## PART I

# **SECTION B - SUPPLIES OR SERVICES AND PRICES/COSTS**

# **B.1 SOLICITATION DESCRIPTION**

The Contractor shall furnish all necessary facilities, materials, and personnel, and shall perform all non-personal services and program support necessary in a requirement titled, "Vape Inspections".

This is a combined synopsis/solicitation for commercial items prepared in accordance with the format in Subpart 12.6, as supplemented with additional information included in this notice. This announcement constitutes the only solicitation; proposals are being requested and a written solicitation will not be issued.

This solicitation is a Request for Proposals (RFP). The solicitation document and incorporated provisions and clauses are those in effect through Federal Acquisition Circular 2005-96. The associated North American Industrial Classification System (NAICS) code for this procurement is <u>541990</u>, All Other Professional, Scientific and Technical Services. Its associated Small Business Size Standard is <u>\$15M</u>.

This requirement is for a woman owned small business Set-Aside as a result of this combined synopsis/solicitation.

# **B.2 CONTRACT TYPE**

The government intends to make a single Indefinite-Delivery, Indefinite-Quantity (IDIQ) Contract award with the issuance of Labor Hour and Firm-Fixed price task orders. The structure of the contract shall be a base period of one (1) year followed by four (4) separate option periods. The total potential period of performance should all four (4) options be awarded is five (5) years.

# **B.3 CONTRACT CEILING**

The IDIQ guaranteed minimum amount will be \$5,000.00 over five (5) years inclusive of options. The contract maximum ceiling amount will be \$23,000,000.00 over five (5) years inclusive of options.

# **B.4 PRICING**

The pricing chart below outlines all of the labor categories that shall be required throughout the life of the contract. The Contractor shall provide services in accordance with the Statement of Work with **fully loaded**, fixed hourly rates.

Labor Rate Pricing Chart:

Labor Category	Estimated Annual Hours	Year 1 Hourly Rates (Base)	Year 2 Hourly Rates (Option #1)	Year 3 Hourly Rates (Option #2)	Year 4 Hourly Rates (Option #3)	Year 5 Hourly Rates (Option #4)
Program Manager	2,080	\$	\$	\$	\$	\$
Program Coordinator	21,560	\$	\$	\$	\$	\$
Inspector	41,600	\$	\$	\$	\$	\$
	Total	\$	\$	\$	\$	\$

Expense	Quantity	Unit	Total
Other Direct Costs	1	Lot	\$80,000
Travel	1	Lot	\$1,000,000

Note: Reference Section C.5 for a full description of each labor category.

## SECTION C - DESCRIPTION/SPECIFICATIONS/WORK STATEMENT

## C.1 BACKGROUND

On June 22, 2009, the President signed the Family Smoking Prevention and Tobacco Control Act (Tobacco Control Act) into law. The Tobacco Control Act amended the Federal Food, Drug, and Cosmetic Act (FD&C Act) by, among other things, adding a new chapter granting the Food and Drug Administration (FDA) authority to regulate the manufacturing, marketing, and distribution of tobacco products to protect the public health and to reduce tobacco use by minors. Under the Tobacco Control Act, establishments engaged in the retail sale of FDA-regulated tobacco products ("retailers") are subject to FDA inspections to document compliance with applicable provisions of the FD&C Act and implementing regulations issued by FDA.

## C.2 OBJECTIVES

The purpose of this contract is to inspect establishments in which regulated tobacco products are manufactured, processed, packed, or held for introduction into interstate commerce or after such introduction; entities subject to inspection may assemble, prepare, repack, prepare, compounded, label or relabel ("establishments"). FDA will utilize the information and evidence collected during inspections to document compliance with the FD&C Act, and all applicable requirements and to consider and potentially pursue enforcement actions.

If FDA determines that the results of an inspection indicate a violation of any applicable requirements, FDA may use information and evidence obtained during inspections to pursue any

of the enforcement actions authorized by the FD&C Act, including, but not limited to, warning letters, civil money penalties, and no-tobacco-sale orders.

# C.3 SCOPE OF WORK

Independently and not as an agent of the Government, the Contractor shall furnish all necessary labor, services, supplies, equipment, facilities, and any other personnel or material resources (except as may be expressly set forth in this Contract as furnished by FDA) and otherwise do all things necessary for the performance of the work described herein.

The Contractor shall inspect establishments engaged in the manufacture, assembly, preparation, compounding, processing, packing or repacking, labeling or relabeling, or holding of regulated tobacco products to document compliance with all applicable provisions of the Food, Drug and Cosmetic Act, including but not limited to: Sections 903(a)(1), 903(a)(7)(A), 910, and 911 of the FD&C Act (21 U.S.C. § 387c(a)(1); 21 U.S.C. § 387c(a)(7)(A); 21 U.S.C. § 387j; 21 U.S.C. § 387k) (available at

https://www.gpo.gov/fdsys/browse/collectionUScode.action?collectionCode=USCODE). Establishments subject to inspection under this Contract include entities engaged in retail activities, including but not limited to "vape shops," where regulated tobacco products may be manufactured, prepared, compounded, or processed within the premises. The Contractor shall inspect all establishments designated on lists provided by FDA.

## Scope-Conducting inspections and providing related support services

Task Orders shall encompass services in one or more of the following task areas:

# Activity 1- Transition-in

Transition-In services provide an orderly transition from the incumbent contractor to the successor contractor. The successor Contractor shall work toward the Government's goal of ensuring minimal disruption to the current operational activities.

The Contractor shall provide Transition-In support during the transition period. Upon completion of the transition-in period, the Contractor shall assume full operating accountability and responsibility for all tasks. Specifics related to the transition-in tasks and timeline will be specified at the Task Order level. Representative transition activities under this task area include:

- a. Develop a Transition-In Plan to ensure full operating accountability and responsibility for the Task Order;
- b. Conduct and coordinate all onboarding activities and obtain and submit all required paperwork, badging, and commissions for all applicable Contractor personnel;
- c. Participate in Transition-In meetings and knowledge transfer activities; and

- d. Ensure Contractor key personnel are available to work immediately upon Task Order award.
- e. Obtaining from the incumbent contractor or FDA (if no incumbent contractor), whichever is applicable, all current contact information for all inspectors and minors currently employed by the incumbent contractor and any subcontractor(s) and all current contact information for all inspectors and minors who participated in an FDA inspection within the past five years while employed by the incumbent contractor, any subcontractor, or a preceding contractor.

# Activity 2 - Program Management

The Contractor shall provide program management services to ensure the quality, timeliness, and accuracy of its work under this Contract and the applicable Task Order/s. Program management also includes budget, schedule, and quality management of each Task Order and all services and deliverables provided thereunder. Representative activities include:

- a. Developing, maintaining, and implementing a quality control plan (QCP) for the Task Order. The QCP shall include quality assurance and quality control activities as described below:
  - Periodic reviews of deliverables and delivered information (including all inspection results, data, documents, and photos delivered to FDA) by persons different than those preparing or collecting the deliverables or delivered information, and
  - Maintenance of QA records detailing the findings of those reviews.
  - Accuracy: Work product, deliverables, delivered data (including but not limited to all reports, inspection results, data, documents, and photos delivered to FDA) shall be accurate in presentation and technical content,
  - Clarity: Work product, deliverables, and delivered data shall be clear and concise.
  - Consistency to Requirements: All services, work product, deliverables, and delivered data must satisfy all requirements of this contract and the applicable Task Order.
  - Timeliness: All services, work product, deliverables, and delivered data shall be submitted by the due date specified in this contract and the applicable Task Order,
  - Format: All work product and deliverables shall be submitted in formats and media mutually agreed upon prior to submission.
  - Mitigation of risks and other performance issues as they arise.
- b. Inspection results are submitted into FDA systems electronically by inspectors promptly after completion of an inspection. The Contractor shall review inspection results submitted by inspectors to ensure conformity with quality and acceptability requirements in the contract and task order;

- c. Provide monthly program status reports to FDA. The contents and format of monthly program status reports will be specified at the Task Order level, and may encompass some or all of the following types of information:
  - Status and progress of tasks
  - Cost and schedule variances against agreed-upon baselines;
  - Significant risks to scheduled deliverables and plans to mitigate any risks;
  - Issues, recommendations, and escalation measures; and
  - Progress against task order service level metrics;
- d. Collecting system and performance metrics associated with each task area, as will be defined in each Task Order;
- e. Proactively informing FDA of any issues, problems and recommendations that should be addressed in order for the overall effective accomplishment of task order goals. Recommendations for actions that need to be taken by FDA or other contractors shall be clearly defined and communicated to FDA and have identified dates for completion.
- f. Prepare materials for, and participate in meetings including, but not limited to: program reviews, management briefings, and other similar meetings. Preparing for and participating in Program Status Review meetings and In-Process Review meetings, in accordance with the terms of this contract (see Section 7.2) and the applicable task order.
- g. Participating in a Kick-Off Meeting at a date and time of FDA's choosing prior to commencement of any inspections. The Kick-Off Meeting may be conducted remotely via teleconference or videoconference
- h. Facilitating processing of background investigations and FDA Commissions, providing timely notification of personnel changes to FDA, and ensuring timely execution of any required follow-up actions related to onboarding new Contract personnel (e.g., initiating background investigations) or processing outgoing personnel (e.g., return of credentials and equipment).
- i. Securing a signed FDA Form 3398 for each Contractor employee and substantially similar agreement from each subcontractor who is or will be involved in the inspection program under this Contract or who has or will have access to any non-public information arising under or related to this Contract.
- j. Securing and maintaining all required information and documents pertaining to inspectors, including maintaining current contact information for currently-employed inspectors and former inspectors who conducted inspections within the past five years.
- k. Monitoring and providing timely notification to FDA of any actual, apparent,

or potential conflicts of interest for any Contractor or subcontractor personnel, and otherwise ensuring that all statutory and contractual requirements relating to conflicts of interest are met.

