Items	(Deviation) RFO NOV 2025
52.216-18	Ordering (Applies to IDIQ Task Orders) (a) " … from effective date of award through the effective period of performance of the contract."	AUG 2020
52.216-19	Order Limitations (a) "…$2,500.00 per Task Order, …" (b) (1) "… in excess of $900,000.00;" (b) (2) "… in excess of $900,000.00;" (b) (3) "… within five (5) calendar days…" (d) "… within seven (7) calendar days…"	OCT 1995

52.216-22	Indefinite Quantity (d) "… contract after the date of final payment under this contract."	(Deviation) RFO AUG 2025
52.217-7	Option for Increased Quantity-Separately Priced Line Item	MAR 1989
	*This clause is applicable to Task Orders	
52.217-8	Option to Extend Services	NOV 1999
	"… The Contracting Officer may exercise the option by written notice to the Contractor any time before the contract expires."	
	*This clause is applicable to the master IDIQ contract and Task Orders	
52.217-9	Option to Extend the Term of the Contract (a) The Government may extend the term of this contract by written notice to the Contractor any time before the contract expires; provided that the Government gives the Contractor a preliminary written notice of its intent to extend any time before the contract expires. The preliminary notice does not commit the Government to an extension. (b) If the Government exercises this option, the extended contract shall be considered to include this option clause. (c) The total duration of this contract, including the exercise of any options under this clause, shall not exceed five (5) years. *This clause is applicable to the fixed price portion of the IDIQ contract and may be used in Task Orders	MAR 2000
52.219-6	Notice of Total Small Business Set-Aside	(Deviation) RFO NOV 2025
52.219-8	Utilization of Small Business Concerns	(Deviation) RFO NOV 2025
52.219-14	Limitations on Subcontracting	(Deviation) RFO AUG 2025
52.222-3	Convict Labor	June 2003
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
52.222-41	Service Contract Labor Standards	AUG 2018
52.222-42	Statement of Equivalent Rates for Federal Hires	MAY 2014
	This Statement is for Information Only: It is not a Wage Determination Employee Class Rate	

	Secretary I $16.54 Electrician $33.70 HVAC Mechanic $24.28 Electronic Technician $26.08 Sheet metal Worker $26.85 Millwright Worker $28.72 Carpenter, Maintenance $23.93 Plumber/Pipefitter $24.91 Stationary Engineer/Boiler $28.22 Stationary Engineer/Water Plant $28.22 Supply Technician $23.12 Material Coordinator $29.58 Laborer $16.85 Electronics Mechanic $26.08 Janitor $13.99 Grounds Laborer $14.96 Grounds Tractor Operator $18.03 Elevator Repairer $54.67	
52.222-43	Fair Labor Standards Act and Service Contract Labor Standards—Price Adjustment	Aug 2018
52.223-2	Affirmative Procurement of Biobased Products Under Service and Construction Contracts	(Deviation) NOV 2025
52.223-3	Hazardous Material Identification and Material Safety Data.	(Deviation) NOV 2025
52.223-5	Pollution Prevention and Right-to-Know Information	May 2024
52.224-3	Privacy Training	JAN 2017
52.227-1	Authorization and Consent	JUN 2020
52.227-2	Notice and Assistance Regarding Patent and Copyright Infringement	JUN 2020
52.228-5	Insurance - Work on a Government Installation	JAN 1997
52.232-9	Limitation on Withholding of Payments	APR 1984
52.232-11	Extras	APR 1984
52.232-18	Availability of Funds	APR 1984
52.232-33	Payment by Electronic Funds Transfer—System for Award Management	Oct 2018
52.237-2	Protection of Government Buildings, Equipment, and Vegetation	APR 1984
52.237-3	Continuity of Services	JAN 1991
52.242-13	Bankruptcy	JUL 1995
52.242-15	Stop-Work Order	AUG 1989
52.242-17	Government Delay of Work	APR 1984
52.245-1	Government Property	SEP 2021
52.245-2	Government Property Installation Operation Services	APR 2012
52.245-9	Use and Charges	APR 2012

HHSAR
Clause No. Title and Date

352.203-70 Anti-Lobbying (Dec 2015)

352.204-71 Information and Information Systems Security (Deviation) (FEB 2024)
352.204-72 Records Management (Deviation) (FEB 2024)
352.204-73 Contractor Personnel Security and Agency Access (Deviation) (FEB 2024)
352.208-70 Printing and Duplication (RFO Deviation) (FEB 2026)
352.223-70 Safety and Health (DEC 2015)
352.232-71 Electronic submission of payment requests (RFO Deviation) (APR 2026)
352.237-75 Key Personnel (DEC 2015)
352.239-79 Information and Communication Technology Accessibility (Deviation) (FEB 2024)

