AWARD/CONTRACT	1. THIS CONTRACT IS A RATED ORDER UNDER DPAS (15 CFR 700)	RATING	PAGE OF PAGES 1 | 46

2. CONTRACT *(Proc. Inst. Ident.)* NO.	3. EFFECTIVE DATE	4. REQUISITION/PURCHASE REQUEST/PROJECT NO.
75F40122C00089	See Block 20C	1258311

5. ISSUED BY	CODE	6. ADMINISTERED BY *(If other than Item 5)*	CODE
DHHS/FDA/OAGS/DAP ATTN: Mary Rose A. Nicol 4041 Powder Mill Road Beltsville MD 20705	DAP	SCD-C	

7. NAME AND ADDRESS OF CONTRACTOR *(No., street, country, State and ZIP Code)*	8. DELIVERY	9. DISCOUNT FOR PROMPT PAYMENT
TEXAS DEPARTMENT OF STATE HEALTH SERVICES Attn: Megan Snyder 1100 WEST 49TH STREET AUSTIN TX 787563199	☐ FOB ORIGIN ☒ OTHER *(See below)*	

CODE 320113643	FACILITY CODE	10. SUBMIT INVOICES (4 copies unless otherwise specified) TO THE ADDRESS SHOWN IN	ITEM

11. SHIP TO/MARK FOR	CODE	12. PAYMENT WILL BE MADE BY	CODE
WHITE OAK CAMPUS, BUILDING 66 The US Food and Drug Administration 10903 New Hampshire Avenue Building 66 Silver Spring MD 20993	WO66	FDA PAYMENT SVCS Attn: FDA Vendor payment Team COLE RM8050 8455 Colesville Road Silver Spring MD 20993	FDA PAYMENT SVCS

13. AUTHORITY FOR USING OTHER THAN FULL AND OPEN COMPETITION:	14. ACCOUNTING AND APPROPRIATION DATA
☐ 10 U.S.C. 2304 (c) ( ) ☒ 41 U.S.C. 3304 (a) ( )	2022.6990914.25614

15A. ITEM NO	15B. SUPPLIES/SERVICES	15C. QUANTITY	15D. UNIT	15E. UNIT PRICE	15F. AMOUNT
	Continued				

15G. TOTAL AMOUNT OF CONTRACT $103,572.76

16. TABLE OF CONTENTS

(X)	SEC.	DESCRIPTION	PAGE(S)	(X)	SEC.	DESCRIPTION	PAGE(S)
		PART I - THE SCHEDULE				PART II - CONTRACT CLAUSES	
X	A	SOLICITATION/CONTRACT FORM	1-3	X	I	CONTRACT CLAUSES	36-45
X	B	SUPPLIES OR SERVICES AND PRICES/COSTS	4-7			PART III - LIST OF DOCUMENTS, EXHIBITS AND OTHER ATTACH.	
X	C	DESCRIPTION/SPECS./WORK STATEMENT	7-12	X	J	LIST OF ATTACHMENTS	45-46
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X	E	INSPECTION AND ACCEPTANCE	12-13		K	REPRESENTATIONS, CERTIFICATIONS AND OTHER STATEMENTS OF OFFERORS	
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CONTRACTING OFFICER WILL COMPLETE ITEM 17 (SEALED-BID OR NEGOTIATED PROCUREMENT) OR 18 (SEALED-BID PROCUREMENT) AS APPLICABLE

17. ☒ CONTRACTOR' S NEGOTIATED AGREEMENT (*Contractor is required to sign this document and return* 1 *copies to issuing office.)* Contractor agrees to furnish and deliver all items or perform all the services set forth or otherwise identified above and on any continuation sheets for the consideration stated herein. The rights and obligations of the parties to this contract shall be subject to and governed by the following documents: (a) this award/contract, (b) the solicitation, if any, and (c) such provisions, representations, certifications, and specifications, as are attached or incorporated by reference herein. *(Attachments are listed herein.)*

18. ☐ SEALED-BID AWARD (*Contractor is not required to sign this document.)* Your bid on Solicitation Number _____, including the additions or changes made by you which additions or changes are set forth in full above, is hereby accepted as to the items listed above and on any continuation sheets. This award consummates the contract which consists of the following documents: (a) the Government's solicitation and your bid, and (b) this award/contract. No further contractual document is necessary. (Block 18 should be checked only when awarding a sealed-bid contract.)

19A. NAME AND TITLE OF SIGNER *(Type or print)*	20A. NAME OF CONTRACTING OFFICER
Timothy Stevenson, DVM, PhD	MARY ROSE A. NICOL

19B. NAME OF CONTRACTOR	19C. DATE SIGNED	20B. UNITED STATES OF AMERICA	20C. DATE SIGNED
TEXAS DEPARTMENT OF STATE HEALTH SERVICES BY Timothy Stevenson Digitally signed by Timothy Stevenson Date: 2022.08.05 14:04:06 -05'00' *(Signature of person authorized to sign)*	5 Aug 2022	BY _____ *(Signature of the Contracting Officer)*	

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STANDARD FORM 26 (Rev. 3/2013)
Prescribed by GSA - FAR (48 CFR) 53.214(a)

NAME OF OFFEROR OR CONTRACTOR

TEXAS DEPARTMENT OF STATE HEALTH SERVICES

ITEM NO. (A)	SUPPLIES/SERVICES (B)	QUANTITY (C)	UNIT (D)	UNIT PRICE (E)	AMOUNT (F)
	Tax ID Number: 32-0113643 DUNS Number: 807391511 TX MEDICAL DEVICES FOR THE FOOD AND DRUG ADMNISTRATION JENNIFER YOUNG (COR) Base Period NTE: $103,572.76 Base Period of Performance: 9-1-2022 to 8-31-2023 Appr. Yr.: 2022 CAN: 6990914 Object Class: 25614 CenterTag: 28201NMDEV22TX0 Period of Performance: 09/01/2022 to 08/31/2023				
1	Level 1 QSIT Inspections Obligated Amount: $32,218.96 Delivery: 08/31/2023	8	EA	4,027.37	32,218.96
2	Level 2 QSIT Inspections Obligated Amount: $71,353.80 Delivery: 08/31/2023	12	EA	5,946.15	71,353.80
3	QSIT LEVEL 1 $4,027.37 @ 8= $32,218.96 QSIT LEVEL 2 $5,946.15 @ 12=$71,353.80 Option Period 1 Period of Performance: 9/1/2023 -8/31/2024 Amount: $103,572.76(Option Line Item)				0.00
4	QSIT LEVEL 1 $4,027.37 @ 8= $32,218.96 QSIT LEVEL 2 $5,946.15 @ 12=$71,353.80 Option Period 2 Period of Performance: 9/1/2024 -8/31/2025 Amount: $103,572.76(Option Line Item)				0.00
5	QSIT LEVEL 1 $4,027.37 @ 8= $32,218.96 QSIT LEVEL 2 $5,946.15 @ 12=$71,353.80 Continued ...				0.00

ITEM NO. (A)	SUPPLIES/SERVICES (B)	QUANTITY (C)	UNIT (D)	UNIT PRICE (E)	AMOUNT (F)
	Option Period 3 Period of Performance: 9/1/2025 -8/31/2026 Amount: $103,572.76(Option Line Item)				
6	QSIT LEVEL 1 $4,027.37 @ 8= $32,218.96 QSIT LEVEL 2 $5,946.15 @ 12=$71,353.80				0.00
	Option Period 4 Period of Performance: 9/1/2026 -8/31/2027 Amount: $103,572.76(Option Line Item)				
	The total amount of award: $517,863.80. The obligation for this award is shown in box 15G.				

SECTION B – SUPPLIES OR SERVICES AND PRICES/COSTS

B-1 – BACKGROUND AND OBJECTIVES

In performing the work as described in Section C: DESCRIPTION/ SPECIFICATIONS/ STATEMENT OF WORK, the Contractor shall review and consider the following:

A. Background

The Medical Device Amendments Act of 1976 was signed into law on May 28, 1976. Its purpose was to amend the Federal Food, Drug, and Cosmetic Act (FD&C Act) to provide for the safety and effectiveness of medical devices intended for human use, and for other purposes. Current Good Manufacturing Practices (CGMP) for medical devices was among the authorities added to the FD&C Act by the amendment. On October 7, 1996, FDA published revised CGMP requirements in the final rule entitled "Quality System Regulation" in the Federal Register. The Quality System Inspection Technique (QSIT) approach is used to conduct inspections against the Quality System Regulation. Under the QSIT approach, Level 1 (abbreviated) and Level 2 (comprehensive) inspections must be performed to ensure the safety of American consumers. The FD&C Act authorizes the U.S. Food and Drug Administration (FDA) to obtain state and/or local assistance in enforcing medical device manufacturing requirements by utilizing risk-based consideration for medical device inspections.

FDA's Office of Medical Devices and Radiological Health (OMDRHO) within FDA's Office of Regulatory Affairs (ORA) coordinates, directs and assists with medical devices and radiological health inspectional activities, including conducting inspections of medical devices and radiation-emitting products, as well as providing technical assistance regarding medical devices and radiological health inspectional operations

B. Objectives

The purpose of this contract is to for FDA to obtain fixed-unit price inspections of Class I and Class II medical devices manufacturers to determine compliance with the Quality System Inspection Technique/Good Manufacturing Practice (QSIT/GMP) regulations. These inspections are to be performed in accordance with the FD&C Act, Compliance Program Guidance Manual (CPGM) 7382.845 (Attachment 1), Guide to Inspection of Quality Systems (Attachment 2), and Investigations Operations Manual (Attachment 3).