- 1. Facilitating timely implementation and completion of all training requirements for all employees or subcontractor employees under this Contract.
- m. Ensuring all statutory and contractual requirements for inspection procedures are communicated, implemented, and followed by all Contractor and subcontractor employees.
- n. Ensuring timely completion of all inspection assignments and timely submission of all deliverables.
- o. The Contractor is responsible for ensuring the quality, completeness, accuracy, adequacy, and contractual compliance of all services, deliverables, and delivered information under this contract and any Task Order. All services shall conform to all contractual and Task Order requirements, and all deliverables and delivered information shall be complete, accurate, and useable by FDA.

# Activity 3-Complete FDA training session for inspectors

All Contractor and subcontractor personnel performing under the Contract must complete an initial training session conducted by FDA prior to performing any work under the Contract. The training will address FDA inspectional jurisdiction, how to conduct inspections, completion of inspectional forms, gathering hardcopy documentary evidence, photographing evidence, submitting forms and evidence to FDA, the importance of protecting non-public information, and the consequences of unauthorized disclosure of non-public information. Inspectors must have their background investigation completed and cleared prior to reviewing the training materials. Training may be conducted remotely via live videoconference with FDA officials. The Contractor must ensure that all parts of the FDA-mandated training are implemented as prescribed and that all Contractor and subcontractor personnel performing under the Contract complete the required training.

Any Contractor or subcontractor personnel hired after the initial training session has been conducted by FDA must complete a training session prior to commencing work under the Contract or conducting any inspections. Upon hiring personnel to perform under the Contract, the Contractor or subcontractor shall promptly contact the FDA to schedule that second training session, and FDA will select a date and time to conduct remote training Commissioned inspectors who make multiple or repeated procedural errors shall be required to complete a mandatory refresher training session. FDA shall identify and notify commissioned inspectors subject to the mandatory refresher training requirement, and FDA will select a date and time to conduct remote refresher training via live videoconference not to exceed two hours in length.

Once the Contractor or any subcontractor receives notice from FDA regarding an inspector subject to the mandatory refresher training requirement, that inspector shall not conduct any inspections until he/she has completed the refresher training course.

# Activity 4- Conduct Inspections

Inspect establishments engaged in the manufacture, assembly, preparation, compounding, processing, packing or repacking, labeling or relabeling, or holding of regulated tobacco products for introduction into interstate commerce or after such introduction to document compliance with all applicable provisions of the Food, Drug and Cosmetic Act, including but not limited to:

Sections 903(a)(1), 903(a)(7)(A), 910, and 911 of the FD&C Act (21 U.S.C. § 387c(a)(1); 21 U.S.C. § 387c(a)(7)(A); 21 U.S.C. § 387j; 21 U.S.C. § 387k).

The Contractor shall inspect all establishments designated on quarterly lists provided by FDA. Inspections of all establishments designated on each quarterly list shall be completed within the quarter to which they are assigned. Lists shall be provided by FDA 30 calendar days prior to the beginning of each quarter and shall encompass establishments located within the United States and territories. For purposes of this clause, "quarter(s)" refers to the quarters comprising the Federal fiscal year (October 1 through December 31; January 1 through March 31; April 1 through June 30; July 1 through September 30).

During each inspection, the Contractor shall complete the following tasks:

- 1. Complete and present to the establishment an original, properly executed, and signed Form FDA 482 (Notice of Inspection). The Contractor shall retain a copy of the signed Form FDA 482 for submission to FDA.
- 2. Complete an inspectional form provided by FDA. An inspectional form shall contain at least fifteen questions pertaining to the following categories of information:
  - a. Administrative information about the establishment, potentially including but not limited to the following information: name, address, city, state, size of establishment, hours of operation.
  - b. Inspectional questions related to all applicable provisions of the Food, Drug and Cosmetic Act, including but not limited to: Sections 903(a)(1), 903(a)(7)(A), 910, and 911 of the FD&C Act, potentially including but not limited to the following topics:
    - Establishment is a retailer, manufacturer, or both.
    - Products the establishment manufactures.
    - Establishment imports or exports regulated tobacco products.
    - Establishment is potentially in violation of Sections 903(a)(1) or 903(a)(7)(A) of the FD&C Act, which prohibit false or misleading labeling and advertising for regulated tobacco products.

- Establishment is potentially in violation of Section 910 of the FD&C Act, which prohibits introducing or delivering for introduction into interstate commerce any "new tobacco product" without an order from FDA authorizing the marketing of the product.
- Establishment is potentially in violation of Section 911 of the FD&C Act, which prohibits introducing or delivering for introduction into interstate commerce any "modified risk tobacco product" without an FDA order in effect.

The Contractor shall observe, review, request, or otherwise obtain access to all information necessary to complete the inspectional form and provide FDA with all information requested therein.

FDA may generate multiple versions of the inspectional form, but all versions shall conform to the parameters of this section.

3. Take photographs of evidence pertaining to the information requested in the inspectional form. The Contractor may be required to photograph evidence including but not limited to documents, written procedures, brochures, products, signage, advertising, and labeling. All photographs must be clear, any inspector's writing in the photograph must be legible (if applicable), and the photograph must fully capture the required information.

The Contractor shall use FDA-furnished handheld devices to take photographs of evidence and electronically submit such photographs to FDA. Use of any other equipment to take photographs during an inspection, or to store or transmit such photographs at any time, is prohibited. Inspections shall not be considered complete until the Contractor has compiled all information requested in the inspectional form, obtained the signed form 482, and obtained clear photographs of all evidence requested by FDA in the inspectional form, except to the extent that any such information, Form 482, or photograph is not obtainable or collectable under the inspectional authorities granted to FDA in 21 U.S.C. §§ 372-74 and 21 U.S.C. § 387e (available at <a href="https://www.gpo.gov/fdsys/browse/collectionUScode.action?collectionCode=USCODE">https://www.gpo.gov/fdsys/browse/collectionUScode.action?collectionCode=USCODE</a>) or the establishment denies access to any information or evidence properly and diligently requested by the Contractor.

The Contractor shall conduct inspections in accordance with the applicable provisions of the FD&C Act). Procedural requirements for all inspections include, but are not limited to, the following:

1. The Contractor shall present FDA-issued credentials and an original, properly executed, and signed Form FDA 482 (Notice of Inspection) to the owner, operator, or agent in charge of the establishment. The Contractor shall retain a copy of the signed Form FDA 482 for submission to FDA.

The Contractor may take actions authorized under 21 U.S.C. §§ 373-74 that are necessary to obtain the information and evidence required by FDA under this Contract, including but not limited to the following statutorily-authorized actions:

1. Entry of any establishment in which regulated tobacco products are manufactured, processed, packed, or held.

- 2. Inspection of:
  - a. All pertinent equipment, finished and unfinished materials, containers, and labeling therein.
  - b. All things therein (including records, files, papers, processes, controls, and facilities) bearing on any violation of the FD&C Act, including whether regulated tobacco products which are adulterated or misbranded within the meaning of the FD&C Act, or which may not be manufactured, introduced into interstate commerce, or sold, or offered for sale by reason of any provision of the FD&C Act, have been or are being manufactured, processed, packed, transported, or held in any such place.

In accordance with 21 U.S.C. § 374, inspections shall not encompass inspection or review of any financial data, sales data other than shipment data, pricing data, personnel data (other than data as to qualification of technical and professional personnel performing functions subject to the FD&C Act), and research data (other than data relating to tobacco products and subject to reporting and inspection under regulations lawfully issued pursuant to Chapter IX of the FD&C Act (21 U.S.C. § 387 et seq.)).

If an inspection cannot be completed, the Contractor must notify FDA within five (5) business days of initiating the inspection. Notification of an incomplete inspection must be submitted electronically via email to the FDA and must include an explanation of the reason(s) why the inspection could not be completed.

c. Evidence Storage

The Contractor shall ensure proper collection, handling, sealing, documentation, storage, and submission of evidence pursuant to FDA protocol to ensure that evidence is maintained in a manner that shall allow FDA to use the evidence to support an enforcement action. The Contractor shall store evidence for the duration of the contract and shall perform a single transfer of all evidence to FDA or an FDA contractor prior to the end of the contract. The contractor must be capable of being promptly furnished to FDA upon request.