PART III LIST OF DOCUMENTS, EXHIBITS, AND OTHER ATTACHMENTS

SECTION J- LIST OF ATTACHMENTS

Attachment J-1: Performance Work Statement; Appendix I, IV, V, VI, VIII, IX, X, XI, XII, XIII, XIV, XV and XVI
Attachment J-2: Appendix II and III; Descriptions of Existing Facilities and Utilities
Attachment J-3: Appendix VII Equipment List
Attachment J-4: Collective Bargaining Agreement, dated 11/21/2024
Attachment J-5: Service Contract Act Wage Determination No. 2015-5121 Rev. 29 Dated 5/13/2026. Applies to subcontractors not covered by the CBA.
Attachment J-6: Service Contract Act Wage Determination No. 1967-0495 Rev. 77 dated 05/13/2026. Applies to subcontractors for elevator repair services.
Attachment J-7: Commitment to Protect Non-public Information Employee Agreement, Form 3398
Attachment J-8: Past Performance Questionnaire
Attachment J-9: Sample Client Letter (will not be physically included in resultant contract)

PART IV REPRESENTATION AND INSTRUCTIONS

SECTION K REPRESENTATIONS, CERTIFICATIONS AND OTHER STATEMENTS OF OFFERORS OR RESPONDENTS

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

This solicitation incorporates one or more solicitation provisions by reference, with the same force and effect as if they were given in full text. Upon request, the Contracting Officer will make their full text available. The offeror is cautioned that the listed provisions may include blocks that must be completed by the offeror and submitted with its quotation or offer. In lieu of submitting the full text of those provisions, the offeror may identify the provision by paragraph identifier and provide the appropriate information with its quotation or offer. Also, the full text of a solicitation provision may be accessed electronically at this/these address(es): https://www.acquisition.gov/far-overhaul and https://www.hhs.gov/grants/contracts/contract-policies-regulations/hhsar/index.html

Provisions

FAR Number	Title	Date
52.203-11	Certification and Disclosure Regarding Payments to Influence Certain Federal Transactions	(Sep 2007)
52.203-18	Prohibition on Contracting with Entities that Require Certain Internal Confidentiality Agreements or Statements-Representation	(Jan 2017)
52.204-7	System for Award Management —Registration	(Deviation) (RFO Aug 2025)
52.209-2	Prohibition On Contracting With Inverted Domestic Corporations--Representation	(Deviation) (RFO NOV 2025)
52.209-7	Information Regarding Responsibility Matters	(Deviation) (RFO Nov 2025)
52.209-12	Certification Regarding Tax Matters	(OCT 2025)
52.219-1	Small Business Program Representations	(Deviation) (RFO Nov 2025)
	"(b)(1)…(NAICS) code for this acquisition is 561210 - Facilities support service.	
	(2) The small business size standard is $47Million."	
52.222-18	Certification Regarding Knowledge of Child Labor for Listed End Products	(DEVIATION) (RFO SEP 2025)
52.223-1	Biobased Product Certification	(Deviation) (RFO Nov 2025)
52.223-4	Recovered Material Certification	(MAY 2008)
52.225-2	Buy American Certificate	(OCT 2022)
52.240-90	Security Prohibitions and Exclusions Representations and Certifications	(Deviation) (RFO Nov 2025)

SECTION L- INSTRUCTIONS, CONDITIONS AND NOTICES TO OFFERORS OR RESPONDENTS

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

This solicitation incorporates one or more solicitation provisions by reference, with the same force and effect as if they were given in full text. Upon request, the Contracting Officer will make their full text available. The offeror is cautioned that the listed provisions may include blocks that must be completed by the offeror and submitted with its quotation or offer. In lieu of submitting the full text of those provisions, the offeror may identify the provision by paragraph identifier and provide the appropriate information with its quotation or offer. Also, the full text of a solicitation provision may be accessed electronically at this/these address(es): https://www.acquisition.gov/far-overhaul and https://www.hhs.gov/grants/contracts/contract-policies-regulations/hhsar/index.html.