B-1 – COMPENSATION

A. This is a firm fixed contract

B. As consideration for full performance of the work stated in Part I, Section C - Scope of Work, the Government may pay the State contractor a unit fixed price not to exceed of

$4,027.37 for QSIT LEVEL 1 Inspections and $5,946.15 for QSIT LEVEL 2 Inspections if all inspections are done for a total contract amount of $103,572.76 . The base period of performance is 12 months, options periods will be included to prevent this expiration using clauses FAR 52.217-8 and 52.217-9.

C. Payment up to the full amount of this contract shall be contingent upon receipt and acceptance by the Government of inspection reports and proper invoices as required by Part I, Section F, F2- Reports/Deliverables and Section G, G-3 - Invoice Submission, and in accordance with the schedule in part F

D. SCHEDULE

Base Period NTE: $103,572.76

Base Period of Performance: 9-1-2022 to 8-31-2023

Item	FFP Unit Price	Estimated Quantity	Price	Total Price
QSIT LEVEL 1	$4,027.37	8	$32,218.96	$32,218.96
QSIT LEVEL 2	$5,946.15	12	$71,353.80	$71,353.80
				$**103,572.76**

Option Period 1 NTE: $103,572.76

Option Period 1 Period of Performance: 9-1-2023 to 8-31-2024

Item	FFP Unit Price	Estimated Quantity	Price	Total Price
QSIT LEVEL 1	$4,027.37	8	$32,218.96	$32,218.96
QSIT LEVEL 2	$5,946.15	12	$71,353.80	$71,353.80
				$**103,572.76**

Option Period 2 NTE: $ 103,572.76

Option Period 2 Period of Performance: 9-1-2024 to 8-31-2025

Item	FFP Unit Price	Estimated Quantity	Price	Total Price
QSIT LEVEL 1	$4,027.37	8	$32,218.96	$32,218.96
QSIT LEVEL 2	$5,946.15	12	$71,353.80	$71,353.80
				$**103,572.76**

Option Period 3 NTE: $103,572.76

Option Period 3 Period of Performance: 9-1-2025 to 8-31-2026

Item	FFP Unit Price	Estimated Quantity	Price	Total Price
QSIT LEVEL 1	$4,027.37	8	$32,218.96	$32,218.96
QSIT LEVEL 2	$5,946.15	12	$71,353.80	$71,353.80
				$**103,572.76**

Option Period 4 NTE: $103,572.76

Option Period 4 Period of Performance: 9-1-2026 to 8-31-2027

Item	FFP Unit Price	Estimated Quantity	Price	Total Price
QSIT LEVEL 1	$	8	$32,218.96	$32,218.96

QSIT LEVEL 2	$	12	$71,353.80	$71,353.80
				$**103,572.76**

52.217-8 Option to Extend up to Six Months NTE: $41,786.38

Period of Performance: 9-1-2027 to 2-28-2028

Item	FFP Unit Price	Estimated Quantity	Price	Total Price
QSIT LEVEL 1	$4,027.37	4	$16,109.48	$16,109.48
QSIT LEVEL 2	$5,946.15	6	$35,676.90	$35,676.90
				$41,786.38

C – DESCRIPTION/SPECIFICATIONS/WORK STATEMENT

C-1 SCOPE OF WORK

A. PROJECT DESCRIPTION

This contract is designed to obtain State assistance in inspectional coverage of Medical Device Class I and II establishments. The Food and Drug Administration (FDA) plays a key role in overseeing the nation's medical device supply. Under the FD&C Act, the FDA's primary role in device safety is to inspect the conditions under which devices are manufactured, processed, packed, distributed, or held.

States play a critical role in overseeing the nation's medical device supply. Some state and local governments conduct inspections in the U.S., including device retailers, manufacturers, assemblers, processors, and distributors within their state boundaries in accordance with their own laws and authorities. The medical device manufacturers inspected by States are under Federal jurisdiction if they are involved in interstate commerce.

The Contractor shall conduct inspections of device establishments to determine compliance with the medical device provisions of the FD&C Act Under this contract.

B. SCOPE

The Contractor shall conduct inspections of assigned Class I and Class II medical device manufacturers using state officials who have been commissioned as officers of the U.S. Department of Health and Human Services, Food and Drug Administration, under the authority of the Federal Food, Drug, and Cosmetic Act (FD&C Act). Under commission, all state Contractors shall adhere to the procedural requirements of the FD&C Act, Compliance Program Guidance Manual (CPGM) 7382.845 (Attachment 1), Guide to Inspection of Quality Systems (Attachment 2), and Investigations Operations Manual (Attachment 3).

C. CONTRAINTS

The contractor shall adhere to the following constraints during performance of this contract:

1. The Contractor shall ensure that all state personnel performing inspections under this contract are adequately trained and have been commissioned by FDA.
2. The Contractor shall notify the COR/ COR Designee (State Liaison) on via email within three (3) business days if a state employee performing inspections under this contract is no longer able to perform inspections as anticipated.
3. The Contractor shall notify the COR/ COR Designee (State Liaison) via email within three (3) business days if the pre-announcement procedures outlined in FDA's Review and Update of Device Establishment Inspection Processes and Standards (Attachment 4) indicate that a manufacturer may no longer be active.
4. The Contractor shall notify the COR/ COR Designee (State Liaison) via email within three (3) business days upon determination that violative products or manufacturer operations could lead to serious illness, injury, or death. This includes instances in which the Contractor determines that violations have the potential of critical regulatory significance as described within Part V of CPGM 7382.845, (Attachment 1). The email notification shall include the firm's name, address, registration number, date of inspection, and summary of significant findings and/or concerns of potential risk to public health.
5. The Contractor shall notify the COR/COR Designee (State Liaison) via email within three (3) business days if a State is considering regulatory action as a result of any significant findings during the course of an inspection performed on FDA's behalf. The email notification shall include the firm's name, address, registration number, date of inspection, and summary of significant findings and/or concerns of potential risk to public health.
6. The Contractor may take independent compliance or enforcement actions (e.g., warning letters, embargos, license revocations, etc.) based on inspectional findings related to Quality System Regulations (21 CFR Parts 820) and under their respective State laws and implementing regulations. When considering actions that include violations of Medical

Device Reporting (MDR) Regulation, (21 CFR, Part 803), Registration and Listing regulations (21 CFR 807), and Corrections and Removals regulations (21 CFR 806) the Contractor shall notify the COR/COR Designee (State Liaison) via email prior to taking action.

   a. The Contractor shall submit reports of compliance or enforcement actions and compliance documents (e.g., warning letters, embargo forms, and license revocation) to the COR/COR Designee (State Liaison) as soon as possible, but no later than fifteen (15) business days after action is taken.

7. The Contractor shall ensure all inspection files are securely maintained in accordance with Section H-1 – Procurements Requiring Information Security and/or Physical Access Security. Each state employee performing inspections or reviewing inspection documents under this contract shall be required to complete FDA's Annual Records Management Training Course (Attachment 5).
8. The Contractor shall notify the COR/ COR Designee (State Liaison) and FDA disclosure team via email at ORAinfoshare@fda.hhs.gov within three (3) business days after receipt of a public records request for information obtained during the performance of the contract. The Contractor is not authorized to release confidential commercial information without permission from the COR/COR Designee. Refer to Section H – Special Contract Requirements for additional requirements for maintaining confidential commercial information.

D. **Task Requirements**

The Contractor shall perform the following tasks as identified below and further described in the attachments to this contract (Refer to Section J):

1. Attend an Annual Work Planning Meeting with COR and OMDRHO Subject Matter Experts (SMEs) to discuss medical device inspection plans and provide the contractor's key point of contact information to include name, phone number and email address.
   a. Prior to the Annual Work Planning Meeting COR/ COR Designee (State Liaison) will provide a "List of Planned Medical Device Inspections" to the Contractor.
   b. During the meeting a refined list of facilities to be inspected during each Period of Performance will be established.
   c. This meeting will be held no later than 30 calendar days after the period of performance begins. The COR/COR Designee (State Liaison) will provide a date and time within 5 business days of award.
   d. Within 5 business days after the Annual Work Planning Meeting, the Contractor shall submit a recommended final "List of Planned Medical Device Inspections" to the COR/COR Designee (State Liaison) for COR approval.
   e. The COR/COR Designee (State Liaison) will approve the recommended final "List of Planned Medical Device Inspections" within 5 business days. After which, the Contractor shall perform inspections.

