

2. CONTRACT (Proc. Inst. Ident.) NO. HHSP223201810206C 3. EFFECTIVE DATE See Block 20C 4. REQUISITION/PURCHASE REQUEST/PROJECT NO. 1207458

5. ISSUED BY CODE DSAAG 6. ADMINISTERED BY (If other than Item 5) CODE
DHHS/FDA/OAGS/DSAAG
ATTN: Cynthia Martin
5630 Fishers Lane
Rockville MD 20857

7. NAME AND ADDRESS OF CONTRACTOR (No. Street, City, Country, State and ZIP Code)
STATE OF MISSOURI 125793
HEALTH AND SENIOR SERVICES, MISSOURI
920 WILDWOOD DR
JEFFERSON CITY MO 651095796

8. DELIVERY
FOB ORIGIN X OTHER (See below)

9. DISCOUNT FOR PROMPT PAYMENT

10. SUBMIT INVOICES (4 copies unless otherwise specified) TO THE ADDRESS SHOWN IN ITEM G-3

CODE 125793 FACILITY CODE

11. SHIP TO/MARK FOR CODE W066 12. PAYMENT WILL BE MADE BY CODE FDA PAYMENT SVCS
WHITE OAK CAMPUS, BUILDING 66
The US Food and Drug Administration
10903 New Hampshire Avenue
Building 66
Silver Spring MD 20993
FDA PAYMENT SVCS
Attn: FDA Vendor payment Team
COLE RM8050
8455 Colesville Road
Silver Spring MD 20993

13. AUTHORITY FOR USING OTHER THAN FULL AND OPEN COMPETITION: 10 U.S.C. 2304 (c) () X 41 U.S.C. 253 (c) (5) 14. ACCOUNTING AND APPROPRIATION DATA 2018.6990914.256E

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

15G. TOTAL AMOUNT OF CONTRACT \$372,494.00

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CONTRACTING OFFICER WILL COMPLETE ITEM 17 (SEALED-BID OR NEGOTIATED PROCUREMENT) OR 18 (SEALED-BID PROCUREMENT) AS APPLICABLE

17. X 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) DIRECTOR
Tonya B. Loucks
19B. NAME OF CONTRACTOR
BY Tonya Loucks
(Signature of person authorized to sign)

20A. NAME OF CONTRACTING OFFICER
ERIKA A. EAM
20B. UNITED STATES OF AMERICA
Erika A. Eam
Digitally signed by Erika A. Eam
DN: c=US, o=U.S. Government, ou=HHS, ou=FDA, ou=people, cn=Erika A. Eam -S, 0.9.2342.19200300.100.1.1=2002517094
Date: 2018.09.26 09:09:37 -04'00'
STANDARD FORM 26 (Rev. 5/2011)
Prescribed by GSA - FAR (48 CFR) 53.214(a)

CONTINUATION SHEET

REFERENCE NO. OF DOCUMENT BEING CONTINUED
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NAME OF OFFEROR OR CONTRACTOR
STATE OF MISSOURI 125793

ITEM NO. (A)	SUPPLIES/SERVICES (B)	QUANTITY (C)	UNIT (D)	UNIT PRICE (E)	AMOUNT (F)
	Tax ID Number: ██████████ DUNS Number: 878092600 3way Invoicing COR: Teresa Bills FOB: Destination Period of Performance: 09/30/2018 to 09/29/2019				
1	Food Inspections Obligated Amount: \$243,375.00 Accounting Info: 2018.6990914.256E Appr. Yr.: 2018 CAN: 6990914 Object Class: 256E CenterTag: 28227NFOOD18MO0 Funded: \$243,375.00	275	EA	885.00	243,375.00
2	Visits/Out of Business (OOB) Obligated Amount: \$18,240.00 Accounting Info: 2018.6990914.256E Appr. Yr.: 2018 CAN: 6990914 Object Class: 256E CenterTag: 28227NFOOD18MO0 Funded: \$18,240.00	60	EA	304.00	18,240.00
3	Juice HACCP Inspections Obligated Amount: \$3,045.00 Accounting Info: 2018.6990914.256E Appr. Yr.: 2018 CAN: 6990914 Object Class: 256E CenterTag: 28227NFOOD18MO0 Funded: \$3,045.00	3	EA	1,015.00	3,045.00
4	LACF Inspections Obligated Amount: \$8,980.00 Accounting Info: 2018.6990914.256E Appr. Yr.: 2018 CAN: 6990914 Object Class: 256E CenterTag: 28227NFOOD18MO0 Funded: \$8,980.00	10	EA	898.00	8,980.00
5	Environmental Sampling Obligated Amount: \$27,916.00 Continued ...	200	EA	139.58	27,916.00

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NAME OF OFFEROR OR CONTRACTOR
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ITEM NO. (A)	SUPPLIES/SERVICES (B)	QUANTITY (C)	UNIT (D)	UNIT PRICE (E)	AMOUNT (F)
	Accounting Info: 2018.6990914.256E.28227NFOOD18MO0 Appr. Yr.: 2018 CenterTag: 28227NFOOD18MO0 Funded: \$27,916.00				
6	Audits Obligated Amount: \$11,748.00 Accounting Info: 2018.6990914.256E Appr. Yr.: 2018 CAN: 6990914 Object Class: 256E CenterTag: 28227NFOOD18MO0 Funded: \$11,748.00	12	EA	979.00	11,748.00
7	Investigations - OEI Obligated Amount: \$27,850.00 Accounting Info: 2018.6990914.256E Appr. Yr.: 2018 CAN: 6990914 Object Class: 256E CenterTag: 28227NFOOD18MO0 Funded: \$27,850.00	50	EA	557.00	27,850.00
8	PC Rules Inspections Obligated Amount: \$31,340.00 Accounting Info: 2018.6990914.256E Appr. Yr.: 2018 CAN: 6990914 Object Class: 256E CenterTag: 28227NFOOD18MO0 Funded: \$31,340.00	10	EA	3,134.00	31,340.00
9	Option Year 1 POP: 9/30/2019 - 9/29/2020 Amount: \$413,666.00 (Option Line Item)				0.00
10	Option Year 2 POP: 9/30/2020 - 9/29/2021 Amount: \$423,362.00 (Option Line Item)				0.00
	Continued ...				