# Activity 5 - Provide support services related to FDA enforcement actions

The Contractor shall take reasonable actions to ensure that inspectors employed by the Contractor shall be available to testify as witnesses, if and when requested by FDA, in administrative hearings and court proceedings related to inspections they conducted. The Contractor shall maintain current contact information for all inspectors currently employed by the Contractor and shall provide FDA with current contact information for any currently-employed inspector within five (5) business days of request. The Contractor shall attempt to maintain and annually verify current contact information for all inspectors who were employed within the past five years but are no longer employed by the Contractor, and the most recent contact information for formerly-employed inspectors shall be provided to FDA within five (5) business days of request.

Submit completed inspectional form, signed Form FDA 482, and all photographs of evidence to FDA within five (5) business days of initiating the inspection.

The Contractor shall submit the completed inspectional form and the signed Form FDA 482 to the FDA within five (5) business days of initiating the inspection. If hard copies of the Form FDA 482 are required, they must be transmitted to FDA by a commercial shipping service that tracks shipments and provides delivery confirmation. The completed inspectional form shall be submitted electronically via the FDA-furnished handheld device.

The Contractor shall electronically submit all photographs of evidence to the FDA within five (5) business days of initiating the inspection. All photographs collected during an inspection must be submitted to the FDA directly from the Contractor's FDA-furnished handheld device.

The Contractor shall respond to any FDA request for clarification regarding incomplete, inaccurate, unclear, or deficient submissions of inspectional forms, FDA 482 forms, collected hardcopy documentary evidence, if available, or photographs of evidence within two (2) business days of receiving such request. Responses shall be submitted to the FDA official that submitted the request for clarification. The contractor will not be required to return to a facility to acquire additional information in conjunction with that specific inspection assignment. If and when necessary, follow up actions will consist of inspectors or key personnel responding to emailed inquiries requesting clarification regarding submitted inspection results, forms, or photos. Responses via email or phone call shall be required.

# Activity 6 - Transition-out

The Contractor shall provide transition-out services, if applicable, to facilitate the transition of contracted activities and services to the Federal Government or to a follow-on Contractor at the end of the period of performance of the Task Order or contract.

The Contractor shall provide transition out activities, including creating and implementing a transition out plan and leading Technical Exchange Meetings (TEMs) with the successor to impart knowledge of all processes, systems, applications, and databases. During this period, the Contractor shall ensure no degradation in support provided under the task order. Between the COR-designated turnover date and the end of the applicable task order period of performance, the outgoing Contractor shall ensure all task order activities are closed out and provide sustainment support to complete the transition.

Representative transition-out duties under each Task Order include:

1. Providing the succeeding contractor or FDA (if no succeeding contractor), whichever is applicable, with all current contact information for all inspectors and minors currently employed by the Contractor and any subcontractor(s) and all current contact information for all inspectors and minors who participated in an FDA inspection within the past five years while employed by the Contractor, any subcontractor, or a preceding contractor.

- 2. Providing FDA with a current inventory of all Government-owned assets possessed or used by the Contractor along with full support in the reconciliation of this inventory. The inventory shall include all physical evidence and FDA-furnished equipment, and the Contractor shall provide the completed inventory log to FDA with the date that the packages are being shipped to FDA.
- 3. The Contractor shall gather and return the following items using FDA-provided shipping label(s):
  - a. FDA issued handheld devices with each device's accessories (including cases, chargers, and/or styluses) from each inspector with a list of the inventory.
  - b. Unused FDA materials, including Form FDA 482.
  - c. All government-furnished equipment and any other equipment for which title vests in the government under any clause of the contract or task order.

Additional details, including the length of the transition-out period, shall be specified at the task order level.

# C. 4 KEY PERSONNEL

The Contractor shall designate a Program Manager who shall be responsible for overall Contract coordination and communicating with FDA. The Program Manager shall be responsible for all aspects of the program management work described herein. This position shall be the main point of contact for FDA.

The Key Personnel specified in this Contract are considered to be essential to work performance. At least 30 calendar days prior to diverting any designated Key Personnel to other programs or contracts (or as soon as possible, if an individual must be replaced, for example, as a result of leaving the employ of the Contractor), the Contractor shall notify the Contracting Officer and Contracting Officer's Representative and shall submit a comprehensive justification for the diversion or replacement request (including proposed substitutions for Key Personnel) to permit evaluation by the Government of the impact on performance under this contract. The Contractor shall not divert or otherwise replace any Key Personnel without the written consent of the Contracting Officer. All changes must be approved by the Contracting Officer (CO) and Contracting Officer's Representative.

# C. 5 LABOR CATEGORY DESCRIPTIONS

# Program Manager

Organizes, directs, and coordinates the planning and execution of all activities and personnel associated with inspection services project. Responsible for customer satisfaction and delivering high levels of quality and timely information as required by the SOW. Meets or exceeds customer expectations by developing and delivering insightful, value-added solutions that address potential customer issues. Demonstrates strong written and oral communication skills and functions as the main point of contact with FDA. Remains current on industry and market

trends to anticipate and identify new business challenges and customer issues to ensure the success of the project,

#### **Program Coordinator**

Under supervision of the Program Manager, shall assist with the planning and execution of all activities and coordination with personnel associated with inspection services. Program Coordinator responsibilities include working closely the Program and liaising with Inspectors to ensure that inspection goals are met. Administrative duties, such as maintaining project documentation and inspection reports are important. Excellent time management and communication skills are required as you'll collaborate with internal team members and FDA to ensure contract deliverables are met.

#### **Inspector** (Commissionable)

Must be a state employee and be able to obtain credentials and commission to conduct inspections in compliance with provisions of the Food, Drug and Cosmetic Act. Must be able to coordinate inspections as well as accurately record information collected from inspection sites for reporting purposes. Must have strong communication skills to communicate with retail sites being inspected as well as the Program Manager and Program Coordinator to convey appropriate information. Additionally, inspectors may be required to testify as witnesses in administrative hearings during the period of performance of the contract.

A FDA commission is a delegated authority from the Commissioner of Food and Drugs to an individual to act on his/her behalf. A health, food, or drug officer or employee of any State, Territory, or political subdivision thereof (herein referred to as "state and local officials") may be commissioned to conduct examinations and investigations on FDA's behalf for the purposes of the Act.

## **SECTION D - PACKAGING AND MARKING**

All deliverables required under this contract shall be packaged, marked and shipped in accordance with the Government specifications below. At a minimum, all deliverables shall be marked with the contract number and contractor name.

1. The Contractor shall guarantee that all required materials shall be delivered in immediate usable and acceptable condition.

2. The Contractor shall scan all deliverables for viruses before submitting to the FDA.

3. Deliverables under this contract shall be prepared and packaged for shipment using standard shipping practices to ensure safe and timely delivery.

## **SECTION E - INSPECTION AND ACCEPTANCE**

The FDA COR will inspect and make acceptance decisions for all materials, documents, and services provided under this contract. For the purpose of this Section, the FDA COR is the authorized representative of the Contracting Officer.

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52.246-6 - Inspection - Time-and-Material and Labor-Hour (MAY 2001)

# **SECTION F - DELIVERIES OR PERFORMANCE**

# F.1 ANTICIPATED DELIVERABLES

Note: Actual deliverables, deliverable schedules, Progress Reports and Status meetings shall be established in the issuance of each individual task order. Additional Reporting Requirements may be included in each Task Order.

<u>Progress Reports</u> - The Contractor shall submit one (1) electronic copy of the Progress Report to the COR and Contracts Specialist. The report shall include a status update on each task worked on and deliverables submitted, any problems encountered, and suggestions for addressing problems each period. If the tasks are cost reimbursable in nature, an accounting of applicable staff who worked on the tasks as well as any deviations from the original projection of hours planned vs. actually incurred will be required.

The Contractor shall submit monthly metrics reports to FDA by the 10th business day of the following month. Monthly reports must accurately track the following metrics:

- Number of establishments assigned for the quarter;
- Number of inspections completed;
- Number of establishments pending inspection;
- Number of inspections not completed identified by reason (e.g., refusal, or investigator unable to meet quota for the quarter).

Monthly reports shall be submitted electronically as a "PDF" attachment emailed to the Contracting Officer's Representative (COR).

**Program Status Review meetings (PSRs)**- The Contractor shall facilitate and participate in PSR meetings as needed. PSRs shall be held in person at the Contractor's facility or remotely via teleconference, at FDA's discretion. PSRs shall encompass review of Contractor's overall performance under the applicable task order, quality and quantity of services (including review of inspection services, results, and all facets of performance), quality and timeliness of deliverables, and any other issues pertaining to performance of the task order under this contract. If requested by FDA, the Contractor shall provide advance copies of all relevant performance and QA data requested by FDA prior to a scheduled PSR.

# **F.2 ORDERING PERIOD**

Task Orders may be issued up to the final day of this contract, and the contract shall remain in force to allow for the completion of all task orders issued. However, the Government shall not issue, and the Contractor shall not accept any new task orders issued subsequent to the performance period of this contract.

## **F.3 PERIOD OF PERFORMANCE**

The period of performance for the base period of the contract shall be one (1) year from the effective date of the contract.