FAR Provisions:

52.237-1, Site Visit (Apr 1984)

HHSAR Title and Date

352.239-73[8] Electronic Information and [Communication] Technology Accessibility Notice (Dec 2015[Feb 2024]) [(DEVIATION)]
(a) Any offeror responding to this solicitation must comply with established HHS Information and Communication Technology (ICT) accessibility standards. Information about Section 508 is available at https://www.hhs.gov/web/section-508/index.html.
(b) The Section 508 accessibility standards applicable to this solicitation are stated in the clause at 352.239-79 Information and Communication Technology Accessibility. In order to facilitate the Government's determination whether proposed ICT supplies, products, platforms, information, and documentation meet applicable Section 508 accessibility standards, offerors must submit an appropriate 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), in accordance with the completion instructions. The purpose of the checklists and conformance reports are to assist HHS acquisition and program officials in determining whether proposed ICT supplies, products, platforms, information, and documentation conform to applicable Section 508 accessibility standards. Checklists and ACRs evaluate—in detail—whether the ICT conforms to specific Section 508 accessibility standards and identifies remediation efforts needed to address conformance issues.
(c) If an offeror claims its supplies or services meet applicable Section 508 accessibility standards, and it is later determined by the Government, i.e., after award of a contract or order, that supplies, products, platforms, information, documentation, or services support delivered do not conform to the described accessibility standards, 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 expense.
(d) In order to facilitate the Government's determination whether proposed ICT supplies meet applicable Section 508 accessibility standards, offerors must submit an Accessibility Conformance Report, in accordance with its completion instructions and tailored to the requirements in the solicitation. The purpose of the Report is to assist HHS acquisition and program officials in determining whether proposed ICT supplies conform to applicable Section 508 accessibility standards. The template allows offerors or developers to self-evaluate their supplies and document, in detail, whether they conform to a specific Section 508 accessibility standard, and any underway remediation efforts addressing conformance issues. Instructions for preparing the HHS Section 508 Evaluation Template are available at https://Section508.gov/.
(e) In order to facilitate the Government's determination whether proposed ICT services meet applicable Section 508 accessibility standards, offerors must provide enough information to assist the Government in determining that the ICT services conform to Section 508 accessibility standards, including any underway remediation efforts addressing conformance issues.
(f) Respondents to this solicitation must identify any inability to conform to Section 508 requirements. If an offeror claims its supplies or services meet applicable Section 508 accessibility standards, and it is later determined by the Government, i.e., after award of a contract or order, that supplies or services delivered do not conform to the described accessibility standards, remediation

of the supplies or services to the level of conformance specified in the contract will be the responsibility of the Contractor at its expense.
(g) Items delivered as electronic content must be accessible to HHS acceptance criteria. Checklist for various formats are available at https://Section508.gov/. Materials, other than items incidental to contract management, that are final items for delivery should be accompanied by the appropriate checklist, except upon approval of the Contracting Officer or Contracting Officer's Representative.
- (End of provision) -

L-2 FAR 52.233-2 Service of Protest (Deviation) (RFO Nov 2025)

(a) Protests, (as defined in FAR 33.102), that are filed directly with an agency, and copies of any protests that are filed with the Government Accountability Office (GAO), must be served on the Contracting Officer identified in the solicitation by obtaining written and dated acknowledgment of receipt from them.

(b) Nick Sartain, Contracting Officer
FDA/OO/OFBA/OAGS/DAP
3900 NCTR Road
Building 50, Room 432
Jefferson, AR 72079(b) The copy of any protest shall be received in the office designated above within one day of filing a protest with the GAO.

L-3 Part I - Business Proposal Instructions

Your business proposal shall consist of three parts: Administrative Data, Representations and Certifications, and Cost or Pricing Data. It should be specific, complete in every detail and separate from your technical proposal.

1. Standard Form 1449 of the Contract. **<u>One (1) original of the completed, signed offer</u>** (Sections A through E) of the solicitation package.

2. Price Proposal
This section shall consist of the Offeror's price to perform the work outlined in the PWS. For evaluation purposes, the offeror's proposed lump sum price as identified in Section B-3, shall furnish a price breakdown with supporting data as specified below.
This information will be used for price analysis. Proposals must provide 120 calendar days for the government acceptance of offers.

a. Administrative Data;

Under the Administrative Data Section of your proposal, it is suggested that you provide adequate information in the following areas:

- Name, title, and signature of person authorized to sign the proposal.

- Name, title and contact information of person(s) authorized to negotiate with the government.
- Other special considerations involved in the instant acquisition.

b. Cost or Pricing Data

Offerors must submit, as a minimum, price proposal fully supported by cost or pricing data adequate to establish the reasonableness of the proposed amount for the base and all option years. **Price proposals for the fixed price portion (Section B-3) shall be broken down by labor category of each individual PWS section, such as Work Management System (PWS Section 2), Craft Shop Services (PWS Section 3), and so on.**

I. Direct Labor

Provide spreadsheet/schedule indicating types or categories of labor, together with man-hours. All estimated overtime shall be identified as such and added to the fixed-price portion of the contract pricing schedule.