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NAME OF OFFEROR OR CONTRACTOR
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ITEM NO. (A)	SUPPLIES/SERVICES (B)	QUANTITY (C)	UNIT (D)	UNIT PRICE (E)	AMOUNT (F)
11	Option Year 3 POP: 9/30/2021 - 9/29/2022 Amount: \$433,454.00 (Option Line Item)				0.00
12	Option Year 4 POP: 9/30/2022 - 9/29/2023 Amount: \$443,888.00 (Option Line Item) FDA Three-Way Match Invoicing Procedures (NO COST TYPE) A. The contractor shall submit all invoices to: U.S. FOOD AND DRUG ADMINISTRATION Attn: Vendor Payments Division of Payment 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. Provide a copy marked courtesy to the COR or Technical Point of Contact (TPOC). The COR/TPOC is Teresa Bills at Teresa.Bills@fda.hhs.gov. 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 award item number for each description, quantity, unit of measure, unit price, and extended price supplies delivered or services performed; Continued ...				0.00

CONTINUATION SHEET

REFERENCE NO. OF DOCUMENT BEING CONTINUED
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NAME OF OFFEROR OR CONTRACTOR
STATE OF MISSOURI 125793

ITEM NO. (A)	SUPPLIES/SERVICES (B)	QUANTITY (C)	UNIT (D)	UNIT PRICE (E)	AMOUNT (F)
	<p>(v) Shipping number and date of shipment, including the bill of lading number and weight of shipment if shipped on government bill of lading;</p> <p>(vi) Terms of any discount for prompt payment offered (Prompt Payment terms other than NET 30);</p> <p>(vii) Name and address of official to whom payment is to be sent (must be the same as that in the purchase order/award, or in a proper notice of assignment)</p> <p>(viii) Name, title, and phone number of person to notify in event of defective invoice;</p> <p>(ix) Taxpayer Identification Number (TIN);</p> <p>(x) banking routing transit number of the financial institution receiving payment for Electronic funds transfer (EFT);</p> <p>(xi) Name and telephone number of the FDA Contracting Officer Representative (COR) or other Program Center/Office point of contact, as referenced on the award;</p> <p>(xii) For all Inspections, Time-and-Materials and Labor-Hour Awards, 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;</p> <p>(xiii) Any other information or documentation required by the award.</p> <p>C. An electronic invoice is acceptable if submitted in adobe acrobat (PDF) format. All items listed in (i) through (xiii) 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.</p> <p>D. Questions regarding invoice payments should be directed to the 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.</p> <p>The total amount of award: \$2,086,864.00. The obligation for this award is shown in box 15G.</p>				

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

This contract is designed to obtain State assistance in inspectional coverage of food establishments. The Food and Drug Administration (FDA) plays a key role in overseeing the nation's food supply. It is responsible for the oversight of most foods involved in interstate commerce, with the major exceptions of meat and poultry. Under the Federal Food, Drug, and Cosmetic Act (FD&C Act), the FDA's primary role in food safety is to inspect the conditions under which food is manufactured, processed, packed, distributed, or held.

States play a critical role in overseeing the nation's food supply. State and local governments conduct most of inspections in the U.S., including food retailers, manufacturers, processors and distributors within their State boundaries in accordance with their own laws and authorities. Many of the food firms inspected by States may also fall under Federal jurisdiction if they are involved in interstate commerce. State food inspectors are generally in the field more frequently than FDA food inspectors and offer an important source of front-line experience and expertise.

This contract is designed to assist in creating a national food safety system that includes State Agencies at all levels of safety to minimize consumers' exposure to adulterated and contaminated food. The Contractor shall conduct inspections of food establishments to determine compliance with the food provisions of the Federal FD&C Act and/or State laws.

B. Objectives

1. To obtain State and local assistance in the inspections of food establishments to determine compliance with the Federal FD&C Act, State law, or both;
2. To obtain State and local assistance in the collection of official follow-up samples as dictated by inspectional observations, inspection program, in support of enforcement actions, and risk;
3. To obtain State and local assistance for analytical support of samples collected using the Association of Official Analytical Chemists (AOAC) or FDA accepted methodology;
4. To obtain State and local reports of the inspections and sample collections as well as State and local reports on any compliance follow-ups and corrections achieved by the actions executed by the contractor under its own program.

B-2 – Compensation

A. The Contract Type is Firm Fixed Price.

B. As consideration for full performance of the work stated in Section C, “Scope of Work”, the Government shall pay the Contractor the not to exceed price of \$2,086,864.00 (total NTE for base plus all 4 option years). The Government shall have no obligation to make payment in excess of the ceiling price. The Government may increase the ceiling price of the contract. If this occurs, a bilateral contract modification will be required.

C. Payment

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 Section F-2 “Reports/Deliverables” and Section G-3 “Invoice Submission,” and in accordance with the schedule in part E.

D. Training/Travel

Training and domestic travel for training are not provided for in this contract. The Contractor is responsible for ensuring staff are trained in accordance with the State’s Training Plan as identified under the Manufactured Food Regulatory Program Standards (MFRPS) Standard 2, or equivalent requirements, in addition to meeting the training requirements specified in the contract.

E. Schedule

Base Year, Total NTE Price \$372,494.00

Period of Performance: September 30, 2018 to September 29, 2019

Item	Unit Each	Quantity NTE	Firm Fixed Price	Total NTE Price
Food Inspections	Each	NTE 275	\$885.00	\$243,375.00
Visits/Out of Business	Each	NTE 60	\$304.00	\$18,240.00
Total				\$261,615.00

The Contractor shall propose to perform on the additional elective inspections that apply to their state as listed below:

Item	Unit Each	Quantity NTE	Firm Fixed Price	Total NTE Price
Juice HACCP Inspections	Each	NTE 3	\$1,015.00	\$3,045.00
LACF Inspections	Each	NTE 10	\$898.00	\$8,980.00
Environmental Sampling	Each	NTE 200	\$139.58	\$27,916.00
Audits	Each	NTE 12	\$979.00	\$11,748.00
Investigations – OEI	Each	NTE 50	\$557.00	\$27,850.00
PC Rules Inspections	Each	NTE 10	\$3,134.00	\$31,340.00

Inspection OOB/Visits are **included** as a separate line item in this contract. Visits/OOBs shall be reimbursed at the negotiated fixed unit price specified above.

The Government reserves the right to bilaterally increase the number of Inspections as stated above.