2. Inspections

    a. The Contractor shall perform Level 1 and Level 2 Quality System Inspection Technique (QSIT) inspections in accordance with FDA's Guide to Inspection of Quality System (Attachment 2) and the COR approved "List of Planned Medical Device Inspections" to determine and document firm compliance with Quality System regulations (21 CFR 820) Medical Device Reporting (MDR) Regulation, (21 CFR 803), Registration and Listing regulations (21 CFR 807) and Corrections and Removals regulations (21 CFR 806). In performing Level 1 and Level 2 inspections, the Contractor shall strictly adhere to the policies and procedures outlined in the following documents:
        i. The Food, Drug, and Cosmetic Act (FD&C Act)
        ii. Compliance Program Guidance Manual (CPGM) 7382.845 (Attachment 1)
        iii. Guide to Inspection of Quality Systems (Attachment 2)
        iv. Investigations Operations Manual (IOM) (Attachment 3)
        v. Review and Update of Device Establishment Inspection Processes and Standards (Attachment 4)

    b. Audit Inspections

        i. During the period of performance, the Contractor shall participate in audit inspections with FDA personnel as provided in the COR approved "List of Planned Medical Device Inspections" according to the procedure and frequency described in Field Management Directive (FMD) – 76 State Contract Evaluation of Inspectional Performance (Attachment 6).
        ii. If the FDA identifies any deficiencies during an audit inspection, the Contractor and the FDA will work together to develop a Corrective Action Plan. Once all corrective actions have been completed, the Contractor shall submit the Appendix J, in accordance with FMD-76 (Attachment 6) to the COR/COR Designee (State Liaison), within 10 business days of completion.
        iii. For billing and invoicing purposes, the Contractor shall treat an audit inspection as either a QSIT Level 1 or QSIT Level 2 inspection as established in the COR approved "List of Planned Medical Device Inspections", applying the policies and procedures identified in Task 2.a.

3. Reports

    a. Establishment Inspection Report (EIR)
        i. The Contractor shall complete an EIR for each inspection in accordance with IOM Chapter 5 Subchapter 5.11 – Reporting (Attachment 3).

ii. The Contractor shall ensure that the EIR is uploaded into the Electronic State Access to Field Accomplishments and Compliance Tracking System (eSAF) within thirty (30) business days after completion of the inspection or prior to the end of the period of performance (Attachment 7).

1. The Contractor shall ensure that Inspection time is charged against the corresponding Program Assignment Code (PAC) codes in eSAF:
    a. QSIT Level 1 inspections reported under 82S008
    b. QSIT Level 2 inspections reported under 82S009

iii. If the FDA discovers an improper inspection report, the Contractor shall correct or submit a new inspection report. COR/COR Designee (State Liaison) will email the Contractor with the details of what is improper in the inspection report within seven (7) calendar days of receipt of the inspection report. The Contractor shall correct the report within 7 calendar days and this process will be repeated until the report is accepted by the COR/COR Designee (State Liaison). The FDA will not pay for an inspection until the Contractor has submitted an inspection report that has been accepted by the COR/COR Designee (State Liaison).

b. Quarterly Summary Report (QSR)

i. The Contractor shall submit a Quarterly Summary Report (QSR) no later than the final date of each contract quarter, based on the contract effective date, during the period of performance in which the inspections were performed. The completed QSR report shall include:

1. Facilities Inspected – A list of the facilities inspected during the reporting period, including:

    - Facility Name
    - Facility Identification Number (FEI) and Facility Registration Number
    - Date of Inspection
    - Level of QSIT inspection performed (Level 1 or Level 2)
    - Summary of Findings

2. Cumulative Inspection Performed – a cumulative total of the number of inspections, audits and/or joint inspections performed since the beginning of the contract period of performance.

3. Facility Status Changes- A list of the facilities with status or address changes discovered by the Contractor, including:

    - Facility name
    - Address
    - Facility Identification Number (FEI) and Facility Registration Number
    - Date inspected
    - Inspector Name

- Change(s)

4. State Adverse Actions – The Contractor shall report any actions taken at the state level against facilities for medical device violations. If there was no adverse action taken, the Contractor shall check "none".

5. Inspections / Work to Be Performed – A brief description of the inspections and work to be scheduled and performed during the next ninety (90) days.

6. Changes to Point of Contact / Inspector Information – A brief description of changes in Point of Contact / Inspector status, business phone numbers, business mailing addresses, e-mail addresses, and/or names.

7. Current Problems – Provide a brief synopsis of problems encountered and proposed corrective action, as well as point of contact and e-mail address or telephone number.

4. Training

a. DV210 – Core Medical Device Investigator Training - The Contractor shall provide a nominee based on the COR-provided information about a future training and submit a Travel Cost Estimate (TCE) (Attachment 8) to the COR/COR designee.

SECTION D – PACKAGING AND MARKING

This section is not applicable to this solicitation/contract.

SECTION E – INSPECTION AND ACCEPTANCE

E-1 – INSPECTION AND ACCEPTANCE

Pursuant to the appropriate inspection clause as provided below, final inspection and acceptance of all items called for by this contract shall be made by the FDA Contracting Officer Representative at the Food and Drug Administration.

52.246-4 Inspection of Services – Fixed Price (Aug 1996)

(a) Definition. "Services," as used in this clause, includes services performed, workmanship, and material furnished or utilized in the performance of services.

(b) The Contractor shall provide and maintain an inspection system acceptable to the Government covering the services under this contract. Complete records of all inspection work performed by the Contractor shall be maintained and made available to the Government during contract performance and for as long afterwards as the contract requires.

(c) The Government has the right to inspect and test all services called for by the contract, to the extent practicable at all time and place during the term of the contract. The Government shall perform inspections and tests in a manner that shall not unduly delay the work.

(d) If the Government performs inspections or tests on the premises of the Contractor or a subcontractor, the Contractor shall furnish, and shall require subcontractors to furnish, at no increase in contract price, all reasonable facilities and assistance for the safe and convenient performance of these duties.

(e) If any of the services do not conform with contract requirements, the Government may require the Contractor to perform the services again in conformity with contract requirements, at no increase in contract amount. When the defects in services cannot be corrected by re-performance, the Government may—

1. Require the Contractor to take necessary action to ensure that future performance conforms to contract requirements; and
2. Reduce the contract price to reflect the reduced value of the services performed.

(f) If the Contractor fails to promptly perform the services again or to take the necessary action to ensure future performance in conformity with contract requirements, the Government may—

1. By contract or otherwise, perform the services and charge to the Contractor any cost incurred by the Government that is directly related to the performance of such service; or
2. Terminate the contract for default.

SECTION F – DELIVERIES OR PERFORMANCE

F-1 – PERIOD OF PERFORMANCE

The period of performance is from: 9-1-2022 through 8-31-2023 (base period). there are four (4) additional option periods (See Article B-2).

F-2 – REPORTS/DELIVERABLES

The Contractor shall submit the following reports/ deliverables by the due dates indicated:

The COR/ COR Designee (State Liaison) will review and provide comments back on deliverables within seven (7) calendar days of receipt. The Contractor will have seven (7) calendar days to incorporate the FDA's comments and resubmit to the COR/COR Designee (State Liaison). This 7-day review cycle will repeat until COR/COR Designee (State Liaison) acceptance of a deliverable.

Reference	Deliverable	Method of Delivery	Frequency/Due Date

Task 1.d	Recommended Final List of Planned Medical Device Inspections	E-mail to COR/COR Designee (State Liaison)	Within 5 business days after the Annual Work Planning Meeting.
Task 2.b.ii	Appendix J	Email to COR/COR Designee (State Liaison)	Within 10 business days of completion of all corrective actions.
Task 3.a	Establishment Inspection Report (EIR)	eSAF	Within thirty (30) business days after completion of the inspection. Each EIR is due during the period of performance in which the inspection was performed (even if inspections are performed with less than thirty (30) business days remaining in the period of performance).
Task 3.b	Quarterly Summary Reports (QSR)	E-mail to COR/COR Designee (State Liaison)	No later than the final date of each contract quarter, based on the contract effective date. The Contractor shall submit all QSRs during the period of performance in which the inspections were performed.
Task 4.a	Travel Cost Estimate	Email to the COR	In accordance with the timeframe requested by the COR.

Copies of the Reports shall be provided to the COR as follows:

- One copy to:
  Jennifer Young

Food and Drug Administration
ORA/Office of Management
Email: Jennifer.Young@fda.hhs.gov
Phone: 214-253-5346

** Acceptable method of delivery is via email.**

SECTION G – CONTRACT ADMINISTRATIVE DATA

G-1 - ADMINISTRATIVE PERSONNEL

The following personnel shall represent the Government for this contract:

1. Contracting Officers Representative (COR):

Jennifer Young
Food and Drug Administration
ORA/Office of Management
Email: Jennifer.Young@fda.hhs.gov
Phone: 214-253-5346

a. The COR may be changed at any time by the Government without prior notice to the Contractor by a unilateral modification to the contract.

b. The responsibilities and limitations of the COR are as follows:

- The COR is responsible for monitoring the Contractor's technical progress, including the surveillance and assessment of performance and recommending to the Contracting Office changes in the requirement. The COR is responsible for the technical aspects of the project and serves as technical liaison with the Contractor.

- The COR is not authorized to make any commitments or otherwise obligate the Government or authorize any changes which may affect the cost, period of performance, or terms and conditions of the contract. Any Contractor request for changes shall be referred to the Contracting Officer (CO) directly or through the COR. No such changes shall be made without the expressed prior authorization of the CO. The CO may designate assistant or alternate CORs to act for the COR by naming such assistant/alternate(s) in writing and transmitting a copy of such designation to the Contractor.

G-2 - TECHNICAL DIRECTION

Performance of work under this contract is subject to the technical direction of the COR/COR Designee. 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 serves to ensure that tasks outlined in the work statement are accomplished satisfactorily. To be a valid Technical Direction Letter (TDL), it must be within the general scope of work stated in the contract, and it would not require any increase to the negotiated price and/or adjust the delivery terms under the contract.

Each TDL issued hereunder is subject to the terms and conditions of this contract. It shall be in writing and include, as a minimum, the following information:

a. Effective date of TDL;
b. Task Order and sequential TDL number;
c. Reference to the relevant section in the statement of work; and
d. Requirements to be performed.