Offeror shall identify any proposed labor category that is exempt from the Fair Labor Standards Act, by denoting such as "(EXEMPT)". All exempt employees pricing shall be escalated for each option year and not subject to change. Indicate whether current rates or escalated rates are used. If escalation is included, state the degree (percentage) and methodology.

II. Subcontracted Effort

Include parts, components, assemblies, and services that are to be produced or performed by others.

III. Overhead, General and Administrative Expense

The administration of task order IDIQ work shall be included in PWS Section 2 fixed price portion of work. No subcontract handling fee, management etc. shall be included in task order proposal that may require subcontracts for portions of the work. All overhead, G&A etc. shall be included in the fixed price portion of the applicable labor categories.

IV. Financial Capacity

The offeror shall indicate if it has the necessary financial capacity, working capital and other resources to perform the contract without assistance from any outside source.

V. Phase-In

The offeror shall detail all cost associated with the phase-in plan set forth in the technical proposal. Cost for Phase-in shall be identified as such and separate from other cost associated with contract performance.

L-4 Part II – Technical Proposal Instructions

Offerors shall submit a Technical Proposal that clearly demonstrates an understanding of the requirements of the Performance Work Statement (PWS) and presents a sound, feasible, and effective approach to performing the work.

The proposal shall emphasize the Offeror's approach, processes, and management methods for successfully executing the contract requirements. The Government will evaluate proposals based on the quality, feasibility, and risk of the proposed approach.

Technical proposals shall not include pricing information. However, resource information (e.g., labor categories, hours, materials, subcontracting approach) shall be included to demonstrate the Offeror's understanding of the requirements.

Failure to provide sufficient detail to evaluate the feasibility and effectiveness of the proposed approach may result in the proposal being rated Low Confidence.

As a minimum, the proposal must clearly provide the following:

(a) The volume of the proposal shall consist of the parts in the format outlined below which are limited to directly responding to the information sought by the Government's Performance Work Statement (PWS). The Contractor's proposal shall address the information in the PWS in the order outlined in this clause.

(b) The technical proposal is limited to a total of thirty (30) pages. Pages beyond the page limits listed shall be removed and not evaluated.

(c) The text of the proposal should be typed and prepared on standard 8-1/2" by 11" paper, double-spaced 11 point font or greater. Charts, tables, or diagrams may be used, however, the offeror may use no more than two (2) 17" by 11"pages and that page(s) will count as one page each towards the page limitation. Title pages and indexes will not be included for page counts limitation purposes unless information regarding the proposal is included on the title or index page.

Offerors shall organize their proposals in accordance with the following factors and sub-factors:

Factor 1: Technical Approach

Offerors shall demonstrate a clear, practical, and process-driven approach for executing operations and maintenance services in accordance with the Performance Work Statement (PWS).

a. Operating Plan

The technical proposal shall include an Operating Plan describing standardized procedures, methodologies, and decision-making processes used to manage and execute O&M services.

The Operating Plan shall address the following areas:

i. Emergency Procedures – Loss of Air, Steam, Water, Electrical, and HVAC
ii. EMCS / Controls Procedures (including instrumentation and calibration)
iii. System Shutdown, Isolation, and Leak Response Procedures
iv. Utility Plant Operations (Water, Boiler, Steam, Cooling Systems)
v. Specialized System Operations (e.g., sewage pre-treatment, district cooling)

b. Quality Control Plan

The QCP shall demonstrate a closed-loop system that ensures quality is maintained during transition and under varying operational conditions.

i. Inspection and verification processes
ii. Deficiency tracking and corrective action procedures

c. Phase-In / Transition Plan

Offerors shall provide a detailed Phase-In Plan for the 20-day transition period.

The plan shall include:

ii. Approach to achieving operational capability during transition.
iii. Knowledge transfer strategy.
iv. Risk identification and mitigation for service disruption.
v. ability to achieve full operational capability.

Factor 2: Select Key Personnel Qualifications

The following positions are designated as Key Personnel:
- On-site Contract Manager
- Operations Manager
- Quality Control Manager
- EMCS Manager
-

For each selected Key Personnel position, the Offeror shall provide:

a. Position Description
   i. Roles and responsibilities of the position.
   ii. How the position supports performance of the PWS.

b. Qualifications and Capability
   i. Summary of minimum relevant experience, education, certifications, licenses and training required for successful performance of the role, as applicable.
   ii. Description of the skills and capabilities required to successfully perform the role.