Option Year 1, Total NTE Price \$413,666.00

Period of Performance: September 30, 2019 to September 29, 2020

Item	Unit Each	Quantity NTE	Firm Fixed Price	Total NTE Price
Food Inspections	Each	NTE 275	\$907.00	\$249,425.00
Visits/Out of Business	Each	NTE 62	\$310.00	\$19,220.00
Total				\$268,645.00

The Contractor shall propose to perform on the additional elective inspections that apply to their state as listed below:

Item	Unit Each	Quantity NTE	Firm Fixed Price	Total NTE Price
Juice HACCP Inspections	Each	NTE 3	\$1,037.00	\$3,111.00
LACF Inspections	Each	NTE 10	\$920.00	\$9,200.00
Environmental Sampling	Each	NTE 200	\$139.58	\$27,916.00
Audits	Each	NTE 12	\$997.00	\$11,964.00
Investigations – OEI	Each	NTE 50	\$573.00	\$28,650.00
PC Rules Inspections	Each	NTE 20	\$3,209.00	\$64,180.00

Inspection OOB/Visits are **included** as a separate line item in this contract. Visits/OOBs shall be reimbursed at the negotiated fixed unit price specified above.

The Government reserves the right to bilaterally increase the number of Inspections as stated above.

Option Year 2, Total NTE Price \$423,362.00

Period of Performance: September 30, 2020 to September 29, 2021

Item	Unit Each	Quantity NTE	Firm Fixed Price	Total NTE Price
Food Inspections	Each	NTE 275	\$928.00	\$255,200.00
Visits/Out of Business	Each	NTE 62	\$317.00	\$19,654.00
Total				\$274,854.00

The Contractor shall propose to perform on the additional elective inspections that apply to their state as listed below:

Item	Unit Each	Quantity NTE	Firm Fixed Price	Total NTE Price
Juice HACCP Inspections	Each	NTE 3	\$1,058.00	\$3,174.00
LACF Inspections	Each	NTE 10	\$941.00	\$9,410.00
Environmental Sampling	Each	NTE 200	\$144.18	\$28,836.00
Audits	Each	NTE 12	\$1,019.00	\$12,228.00
Investigations – OEI	Each	NTE 50	\$584.00	\$29,200.00
PC Rules Inspections	Each	NTE 20	\$3,283.00	\$65,660.00

Inspection OOB/Visits are **included** as a separate line item in this contract. Visits/OOBs shall be reimbursed at the negotiated fixed unit price specified above.

The Government reserves the right to bilaterally increase the number of Inspections as stated above.

Option Year 3, Total NTE Price \$433,454.00

Period of Performance: September 30, 2021 to September 29, 2022

Item	Unit Each	Quantity NTE	Firm Fixed Price	Total NTE Price
Food Inspections	Each	NTE 275	\$951.00	\$261,525.00
Visits/Out of Business	Each	NTE 62	\$323.00	\$20,026.00
Total				\$281,551.00

The Contractor shall propose to perform on the additional elective inspections that apply to their state as listed below:

Item	Unit Each	Quantity NTE	Firm Fixed Price	Total NTE Price
Juice HACCP Inspections	Each	NTE 3	\$1,081.00	\$3,243.00
LACF Inspections	Each	NTE 10	\$964.00	\$9,640.00
Environmental Sampling	Each	NTE 200	\$146.50	\$29,300.00
Audits	Each	NTE 12	\$1,040.00	\$12,480.00
Investigations – OEI	Each	NTE 50	\$600.00	\$30,000.00
PC Rules Inspections	Each	NTE 20	\$3,362.00	\$67,240.00

Inspection OOB/Visits are **included** as a separate line item in this contract. Visits/OOBs shall be reimbursed at the negotiated fixed unit price specified above.

The Government reserves the right to bilaterally increase the number of Inspections as stated above.

Option Year 4, Total NTE Price \$443,888.00

Period of Performance: September 30, 2022 to September 29, 2023

Item	Unit Each	Quantity NTE	Firm Fixed Price	Total NTE Price
Food Inspections	Each	NTE 275	\$974.00	\$267,850.00
Visits/Out of Business	Each	NTE 62	\$330.00	\$20,460.00
Total				\$288,310.00

The Contractor shall propose to perform on the additional elective inspections that apply to their state as listed below:

Item	Unit Each	Quantity NTE	Firm Fixed Price	Total NTE Price
Juice HACCP Inspections	Each	NTE 3	\$1,104.00	\$3,312.00
LACF Inspections	Each	NTE 10	\$987.00	\$9,870.00
Environmental Sampling	Each	NTE 200	\$148.90	\$29,780.00
Audits	Each	NTE 12	\$1,063.00	\$12,756.00
Investigations – OEI	Each	NTE 50	\$620.00	\$31,000.00
PC Rules Inspections	Each	NTE 20	\$3,443.00	\$68,860.00

Inspection OOB/Visits are **included** as a separate line item in this contract. Visits/OOBs shall be reimbursed at the negotiated fixed unit price specified above.

The Government reserves the right to bilaterally increase the number of Inspections as stated above.

SECTION C – DESCRIPTION/ SPECIFICATIONS/ STATEMENT OF WORK

Scope of Work

Independently, and not as an agent of the Government, the Contractor shall furnish the necessary personnel, materials, services, facilities, except as provided in the schedule, and otherwise do all things necessary for or incidental to the performance of the work.

The Contractor shall conduct establishment inspections, consisting of initial inspections, necessary re-inspections (as assigned by the District), visits, and other work as assigned by the District as needed. The Contractor shall also conduct follow-up to any open consumer complaints associated with the firm unless otherwise directed by the District. In limited situations, the District may request immediate follow-up at a firm due to a consumer complaint, verification of corrective actions, or investigation of other significant public health and regulatory issues.

The Contractor's establishment inspections shall comply with the General Requirements for Conducting Inspections (a. General Requirements for Conducting Inspections, of this document). The Contractor shall ensure staff is trained in accordance with the State's Training Plan as identified under the Manufactured Food Regulatory Program Standards (MFRPS) Standard 2, or equivalent requirements, in addition to meeting the training requirements specified in the contract. The State and District will agree upon the specific requirements for conducting and reporting inspections and other work performed as part of the work planning meeting. The Contractor may refer to the Investigations Operations Manual 2017 (or most recent version when notified by FDA), Chapter 5 – Establishment Inspections (specifically, Sections 5.3.6, 5.4, and 5.10.4.3) for guidance on conducting inspections, collecting evidence, and writing Establishment Inspection Reports (EIRs) (<http://www.fda.gov/ICECI/Inspections/IOM/default.htm>).