Technical direction must be within the scope of this statement of work (SOW). The COR does not have authority to issue technical direction that:

a. Constitutes a change of assignment or additional work outside the specification(s)/statement of work;
b. Constitutes a change as defined in the clause entitled "Changes";
c. In any manner causes an increase or decrease in the contract price, or the time required for contract performance;
d. Changes any of the terms, conditions, or specification(s)/work statement of the contract;
e. Interferes with the contractor's right to perform under the terms and conditions of the contract; or
f. Directs, supervises or otherwise controls the actions of the contractor's employees
Technical direction may be oral or in writing. The COR/COR Designee shall confirm oral direction in writing within three (3) work days.

The Contractor shall not comply with any TDL if the Contractor believes it is not a valid TDL. In the event of a conflict between a TDL and the scope of the contract/order, the terms of the contract/order shall prevail. If the Contractor believes or has reason to believe that a TDL is not valid, the Contractor shall notify the COR/COR Designee and Contracting Officer thereof by email within three (3) days of receiving the TDL in question. The Contracting Officer will give appropriate direction to the Contractor and COR to resolve the TDL issue. Technical Direction provided in meetings with minutes submitted by the Contractor for Government acceptance does not need to be documented via TDL. The Technical Direction shall be documented in the meeting minutes. Contractor's failure to comply with this clause is grounds for finding that incurred costs are not allowable.

G-3 - INVOICE SUBMISSION

1. Invoice Type

   Fixed Price – Quarterly

2. Invoices

Invoices submitted under this contract must comply with the requirements set forth in HHSAR 352.232-71 Electronic Submission of Payment Requests (FEB 2022) and/or other applicable FAR clauses specified herein. To constitute a proper invoice, the invoice must be submitted on company letterhead and include each of the following:

352.232-71 Electronic Submission of Payment Requests (FEB 2022)

(a) Definitions. As used in this clause—

Payment request means a bill, voucher, invoice, or request for contract financing payment with associated supporting documentation. The payment request must comply with the requirements identified in FAR 32.905(b), "Content of Invoices" and the applicable Payment clause included in this contract.

(b) Except as provided in paragraph (c) of this clause, the Contractor shall submit payment requests electronically using the Department of Treasury Invoice Processing Platform (IPP) or successor system. Information regarding IPP, including IPP Customer Support contact information, is available at www.ipp.gov or any successor site.

(c) The Contractor may submit payment requests using other than IPP only when the Contracting Officer authorizes alternate procedures in writing in accordance with HHS procedures.

(d) If alternate payment procedures are authorized, the Contractor shall include a copy of the Contracting Officer's written authorization with each payment request.

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 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.

(1) 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:

(1) list of all invoices submitted to date under the subject award, including the following:
- invoice number, amount, & date submitted
- corresponding payment amount & date received
- total amount of all payments received to date under the subject contract or order
- 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.

G-4 - GOVERNMENT FURNISHED MATERIALS

None

G-5 - CONTRACTING OFFICER'S AUTHORITY

The Contracting Officer (CO) identified below has responsibility for ensuring the performance of all necessary actions for effective contracting; ensuring compliance with the terms of the contract and safeguarding the interests of the United States in its contractual relationships. The CO is the only individual who has the authority to enter into, administer, or terminate this contract and is the only person authorized to approve changes to any of the requirements under this contract, and notwithstanding any provision contained elsewhere in this contract, this authority remains solely with the CO.

No statement, whether oral or written, by anyone other than the Contracting Officer, shall be interpreted as modifying the terms and conditions of this Contract. It is the Contractor's responsibility to contact the CO immediately if there is even the appearance of any technical direction that is or may be outside the scope of the contract. The Government will not reimburse the Contractor for any work not authorized by the CO, including work outside the scope of the contract.

Name: Mary Rose A. Nicol, Contracting Officer
Email: MaryRose.Nicol@fda.hhs.gov

G-6 – CONTRACTING OFFICER REPRESENTATIVE

The Contracting Officer may designate other Government personnel (known as the Contracting Officer's Representative) to act as the authorized representative for contract administration functions which do not involve changes to the scope, price, schedule, or terms and conditions of the contract. The designation will be in writing, signed by the Contracting Officer, and will set forth the authorities and limitations of the representative(s) under the contract. Such designation will not contain authority to sign contractual documents, order contract changes, modify contract terms, or create any commitment or liability on the part of the Government different from that set forth in the contract. The Contractor shall immediately contact the Contracting Officer if there is any question regarding the authority of an individual to act on behalf of the Contracting Officer under this contract.

G-7 – POST AWARD EVALUATION OF CONTRACTOR PERFORMANCE

In accordance with Federal Acquisition Regulation (FAR) 42.15, 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 http://www.cpars.csd.disa.mil/cparsmain.htm. 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 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.

Contractors may obtain CPARS training material and register for on-line training at http://www.cpars.csd.disa.mil/allapps/cpcbtdlf.htm. There is no fee for registration or use of the CPARS.

SECTION H - SPECIAL CONTRACT REQUIREMENTS

H-1 - PROCUREMENTS REQUIRING INFORMATION SECURITY AND/OR PHYSICAL ACCESS SECURITY

A. Baseline Security Requirements

1) **Applicability.** The requirements herein apply whether the entire contract or order (hereafter "contract"), or portion thereof, includes either or both of the following:

a. Access (Physical or Logical) to Government Information: A Contractor (and/or any subcontractor) employee will have or will be given the ability to have, routine physical (entry) or logical (electronic) access to government information.

b. 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 HHS 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.

2) **Safeguarding Information and Information Systems.** In accordance with the Federal Information Processing Standards Publication (FIPS)199, *Standards for Security Categorization of Federal Information and Information Systems*, the Contractor (and/or any subcontractor) shall:

a. Protect government information and information systems in order to ensure:

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.

b. Provide security for any Contractor systems, and information contained therein, connected to an FDA network or operated by the Contractor on behalf of FDA regardless of location. In addition, if new or unanticipated threats or hazards are discovered by either the agency or contractor, or if existing safeguards have ceased to function, the discoverer shall immediately, **within one (1) hour or less**, bring the situation to the attention of the other party. This includes notifying the FDA Systems Management Center (SMC) within one (1) hour of discovery/detection in the event of an information security incident.

c. Adopt and implement the policies, procedures, controls, and standards required by the HHS/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 Policy (IS2P), by contacting the CO/COR or emailing your ISSO.

d. Comply with the Privacy Act requirements and tailor FAR clauses as needed.

3) **Information Security Categorization**. 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 Categorie*s, Appendix C, and based on information provided by the ISSO or other security representative, the

risk level for each Security Objective and the Overall Risk Level, which is the highest watermark of the three factors (Confidentiality, Integrity, and Availability) of the information or information system are the following:

Confidentiality: [ ] Low [x] Moderate [ ] High
Integrity: [ ] Low [x] Moderate [ ] High
Availability: [ ] Low [x] Moderate [ ] High
Overall Risk Level: [ ] Low [x] Moderate [ ] High

Based on information provided by the Privacy Office, system/data owner, or other privacy representative, it has been determined that this solicitation/contract involves:

[ ] No PII [x] Yes PII

Personally Identifiable Information (PII). Per the OMB Circular A-130, "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.

PII Confidentiality Impact Level has been determined to be: [ ] Low [X] Moderate [ ] High

4) **Controlled Unclassified Information (CUI).** CUI is defined 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. All sensitive information that has been identified as CUI by a regulation or statute, handled by this solicitation/contract, shall be:

a. marked appropriately;

b. disclosed to authorized personnel on a Need-To-Know basis;

c. protected in accordance with NIST SP 800-53, *Security and Privacy Controls for Federal 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

d. returned to FDA control, destroyed when no longer needed, or held until otherwise directed.

5) **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) shall protect all government information that is or may be sensitive in accordance with OMB Memorandum M-06-16, *Protection of Sensitive Agency Information* by securing it with a FIPS 140-2 validated solution.

Destruction of information and/or data shall be accomplished in accordance with NIST SP 800-

88, *Guidelines for Media Sanitization* and the FDA IS2P Appendix T: *Sanitization of Computer-Related Storage Media*. **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 shall be used only for the purpose of carrying out the provisions of this contract and shall not be disclosed or made known in any manner to any persons except as may be necessary in the performance of the contract without obtaining permission from FDA disclosure team members at ORAinfoshare@fda.hhs.gov and the COR/COR Designee. The Contractor assumes responsibility for protection of the confidentiality of Government records and shall ensure that all work performed by its employees and subcontractors shall 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 shall 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 shall be protected in accordance with //HHS and *FDA* policies. Unauthorized disclosure of information will be subject to the HHS/*FDA* sanction policies and/or governed by the following laws and regulations:

a. 18 U.S.C. 641 (Criminal Code: Public Money, Property or Records);
b. 18 U.S.C. 1905 (Criminal Code: Disclosure of Confidential Information); and
c. 44 U.S.C. Chapter 35, Subchapter I (Paperwork Reduction Act).

6) **Internet Protocol Version 6 (IPv6).** All procurements using Internet Protocol shall comply with OMB Memorandum M-05-22, *Transition Planning for Internet Protocol Version 6 (IPv6)*.

7) **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 shall 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, the HTTPS is not required, but it is highly recommended.

8) **Contract Documentation**. The Contractor shall use FDA-provided templates, policies, forms and other agency documents to comply with contract deliverables as appropriate.