Offerors are responsible for proposing select key personnel position descriptions and minimum qualifications sufficient to successfully perform the required duties. For each selected Key

Personnel position, the Offeror shall clearly identify the roles, responsibilities, and minimum qualifications proposed for performance of the contract, including relevant experience, education, certifications, licenses, and training, as applicable. If awarded, the Contractor shall staff each selected Key Personnel position with an individual who meets or exceeds the qualifications proposed and accepted by the Government for that position.

Factor 3: Staffing Approach and Workforce Management

Offerors shall describe their approach to planning, staffing, managing, and sustaining a qualified workforce to perform all requirements of the PWS.

The proposal shall include:

a. A staffing approach describing labor categories, skill mix, and allocation of resources across PWS functional areas
b. A high-level organizational structure illustrating lines of authority, communication, and integration of on-site and off-site personnel.
c. Description of workforce management strategies, including:
    i. Recruiting and hiring approach.
    ii. Retention and workforce stability.
    iii. Backfill procedures and continuity of operations.
d. Approach to scaling staffing levels to accommodate workload variability, task orders, and emergency requirements.
e. Supervisory approach, including how personnel performance will be directed and overseen.
f. Approach to managing subcontractors, if applicable.
g. Approach to training, certifications, and maintaining workforce capability.

L-5 Part III – Recent and Relevant Past Performance Instructions

Offerors shall identify a minimum of three (3) but no more than five (5) of the most relevant contracts within the last three (3) years of the solicitation closing date and shall send to each of those clients the Past Performance Evaluation Questionnaire set forth in Section D, Attachment J-8 together with a Sample Client Letter adhering to the sample format set forth in Section D, Attachment J-9, Sample Client Letter with instructions that the Past Performance Evaluation Questionnaires be returned by the Client directly to Warren Dutter, Contract Specialist at the email addresses set forth in the Attachment 9 Sample Client Letter. Offerors are responsible for completing the "Contract Identification" information set forth in Paragraph 1 of the Attachment J-8, Past Performance Evaluation Questionnaire before sending the client letter and questionnaire to the client for completion. Any finalized, applicable Contractor Performance Assessment Reports (CPAR) may be provided in lieu of the Past Performance Questionnaire and Sample Client Letters. If finalized CPARS evaluations are provided Paragraph 1 of Attachment J-8 must still be completed and submitted with proposal.

Offerors Past Performance proposal shall consist of a copy of each Client Letter and Past

Performance Evaluation Questionnaire (with the "Contract Identification" information set forth in Paragraph 1 of the questionnaire completed) sent by the offeror to the client.

Recency is within three years prior to the solicitation closing date.

Offerors shall submit the following information as part of their Past Performance proposal for each contract identified above:

With respect to the relevancy of completed contracts, and specifically as it relates to completion of the "Relevance of the referenced contract to the current requirement", offerors shall compare and contrast their completed contracts described in the "Description of Work" addressed in Paragraph 1 of each Questionnaire as it relates to the current scope of work in Section B of this requirement. Relevant is defined as recent projects with similar size, scope and complexity as identified in this requirement such as (1) in the operation and maintenance of a multi-building research facility that includes both animal care and laboratory facilities; (2) in the operation, maintenance and testing of complex research equipment (examples of such equipment are environmental monitoring systems, autoclaves, fume hoods, etc.); (3) a thorough understanding of the operation and maintenance of utility systems; (4) in the operation and maintenance of sophisticated HVAC equipment and controls associated with environmental monitoring systems for use in highly technical research facilities; (5) in performing alteration work in occupied laboratory environments; (6) Extent of experience in operation and maintenance facilities in AAALAC Accredited Laboratories; (7) specific and specialized experience in the protection of occupants, structures, equipment and on-going research;

Number of buildings at the site and approximate total square footage;
Number of personnel involved on site;

For past performance evaluation, the recency and relevancy of a provided contract reference will only be used for the past performance evaluation if a PPEQ is received from the offeror's reference or a CPARS evaluation is provided for that contract reference. Past performance is an assessment of how relevant the referenced effort is to the Government's requirements and how well the offeror performed. With no PPEQ or CPARS evaluation, the Government cannot assess the quality of performance for that reference, and that contract reference will not be considered in the past performance evaluation.

An offeror without a relevant record of past performance or for whom information on current or past performance is not available will not be evaluated favorably or unfavorably, but will be given a "neutral confidence" rating. Favorable past performance is considered higher than neutral past performance.