The inspections can be accomplished under the authority of the State's law and the inspector's State credentials if the contracting State has adopted all applicable sections of Title 21 of the Code of Federal Regulations (CFR) or can demonstrate equivalent State requirements. A legal review should be conducted by the State agency's counsel to determine if the State regulatory requirements are equivalent in effect to the current Federal requirements. It is the responsibility of the Contractor to determine whether the State regulatory requirements are equivalent to the Federal requirements.

If the contracting State has not adopted all applicable sections of Title 21 of the CFR or demonstrated equivalent State requirements, the Contractor shall conduct inspections under this contract using State officials who have been commissioned and credentialed as officers of the Department of Health and Human Services (DHHS), FDA, as set forth in section 704(a)(1) of the Federal FD&C Act. Commissioned officials will use current credentials and use FDA forms as necessary during an inspection.

The Contractor shall discuss and verify compliance with the above delineated regulatory authority requirements with the District prior to commencing contract inspection work.

The Contractor will place major inspectional emphasis upon determining significant violations to the Food Good Manufacturing Practices (GMPs), unsanitary conditions, and practices that may render the food adulterated or injurious to health. During inspections of assigned firms, practices and conditions that involve the introduction, lack of controls, and/or growth promotion of pathogenic organisms or other conditions that may result in the food becoming filthy, putrid, decomposed, or contaminated with foreign objects shall be determined and documented.

Compliance with federal law, such as the "Public Health Security and Bioterrorism Preparedness and Response Act of 2002;" the Federal FD&C Act, Section 402(a)(3) and (4); Federal Regulations, e.g. the GMP Regulations (21 CFR 110); modernized cGMP and Risk-Based Preventive Controls (21 CFR 117) or Section 10(a)(3) and (4) of the Uniform State Food, Drug and Cosmetic Bill; or equivalent State GMPs will be determined. Where applicable, use the Hazard Analysis and Critical Control Point (HACCP) concept to evaluate a firm's quality assurance program and its operations.

The Food Safety Modernization Act (FSMA) was signed into law on January 4, 2011. FSMA enables FDA to focus more on prevention of food safety problems, provides new enforcement tools, and encourages partnerships with States, locals, territories, and tribes. One of the foundational rules for FSMA implementation is the Current Good Manufacturing Practices and Hazard Analysis and Risk-Based Preventive Controls for Human Food (21 CFR Part 117, also abbreviated as the Human Food PC Rule). The Human Food PC Rule became final in September 2015 with compliance dates for some firms in September 2016. All firms are required to comply with the Human Food PC Rule by September 2018.

Inspectors must complete the 21 CFR 117 Modernized Good Manufacturing Practice (GMP) Inspections Webinar, FD8000L, found in Pathlore prior to conducting modernized cGMP inspections. Modernized cGMP inspections are also referred to as limited scope PC rule inspections. Refer to Attachment 6 for instructions on accessing the course in Pathlore. This webinar provides introductory overview of some of the subparts of the new 21 CFR 117 Modernized Good Manufacturing Practice (GMP) Inspections. This is also pre-work for the classroom training for food safety staff to support for overseeing industry compliance with the PC rules through inspection and compliance activities.

In addition, the contractor shall conduct establishment inspections based on the plans and requirements established during the Work Planning Sessions (a. General Requirements for Conducting Inspections, No. 5 of this document). Inspections may also be assigned outside of the workplanning meeting in follow-up to a recall (typically Class I), consumer complaint, or Reportable Food Registry (RFR); a violative inspection; confirm corrective actions have been completed; or to address other regulatory or public health concerns. These types of follow-up inspections can be billed under the appropriate inspection type.

The Establishment Inspection Report (EIR) and form FDA 483 (Inspectional Observations), or equivalent forms, shall detail the conditions found by the Contractor with sufficient narrative and evidence to enable an FDA assessment of the significance of any objectionable conditions or practices. Where microbiologically oriented inspections are conducted, a more detailed description of the manufacturing process, routes of contamination, etc., shall also be made. The Contractor shall record the corrective actions taken by the firm in response to identified significant violations, including the firm's response to the Contractor, in the summary section of the inspection report and Electronic State Access to Facts (eSAF) (or other FDA-approved systems, such as the National Food Safety Data Exchange (NFSDX)).

All information collected during the performance of this contract shall be considered as confidential commercial information, including the Establishment Inspection Report (EIR), FDA 483, or equivalent forms, evidence collected, and all other supporting documentation. Evidence and supporting documentation may include supplier, receiving, and distribution records, photographs, complaint records, laboratory results, and other documents collected during the performance of the contract. The Contractor shall notify the District within three (3) business days after receipt of a public records request for information obtained during the performance of the contract is received. The Contractor is not authorized to release confidential commercial information. Refer to Section H – Special Contract Requirements for additional requirements for maintaining confidential commercial information.

a. Elective Work (Refer to Detailed Tasks, Part b. Electives)

- Seafood HACCP Inspections
- Juice HACCP Inspections
- Acidified/Low-Acid Canned Food Inspections
- Samples
- Import Products
- Environmental Sampling
- Domestic/Import Samples
- Audit Program
- Manufactured Food Regulatory Program Standards (MFRPS)
- Investigations – Official Establishment Inventory (OEI) and Direct Recall Audit Checks (RACs)
- Preventive Control (PC) Rules Inspections
- Sprout Inspections

b. Training (Refer to Detailed Tasks, Part c. Training)**Detailed Tasks****a. General Requirements for Conducting Inspections**

The contractor shall comply with the following requirements when conducting inspections under this contract:

1. BioTerrorism Act of 2002**i. Food Defense Security Preventive Measure Guidance**

During the inspection, the contractor should determine if the facility is aware of food defense security preventive measures. If the facility is not aware of these measures, the inspector should facilitate an exchange of information to heighten awareness of the subject of food defense. Inform the establishment management of the appropriate security preventive guidance or provide information on how to obtain the guidance from FDA. Guidance related to Food Defense and Emergency Response efforts are available on FDA/CFSAN's web site:

<http://www.fda.gov/Food/FoodDefense/default.htm>

ii. Registration

As assigned by the District Office, the contractor shall make sure that the firm's management is aware of the BioTerrorism Act (BT Act) registration requirements and any updates to that information. The firm's management shall also be informed that information regarding food security, the BT Act, facility registration, required and

optional information, definitions, exemptions, and penalties for failure to register, etc., is available at the following website:

<http://www.fda.gov/food/guidanceregulation/foodfacilityregistration/default.htm>

All food facilities that are required to register with FDA under section 415 of the Federal FD&C Act must renew their registrations with FDA biennially. The contractor shall inform the firm that changes to the BT Act require food facilities to submit registrations to FDA containing information previously considered optional. Additional information regarding Registration Renewal may be found at:

<http://www.fda.gov/Food/GuidanceRegulation/FSMA/ucm314178.htm#new> .