9) **Standard for Encryption.** The Contractor (and/or any subcontractor) shall:

a. Comply with the *HHS Standard for Encryption of Computing Devices and Information* to prevent unauthorized access to government information.

b. 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 FIPS 140-2 validated encryption solution.

c. All devices (i.e.: desktops, laptops, mobile devices, etc.) that store, transmit, or process non-public FDA information should utilize FDA-provided or FDA information security authorized devices that 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).

d. Verify that the encryption solutions in use are compliant with FIPS 140-2. The Contractor shall provide a written copy of the validation documentation to the COR.

e. 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. Encryption keys (PIV card) shall be provided to the COR upon request and at the conclusion of the contract. Upon completion of contract, contractor ensures that COR is able to access and read any encrypted data.

10) **Contractor Non-Disclosure Agreement (NDA) (Attachment 9)**. The FDA Contracting Officer shall provide a Non-Disclosure Agreement to the Contractor. The Contractor shall have the agreement signed by the Agency official authorized to sign the form. A copy of each signed and witnessed NDA shall be submitted to the CO and/or COR prior to performing any work under this acquisition.

11) **Privacy Threshold Analysis (PTA)/Privacy Impact Assessment (PIA)** – The Contractor shall assist the procuring activity representative, program office and the FDA SOP or designee with conducting a PTA for the information system and/or information handled under this contract to determine whether or not a full PIA needs to be completed.

a. If the results of the PTA show that a full PIA is needed, the Contractor shall assist procuring activity representative, program office and the FDA SOP or designee 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).

b. The Contractor shall assist the procuring activity representative, program office and the FDA SOP or designee in reviewing and updating the PIA at least every ***three years*** throughout the Enterprise Performance Life Cycle (EPLC) /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.

B. Training

1) **Mandatory Training for All Contractor Staff.** All Contractor (and/or any subcontractor) employees assigned to work on this contract shall complete the applicable FDA Contractor

Information Security Awareness, Privacy, and Records Management training (provided upon contract award) before performing any work under this contract. Thereafter, the employees shall complete FDA Information Security Awareness, Privacy, and Records Management training at least ***annually***, during the life of this contract. All provided training shall be compliant with HHS and FDA training policies.

2) **Role-based Training.** All Contractor (and/or any subcontractor) employees with significant security responsibilities (as determined by the FDA Program Manager) must complete role-based training ***annually*** commensurate with their role and responsibilities in accordance with HHS and FDA policy and *FDA Role-Based Training (RBT) of Personnel with Significant Security Responsibilities Standard Operating Procedures (SOP)* https://www.hhs.gov/about/agencies/asa/ocio/cybersecurity/security-awareness-training/index.html..

3) **Training Records.** The Contractor (and/or any subcontractor) shall maintain training records for all its employees working under this contract in accordance with HHS and FDA policy. A copy of the training records shall be provided to the CO and/or COR within ***30 days*** after contract award and ***annually*** thereafter or upon request.

C. Rules of Behavior
1) The Contractor (and/or any subcontractor) shall ensure that all employees performing on the contract comply with the *HHS Information Technology General Rules of Behavior* https://www.hhs.gov/web/governance/digital-strategy/it-policy-archive/hhs-rules-of-behavior-for-the-use-of-hhs-information-and-it-resources-policy.html.

2) All Contractor employees performing on the contract must read and adhere to the Rules of Behavior (ROB) before accessing HHS and FDA 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.

D. Incident Response

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

The Federal Information Security Modernization Act (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." The HHS *Policy for IT Security and Privacy Incident Reporting and Response* further defines incidents as events involving cybersecurity and privacy threats, such as viruses, malicious user activity, loss of, unauthorized disclosure or destruction of data, and so on.

A privacy breach is a type of incident and is defined by FISMA as 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. The HHS *Policy for IT Security and Privacy Incident Reporting and Response* further defines a breach as "a suspected or confirmed incident involving PII."

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

1) Protect all sensitive information, including any PII created, stored, or transmitted in the performance of this contract to avoid a secondary sensitive information incident with FIPS 140-2 validated encryption.

2) 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 shall send FDA approved notifications to affected individuals as directed by FDA's SOP.

3) Report all suspected and confirmed information security and privacy incidents and breaches to the FDA Systems Management Center, COR, CO, and other stakeholders, (Recommend adding the FDA Senior Official for Privacy with contact information and either defining or deleting "other stakeholders.") including incidents 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 of discovery/detection**, 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, contract information, impact classifications/threat vector, and the type of information compromised. In addition, the Contractor shall:

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

b. not include any sensitive information in the subject or body of any reporting e-mail; and

c. encrypt sensitive information in attachments to email, media, etc.

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

5) 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 demand.

E. Position Sensitivity Designations

All Contractor (and/or any subcontractor) employees must obtain a background investigation commensurate with their position sensitivity designation that complies with Parts 1400 and 731 of Title 5, Code of Federal Regulations (CFR).

The following position sensitivity designation levels apply to this solicitation/contract: Tier 2

F. Homeland Security Presidential Directive (HSPD)-12

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

Roster. The Contractor (and/or any subcontractor) shall 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 and any revisions to the roster as a result of staffing changes shall 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 shall be submitted within a timeline as directed by the COR and/or CO. The COR will notify the Contractor of the appropriate level of investigation required for each staff member.

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

G. Contract Initiation and Expiration

1) **General Security Requirements.** The Contractor (and/or any subcontractor) shall 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 shall follow the FDA EPLC framework and methodology in accordance with the FDA EPLC Project documentation, located here: http://sharepoint.fda.gov/orgs/DelMgmtSupport/IntakeProc/EPLCv2/SitePages/v2/EPLCHome.aspx

2) **System Documentation.** Contractors (and/or any subcontractors) must follow and adhere to NIST SP 800-64, *Security Considerations in the System Development Life Cycle*, 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.

3) **Sanitization of Government Files and Information.** As part of contract closeout and at expiration of the contract, the Contractor (and/or any subcontractor) shall provide all required documentation in accordance with FDA OAGS SMGs 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 and FDA IS2P Appendix T: *Sanitization of Computer-Related Storage Media.*

4) **Notification.** The Contractor (and/or any subcontractor) shall notify the CO and/or COR as soon as it is known that an employee will stop working under this contract.

5) **Contractor Responsibilities Upon Physical Completion of the Contract**. The contractor (and/or any subcontractors) shall 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 shall 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/or FDA policies.

6) 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 http://inside.fda.gov:9003/EmployeeResources/NewEmployee/eDepartDepartureSystem/default.htm as soon as it is known that an employee will terminate work under this contract within days of the employee's exit from the contract. All documentation shall be made available to the CO and/or COR upon request.

H. Records Management and Retention

The Contractor (and/or any subcontractor) shall 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/FDA policies and shall not dispose of any records unless authorized by HHS/*FDA.*

In the event that a contractor (and/or any subcontractor) accidentally disposes of or destroys a record without proper authorization, it shall be documented and reported as an incident in accordance with HHS/FDA policies.

H-2 - ACCESSIBILITY AND SECTION 508

Electronic and Information Technology Accessibility Notice (December 18, 2015):

(a) Section 508 of the Rehabilitation Act of 1973 (29 U.S.C. 794d), as amended by the

Workforce Investment Act of 1998 and the Architectural and Transportation Barriers Compliance Board Electronic and Information (EIT) Accessibility Standards (36 CFR part 1194), require that when Federal agencies develop, procure, maintain, or use electronic and information technology, Federal employees with disabilities have access to and use of information and data that is comparable to the access and use by Federal employees who are not individuals with disabilities, unless an undue burden would be imposed on the agency. Section 508 also requires that individuals with disabilities, who are members of the public seeking information or services from a Federal agency, have access to and use of information and data that is comparable to that provided to the public who are not individuals with disabilities, unless an undue burden would be imposed on the agency.
(b) Accordingly, any offeror responding to this solicitation must comply with established HHS EIT accessibility standards. Information about Section 508 is available at https://www.hhs.gov/web/section-508/index.html. The complete text of the Section 508 Final Provisions can be accessed at https://www.access-board.gov/ict.html.

(c) The Section 508 accessibility standards applicable to this solicitation are stated in the clause at 352.239-74, Electronic and Information Technology Accessibility.

In order to facilitate the Government's determination whether proposed EIT supplies meet applicable Section 508 accessibility standards, offerors must submit an HHS Section 508 Product Assessment Template, in accordance with its completion instructions. The purpose of the template is to assist HHS acquisition and program officials in determining whether proposed EIT 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 under Section 508 policy on the HHS website http://www.hhs.gov/web/508.
In order to facilitate the Government's determination whether proposed EIT services meet applicable Section 508 accessibility standards, offerors must provide enough information to assist the Government in determining that the EIT services conform to Section 508 accessibility standards, including any underway remediation efforts addressing conformance issues.

(d) Respondents to this solicitation must identify any exception to Section 508 requirements. If a 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.

(e) Pursuant to Section 508 of the Rehabilitation Act of 1973 (29 U.S.C. 794d), as amended by the Workforce Investment Act of 1998, all electronic and information technology (EIT) supplies and services developed, acquired, or maintained under this contract or order must comply with the "Architectural and Transportation Barriers Compliance Board Electronic and Information Technology (EIT) Accessibility Standards" set forth by the Architectural and Transportation Barriers Compliance Board (also referred to as the "Access Board") in 36 CFR part 1194. Information about Section 508 is available at https://www.hhs.gov/web/section-508/index.html

The complete text of Section 508 Final Provisions can be accessed at https://www.access-board.gov/ict.html.