L-6 Proposal E-mailing Instructions.

Proposals **WILL NOT** be accepted through US mail or delivery services.

Submit Proposals to Warren Dutter at warren.dutter@fda.hhs.gov.

L-7 Proposal Disqualification

Failure to address the information required by the instructions provided herein may result in technical disqualification whereby the proposal will not be evaluated further due to being considered Non-Responsive. Proposals considered Non-Responsive for any reason will not be evaluated further (Past Performance or Business Proposal). Technical proposals rated low confidence may be excluded from further evaluation from a past performance and business proposal.

L-8 Instructions for Submission of Questions

Offerors must submit all questions in writing, referencing section and paragraph of the solicitation or PWS. All questions must be submitted no later than **July 2, 2026, 1:00 p.m.** Central Time, to Warren Dutter at warren.dutter@fda.hhs.gov. Phone calls will not be accepted. Responses to questions received prior to the due date and time will be addressed via an amendment to the solicitation posted on https://www.sam.gov.

L-9 Pre-Proposal Conference

A pre-proposal conference will be held with prospective offerors at **9:00 a.m**. local prevailing time on **June 30, 2026** in the Building 10 conference room at the Jefferson Laboratory Complex, Jefferson, Arkansas.

The pre-proposal conference will be held for the purpose of providing information concerning the Government's requirements which may be helpful in the preparation of proposals and for answering any questions which you may have regarding this RFP.

Because of space limitations, each prospective offeror will be limited to a total of three (3) representatives. Attendance at the pre-proposal conference is recommended; however, attendance is not a prerequisite for proposal submission and will not be considered a factor in proposal evaluation.

All firms interested in attending the pre-proposal conference/site visit must submit the following information by email to **warren.dutter@fda.hhs.gov** no later than **June 25, 2026 by 1:00 P.M**. Central Time.

1. Full name of individual(s) attending and telephone number
2. If they are a U.S. citizen or a permanent resident.
3. Company name and phone number.

All attendees are required to report to building #21 (Security) and present a valid government issued **REAL ID**. Access to the facility shall not be granted if the visitor(s) refuses to cooperate with these security measures.

- Permanent residents must present their permanent residency card (green card) to security.
- The visitor(s) must sign the visitor logbook and be screened via the metal detector.

- All the visitor's possessions will also be screened. Food items, video/audio tapes, computer equipment, disks and other magnetic media are not affected by the X-ray machine and will be scanned.
- The guards will then issue a visitor badge and contact the escort identified in the email.
- The visitor will turn in their visitor badge and sign-out on the logbook upon exiting building #21.

Questions that firms would like addressed at the pre-proposal conference must be received by **June 25, 2026 by 1:00 P.M.** Central Time.

NOTE: OFFERORS ARE INSTRUCTED SPECIFICALLY TO CONTACT ONLY THE CONTRACTING OFFICE ISSUING THIS SOLICITATION CONCERNING ANY ASPECT OF THIS REQUIREMENT PRIOR TO AWARD.

SECTION M- EVALUATION FACTORS FOR AWARD

M-1 52.212-2 Evaluation—Commercial Products and Commercial Services (Deviation) (RFO Nov 2025

(a) The Government will award a contract resulting from this solicitation to the responsible offeror whose offer conforming to the solicitation will be most advantageous to the Government, price and other factors considered. Technical Proposal and Recent/Relevant Past Performance, are equal in importance and when combined are significantly more important than cost or price in determining the best overall value to the Government. Technical Proposal Factors 1, 2, and 3 are of equal importance.

1. Technical Proposal
    a. Factor 1: **Technical Approach**
    b. Factor 2: Select **Key Personnel Qualifications**
    c. Factor 3: **Staffing Approach and Workforce Management**
2. Recent and Relevant Past Performance
3. Price

M-2 Evaluation Factors

Technical Proposal

The Government will evaluate the Offeror's technical proposal using the factors below, considering the completeness and thoroughness of the proposal.

<u>Factor 1: Technical Approach</u>

The evaluation will assess the Offeror's:

a) Technical Approach and Operating Plan

i. Clarity and practicality of the proposed approach to accomplishing the operating plan requirements specified in the PWS.
ii. Demonstrated ability to apply the approach in a structured and repeatable manner.

b) Quality Control Plan
   i. Presence of a clear approach to inspection, deficiency tracking, and corrective action procedures.

c) Phase-In Plan
   i. Feasibility of the transition approach and ability to achieve full operational capability with minimal disruption.
   ii. Ability to perform with limited reliance on incumbent personnel or site-specific knowledge.