The FDA Unified Registration and Listing System (FURLS) was built to register all domestic and foreign facilities that export food to the U.S. electronically. Contractors shall establish user accounts for at least two (2) key personnel in the FDA Unified Registration and Listing Systems (FURLS) within the first 60 calendar days of the contract period of performance. Key personnel should have direct responsibility for meeting the obligations of the contract. Contractors are required to access FURLS to determine the registration status of the firm prior to conducting an inspection.

For facilities that are required to register, but have not yet done so, the contractor shall encourage electronic registration at the following website:

<https://www.access.fda.gov/>

iii. Documentation

The fact that the discussion regarding the firm's security measures took place and, if applicable, guidance documents were provided should be recorded in the Summary section of the inspection report. The details of inspectional findings regarding security should **NOT** be recorded.

The contractor shall document the registration status of the firm and registrations discussions with firm management in the "Summary of Findings and Discussion with Management" sections in their inspection report. Observations about failure to register or implement food defense measures are **NOT** to be placed on the FDA 483 or equivalent form. If a facility is not registered and they do not intend to register, the contractor is to notify the local FDA District office.

2. Preventive Controls for Human Food and Other Finalized Rules under the Food Safety Modernization Act (FSMA) of 2011

- i. The FDA FSMA Preventive Controls for Human Food rule became final on September 10, 2015. The compliance dates are staggered with compliance dates for some firms beginning in September 2016. The new rule requires that food facilities have safety plans that set forth how they will identify and minimize hazards. Requiring preventive measures at facilities that produce human food is an important step in reducing foodborne illness.

To assist FDA in communicating the Preventive Controls rule, the contractor shall print and hand out or provide electronically the attached FSMA Facts Final Rule on Preventive Controls for Human Food Information Sheet (or most recent version when notified by FDA) to the most responsible individual at the inspected establishment during the opening meeting. The information sheet (Attachment 7 or most recent version when notified by FDA) provides the key requirements and compliance dates.

- ii. The goal of the Sanitary Transportation of Human and Animal Food rule under FSMA is to prevent practices that create food safety risks, such as failure to properly refrigerate food, inadequate cleaning of vehicles, and failure to properly protect food during transportation. Specifically, the rule establishes requirements for vehicles and transportation equipment, transportation operations, information exchange, training, records, and waivers.

To assist FDA in communicating the rule on Sanitary Transportation of Human and Animal Food under FSMA, the contractor shall print and hand out or provide electronically the attached FSMA Facts Proposed Rule on Sanitary Transportation of Human and Animal Food Fact Sheet (Attachment 8 or most recent version when notified by FDA) to the most responsible individual at the inspected establishment during the opening meeting. The information sheet provides the key requirements and compliance dates.

- iii. The FDA FSMA rule on Mitigation Strategies to Protect Food Against Intentional Adulteration requires the covered facilities to conduct a vulnerability assessment and create a written food defense plan to address significant vulnerabilities in a food operation. The rule aims to prevent acts on the food supply intended to cause wide-scale public harm. The rule has staggered compliance dates based on business size.

To assist FDA in communicating the final rule and its requirements, the contractor shall print and hand out or provide electronically the attached rule fact sheet (Attachment 9 or most recent version when notified by FDA) to the most responsible individual at the inspected establishment during the inspection. The fact sheet provides information on key requirements, exemptions, and compliance dates.

- iv. **Final Rule on Foreign Supplier Verification Programs (FSVP)**
The FDA FSMA Rule on Foreign Supplier Verification Programs (FSVP) for Importers of Food for Humans and Animals is final, and the first compliance dates began May 30, 2017. The final rule requires that importers perform certain risk-based activities to verify that food imported into the US has been produced in a manner to meet applicable US food safety standards.

To assist FDA in communicating the final rule and its requirements, the contractor shall print and hand out or provide electronically the attached rule fact sheet

(Attachment 29 or most recent version when notified by FDA) to the most responsible individual at the inspected establishment during the inspection. The fact sheet provides information on key requirements and exemptions.

v. Documentation

The contractor shall document if the Preventive Controls Rule, Sanitary Transportation of Human and Animal Food Rule, Protecting Food Against Intentional Adulteration Rule, and FSVP Rule Fact Sheets were provided to the firm as part of the EIR and in eSAF (or other FDA-approved systems, such as NFSDX).

3. Inspection Priorities

The establishments available for inspection by the contractor are those that come under the jurisdiction of both the Contractor and FDA and are considered an inspection priority by FDA. FDA may add firms to the Official Establishment Inventory (OEI) during work planning sessions (reference No 5. below), or as needed.

Shellfish establishments which are a State inspection responsibility only under the National Shellfish Sanitation Program are not eligible for coverage under this contract. Grade A milk facilities where only Grade A products are produced under the Interstate Milk Shippers Program are not eligible for coverage under this contract. In addition, firms that solely engage in the manufacture and distribution of Dietary Supplements are not covered under this contract.

Inspection of firms is to be consistent with Agency objective of reducing foodborne outbreaks by determining compliance with various regulations that cover potentially high risk products, such as unpasteurized juices, non-Grade A dairy products, and egg containing products, where the contractor has jurisdiction over those establishments. However, inspection assignments will include a mix of both High Risk and Non-High Risk establishments. The contractor shall have the contractual obligation to perform each type of inspection selected and assigned during workplanning. The contractor shall ensure that the inspection is performed by personnel that have completed the necessary training requirements.

The firm must be operational and in production during the inspection unless otherwise approved by the District. Examples of exceptions that may be approved by the District and billed as an inspection include:

- Responding to a consumer complaint or recall (typically Class I)
- Reportable Food Registry (RFR) follow-up
- Verification of deficiency letter responses and corrective actions taken by a firm
- Verification of corrective actions following an inspection with egregious or significant violations

- Other inspections of regulatory or public health significance

Prioritization and assignment of establishments by FDA for coverage under the contract will result from the Work Planning Session (reference No. 6 below) and take into consideration the following priorities from FDA Compliance Programs:

The greatest inspection priority is placed on “High Risk” firms, Performance Goals (PGs), and meeting mandatory inspection frequency mandates established by FSMA as identified by the FDA District Office. To meet FDA mandated inspection frequencies, assignments will include a “cover-by” date. The State shall complete the inspection by the cover-by date.