(f) The Section 508 accessibility standards applicable to this contract or order are identified in the Statement of Work or Specification or Performance Work Statement. The contractor must provide any necessary updates to the submitted HHS Product Assessment Template(s) at the end of each contract or order exceeding the simplified acquisition threshold (see FAR 2.101) when the contract or order duration is one year or less. If it is determined by the Government that EIT supplies and services provided by the Contractor do not conform to the described accessibility standards in the contract, remediation of the supplies or services to the level of conformance specified in the contract will be the responsibility of the Contractor at its own expense.

(g) The Section 508 accessibility standards applicable to this contract are:

- Must meet WCAG 2.0 A and AA
- E101.2 Equivalent Facilitation (Appendix A, Application and Scoping Requirements)
- E203 Access to Functionality (Appendix A, Application and Scoping Requirements)
- E204 Functional Performance Criteria (Appendix A, Application and Scoping Requirements)
- E205 Electronic Content (Appendix A, Application and Scoping Requirements)
- E208 Support Documentation and Services (Appendix A, Application and Scoping Requirements)
- Chapter 6 Support Documentation and Services (Appendix C, Functional Performance Criteria and Technical Requirements)
- 302 Functional Performance Criteria (Appendix C, Functional Performance Criteria and Technical Requirements)
- Electronic content must be accessible to HHS acceptance criteria. Checklist for various formats are available at https://www.hhs.gov/web/section-508/accessibility-checklists/index.html
  , or from the Section 508 Coordinator listed at https://www.hhs.gov/web/section-508/additional-resources/section-508-contacts/index.html. Materials that are final items for delivery should be accompanied by the appropriate checklist, except upon approval of the Contracting Officer or Representative.

(h) In the event of a modification(s) to this contract or order, which adds new EIT supplies or services or revises the type of, or specifications for, supplies or services, the Contracting Officer may require that the Contractor submit a completed HHS Section 508 Product Assessment Template and any other additional information necessary to assist the Government in determining that the EIT supplies or services conform to Section 508 accessibility standards. Instructions for documenting accessibility via the HHS Section 508 Product Assessment Template may be found under Section 508 policy on the HHS website: https://www.hhs.gov/web/section-508/index.html If it is determined by the Government that EIT supplies and services provided by the Contractor do not conform to the described accessibility standards in the contract, remediation of the supplies or services to the level of conformance specified in the contract will be the responsibility of the Contractor at its own expense.

(i) If this is an Indefinite Delivery contract, a Blanket Purchase Agreement

or a Basic Ordering Agreement, the task/delivery order requests that include EIT supplies or services will define the specifications and accessibility standards for the order. In those cases, the Contractor may be required to provide a completed HHS Section 508 Product Assessment Template and any other additional information necessary to assist the Government in determining that the EIT supplies or services conform to Section 508 accessibility standards. Instructions for documenting accessibility via the HHS Section 508 Product Assessment Template may be found at http://www.hhs.gov/web/508. If it is determined by the Government that EIT supplies and services provided by the Contractor do not conform to the described accessibility standards in the provided documentation, remediation of the supplies or services to the level of conformance specified in the contract will be the responsibility of the Contractor at its own expense.

Contractor Personnel Security Clearance Standards and Residency Requirements (October 2017)

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. A **roster** of contractor employee names, identifying Key Personnel and Tier designation(s);
   b. Confirmation all individual employee security information has been submitted properly; and
   c. "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.

1. 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.

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

2. Background investigations may be conducted by the state which employs the contractor. The state completed investigation must meet the standards required by FDA. Investigation completion should be within the last ten (10) years and include the following: criminal check which includes fingerprinting, reference checks (employment, residence and personal reference) and credit check. FDA will require a verification letter that states an adequate investigation has been completed. This verification should be submitted on agency letterhead advise the FDA Personnel Security Staff of the details of such clearance.

3. 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 Tier 2.
   There are three (3) potential position risk designations, which are:

      i. 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.

ii. 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.

4. 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.

5. 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 the table 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:

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

6. 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.

7. 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 Badging and Credentialing Office for their building pass.

*Food and Drug Administration Badging and Credentialing Office, 8:00 a.m. – 11:00 a.m. and 1:00 p.m. – 3:00 p.m., Eastern Time 10903 New Hampshire Avenue, Building 32, Room 1205 Silver Spring, MD 20993 No appointment necessary Telephone: (301) 796-4000

Table 2: Accepted Forms of Identification

Appendix A

LIST A Documents that Establish Both Identity and Employment Authorization	OR	LIST B Documents that Establish Identity	AND	LIST C Documents that Establish Employment Authorization
1. U.S. Passport or U.S. Passport Card		1. Driver's license or ID card issued by a State or outlying possession of the United States provided it contains a photograph or information such as name, date of birth, gender, height, eye color, and address		1. A Social Security Account Number card, unless the card includes one of the following restrictions: (1) NOT VALID FOR EMPLOYMENT (2) VALID FOR WORK ONLY WITH INS AUTHORIZATION (3) VALID FOR WORK ONLY WITH DHS AUTHORIZATION
2. Permanent Resident Card or Alien Registration Receipt Card (Form I-551)		2. ID card issued by federal, state or local government agencies or entities, provided it contains a photograph or information such as name, date of birth, gender, height, eye color, and address		2. Certification of report of birth issued by the Department of State (Forms DS-1350, FS-545, FS-240)
3. Foreign passport that contains a temporary I-551 stamp or temporary I-551 printed notation on a machine-readable immigrant visa		3. School ID card with a photograph		3. Original or certified copy of birth certificate issued by a State, county, municipal authority, or territory of the United States bearing an official seal
4. Employment Authorization Document that contains a photograph (Form I-766)		4. Voter's registration card		4. Native American tribal document
5. For a nonimmigrant alien authorized to work for a specific employer because of his or her status: a. Foreign passport; and b. Form I-94 or Form I-94A that has the following: (1) The same name as the passport; and (2) An endorsement of the alien's nonimmigrant status as long as that period of endorsement has not yet expired and the proposed employment is not in conflict with any restrictions or limitations identified on the form.		5. U.S. Military card or draft record		5. U.S. Citizen ID Card (Form I-197)
		6. Military dependent's ID card		6. Identification Card for Use of Resident Citizen in the United States (Form I-179)
		7. U.S. Coast Guard Merchant Mariner Card		7. Employment authorization document issued by the Department of Homeland Security
6. Passport from the Federated 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 United States and the FSM or RMI		8. Native American tribal document		
		9. Driver's license issued by a Canadian government authority		
		For persons under age 18 who are unable to present a document listed above:		
		10. School record or report card		
		11. Clinic, doctor, or hospital record		
		12. Day-care or nursery school record		

SECTION I – CONTRACT CLAUSES

I-1 – CLAUSES INCORPORATED BY REFERENCE (FAR 52.252-2 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 shall make their full text available. Also, the full text of a clause may be accessed electronically at the following address (es):

http://acquisition.gov/far/
http://www.hhs.gov/policies/hhsar/

1. Federal Acquisition Regulation (FAR) (48 CFR Chapter 1) Clauses

Reg	Clause	Date	Clause Title
FAR	52.202-1	Jun -2020	Definitions
FAR	52.203-3	Apr-1984	Gratuities
FAR	52.203-5	May-2014	Covenant Against Contingent Fees
FAR	52.203-6	Jun-2020	Restrictions on Subcontractor Sales to the Government
FAR	52.203-7	Jun-2020	Anti-Kickback Procedures
FAR	52.203-8	May-2014	Cancellation, Rescission, and Recovery of Funds for Illegal or Improper Activity
FAR	52.203-10	May-2014	Price or Fee Adjustment for Illegal or Improper Activity
FAR	52.203-12	Jun-2020	Limitation on Payments to Influence Certain Federal Transactions
FAR	52.203-13	Nov-2021	Contractor Code of Business Ethics and Conduct
FAR	52.203-17	Jun-2020	Contractor Employee Whistleblower Rights and Requirement to Inform Employees of Whistleblower Rights
FAR	52.203-19	Jan-2017	Prohibition on Requiring Certain Internal Confidentiality Agreements or Statements
FAR	52.204-1	Dec-1989	Approval of Contract
FAR	52.204-2	Mar-2021	Security Requirements
FAR	52.204-4	May-2011	Printed or Copied Double-Sided on Recycled Paper
FAR	52.204-7	Oct-2018	System for Award Management
FAR	52.204-9	Jan-2011	Personal Identity Verification of Contractor Personnel
FAR	52.204-14	Oct-2016	Service Contract Reporting Requirements
FAR	52.204-23	Nov-2021	Prohibition on Contracting for Hardware, Software, and Services Developed or Provided by Kaspersky Lab and Other Covered Entities
FAR	52.204-25	Nov-2021	Prohibition on Contracting for Certain Telecommunications and Video Surveillance Services or Equipment
FAR	52.209-6	Nov-2021	Protecting the Government's Interests When Subcontracting With Contractors Debarred, Suspended, or Proposed for Debarment