Base Year	Dates TBD
Dase Tear	Dates IBD

### **F.4 OPTION PERIODS**

Option	PERIOD		
Option Period One (1)	One (1) year from the effective date of the base period award		
Option Period Two (2)	Two (2) years from the effective date of base period award		
Option Period Three (3)	Three (3) years from the effective date of the base period award		
Option Period Four (4)	Four (4) years from the effective date of base period award		

## **F.5 PLACE OF PERFORMANCE**

The place of performance will be specified at the Task Order level. Task orders may be issued for performance in any of the United States or its territories.

# SECTION G - CONTRACT ADMINISTRATION DATA

# **G.1 ORDERING PROCEDURES**

Ordering services under this contract shall be accomplished by the issuance of written task orders specifying the inspection services required by State. All task orders issued under this contract shall conform to the provisions of the contract clauses in Section 7 entitled "Ordering." The only office authorized to process task orders through the Office of Acquisitions & Grants Services is the Food and Drug Administration (FDA) Contracting Officer.

## TASK ORDER PROCESSING

All task orders issued hereunder are subject to the terms and conditions of this contract. This contract shall control in the event of conflict with any task order. A task orders shall be "issued" for purposes of this contract upon the effective date of the order. The general process for individual task orders is as follows:

a) The FDA will prepare a statement of work. The SOW will include, at a minimum, the following elements:

1. Description of work in terms of the purpose or objectives of the work and location to be performed.

2. Description of how the work performance is assessed relative to objectives, goals, and outcomes.

- 3. Period and place of performance
- 4. Reporting requirements and deliverables

5. Whether the order will be fixed price, labor hour, time and material or a hybrid type task order.

b) Requests for Task Order Proposals (RTOPs) shall only be issued by the Contracting Officer.

c) The Contractor shall prepare and submit a task proposal addressing all areas of the requirement. The Contractor shall submit the task proposal within the time period specified in the RTOP and adhere to the ceiling rates established in the contract. No separate payment will be made to the contractor for the cost to prepare, submit and/or negotiate a task order proposal.

The Government shall evaluate task order proposals for technical acceptability and price reasonableness.

# G.2 CONTRACTING OFFICERS REPRESENTATIVE (COR)

The following COR will represent the Government for the purpose of this contract: (To Be Determined Upon Contract Award)

The COR is responsible for: (1) monitoring the Contractor's technical progress, including the surveillance and assessment of performance and recommending to the Contracting Officer changes in requirements; (2) interpreting the Statement of Work and any other technical performance requirements; (3) performing technical evaluation as required; (4) performing technical inspections and acceptances required by this contract; and (5) assisting in the resolution of technical problems encountered during performance.

## G.3 CONTRACTING OFFICER (CO)

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

The contact information for the Contracting Officer is: Matthew J. Bucher 5630 Fishers Lane Rockville, MD 20857 Email: Matthew.Bucher@fda.hhs.gov

Tel: (240) 402-7566

The contact information for the Contract Specialist is: Christopher R. McGucken 5630 Fishers Lane Rockville, MD 20857 Email: Christopher.McGucken@fda.hhs.gov Tel: (240) 402-7566

### G.4 INVOICE SUBMISSION

A. The contractor shall submit all invoices to:

U.S. FOOD AND DRUG ADMINISTRATION Attn: Vendor Payments Office of Financial Services 10903 New Hampshire Ave WO32 - Second Floor MAIL HUB 2145 Silver Spring, MD 20993-0002 301-827-3742 FDAVendorPaymentsTeam@fda.hhs.gov \*\*\* Acceptable methods of delivery include: E-mail (preferred) and Standard Mail.

B. Invoices submitted under this contract must comply with the requirements set forth in FAR Clauses 52.232-25 (Prompt Payment) and 52.232-33 (Payment by Electronic Funds Transfer - System for Award Management) 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:

(i) Name and address of the contractor;

(ii) Invoice date and invoice number;

(iii) Contract/Order number (including a reference to any base award for Indefinite-

Delivery/Indefinite-Quantity Contracts or Blanket Purchase Agreements);

(iv) Description, quantity, unit of measure, unit price, and extended price supplies delivered or services performed, including:

(a) period of performance for which costs are claimed;

(b) itemized travel costs, including origin and destination;

(c) any other supporting information necessary to clarify questionable expenditures;

(d) the contractor shall include the Contract Line Item/Funding line item for each description,

quantity, unit of measure, unit price, and extended price supplies delivered or services performed; (v) Shipping number and date of shipment, including the bill of lading number and weight of shipment if shipped on government bill of lading;

(vi) Terms of any discount for prompt payment offered (Prompt Payment terms other than NET 30);

(vii) Name and address of contractor official to whom payment is to be sent (must be the same as that in the contract or in a proper notice of assignment);

(viii) Name, title, and phone number of person to notify in event of defective invoice;

(ix) Taxpayer Identification Number (TIN);

(x) Electronic funds transfer (EFT) banking information, including routing transit number of the financial institution receiving payment;

(xi) Name and telephone number of the FDA Approving Official (i.e., Contracting Officer (CO) or Contract Specialist (CS), as referenced in the award document);

(xii) Name and telephone number of the FDA Contracting Officer Representative (COR) or other program center/office point of contact, as referenced in the award document;

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

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

(1) invoice number, amount, & date submitted

(2) corresponding payment amount & date received

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

(c) and, for definitized contracts or orders only, total estimated amounts yet to be invoiced for the current, active period of performance;

(xiv) Any other information or documentation required by the contract/order award.

C. An electronic invoice is acceptable if submitted in Adobe Acrobat (PDF) format. All items listed in (i) through (xii) of this clause must be included in the electronic invoice. Electronic invoices must be on company letterhead and must contain no ink changes and be legible for printing.

D. Questions regarding invoice payments should be directed to the FDA Payment Office at the email address or phone number provided above in Section A.

# **SECTION H - SPECIAL CONTRACT REQUIREMENTS**

# H.1 CONTRACTOR PERFORMANCE EVALUATION(S)

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 30 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 30 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. Evaluations will also be stored for a 3 year period in the Past Performance Information Retrieval System (PPIRS) at www.ppirs.gov.

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

## PART II

# **SECTION I - CONTRACT CLAUSES**

# I.1 HHSAR CLAUSES INCORPORTATED BY REFERENCE

This contract incorporates one or more clauses by reference with the same force and effect as if they were given in full text. Upon request, the Contracting Officer will make their full text available. Also, the full text of a clause may be accessed electronically at: <a href="http://www.hhs.gov/policies/hhsar/subpart301-1.html">http://www.hhs.gov/policies/hhsar/subpart301-1.html</a>.

352.203-70, Anti-Lobbying (DEC 2015)

352.222-70, Contractor Cooperation in Equal Employment Opportunity Investigations (DEC 2015)

352.223-70, Safety and Health (DEC 2015)

352.227-70, Publications and Publicity (DEC 2015)

352.239-74, Electronic and Information Technology Accessibility (DEC 2015)

# I.2 52.252-2 FAR CLAUSES INCORPORATED BY REFERENCE (FEB 1998)

This contract incorporates one or more clauses by reference, with the same force and effect as if they were given in full text. Upon request, the Contracting Officer will make their full text available. Also, the full text of a clause may be accessed electronically at: <a href="https://www.acquisition.gov/far/index.html">www.acquisition.gov/far/index.html</a>.

52.216-7, ALLOWABLE COST AND PAYMENT (JUN 2013) 52.227-17, RIGHTS IN DATA – SPECIAL WORKS (DEC 2007) 52.232-40, PROVIDING ACCELERATED PAYMENTS TO SMALL BUSINESS SUBCONTRACTORS (DEC 2013)

# I.3 FAR CLAUSES BY FULL TEXT

# 52.212-5 Contract Terms and Conditions Required To Implement Statutes or Executive Orders Commercial Items (NOV 2017).

As prescribed in 12.301(b)(4), insert the following clause:

(a) The Contractor shall comply with the following Federal Acquisition Regulation (FAR) clauses, which are incorporated in this contract by reference, to implement provisions of law or Executive orders applicable to acquisitions of commercial items:

(1) <u>52.203-19</u>, Prohibition on Requiring Certain Internal Confidentiality Agreements or Statements (JAN 2017) (section 743 of Division E, Title VII, of the Consolidated and Further

Continuing Appropriations Act, 2015 (Pub. L. 113-235) and its successor provisions in subsequent appropriations acts (and as extended in continuing resolutions)).

(2) <u>52.209-10</u>, Prohibition on Contracting with Inverted Domestic Corporations (Nov 2015).

(3) <u>52.233-3</u>, Protest After Award (AUG 1996) (<u>31 U.S.C. 3553</u>).

(4) <u>52.233-4</u>, Applicable Law for Breach of Contract Claim (OCT 2004)(Public Laws 108-77 and 108-78 (<u>19 U.S.C. 3805 note</u>)).

(b) The Contractor shall comply with the FAR clauses in this paragraph (b) that the Contracting Officer has indicated as being incorporated in this contract by reference to implement provisions of law or Executive orders applicable to acquisitions of commercial items:

X (1) <u>52.203-6</u>, Restrictions on Subcontractor Sales to the Government (Sept 2006), with Alternate I (Oct 1995) (<u>41 U.S.C. 4704</u> and <u>10 U.S.C. 2402</u>).