Factor 2: Key Personnel Qualifications

The evaluation will assess the Offeror's:

a) Position Descriptions
   i. Clarity of roles and responsibilities and alignment of each position to the requirements of the PWS.

b) Qualifications and Capability
   i. Relevance of proposed experience, education, certifications, licenses, and training.
   ii. Demonstrated capability of proposed position descriptions and minimum qualifications to perform assigned duties.

c) Overall Key Personnel Approach
   i. Appropriateness of proposed Key Personnel positions to perform required duties.
   ii. Use of additional Key Personnel positions (if proposed) to support performance of the PWS.

Factor 3: Staffing Approach and Workforce Management

The Government will evaluate the extent to which the Offeror's staffing approach demonstrates a realistic, effective, and low-risk approach to planning, staffing, managing, and sustaining a qualified workforce capable of performing all PWS requirements.

a. Staffing Approach and Resource Alignment

The extent to which the proposed labor categories, skill mix, staffing levels, and allocation of resources are appropriate for the PWS functional areas and contract requirements.

b. Workforce Organization, Oversight, and Integration

The effectiveness of the proposed organizational structure, lines of authority, communication, supervisory approach, and integration of on-site, off-site, and subcontractor personnel, if applicable.

c. Workforce Management, Continuity, and Capability

The effectiveness of the Offeror's approach to recruiting, hiring, retention, backfill procedures, continuity of operations, training, certifications, and maintaining workforce capability throughout contract performance.

d. Scalability and Workforce Risk Mitigation

The extent to which the approach demonstrates flexibility to respond to workload variability, task orders, emergency requirements, staffing shortages, turnover, surge demands, and other workforce-related risks.

Recent/Relevant Past Performance

The past performance evaluation will assess the relative risks associated with an offeror's likelihood of success in performing the solicitation's requirements as indicated by the offeror's record of recent and relevant past performance (i.e., what, when, how well, size and complexity). Recent is defined as within the last three years from the solicitation closing date. Relevant is defined as recent projects with similar size, scope and complexity as identified in this requirement such as (1) in the operation and maintenance of a multi-building research facility that includes both animal care and laboratory facilities; (2) in the operation, maintenance and testing of complex research equipment (examples of such equipment are environmental monitoring systems, autoclaves, fume hoods, etc.); (3) a thorough understanding of the operation and maintenance of utility systems; (4) in the operation and maintenance of sophisticated HVAC equipment and controls associated with environmental monitoring systems for use in highly technical research facilities; (5) in performing alteration work in occupied laboratory environments; (6) Extent of experience in operation and maintenance facilities in AAALAC Accredited Laboratories; and (7) specific and specialized experience in the protection of occupants, structures, equipment and on-going research. Evaluations may consider, but not be limited to, the record of 1) conforming to specifications and standards of good workmanship; 2) maintaining program execution within cost; 3) adherence to contract schedules, including the administrative aspects of performance; 4) ability to resolve technical and manufacturing problems quickly and effectively; 5) business-like concern for the interest of its customers; 6) establishing and maintaining adequate management of subcontractors; 7) providing quality services.

If a referenced contract does not result in receipt of a PPEQ and does not have a CPARS evaluation record, that contract reference will not be considered in the past performance evaluation because there is no performance record available to evaluate quality of performance.

The Government reserves the right to consider past performance information from any other source (e.g. Contractors Past Assessment Rating System (CPARS)) when evaluating past performance. An offeror without a relevant record of past performance or for whom information on current or past performance is not available will not be evaluated favorably or unfavorably. Favorable past performance is considered higher than neutral past performance.

Factor 3 – Price

Price will be non-scored factor. For evaluation purposes total price in section B-2 of the solicitation will be used for price evaluation.

Total evaluated price will include:

A. Phase – In Period (CLIN 1)

B. Fixed-Price Lump Sum (CLINs 2-11)

C. Indefinite Delivery/Indefinite Quantity Work All Ordering Periods.

The Government will evaluate the price proposal for completeness by determining if all information/data required by the solicitation has been submitted, is traceable to the PWS and supports the offer. If the pricing information is not easily traceable, is incomplete or ambiguous, it may result in the overall proposal being considered unacceptable.

Proposals that are unrealistic in terms of technical commitment or unreasonably low or high in price will be deemed reflective of an inherent lack of technical competence or indicative of failure to comprehend the complexity and risk involved in the contract requirements and may be grounds for rejection of the proposal.