FAR	52.215-2	Jun-2020	Audit and Records - Negotiation
FAR	52.215-8	Oct-1997	Order of Precedence - Uniform Contract Format
FAR	52.215-15	Oct-2010	Pension Adjustments and Asset Reversions
FAR	52.215-18	Jul-2005	Reversion or Adjustment of Plans for Post-Retirement Benefits (PRB) other than Pensions
FAR	52.215-19	Oct-1997	Notification of Ownership Changes
FAR	52.216-7	Aug-2018	Allowable Cost and Payment
FAR	52.222-3	Jun-2003	Convict Labor
FAR	52.222-21	Apr-2015	Prohibition of Segregated Facilities
FAR	52.222-26	Sept-2016	Equal Opportunity
FAR	52.222-35	Jun-2020	Equal Opportunity for Veterans
FAR	52.222-36	Jun-2020	Equal Opportunity for Workers with Disabilities
FAR	52.222-37	Jun-2020	Employment Reports on Veterans
FAR	52.222-50	Nov-2021	Combating Trafficking in Persons
FAR	52.222-54	Nov-2021	Employment Eligibility Verification
FAR	52.223-6	May-2001	Drug-Free Workplace
FAR	52.223-18	Jun-2020	Encouraging Contractor Policies to Ban Text Messaging While Driving
FAR	52.232-20	Apr-1984	Limitation of Cost
FAR	52.224-2	Apr-1984	Privacy Act
FAR	52.224-3	Jan-2017	Privacy Training
FAR	52.227-1	Jun-2020	Authorization and Consent
FAR	52.227-2	Jun-2020	Notice and Assistance Regarding Patent and Copyright Infringement
FAR	52.227-14	May-2014	Rights in Data-General
FAR	52.229-4	Feb-2013	Federal, State and Local Taxes (State and Local Adjustments)
FAR	52.232-1	Apr-1984	Payments
FAR	52.232-7	Nov-2021	Payments under Time-and-Materials and Labor-Hour Contracts
FAR	52.232-8	Feb-2002	Discounts for Prompt Payment
FAR	52.232-9	Apr-1984	Limitation on Withholding of Payments
FAR	52.232-11	Apr-1984	Extras
FAR	52.232-18	Apr-1984	Availability of Funds
FAR	52.232-23	May-2014	Assignment of Claims
FAR	52.232-25	Jan-2017	Prompt Payment
FAR	52.232-33	Oct-2018	Payment by Electronic Funds Transfer—System for Award Management
FAR	52.233-1	May-2014	Disputes
FAR	52.233-3	Aug-1996	Protest After Award

FAR	52.233-4	Oct-2004	Applicable Law for Breach of Contract Claim
FAR	52.239-1	Aug-1996	Privacy or Security Safeguards
FAR	52.242-1	Apr-1984	Notice of Intent to Disallow Costs
FAR	52.243-1	Aug-1987	Changes - Fixed-Price, Alternate I (Apr 1984)
FAR	52.245-1	Sept-2021	Government Property – Alternate I (Apr 2012)
FAR	52.246-25	Feb-1997	Limitation of Liability - Services
FAR	52.249-4	Apr-1984	Termination for Convenience of the Government (Services) (Short Form)
FAR	52.249-8	Apr-1984	Default
FAR	52.253-1	Jan-1991	Computer Generated Forms

2. Department of Health and Human Services Acquisition Regulation (HHSAR) (48 CFR Chapter 3) Clauses

HHSAR	352.203-70	Dec-2015	Anti-Lobbying
HHSAR	352.211-3	Dec-2015	Paperwork Reduction Act
HHSAR	352.222-70	Dec-2015	Contractor Cooperation in Equal Employment Opportunity Investigations
HHSAR	352.223-70	Dec-2015	Safety and Health
HHSAR	352.224-70	Dec-2015	Privacy Act
HHSAR	352.224-71	Dec-2015	Confidential Information
HHSAR	352.231-70	Dec-2015	Salary Rate Limitation
HHSAR	352.239-74	Dec-2015	Electronic and Information Technology Accessibility

I-2 – CLAUSES IN FULL TEXT

52.204-13 System for Award Management Maintenance (Oct 2018)

(a) Definitions. As used in this clause—

Electronic Funds Transfer (EFT) indicator means a four-character suffix to the unique entity identifier. The suffix is assigned at the discretion of the commercial, nonprofit, or Government entity to establish additional System for Award Management (SAM) records for identifying alternative EFT accounts (see subpart 32.11) for the same entity.

Registered in the System for Award Management (SAM) means that–

(1) The Contractor has entered all mandatory information, including the unique entity identifier and the EFT indicator (if applicable), the Commercial and Government Entity (CAGE) code, as well as data required by the Federal Funding Accountability and Transparency Act of 2006 (see subpart 4.14), into SAM;

(2) The Contractor has completed the Core, Assertions, Representations and Certifications, and Points of Contact sections of the registration in SAM;

(3) The Government has validated all mandatory data fields, to include validation of the Taxpayer Identification Number (TIN) with the Internal Revenue Service (IRS). The Contractor will be required to provide consent for TIN validation to the Government as a part of the SAM registration process; and

(4) The Government has marked the record "Active".

System for Award Management (SAM) means the primary Government repository for prospective Federal awardee and Federal awardee information and the centralized Government system for certain contracting, grants, and other assistance-related processes. It includes–

(1) Data collected from prospective Federal awardees required for the conduct of business with the Government;

(2) Prospective contractor-submitted annual representations and certifications in accordance with FAR subpart 4.12; and

(3) Identification of those parties excluded from receiving Federal contracts, certain subcontracts, and certain types of Federal financial and non-financial assistance and benefits.

Unique entity identifier means a number or other identifier used to identify a specific commercial, nonprofit, or Government entity. See www.sam.gov for the designated entity for establishing unique entity identifiers.

(b) If the solicitation for this contract contained the provision 52.204-7 with its Alternate I, and the Contractor was unable to register prior to award, the Contractor shall be registered in SAM within 30 days after award or before three days prior to submission of the first invoice, whichever occurs first.

(c) The Contractor shall maintain registration in SAM during contract performance and through final payment of any contract, basic agreement, basic ordering agreement, or blanket purchasing agreement. The Contractor is responsible for the currency, accuracy and completeness of the data within SAM, and for any liability resulting from the Government's reliance on inaccurate or incomplete data. To remain registered in SAM after the initial registration, the Contractor is required to review and update on an annual basis, from the date of initial registration or subsequent updates, its information in SAM to ensure it is current, accurate and complete. Updating information in SAM does not alter the terms and conditions of this contract and is not a substitute for a properly executed contractual document.

(d)

(1)

(i) If a Contractor has legally changed its business name or "doing business as" name (whichever is shown on the contract), or has transferred the assets used in performing the contract, but has not completed the necessary requirements regarding novation and change-of-name agreements in subpart 42.12, the Contractor shall provide the responsible Contracting Officer a minimum of one business day's written notification of its intention to—

(A) Change the name in SAM;

(B) Comply with the requirements of subpart 42.12 of the FAR; and

(C) Agree in writing to the timeline and procedures specified by the responsible Contracting Officer. The Contractor shall provide with the notification sufficient documentation to support the legally changed name.

(ii) If the Contractor fails to comply with the requirements of paragraph (d)(1)(i) of this clause, or fails to perform the agreement at paragraph (d)(1)(i)(C) of this clause, and, in the absence of a properly executed novation or change-of-name agreement, the SAM information that shows the Contractor to be other than the Contractor indicated in the contract will be

considered to be incorrect information within the meaning of the "Suspension of Payment" paragraph of the electronic funds transfer (EFT) clause of this contract.

(2) The Contractor shall not change the name or address for EFT payments or manual payments, as appropriate, in SAM record to reflect an assignee for the purpose of assignment of claims (see FAR subpart 32.8, Assignment of Claims). Assignees shall be separately registered in the SAM. Information provided to the Contractor's SAM record that indicates payments, including those made by EFT, to an ultimate recipient other than that Contractor will be considered to be incorrect information within the meaning of the "Suspension of Payment" paragraph of the EFT clause of this contract.

(3) The Contractor shall ensure that the unique entity identifier is maintained with the entity designated at www.sam.gov for establishment of the unique entity identifier throughout the life of the contract. The Contractor shall communicate any change to the unique entity identifier to the Contracting Officer within 30 days after the change, so an appropriate modification can be issued to update the data on the contract. A change in the unique entity identifier does not necessarily require a novation be accomplished.

(e) Contractors may obtain additional information on registration and annual confirmation requirements at https://www.sam.gov.

52.216-5 Price Redetermination—Prospective (Jan 2022)

(a) *General*. The unit prices and the total price stated in this contract shall be periodically redetermined in accordance with this clause, except that-

(1) The prices for supplies delivered and services performed before the first effective date of price redetermination (see paragraph (c) of this clause) shall remain fixed; and

(2) In no event shall the total amount paid under this contract exceed any ceiling price included in the contract.

(b) Definition. "Costs," as used in this clause, means allowable costs in accordance with part 31 of the Federal Acquisition Regulation (FAR) in effect on the date of this contract.

(c) *Price redetermination periods*. For the purpose of price redetermination, performance of this contract is divided into successive periods. The first period shall extend from the date of the contract to ***12 months***, and the second and each succeeding period shall extend for **12 months** from the end of the last preceding period, except that the parties may agree to vary the length of the final period. The first day of the second and each succeeding period shall be the effective date of price redetermination for that period.

(d) Data submission.

(1) Not more than **180 days** nor less than **30 days** before the end of each redetermination period, except the last, the Contractor shall submit-

(i) Proposed prices for supplies that may be delivered or services that may be performed in the next succeeding period, and-

(A) An estimate and breakdown of the costs of these supplies or services in the format of Table 15-2, FAR 15.408, or in any other form on which the parties may agree;

(B) Sufficient data to support the accuracy and reliability of this estimate; and

(C) An explanation of the differences between this estimate and the original (or last preceding) estimate for the same supplies or services; and

(ii) A statement of all costs incurred in performing this contract through the end of the **12 months** before the submission of proposed prices in the format of Table 15-2, FAR 15.408 (or in any other form on which the parties may agree), with sufficient supporting data to disclose unit costs and cost trends for-

(A) Supplies delivered and services performed; and

(B) Inventories of work in process and undelivered contract supplies on hand (estimated to the extent necessary).