\_X\_ (2) <u>52.203-13</u>, Contractor Code of Business Ethics and Conduct (Oct 2015) (<u>41 U.S.C.</u> <u>3509</u>)).

(3) <u>52.203-15</u>, Whistleblower Protections under the American Recovery and Reinvestment Act of 2009 (June 2010) (Section 1553 of Pub. L. 111-5). (Applies to contracts funded by the American Recovery and Reinvestment Act of 2009.)

X (4) <u>52.204-10</u>, Reporting Executive Compensation and First-Tier Subcontract Awards (Oct 2016) (Pub. L. 109-282) (<u>31 U.S.C. 6101 note</u>).

\_\_\_(5) [Reserved].

(6) <u>52.204-14</u>, Service Contract Reporting Requirements (Oct 2016) (Pub. L. 111-117, section 743 of Div. C).

X (7) <u>52.204-15</u>, Service Contract Reporting Requirements for Indefinite-Delivery Contracts (Oct 2016) (Pub. L. 111-117, section 743 of Div. C).

X (8) <u>52.209-6</u>, Protecting the Government's Interest When Subcontracting with Contractors Debarred, Suspended, or Proposed for Debarment. (Oct 2015) (31 U.S.C. 6101 note).

X (9) <u>52.209-9</u>, Updates of Publicly Available Information Regarding Responsibility Matters (Jul 2013) (41 U.S.C. 2313).

\_\_\_(10) [Reserved].

(11)(i) <u>52.219-3</u>, Notice of HUBZone Set-Aside or Sole-Source Award (Nov 2011) (<u>15</u> <u>U.S.C. 657a</u>).

\_\_\_ (ii) Alternate I (Nov 2011) of <u>52.219-3</u>.

(12)(i) <u>52.219-4</u>, Notice of Price Evaluation Preference for HUBZone Small Business Concerns (OCT 2014) (if the offeror elects to waive the preference, it shall so indicate in its offer) (<u>15 U.S.C. 657a</u>).

\_\_\_ (ii) Alternate I (JAN 2011) of <u>52.219-4</u>.

\_\_(13) [Reserved]

- X (14)(i) 52.219-6, Notice of Total Small Business Set-Aside (Nov 2011) (15 U.S.C. 644).
- \_\_(ii) Alternate I (Nov 2011).
- \_\_(iii) Alternate II (Nov 2011).
- \_\_\_(15)(i) <u>52.219-7</u>, Notice of Partial Small Business Set-Aside (June 2003) (<u>15 U.S.C. 644</u>).
- \_\_\_(ii) Alternate I (Oct 1995) of <u>52.219-7</u>.
- \_\_\_(iii) Alternate II (Mar 2004) of <u>52.219-7</u>.

X (16) 52.219-8, Utilization of Small Business Concerns (Nov 2016) (15 U.S.C. 637(d)(2) and (3)).

- \_\_\_(17)(i) <u>52.219-9</u>, Small Business Subcontracting Plan (Jan 2017) (<u>15 U.S.C. 637(d)(4)</u>).
- \_\_\_(ii) Alternate I (Nov 2016) of <u>52.219-9</u>.
- \_\_\_ (iii) Alternate II (Nov 2016) of <u>52.219-9</u>.
- \_\_\_ (iv) Alternate III (Nov 2016) of <u>52.219-9</u>.
- \_\_\_\_(v) Alternate IV (Nov 2016) of <u>52.219-9</u>.
- X (18) <u>52.219-13</u>, Notice of Set-Aside of Orders (Nov 2011) (<u>15 U.S.C. 644(r)</u>).
- \_\_\_(19) <u>52.219-14</u>, Limitations on Subcontracting (Jan 2017) (<u>15 U.S.C. 637(a)(14)</u>).

\_\_\_(20) <u>52.219-16</u>, Liquidated Damages. Subcontracting Plan (Jan 1999) (<u>15 U.S.C.</u> <u>637(d)(4)(F)(i)</u>).

(21) <u>52.219-27</u>, Notice of Service-Disabled Veteran-Owned Small Business Set-Aside (Nov 2011) (<u>15 U.S.C. 657 f</u>).

X (22) 52.219-28, Post Award Small Business Program Rerepresentation (Jul 2013) (15 U.S.C. 632(a)(2)).

(23) <u>52.219-29</u>, Notice of Set-Aside for, or Sole Source Award to, Economically Disadvantaged Women-Owned Small Business Concerns (Dec 2015) (<u>15 U.S.C. 637(m)</u>).

X (24) 52.219-30, Notice of Set-Aside for, or Sole Source Award to, Women-Owned Small Business Concerns Eligible Under the Women-Owned Small Business Program (Dec 2015) (15 U.S.C. 637(m)).

X (25) <u>52.222-3</u>, Convict Labor (June 2003) (E.O. 11755).

X (26) <u>52.222-19</u>, Child Labor. Cooperation with Authorities and Remedies (Oct 2016) (E.O. 13126).

X (27) <u>52.222-21</u>, Prohibition of Segregated Facilities (Apr 2015).

X (28) <u>52.222-26</u>, Equal Opportunity (Sept 2016) (E.O. 11246).

X (29) <u>52.222-35</u>, Equal Opportunity for Veterans (Oct 2015)(<u>38 U.S.C. 4212</u>).

X (30) <u>52.222-36</u>, Equal Opportunity for Workers with Disabilities (Jul 2014) (<u>29 U.S.C. 793</u>).

\_\_\_\_(31) <u>52.222-37</u>, Employment Reports on Veterans (FEB 2016) (38 U.S.C. 4212).

X (32) <u>52.222-40</u>, Notification of Employee Rights Under the National Labor Relations Act (Dec 2010) (E.O. 13496).

X (33)(i) <u>52.222-50</u>, Combating Trafficking in Persons (Mar 2015) (<u>22 U.S.C. chapter 78</u> and E.O. 13627).

\_\_\_\_(ii) Alternate I (Mar 2015) of <u>52.222-50</u> (<u>22 U.S.C. chapter 78</u> and E.O. 13627).

X (34) 52.222-54, Employment Eligibility Verification (OCT 2015). (Executive Order 12989). (Not applicable to the acquisition of commercially available off-the-shelf items or certain other types of commercial items as prescribed in 22.1803.)

\_\_\_(35)(i) <u>52.223-9</u>, Estimate of Percentage of Recovered Material Content for EPA–Designated Items (May 2008) (<u>42 U.S.C. 6962(c)(3)(A)(ii)</u>). (Not applicable to the acquisition of commercially available off-the-shelf items.)

\_\_\_ (ii) Alternate I (May 2008) of 52.223-9 (42 U.S.C. 6962(i)(2)(C)). (Not applicable to the acquisition of commercially available off-the-shelf items.)

(36) <u>52.223-11</u>, Ozone-Depleting Substances and High Global Warming Potential Hydrofluorocarbons (JUN 2016) (E.O. 13693).

\_\_\_ (37) <u>52.223-12</u>, Maintenance, Service, Repair, or Disposal of Refrigeration Equipment and Air Conditioners (JUN 2016) (E.O. 13693).

\_\_\_(38)(i) <u>52.223-13</u>, Acquisition of EPEAT®-Registered Imaging Equipment (JUN 2014) (E.O.s 13423 and 13514).

\_\_\_(ii) Alternate I (Oct 2015) of <u>52.223-13</u>.

\_\_\_ (39)(i) <u>52.223-14</u>, Acquisition of EPEAT®-Registered Televisions (JUN 2014) (E.O.s 13423 and 13514).

\_\_\_ (ii) Alternate I (Jun 2014) of <u>52.223-14</u>.

\_\_\_ (40) <u>52.223-15</u>, Energy Efficiency in Energy-Consuming Products (DEC 2007) (<u>42 U.S.C.</u> <u>8259b</u>).

\_\_\_ (41)(i) <u>52.223-16</u>, Acquisition of EPEAT®-Registered Personal Computer Products (OCT 2015) (E.O.s 13423 and 13514).

\_\_\_ (ii) Alternate I (Jun 2014) of <u>52.223-16</u>.

X (42) <u>52.223-18</u>, Encouraging Contractor Policies to Ban Text Messaging While Driving (AUG 2011) (E.O. 13513).

\_\_\_\_(43) <u>52.223-20</u>, Aerosols (JUN 2016) (E.O. 13693).

\_\_\_\_(44) <u>52.223-21</u>, Foams (JUN 2016) (E.O. 13693).

\_\_\_\_(45)(i) <u>52.224-3</u>, Privacy Training (JAN 2017) (5 U.S.C. 552a).

\_\_\_(ii) Alternate I (JAN 2017) of 52.224-3.

\_\_\_\_(46) <u>52.225-1</u>, Buy American. Supplies (May 2014) (<u>41 U.S.C. chapter 83</u>).

\_\_\_\_(47)(i) <u>52.225-3</u>, Buy American Free Trade Agreements. Israeli Trade Act (May 2014) (<u>41</u> <u>U.S.C. chapter 83, 19 U.S.C. 3301</u> note, <u>19 U.S.C. 2112</u> note, <u>19 U.S.C. 3805</u> note, <u>19 U.S.C.</u> <u>4001</u> note, Pub. L. 103-182, 108-77, 108-78, 108-286, 108-302, 109-53, 109-169, 109-283, 110-138, 112-41, 112-42, and 112-43.