High risk firms are identified utilizing a decision-making process based on the risk factors identified in section 421(a)(1) of the Federal FD&C Act (<http://www.fda.gov/food/guidanceregulation/fsma/ucm295345.htm>).

- i. Firms classified OAI, one or more times during the past three (3) years. Also, firms with a pattern and history of violations or other items of regulatory concern over this time period, whether or not inspections were classified as OAI.
- ii. Firms that could have potential problems or which produce a product with a history of known or potential health hazards, such as Class I recalls or outbreaks. Potential problems may be discovered using District and State intelligence information (e.g., past inspections, industry information, consumer complaints, news reports, etc.). Examples of such firms are the producers of:
 - cream filled baked goods,
 - ice cream,
 - soft cheeses, which comprise soft fresh, soft ripened, soft unripened cheeses,
 - other items which receive little or no further processing before consumption by the consumer (e.g., ready-to-eat, heat & serve),
 - products in which time/temperature problems could occur (e.g., commodities which support microbial growth when abused), and
 - fish and fishery products manufacturers
- iii. In addition to the GMP and other relevant regulations, inspections of certain food processors shall be conducted in accordance with the following guidelines:
 - Domestic Fish and Fishery Products Inspection Program (Seafood Hazard Analysis and Critical Control Points (HACCP) shall be performed in accordance with CPGM 7303.842 (Attachment 10).
 - Juice HACCP inspections shall be performed in accordance with CPGM 7303.847 (Attachment 11).

- Domestic Acidified (AF) and Low-Acid Canned foods (LACF) Inspections shall be performed in accordance with CPGM 7303.803A (Attachment 12).
- iv. Firms selected because of the violative history of the firm or overall industry.
 - v. Firms never inspected by FDA or never inspected under the Food Safety Program should be given precedence over firms previously inspected or inspected under the Food Safety Program and classified as No Action Indicated (NAI).
 - vi. Warehouse establishments considered “high risk”; ones that have had previous violative inspections; consumer complaints; new establishments; or have not been inspected in the past 5 years.

4. Work Planning Sessions

An annual work planning session(s) between the appropriate FDA District Office and State contractor personnel shall occur no later than thirty (30) business days after the start of the contract period of performance. The District Technical Advisor will draft the work planning session(s) minutes for review by the State within thirty (30) business days. Corrections must be agreed upon by both the State and District. The goals of the session(s) are to:

- i. Coordinate an inspection schedule that will avoid duplication of inspections and ensure that the work obligated on the contract is aligned with anticipated work assignments.

For contracts with periods of performance that start on or before September 1:

- A minimum of twenty (20%) of the assignments required to meet the contract obligation will be made during the workplanning session.
- All remaining assignments will be issued by the start of the 2nd quarter of the contract period of performance.
- At the discretion of the State and District, an additional workplanning meeting may be necessary.

For contracts with periods of performance that begin after September 1, all assignments required to meet the contract obligation will be assigned during the workplanning meeting.

- ii. Develop a consensus of the priority in the selection of firms to inspect. Firms with the highest priority for inspection should be agreed upon. Discuss and select firms for environmental sampling, if selected as an option.
- iii. To meet FDA mandated inspection frequencies, assignments may include a cover-by date. The inspection shall be completed by the cover-by date.

- iv. Discuss types of follow-up inspections that may be assigned outside of the workplanning session and expectations. For example, follow-up to a recall, RFR, or consumer complaint or verification of corrective actions taken by a firm.
- v. Discuss and ensure clarity in regards to the definition of a “visit” per the contract, criteria for considering a firm “OOB” or out of business, and reporting requirements.
- vi. Review FDA and State firm inventories for the identification of new firms and updating firm information, such as operational status, products being manufactured or stored, distribution of products, name, address, etc. In addition, the FDA will provide the Firm Establishment Identification (FEI) numbers for all firms on the inspection schedule.
- vii. Develop an audit schedule when assigning the firms to be inspected under contract. Firm selection should be based on the inspection priorities listed in the “Statement of Work” section of the contract and contractual obligation of the contractor, including the current audit phase.
- viii. Confirm that State regulatory authorities are equivalent to Federal requirements, or the State officials are commissioned.
- ix. Review the utilization of eSAF (or other FDA-approved systems, such as NFSDX) and data entry requirements.
- x. Establish and exchange primary contact information. Along with program management, it is recommended that senior management from the State and District are also part of the process.
- xi. Confirm understanding of key contract deliverables and schedules. The requirements and critical elements of the reporting requirements for establishment inspections and other work will be agreed upon by the State and District. Target completion goals for meeting the contract obligation in established limits shall be also agreed upon by the State and District. Examples of target completion goals are completion of a specified percentage or firms that must be inspected by an agreed upon date. The target completion goals should consider the availability of the firms for inspection (such as seasonal firms), District performance goals, and State resources.
- xii. Confirm training requirements are met by State officials to perform inspections, audits, and other work obligated under the contract.
- xiii. Determine appropriate samples to be collected under contract, if selected as an option.
- xiv. Discuss the corrective action plan requirement and triggers for submitting a corrective action plan.
- xv. Discuss training needs, sharing of resources, and other collaborative efforts.

A minimum of one additional meeting shall be held with the District and State during the second or third quarter of the contract performance period to review the progress of the State and verify the contract deliverables are being satisfactorily met.

5. Frequency of Inspection

The inspections conducted under this contract shall be scheduled in accordance with the provisions of the FDA Compliance Programs referenced below in the section titled "Compliance Documents" and any other relevant guidance.

The FSMA establishes a mandated inspection frequency, based on risk, for food facilities. High-risk (HR) facilities must be inspected once every 3 years. Non-high-risk (NHR) facilities must be inspected once every 5 years. These inspection frequencies are minimums and some firms may be inspected on a more frequent basis at the discretion of the District.

In addition, firms with an assigned "cover-by" dates shall be inspected by the date specified. The District and State will confirm the firm assignments and priorities for completion during the workplanning session.