Options. The Government will evaluate offers for award purposes by adding the total price for all options to the total price for the basic requirement. The Government may determine that an offer is unacceptable if the option prices are significantly unbalanced. Evaluation of options shall not obligate the Government to exercise the option(s).

A written notice of award or acceptance of an offer, mailed or otherwise furnished to the successful offeror within the time for acceptance specified in the offer, shall result in a binding contract

without further action by either party. Before the offer's specified expiration time, the Government may accept an offer (or part of an offer), whether or not there are negotiations after its receipt, unless a written notice of withdrawal is received before award.

M-3 Evaluation Criteria

Technical Proposal

Technical Proposal Factors 1, 2, and 3 will be evaluated by level of confidence and categorized as High Confidence, Some Confidence and Low Confidence.

Confidence ratings are defined below:

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.

Proposals received shall first be evaluated from a technical standpoint without regard to proposed price. Those proposals which are considered to have a rating of High or Some Confidence shall then be evaluated from a price and past performance standpoint. Proposals that are considered to have a Low Confidence rating may not be evaluated from a past performance and price standpoint and may be excluded from further consideration.

Recent/Relevant Past Performance

The Government will evaluate past performance based on the responses to the offeror's Past Performance Evaluation Questionnaire (PPEQ), completed CPARS evaluations. The Government will assign a performance confidence assessment based on its evaluation of the relative risks associated with the likelihood of successful performance of the PWS, as reflected in the entity's record of recent and relevant past performance, including what work was performed, when it was performed, how well it was performed, and the size, scope, and complexity of the referenced effort.

For purposes of this evaluation, recent means a contract completed or substantially completed within three years prior to the solicitation closing date. Relevant means a contract effort similar in dollar value, scope, and complexity to the requirements of this solicitation.

If a referenced contract does not result in receipt of a PPEQ and does not have a CPARS evaluation record, that contract reference will not be considered in the past performance evaluation because there is no performance record available to evaluate quality of performance.

The Government reserves the right to consider past performance information from sources other than those identified by the offeror, including CPARS and other sources available to the Government.

An offeror without a relevant record of past performance, or for whom information on current or past performance is not available, will not be evaluated favorably or unfavorably, but will be assigned a rating of Unknown Confidence/Neutral.

More favorable past performance is considered more advantageous than neutral past performance.

PAST PERFORMANCE RELEVANCY	
RATING	**DEFINITION**
VERY RELEVANT	Present/past performance effort involved essentially the same tasks, magnitude of effort, and complexities this solicitation requires.
RELEVANT	Present/past performance effort involved much of the tasks, magnitude of effort, and complexities this solicitation requires.
SOMEWHAT RELEVANT	Present/past performance contractual effort involved some of the tasks, magnitude of effort, and complexities this solicitation requires.
NOT RELEVANT	Present/past performance effort involved little or none of the scope and magnitude of effort and complexities this solicitation requires.

PAST PERFORMANCE RECENCY	
RATING	**DEFINITION**
RECENT	Present/past performance provided was conducted within the last three (3) years.

NOT RECENT	Present/past performance provided was conducted more than three (3) years ago.

PERFORMANCE CONFIDENCE ASSESSMENT	
RATING	**DEFINITION**
HIGH CONFIDENCE	Based on the Offeror's recent/relevant performance record, the Government has a high expectation that the Offeror will successfully perform the required effort and virtually no risk of unsuccessful performance.
SOME CONFIDENCE	Based on the Offeror's recent/relevant performance record, the Government has a reasonable expectation that the Offeror will successfully perform the required effort and low risk of unsuccessful performance.
LOW CONFIDENCE	Based on the Offeror's recent/relevant performance record, the Government has a low expectation that the Offeror will successfully perform the required effort and a high risk of unsuccessful performance.
UNKNOWN CONFIDENCE/ NEUTRAL	No recent/relevant performance record is available, or the Offeror's performance record is so sparse that no meaningful confidence assessment rating can be reasonably assigned.

M-4 Basis for Award

A single Award will be made to the offeror whose proposal represents the most advantageous or best value to the government considering Technical, Recent/Relevant Past Performance and Price. The Contracting Officer shall determine what trade-offs between technical merit, past performance and price offers the greatest overall value to the Government, price and other non-price related factors considered.

Offerors are advised that award may be made without discussion concerning the proposal received. Therefore, proposals should be submitted initially on the most favorable terms from a cost/price and technical standpoint.

As technical proposals become more equal, price becomes more important. Overall price to the Government may become the ultimate determining factor for award of the contract as proposals become more equal based on the other factors.

(End of Provision)