- \_\_\_ (ii) Alternate I (May 2014) of <u>52.225-3</u>.
- \_\_\_ (iii) Alternate II (May 2014) of <u>52.225-3</u>.

\_\_\_ (iv) Alternate III (May 2014) of <u>52.225-3</u>.

\_\_\_\_(48) <u>52.225-5</u>, Trade Agreements (OCT 2016) (<u>19 U.S.C. 2501</u>, et seq., <u>19 U.S.C. 3301</u> note).

X (49) 52.225-13, Restrictions on Certain Foreign Purchases (June 2008) (E.O.'s, proclamations, and statutes administered by the Office of Foreign Assets Control of the Department of the Treasury).

\_\_\_\_(50) <u>52.225-26</u>, Contractors Performing Private Security Functions Outside the United States (Oct 2016) (Section 862, as amended, of the National Defense Authorization Act for Fiscal Year 2008; <u>10 U.S.C. 2302 Note</u>).

\_\_\_ (51) <u>52.226-4</u>, Notice of Disaster or Emergency Area Set-Aside (Nov 2007) (<u>42 U.S.C.</u> <u>5150</u>).

\_\_ (52) <u>52.226-5</u>, Restrictions on Subcontracting Outside Disaster or Emergency Area (Nov 2007) (<u>42 U.S.C. 5150</u>).

\_\_ (53) <u>52.232-29</u>, Terms for Financing of Purchases of Commercial Items (Feb 2002) (<u>41</u> <u>U.S.C. 4505</u>, <u>10 U.S.C. 2307(f)</u>).

\_\_ (54) <u>52.232-30</u>, Installment Payments for Commercial Items (Jan 2017) (<u>41 U.S.C. 4505</u>, <u>10</u> <u>U.S.C. 2307(f)</u>).

X (55) <u>52.232-33</u>, Payment by Electronic Funds Transfer. System for Award Management (Jul 2013) (<u>31 U.S.C. 3332</u>).

X (56) <u>52.232-34</u>, Payment by Electronic Funds Transfer. Other than System for Award Management (Jul 2013) (<u>31 U.S.C. 3332</u>).

\_\_\_ (57) <u>52.232-36</u>, Payment by Third Party (May 2014) (<u>31 U.S.C. 3332</u>).

\_\_\_(58) <u>52.239-1</u>, Privacy or Security Safeguards (Aug 1996) (<u>5 U.S.C. 552a</u>).

\_\_\_(59) <u>52.242-5</u>, Payments to Small Business Subcontractors (JAN 2017)(15 U.S.C. 637(d)(12)).

\_\_\_(60)(i) <u>52.247-64</u>, Preference for Privately Owned U.S.-Flag Commercial Vessels (Feb 2006) (<u>46 U.S.C. Appx. 1241(b)</u> and <u>10 U.S.C. 2631</u>).

\_\_\_ (ii) Alternate I (Apr 2003) of <u>52.247-64</u>.

(c) The Contractor shall comply with the FAR clauses in this paragraph (c), applicable to commercial services, that the Contracting Officer has indicated as being incorporated in this contract by reference to implement provisions of law or Executive orders applicable to acquisitions of commercial items:

\_\_\_(1) <u>52.222-17</u>, Nondisplacement of Qualified Workers (May 2014)(E.O. 13495).

(2) <u>52.222-41</u>, Service Contract Labor Standards (May 2014) (<u>41 U.S.C. chapter 67</u>).

\_\_\_ (3) <u>52.222-42</u>, Statement of Equivalent Rates for Federal Hires (May 2014) (<u>29 U.S.C. 206</u> and <u>41 U.S.C. chapter 67</u>).

(4) <u>52.222-43</u>, Fair Labor Standards Act and Service Contract Labor Standards-Price Adjustment (Multiple Year and Option Contracts) (May 2014) (<u>29 U.S.C. 206</u> and <u>41 U.S.C.</u> <u>chapter 67</u>).

\_\_ (5) <u>52.222-44</u>, Fair Labor Standards Act and Service Contract Labor Standards. Price Adjustment (May 2014) (<u>29 U.S.C. 206</u> and <u>41 U.S.C. chapter 67</u>).

(6) <u>52.222-51</u>, Exemption from Application of the Service Contract Labor Standards to Contracts for Maintenance, Calibration, or Repair of Certain Equipment. Requirements (May 2014) (<u>41 U.S.C. chapter 67</u>).

\_\_\_ (7) <u>52.222-53</u>, Exemption from Application of the Service Contract Labor Standards to Contracts for Certain Services. Requirements (May 2014) (<u>41 U.S.C. chapter 67</u>).

(8) <u>52.222-55</u>, Minimum Wages Under Executive Order 13658 (Dec 2015).

\_\_\_\_(9) <u>52.222-62</u>, Paid Sick Leave Under Executive Order 13706 (JAN 2017) (E.O. 13706).

(10) <u>52.226-6</u>, Promoting Excess Food Donation to Nonprofit Organizations (May 2014) (<u>42</u> <u>U.S.C. 1792</u>).

\_\_\_(11) <u>52.237-11</u>, Accepting and Dispensing of \$1 Coin (Sept 2008) (<u>31 U.S.C. 5112(p)(1)</u>).

(d) Comptroller General Examination of Record. The Contractor shall comply with the provisions of this paragraph (d) if this contract was awarded using other than sealed bid, is in excess of the simplified acquisition threshold, and does not contain the clause at 52.215-2, Audit and Records Negotiation.

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

(2) The Contractor shall make available at its offices at all reasonable times the records, materials, and other evidence for examination, audit, or reproduction, until 3 years after final payment under this contract or for any shorter period specified in FAR <u>subpart 4.7</u>, Contractor Records Retention, of the other clauses of this contract. If this contract is completely or partially terminated, the records relating to the work terminated shall be made available for 3 years after any resulting final termination settlement. Records relating to appeals under the disputes clause

or to litigation or the settlement of claims arising under or relating to this contract shall be made available until such appeals, litigation, or claims are finally resolved.

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

(e)(1) Notwithstanding the requirements of the clauses in paragraphs (a), (b), (c), and (d) of this clause, the Contractor is not required to flow down any FAR clause, other than those in this paragraph (e)(1) in a subcontract for commercial items. Unless otherwise indicated below, the extent of the flow down shall be as required by the clause.

(i) <u>52.203-13</u>, Contractor Code of Business Ethics and Conduct (Oct 2015) (<u>41 U.S.C. 3509</u>).

(ii) <u>52.203-19</u>, Prohibition on Requiring Certain Internal Confidentiality Agreements or Statements (Jan 2017) (section 743 of Division E, Title VII, of the Consolidated and Further Continuing Appropriations Act, 2015 (Pub. L. 113-235) and its successor provisions in subsequent appropriations acts (and as extended in continuing resolutions)).

(iii) <u>52.219-8</u>, Utilization of Small Business Concerns (Nov 2016) (<u>15 U.S.C. 637(d)(2)</u> and (3)), in all subcontracts that offer further subcontracting opportunities. If the subcontract (except subcontracts to small business concerns) exceeds \$700,000 (\$1.5 million for construction of any public facility), the subcontractor must include <u>52.219-8</u> in lower tier subcontracts that offer subcontracting opportunities.

(iv) <u>52.222-17</u>, Nondisplacement of Qualified Workers (May 2014) (E.O. 13495). Flow down required in accordance with paragraph (l) of FAR clause <u>52.222-17</u>.

- (v) <u>52.222-21</u>, Prohibition of Segregated Facilities (Apr 2015)
- (vi) <u>52.222-26</u>, Equal Opportunity (Sept 2016) (E.O. 11246).
- (vii) <u>52.222-35</u>, Equal Opportunity for Veterans (Oct 2015) (<u>38 U.S.C. 4212</u>).
- (viii) <u>52.222-36</u>, Equal Opportunity for Workers with Disabilities (Jul 2014) (<u>29 U.S.C. 793</u>).
- (ix) <u>52.222-37</u>, Employment Reports on Veterans (Feb 2016) (<u>38 U.S.C. 4212</u>)

(x) 52.222-40, Notification of Employee Rights Under the National Labor Relations Act (Dec 2010) (E.O. 13496). Flow down required in accordance with paragraph (f) of FAR clause 52.222-40.

(xi) 52.222-41, Service Contract Labor Standards (May 2014) (41 U.S.C. chapter 67).

(xii)

\_\_(A) <u>52.222-50</u>, Combating Trafficking in Persons (Mar 2015) (<u>22 U.S.C. chapter 78</u> and E.O 13627).

(B) Alternate I (Mar 2015) of <u>52.222-50</u> (<u>22 U.S.C. chapter 78 and E.O 13627</u>).

(xiii) <u>52.222-51</u>, Exemption from Application of the Service Contract Labor Standards to Contracts for Maintenance, Calibration, or Repair of Certain Equipment-Requirements (May 2014) (<u>41 U.S.C. chapter 67</u>).