(2) The Contractor shall also submit, to the extent that it becomes available before negotiations on redetermined prices are concluded-

(i) Supplemental statements of costs incurred after the date stated in subdivision (d)(1)(ii) of this section for-

(A) Supplies delivered and services performed; and

(B) Inventories of work in process and undelivered contract supplies on hand (estimated to the extent necessary); and

(ii) Any other relevant data that the Contracting Officer may reasonably require.

(3) If the Contractor fails to submit the data required by paragraphs (d)(1) and (2) of this section, within the time specified, the Contracting Officer may suspend payments under this contract until the data are furnished. If it is later determined that the Government has overpaid the Contractor, the Contractor shall repay the excess to the Government immediately. Unless repaid within 30 days after the end of the data submittal period, the amount of the excess shall bear interest, computed from the date the data were due to the date of repayment, at the rate established in accordance with the Interest clause.

(e) *Price redetermination*. Upon the Contracting Officer's receipt of the data required by paragraph (d) of this section, the Contracting Officer and the Contractor shall promptly negotiate to redetermine fair and reasonable prices for supplies that may be delivered or services that may be performed in the period following the effective date of price redetermination.

(f) Contract *modifications*. Each negotiated redetermination of prices shall be evidenced by a modification to this contract, signed by the Contractor and the Contracting Officer, stating the redetermined prices that apply during the redetermination period.

(g) *Adjusting billing prices*. Pending execution of the contract modification (see paragraph (f) of this section), the Contractor shall submit invoices or vouchers in accordance with the billing prices stated in this contract. If at any time it appears that the then-current billing prices will be substantially greater than the estimated final prices, or if the Contractor submits data showing that the redetermined price will be substantially greater than the current billing prices, the parties shall negotiate an appropriate decrease or increase in billing prices. Any billing price adjustment shall be reflected in a contract modification and shall not affect the redetermination of prices under this clause. After the contract modification for price redetermination is executed, the total amount paid or to be paid on all invoices or vouchers shall be adjusted to reflect the agreed-upon prices, and any requested additional payments, refunds, or credits shall be made promptly.

(h) *Quarterly limitation on payments statement*. This paragraph (h) applies only during periods for which firm prices have not been established.

(1) Within 45 days after the end of the quarter of the Contractor's fiscal year in which a delivery is first made (or services are first performed) and accepted by the Government under this contract, and for each quarter thereafter, the Contractor shall submit to the contract administration office (with a copy to the contracting office and the cognizant contract auditor) a

statement, cumulative from the beginning of the contract, showing-

(i) The total contract price of all supplies delivered (or services performed) and accepted by the Government and for which final prices have been established;

(ii) The total costs (estimated to the extent necessary) reasonably incurred for, and properly allocable solely to, the supplies delivered (or services performed) and accepted by the Government and for which final prices have not been established;

(iii) The portion of the total interim profit (used in establishing the initial contract price or agreed to for the purpose of this paragraph (h)) that is in direct proportion to the supplies delivered (or services performed) and accepted by the Government and for which final prices have not been established; and

(iv) The total amount of all invoices or vouchers for supplies delivered (or services performed) and accepted by the Government (including amounts applied or to be applied to liquidate progress payments).

(2) The statement required by paragraph (h)(1) of this section need not be submitted for any quarter for which either no costs are to be reported under subdivision (h)(1)(ii) of this section, or revised billing prices have been established in accordance with paragraph (g) of this section, and do not exceed the existing contract price, the Contractor's price-redetermination proposal, or a price based on the most recent quarterly statement, whichever is least.

(3) Notwithstanding any provision of this contract authorizing greater payments, if on any quarterly statement the amount under subdivision (h)(1)(iv) of this section exceeds the sum due the Contractor, as computed in accordance with subdivisions (h)(1)(i), (ii), and (iii) of this section, the Contractor shall immediately refund or credit to the Government the amount of this excess. The Contractor may, when appropriate, reduce this refund or credit by the amount of previous refunds or credits affected under this clause. If any portion of the excess has been applied to the liquidation of progress payments, then that portion may, instead of being refunded, be added to the unliquidated progress payment account, consistent with the Progress Payments clause. The Contractor shall provide complete details to support any claimed reductions in refunds.

(4) If the Contractor fails to submit the quarterly statement within 45 days after the end of each quarter and it is later determined that the Government has overpaid the Contractor, the Contractor shall repay the excess to the Government immediately. Unless repaid within 30 days after the end of the statement submittal period, the amount of the excess shall bear interest, computed from the date the quarterly statement was due to the date of repayment, at the rate established in accordance with the Interest clause.

(i) *Subcontracts*. No subcontract placed under this contract may provide for payment on a cost-plus-a-percentage-of-cost- basis.

(j) *Disagreements*. If the Contractor and the Contracting Officer fail to agree upon redetermined prices for any price redetermination period within 60 days (or within such other period as the parties agree) after the date on which the data required by paragraph (d) of this section are to be submitted, the Contracting Officer shall promptly issue a decision in accordance with the Disputes clause. For the purpose of paragraphs (f), (g), and (h) of this section, and pending final settlement of the disagreement on appeal, by failure to appeal, or by agreement, this decision shall be treated as an executed contract modification. Pending final settlement, price redetermination for subsequent periods, if any, shall continue to be negotiated as provided in this clause.

(k) *Termination*. If this contract is terminated, prices shall continue to be established in

accordance with this clause for (1) completed supplies and services accepted by the Government and (2) those supplies and services not terminated under a partial termination. All other elements of the termination shall be resolved in accordance with other applicable clauses of this contract.

(End of clause)

52.217-8 Option to Extend Services (Nov 1999)

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

52.217-9 Option to Extend the Term of the Contract (MAR 2000)

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.

52.242-15 Stop-Work Order (Aug. 1989)

(a) The Contracting Officer may, at any time, by written order to the Contractor, require the Contractor to stop all, or any part, of the work called for by this contract for a period of 90 days after the order is delivered to the Contractor, and for any further period to which the parties may agree. The order shall be specifically identified as a stop-work order issued under this clause. Upon receipt of the order, the Contractor shall immediately comply with its terms and take all reasonable steps to minimize the incurrence of costs allocable to the work covered by the order during the period of work stoppage. Within a period of 90 days after a stop-work is delivered to the Contractor, or within any extension of that period to which the parties shall have agreed, the Contracting Officer shall either—

(1) Cancel the stop-work order; or

(2) Terminate the work covered by the order as provided in the Default, or the Termination for Convenience of the Government, clause of this contract.

(b) If a stop-work order issued under this clause is canceled or the period of the order or any extension thereof expires, the Contractor shall resume work. The Contracting Officer shall make an equitable adjustment in the delivery schedule or contract price, or both, and the contract shall be modified, in writing, accordingly, if—

(1) The stop-work order results in an increase in the time required for, or in the Contractor's cost properly allocable to, the performance of any part of this contract; and

(2) The Contractor asserts its right to the adjustment within 30 days after the end of the period of work stoppage; provided, that, if the Contracting Officer decides the facts justify the action, the Contracting Officer may receive and act upon the claim submitted at any time before final payment under this contract.

(c) If a stop-work order is not canceled and the work covered by the order is terminated for the convenience of the Government, the Contracting Officer shall allow reasonable costs resulting from the stop-work order in arriving at the termination settlement.

(d) If a stop-work order is not canceled and the work covered by the order is terminated for default, the Contracting Officer shall allow, by equitable adjustment or otherwise, reasonable costs resulting from the stop-work order.

Alternate I (Apr 1984). If this clause is inserted in a cost-reimbursement contract, substitute in paragraph (a)(2) the words "the Termination clause of this contract" for the words "the Default, or the Termination for Convenience of the Government clause of this contract." In paragraph (b) substitute the words "an equitable adjustment in the delivery schedule, the estimated cost, the fee, or a combination thereof, and in any other terms of the contract that may be affected" for the words "an equitable adjustment in the delivery schedule or contract price, or both."

SECTION J - LIST OF ATTACHMENTS

The following attachments are incorporated into this solicitation/contract.

Attachment Number	Title	Link or Document
1	Compliance Program Guidance Manual (CGPM 7382.845) – Inspection of Medical Device Manufacturers	 CPG7382.84
2	Guide to Inspection of Quality Systems	 Guide-to-Inspections -of-Quality-Systems.p
3	FDA Investigations Operations Manual (IOM)	 IOM 2021

4	Review and Update of Device Establishment Inspection Processes and Standards	 Device Establishment Inspection Processes a
5	Records Management Training Presentation	 2021 Annual FDA Records Management
6	FMD-76 State Contract Evaluation of Inspectional Performance	 FMD-76.pdf
7	Electronic State Access to Field Accomplishments and Compliance Tracking System (e-SAF)	 eSAF Contract Attachment.pdf
8	Travel Cost Estimate	 Attachment 5 - Travel Cost Estimate (TCE).xls
9	Non-Disclosure Agreement	 NDA Single Signature Rev DIDP e
10	Disclosure of Lobbying	 Disclosure of Lobbying.pdf