A complete inspection requires the firm to be operational and in production unless approved by the District. If a complete inspection cannot be performed due to the firm not being operational or in production, then a visit should be charged. The Contractor is strongly encouraged to use electronic resources (such as licensing, Secretary of State records, and Internet research) to verify the firm's operational status prior to conducting a physical on-site visit. The Contractor is encouraged to communicate concerns about the firm's operational status with the District prior to conducting the inspection.

HR firms are identified based on the risk factors identified in section 421(a)(1) of the FD&C Act. Each District has access to the Official Establishment Inventory (OEI).

- i. Inspections for cause may be scheduled more frequently than described above, e.g., follow-up to a consumer complaint or reinspection as assigned by the District.
- ii. An Inspection Visit is defined as when an inspection is attempted as assigned by the District and the establishment is found to be: "Out of Business" (OOB), not an official establishment (NOE) as defined by FDA, not subject to coverage under the food contract, relocated outside of the contractor's geographical jurisdiction, or when a complete inspection cannot be accomplished during the contract period of performance for unforeseen circumstances. Investigational contractor activities completed under the Investigative elective are not considered a visit, even if the result is a finding of OOB or NOE.

A visit shall be documented by providing the District with an establishment inspection report or other form as directed by the District. The report shall document

all efforts made by the Contractor to conduct a full inspection and research performed to verify the operational status, location, and activities of the firm. The Contractor should request a replacement assignment or inspection within twenty (20) business days of a visit being encountered, if necessary.

OOB is defined as a firm that is no longer in business for reasons other than having moved. Reasonable efforts to verify a firm is OOB shall include a physical visit and at least one additional verification step. Options include: 1. Verification with the local post office that the firm no longer receives mail at the address and does not have a forwarding address. 2. Verification of the suspension or dissolution of the corporate entity with the applicable State. 3. Interview of representatives of neighboring establishments, current tenants at the indicated address, or others (such as real estate agents) who may have knowledge of the disposition of the firm's operations at the location.

The contractor shall perform similar reasonable efforts to locate firms that have moved or relocated. If a firm has relocated to a new location within the contractor's geographical jurisdiction, a complete inspection shall be conducted at the new location. Payment for the inspection at the new location will be made. A visit, in addition to the inspection, may be charged if the firm has moved more than 50 miles. If a firm has relocated to a new location out of the contractor's jurisdiction, a visit may be charged.

NOE is defined as an establishment that is no longer manipulates product or is engaged in activities subject to FDA regulation, but remains in business. The activities performed by an NOE firm shall be fully documented in the report to allow for a correct determination of the firm's status by FDA. Additional guidance is found in Field Management Directive (FMD)-130 OEI Development and Maintenance Procedures (Date Revised July 17, 2006), <http://www.fda.gov/ICECI/Inspections/FieldManagementDirectives/ucm096034.htm>

Due to errors in the FDA inventory, firms that are not subject to contract inspection may still engage in activities under FDA jurisdiction. While the firm may not be considered OOB or NOE by FDA, the contractor may charge for a visit if the firm is determined by the District to not be eligible for inspection under the contract.

Reasonable efforts to conduct a complete inspection must be approved by the District.

- iii. Joint inspections with FDA personnel to achieve nationwide uniformity, training, evaluation, and audits should be planned and included within the inspections to be accomplished by the Contractor.
- iv. Compliance actions are not provided for under this contract. However, it is anticipated the Contractor will vigorously pursue any necessary compliance follow-up to violative conditions encountered during inspections made under this contract under State authorities. Such actions may include embargo, stop-sales, administrative plant closures or orders, civil penalties, warnings, license revocations, court actions,

etc. The contractor shall notify and coordinate such State actions with the FDA District. Where appropriate correction has not been achieved by the Contractor, FDA may initiate compliance actions under the Federal FD&C Act.

- v. If an inspection conducted under contract results in a final District classification of OAI, and is supported by violations that are “materially related to food safety,” the State will be notified by the District. Any re-inspections of the firm will be conducted by the FDA District office.

6. Compliance Documents

The activities under the contract shall be conducted using procedures, techniques, and reporting forms equivalent to FDA or as required by State law. The contract inspections shall be conducted in accordance with the applicable sections of the following current FDA Compliance Programs and/or any other documents including assignments issued by FDA. FDA offices will provide technical guidance or any necessary documents to the Contractor.

i. Reference Documents

The following food compliance programs are incorporated by reference as guidance for the conduct of contract inspections. FDA will furnish updated copies to the Contractor where appropriate.

- Domestic Food Safety Program (CPGM 7303.803), Program Assignment Code (PAC) 03S001 (Attachment 13).
- Domestic Fish and Fishery Inspection Program (CPGM 7303.842), PAC 03S002 (Attachment 10).
- Juice HACCP Compliance Program (CPGM 7303.847), PAC 03S004 (Attachment 11).
- Domestic Acidified and Low-Acid Canned Foods (CPGM 7303.803A), PAC 03S005 (Attachment 12).
- Domestic and Imported Cheese & Cheese Products Program (CPGM 7303.037), Assigned under PAC 03S001 (Attachment 14).
- Domestic and Import NLEA, Nutrient Sampling and Analysis, and General Food Labeling Program (CPGM 7321.005), Assigned under PAC 03S003 (Attachment 15).
<http://www.fda.gov/Food/ComplianceEnforcement/FoodCompliancePrograms/ucm238066.htm>

ii. Bottled Water Plants

Bottled water plants shall be inspected to determine compliance with the bottled water GMP regulation, 21 CFR 129, which includes testing requirements. If indicated by inspectional observations, one finished product sample may be collected to determine compliance with the standard of identity and quality for bottled water in 21 CFR 165.110 (formerly 103.35; See FEDERAL REGISTER 60 57076-57130, Effective date: May 13, 1996). If a sample is collected, contractor shall analyze the sample for: microbiological quality, benzene and chloroform via a screen for volatile organic compounds, and for the heavy metals lead, cadmium, mercury, and arsenic. The Contractor shall submit Sample Reports upon final results determination to the FDA District Office and enter the results into eLEXNET.

iii. Additives and Allergens

Other factors which could affect the safety of a food product should also be covered. During an inspection of a food manufacturer, the use of color additives, food additives, and food allergens shall be determined and reported in accordance with compliance programs required herein. The Contractor shall focus on the specific additives identified in the Domestic Food Safety Compliance Program Guidance Manual (CPGM) 7303.803.

iv. Nutrition Labeling

Nutrition labeling is required in 21 CFR 101.9 for all food products offered for sale, except for exempt foods under 21 CFR 101.9(j). On May 20, 2016, the FDA announced the new Nutrition Facts label for packaged foods, which includes updates to the required nutrient declarations, serving sizes, and formatting requirements.