(xiv) <u>52.222-53</u>, Exemption from Application of the Service Contract Labor Standards to Contracts for Certain Services-Requirements (May 2014) (<u>41 U.S.C. chapter 67</u>).

(xv) <u>52.222-54</u>, Employment Eligibility Verification (OCT 2015) (E.O. 12989).

(xvi) <u>52.222-55</u>, Minimum Wages Under Executive Order 13658 (Dec 2015).

(xvii) <u>52.222-62</u>, Paid Sick Leave Under Executive Order 13706 (JAN 2017) (E.O. 13706).

(xviii)(A) 52.224-3, Privacy Training (JAN 2017) (5 U.S.C. 552a).

(B) Alternate I (JAN 2017) of 52.224-3.

(xix) <u>52.225-26</u>, Contractors Performing Private Security Functions Outside the United States (Oct 2016) (Section 862, as amended, of the National Defense Authorization Act for Fiscal Year 2008; <u>10 U.S.C. 2302 Note</u>).

(xx) <u>52.226-6</u>, Promoting Excess Food Donation to Nonprofit Organizations (May 2014) (<u>42</u> <u>U.S.C. 1792</u>). Flow down required in accordance with paragraph (e) of FAR clause <u>52.226-6</u>.

(xxi) <u>52.247-64</u>, Preference for Privately Owned U.S.-Flag Commercial Vessels (Feb 2006) (<u>46</u> <u>U.S.C. Appx. 1241(b)</u> and <u>10 U.S.C. 2631</u>). Flow down required in accordance with paragraph (d) of FAR clause <u>52.247-64</u>.

(2) While not required, the Contractor may include in its subcontracts for commercial items a minimal number of additional clauses necessary to satisfy its contractual obligations.

Alternate I (Feb 2000). As prescribed in <u>12.301(b)(4)(i)</u>, delete paragraph (d) from the basic clause, redesignate paragraph (e) as paragraph (d), and revise the reference to "paragraphs (a), (b), (c), or (d) of this clause" in the redesignated paragraph (d) to read "paragraphs (a), (b), and (c) of this clause."

Alternate II (Nov 2017). As prescribed in 12.301(b)(4)(ii), substitute the following paragraphs (d)(1) and (e)(1) for paragraphs (d)(1) and (e)(1) of the basic clause as follows:

(d)(1) The Comptroller General of the United States, an appropriate Inspector General appointed under section 3 or 8G of the Inspector General Act of 1978 (<u>5 U.S.C. App.</u>), or an authorized representative of either of the foregoing officials shall have access to and right to.

(i) Examine any of the Contractor's or any subcontractors' records that pertain to, and involve transactions relating to, this contract; and

(ii) Interview any officer or employee regarding such transactions.

(e)(1) Notwithstanding the requirements of the clauses in paragraphs (a), (b), and (c), of this clause, the Contractor is not required to flow down any FAR clause in a subcontract for commercial items, other than.

(i) Paragraph (d) of this clause. This paragraph flows down to all subcontracts, except the authority of the Inspector General under paragraph (d)(1)(ii) does not flow down; and

(ii) Those clauses listed in this paragraph (e)(1). Unless otherwise indicated below, the extent of the flow down shall be as required by the clause.

(A) <u>52.203-13</u>, Contractor Code of Business Ethics and Conduct (Oct 2015) (<u>41 U.S.C. 3509</u>).

(B) <u>52.203-15</u>, Whistleblower Protections Under the American Recovery and Reinvestment Act of 2009 (Jun 2010) (Section 1553 of Pub. L. 111-5).

(C) <u>52.219-8</u>, Utilization of Small Business Concerns (Nov 2016) (<u>15 U.S.C. 637(d)(2) and (3)</u>), in all subcontracts that offer further subcontracting opportunities. If the subcontract (except subcontracts to small business concerns) exceeds \$700,000 (\$1.5 million for construction of any public facility), the subcontractor must include <u>52.219-8</u> in lower tier subcontracts that offer subcontracting opportunities.

- (D) <u>52.222-21</u>, Prohibition of Segregated Facilities (Apr 2015).
- (E) <u>52.222-26</u>, Equal Opportunity (Sept 2016) (E.O. 11246).
- (F) <u>52.222-35</u>, Equal Opportunity for Veterans (Oct 2015) (<u>38 U.S.C. 4212</u>).
- (G) <u>52.222-36</u>, Equal Opportunity for Workers with Disabilities (Jul 2014) (<u>29 U.S.C. 793</u>).

(H) 52.222-40, Notification of Employee Rights Under the National Labor Relations Act (Dec 2010) (E.O. 13496). Flow down required in accordance with paragraph (f) of FAR clause 52.222-40.

(I) <u>52.222-41</u>, Service Contract Labor Standards (May 2014) (<u>41 U.S.C. chapter 67</u>).

(J) \_\_\_(1) <u>52.222-50</u>, Combating Trafficking in Persons (Mar 2015) (<u>22 U.S.C. chapter 78</u> and E.O 13627).

(2) Alternate I (Mar 2015) of <u>52.222-50</u> (<u>22 U.S.C. chapter 78 and E.O 13627</u>).

(K) <u>52.222-51</u>, Exemption from Application of the Service Contract Labor Standards to Contracts for Maintenance, Calibration, or Repair of Certain Equipment.Requirements (May 2014) (<u>41 U.S.C. chapter 67</u>).

(L) <u>52.222-53</u>, Exemption from Application of the Service Contract Labor Standards to Contracts for Certain Services.Requirements (May 2014) (<u>41 U.S.C. chapter 67</u>).

(M) <u>52.222-54</u>, Employment Eligibility Verification (Oct 2015) (Executive Order 12989).

(N) <u>52.222-55</u>, Minimum Wages Under Executive Order 13658 (Dec 2015).

(O) <u>52.222-62</u>, Paid Sick Leave Under Executive Order 13706 (JAN 2017) (E.O. 13706).

(P)(1)52.224-3, Privacy Training (JAN 2017) (5 U.S.C. 552a).

(2)Alternate I (JAN 2017) of 52.224-3.

(Q) <u>52.225-26</u>, Contractors Performing Private Security Functions Outside the United States (OCT 2016) (Section 862, as amended, of the National Defense Authorization Act for Fiscal Year 2008; 10 U.S.C. 2302 Note)

(R) <u>52.226-6</u>, Promoting Excess Food Donation to Nonprofit Organizations. (May 2014) (<u>42</u> <u>U.S.C. 1792</u>). Flow down required in accordance with paragraph (e) of FAR clause <u>52.226-6</u>.

(S) <u>52.247-64</u>, Preference for Privately Owned U.S.-Flag Commercial Vessels (Feb 2006) (<u>46</u> <u>U.S.C. Appx. 1241(b)</u> and <u>10 U.S.C. 2631</u>). Flow down required in accordance with paragraph (d) of FAR clause <u>52.247-64</u>.

# 52.216-18, ORDERING (OCT 1995)

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

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

(c) If mailed, a delivery order or task order is considered "issued" when the Government deposits the order in the mail. Orders may be issued orally, by facsimile, or by electronic commerce methods only if authorized in the Schedule.

# 52.216-19 ORDER LIMITATIONS (OCT 1995)

(a) Minimum order. When the Government requires supplies or services covered by this contract in an amount of less than \$3,500, the Government is not obligated to purchase, nor is the Contractor obligated to furnish, those supplies or services under the contract.(b) Maximum order. The Contractor is not obligated to honor—

- (1) Any order for a single item in excess of \$5,000,000
- (2) Any order for a combination of items in excess of \$23,000,000; or
- (3) A series of orders from the same ordering office within 30 days that together call for quantities exceeding the limitation in paragraph (b)(1) or (2) of this section.

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

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

# 52.216-22 INDEFINITE QUANTITY (OCT 1995)

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

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

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

(d) Any order issued during the effective period of this contract and not completed within that period shall be completed by the Contractor within the time specified in the order. The contract shall govern the Contractor's and Government's rights and obligations with respect to that order to the same extent as if the order were completed during the contract's effective period; *provided*, that the Contractor shall not be required to make any deliveries under this contract after contract expiration.

## 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 prior to contract expiration.

## 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 prior to the expiration date of the contract provided that the Government gives the Contractor a preliminary written notice of its intent to extend at least 30 days before the contract expires. The preliminary notice does not commit the Government to an extension.

(b) If the Government exercises this option, the extended contract shall be considered to include this option clause.

(c) The total duration of this contract, including the exercise of any options under this clause, shall not exceed five (5) years and six (6) months.

# PART III

## **SECTION J - LIST OF ATTACHMENTS**

Attachment 1- Price Matrix

Attachment 2- Personnel Security Requirements

Attachment 3- Information Technology (IT) Security Requirements

## PART IV

## SECTION K - REPRESENTATIONS, CERTIFICATIONS, AND OTHER STATEMENTS OF OFFEROR OR OFFERORS

# 52.212-3 OFFEROR REPRESENTATIONS AND CERTIFICATIONS—COMMERCIAL ITEMS (NOV 2017)

The Offeror shall complete only paragraph (b) of this provision if the Offeror has completed the annual representations and certification electronically via the System for Award Management (SAM) website located at <u>https://www.sam.gov/portal</u>. If the Offeror has not completed the annual representations and certifications electronically, the Offeror shall complete only paragraphs (c) through (u) of this provision.

(b)

(1) Annual Representations and Certifications. Any changes provided by the offeror in paragraph (b)(2) of this provision do not automatically change the representations and certifications posted on the SAM website.

(2) The offeror has completed the annual representations and certifications electronically via the SAM website accessed through https://www.acquisition.gov. After reviewing the SAM database information, the offeror verifies by submission of this offer that the representation and certifications currently posted electronically at FAR 52.212-3, Offeror Representations and Certifications—Commercial Items, have been entered or updated in the last 12 months, are current, accurate, complete, and applicable to this solicitation (including the business size standard applicable to the NAICS code referenced for this solicitation), as of the date of this offer and are incorporated in this offer by reference (see FAR 4.1201), except for paragraphs \_\_\_. [Offeror to identify the applicable paragraphs at (c) through (u) of this provision that the offeror has completed for the purposes of this solicitation only, if any. These amended representation(s) and/or certification(s) are also incorporated in this offer and are current, accurate, and complete as of the date of this offer. Any changes provided by the offeror are applicable to this solicitation only, and do not result in an update to the representations and certifications posted electronically on SAM.]

# 52.209-7 INFORMATION REGARDING RESPONSIBILITY MATTERS (JUL 2013)

(a) Definitions. As used in this provision—

"Administrative proceeding" means a non-judicial process that is adjudicatory in nature in order to make a determination of fault or liability (e.g., Securities and Exchange Commission Administrative Proceedings, Civilian Board of Contract Appeals Proceedings, and Armed Services Board of Contract Appeals Proceedings). This includes administrative proceedings at the Federal and State level but only in connection with performance of a Federal contract or

grant. It does not include agency actions such as contract audits, site visits, corrective plans, or inspection of deliverables.

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

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

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

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

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

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

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

(i) In a criminal proceeding, a conviction.

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

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

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

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

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

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

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

# SECTION L - INSTRUCTIONS, CONDITIONS, AND NOTICES TO OFFERORS

# L.1 OFFEROR RESPONSE DATES AND TIME

RFP Due Date: All proposals and revisions shall be submitted electronically via email to Christopher.McGucken@fda.hhs.gov and received by 11 am Eastern Time on March 7th, 2018.

All questions in response to this RFP are due no later than February 23<sup>rd</sup>, 2018 3:00PM Eastern Time.

#### Note: Late proposals will not be evaluated.

#### L.2 PROPOSAL INSTRUCTIONS

<u>Note:</u> The Government reserves the right to evaluate proposals and make awards without discussion with Offerors. Therefore, the Offeror's initial proposal should contain the Offeror's best terms from a cost/price and technical standpoint. However, the Government may conduct discussions if the Contracting Officer determines they are necessary.

#### Format

#### Cover Letter

The cover letter shall include; a POC (name and telephone number); a statement from the Offeror verifying that they are SAM.GOV Registered and qualify as a women owned small business under NAICS code 541990 . **DUNS and TIN number shall be included in the cover letter.** 

Proposals shall be submitted in two separate volumes:

- Volume I Technical
- Volume II Price

#### **Volume I- Technical**

The Offeror shall submit a proposal describing how the work will be accomplished in accordance with the requirements listed in Section C.3.

There is no page count for the technical proposal. However, the Government is interested in efficiency. Please provide only as much information as needed in order to demonstrate that your firm has the requested capabilities.

Offerors shall include the following sections in their technical proposal:

- Project Plan/Approach
- Staffing and Commissionable Employees \*
- Relevant Past Performance

\*Defined in Section C.5 and Attachment 2.

#### **Project Plan/Approach**

The offeror shall clearly and concisely describe project responsibilities and personnel, any

proposed subcontracting arrangements, communication and coordination, scheduling of all tasks and subtasks, meetings, and deliverables. The description shall include a discussion of the Project Manager's role, the organizational structure, and how the Offeror will manage the contract.

The Project Plan must address each portion of the SOW and be sufficiently detailed so as to allow the government to evaluate the feasibility of the proposed plan. The Plan must include a discussion of your methodology to meet all the requirements of the contemplated contract. The Plan shall be specific, detailed, and complete enough to clearly and fully demonstrate that you understand the requirements and the inherent problems associated with the objectives of this procurement.

## Staffing and Commissionable Employees \*

Offeror shall demonstrate that they have appropriate personnel to perform Activities 1 through 6 as described in the SOW. Using a tabular format the offeror shall include a listing of proposed personnel with particular attention to Key Personnel. The Program Manager is the only position designated as Key Personnel for contractual purposes.

Information included should identify the proposed staff member's role and describe how these individuals' skills will enable them to provide the services described in the SOW. Resumes for all labor categories and staff shall be included in this volume.

Inspectors/Commissionable employees will be identified or the plan to obtain these employees will be described in this section. The offeror must demonstrate that Inspectors that meet the criteria in C.5 and Attachment 2 of the solicitation. FDA prefers a majority of the Inspectors conducting the compliance check inspections be dedicated on a full-time basis. If the Contractor utilizes part-time Inspectors, those inspectors must maintain regular performance of inspections in order to remain active on this contract. Inspectors that do not perform a minimum of 10 inspections per month will be deactivated from the program.

Resumes shall, at a minimum, demonstrate the following:

The type and relevance of the education and experience of the individual proposed to work on projects. Experience on other projects that are similar in size and scope are acceptable. Experiences on projects that are not similar, but may be relevant are also acceptable.

A *Letter of Commitment* shall be provided for all Contractor-identified personnel. The letter shall indicate that the employee commits to the Offeror that he/she intends to work for at least one (1) year on the resultant contract if awarded to the Offeror.

\*Defined in Section C.5 and Attachment 2.

#### **Relevant Past Performance**

Offerors shall demonstrate its experience in conducting inspection services and reporting as described in the SOW. The offeror shall identify up to three (3) most relevant contracts currently being performed or contracts that have been completed but performed within the last three (3) years from the issuance of this solicitation. Contracts may be either government or commercial. For each relevant contract, the Offeror shall list the following: List the contract name, description of relevant experience, period of performance, place of performance, project contact name and telephone number.

## **Volume II- Price**

The price proposal shall be comprised of the following elements:

- The offeror shall complete the price matrix for hourly rates from Section B.4 and Attachment 1 with **fully loaded** hourly rates proposed for each labor category and for each year. The fully loaded rate should consider that this is a nation-wide IDIQ contract and the labor rates may vary greatly depending on the geographic region. Therefore, the contract shall provide the government with an average labor rate that will be applicable to all work regardless of the geographic location. The offeror will also provide information on how that average hourly rate was calculated. The labor hours in the table are estimates for evaluation purposes <u>only</u>. The offeror must submit pricing data adequate to establish the reasonableness of the proposed amounts.
- Attachment 1 shall be submitted as an excel spreadsheet for evaluation purposes.
- Representations and Certifications from Section K
- Expenses for Other Direct Costs and travel set in section B.4, at \$80,000.00, and \$1,000,000.00 will cover the entire duration of the contract. These expenses will be applied at the task order level and proper documentation in accordance with FAR 31 will be required to support any expenses. Offerors shall include these expenses, as is, as a part of their total overall price.

The proposal must stipulate that it is predicated upon all the terms and conditions of this RFP.

# **SECTION M - EVALUATION FACTORS FOR AWARD**

## M.1 EVALUATION CRITERIA

The Government's source selection decision will be based on a Best Value Tradeoff process which incorporates the following technical factors: Project Plan, Staffing and Commissionable Employees, and Relevant Past Performance as well as Price.

# **TECHNICAL EVALUATION**

The following technical criteria are described below:

# Criteria 1 – Project Plan/Approach

Offerors will be evaluated on the quality of their plan for executing each activity described in the Statement of Work. This evaluation will include the Offeror's ability to describe how the special security requirements in Section H of the RFP will be addressed.

# Criteria 2 - Staffing and Commissionable Employees

Offerors will be evaluated on their personnel's demonstrated ability to describe that they currently have the personnel to perform Activities 1 through 6 as described in the SOW as well as the ability to obtain skilled and Commissionable employees.

# **Criteria 3- Relevant Past Performance**

The Government will evaluate three recent, relevant experience summaries (performed within the last three years) for similar requirements in terms of size and scope to the work described in this solicitation. Offerors will also be evaluated on any problems identified during the course of the contract as well as corrective actions taken. The Government reserves the right to evaluate Relevant Past Performance using PPIRS, CPARS, and other Agency contracts.

# Criteria 4- Price

The Government will evaluate the total overall price of offeror's proposal for reasonableness. When reviewing overall price, the Government will consider the rates of each category for each period (inclusive of options) multiplied by the estimated number of hours with the addition of \$80,000.00 for Other Direct Costs, and \$1,000,000.00 for travel.

# M.2 AWARD DECISION

Award for the IDIQ will be made to the party whose proposal offers the best value to the Government based on Project Plan/Approach, Staffing and Commissionable Employees, Relevant Past Performance, and Price. The Government may award this contract to other than the lowest price technically acceptable proposal. All factors are of equal importance.