For more information on the new requirements, please visit:

<http://www.fda.gov/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/LabelingNutrition/ucm385663.htm>

<https://www.fda.gov/Food/ComplianceEnforcement/FoodCompliancePrograms/ucm238066.htm>.

Manufacturers may begin revising labels now to meet the new requirements or they may continue to follow existing requirements. However, firms should not use labels which mix the old and new format (hybrid labels). During contract inspections of manufacturers, labelers, or re-labelers, States shall review labels being used to determine if they comply with the old or new nutrition labeling regulations. The inspections shall also include the determination and reporting on the exempt status of the firm or labels, and whether the products are shipped in interstate commerce.

The label review shall be conducted in accordance with the current Compliance Program and the current Guidelines for State Coverage of NLEA Under Food

Inspection Contracts, included as Attachment 1 (or most recent version after notified by FDA).

When the District Technical Advisor determines the Contractor is accurately identifying the violations emphasized in the assignment/program, submission of non-violative labels will not be required. The Contractor shall collect and submit to the District interstate documentation for all violative labels. Three (3) copies or photos of violative labels shall be collected along with any other supporting evidence for the violations referenced in the report.

All follow-up action, including regulatory actions, shall be coordinated with the appropriate FDA District Office unless an immediate public health risk exists.

v. Listeria

The Contractor shall perform inspections in accordance with the FDA published draft guidance entitled "Guidance for Industry: Control of *Listeria monocytogenes* in Refrigerated or Frozen Ready-To-Eat Foods, February 2008" (Attachment 16). This draft guidance complements FDA's current good manufacturing practices (CGMP) regulations by providing specific guidance on the control of *Listeria monocytogenes* in the processing of refrigerated or frozen ready-to-eat foods (RF-RTE foods). The draft *Listeria* guidance and the CGMP regulations are intended to assist processors in controlling *Listeria monocytogenes* in the food processing environment during the manufacture of RF-RTE foods.

7. Quality Control/ Performance Standards

FDA will evaluate the Contractor's overall performance throughout the contract period. This will be accomplished by a variety of techniques. Inspectional performance evaluation will include review of inspection reports, audits, and joint inspections conducted as contract inspections. Such inspections will be scheduled by the FDA District Office in concert with the Contractor. For comprehensive information regarding the FDA Audit Program, refer to Field Management Directive (FMD)-76 State Contracts – Evaluation of Inspectional Performance (Attachment 17, or most recent version when notified by FDA).

i. Analytical Support Evaluation

Analytical support evaluation will include, where appropriate: review of sample reports, joint bench work in FDA or State laboratories, on-site review of State laboratory facilities and equipment, and participation in split sample programs, wherein microbiological and microanalytical (filth) split samples will be analyzed by State laboratories supporting contract inspections. These split samples will be a part of the FDA-State Laboratory Quality Assurance Programs.

ii. Inspector Performance Audit Standard

All contractor inspectors shall be audited at the frequency described in the most recent version of FMD-76.

iii. Inspector Performance Measurement

All contractor inspectors shall successfully pass audit requirements with an acceptable rating. For audit requirements, refer to the most recent version of FMD-76.

iv. Inspector (Individual) Performance Deficiencies and Correction

The District or State agency shall document and correct inspector (individual) performance deficiencies as described in the most recent version of FMD-76, including the completion of a Corrective Action Plan for Program and Individual Performance Deficiencies (Appendix J of FMD-76). All contractor inspectors who receive an overall score of “needs improvement” shall receive remedial training in deficient areas as agreed upon by the District and State program. The State inspector shall discontinue conducting contract inspections until remedial training is completed and audits performed by the State program and District verify the deficiency has been corrected. The State program may be required to address performance issues noted during an inspection audit.

Refer to FMD-76 for additional details.

v. Contract Program Audit Performance Evaluation and Correcting Deficiencies

The District will coordinate with the State to take appropriate action when the Audit Program identifies deficiencies in the program’s performance of the contract inspections as described in the most recent version of FMD-76. An unacceptable audit will not cause a contract to be altered or unpaid, nor will payment for the contract inspection be withheld. The contractor will be evaluated on its overall work performance and all audits conducted during the contract year, not the outcome of one contract audit. Audit findings may indicate an overall program deficiency or a deficiency with a specific performance element. Program performance deficiencies will require the completion of a Corrective Action Plan for Program and Individual Performance Deficiencies (Appendix J of FMD-76). The State program may be required to address performance issues noted during an inspection audit.

Refer to the most recent version of FMD-76 for additional details.

vi. Contract Performance Standard

In accordance with contract requirements, the contractor shall conduct assigned initial inspections, necessary re-inspections, and visits within the State and all completed

inspection results shall be received by the FDA District Office no later than thirty (30) business days after completion of the inspection. Inspections are defined as completed when the inspectional activity at the firm has concluded, the Form FDA 483 (or equivalent form) has been issued to the firm (if appropriate), and the closeout discussion has been held. The inspection results shall be entered in eSAF (or other FDA-approved systems, such as NFSDX) and received by the District office within thirty (30) business days after completion of the inspection. Submission of the establishment inspection report may be electronic or hard copy via mail, as determined by the District. Within thirty (30) business days of receipt, the responses received from the firm detailing corrective actions in response to a contract inspection shall be received by the District. In addition, the State shall notify the District via email within three (3) business days upon determination that significant violations are identified during the inspection or State regulatory action is being considered or planned.

The District and FDA/ORA/Office of Regulatory Science (ORAHQORSMANAGEMENT@fda.hhs.gov) shall be notified within one (1) business day of potentially significant positive laboratory results, preliminary positive (Can't Rule Out (CRO)) pending confirmation, or when a sample is determined to be confirmed positive. Sample reports for positive (violative) samples shall be submitted to the District within three (3) business days of final determination. Sample reports for negative samples (non-violative) shall be received by the District within (30) business days of final determination.

At least 90% of all submitted reports shall be timely, accurate, and acceptable for data entry, analyses, and processing.

vii. Contract Performance Measurement

The Government will measure compliance with contract inspection requirements by reviewing inspection records and conducting audits or joint inspections. Results of all FDA quality assurance reviews will be furnished to the contractor. A sample of inspection records will be reviewed by FDA to verify that the required data and information are complete and accurate.

viii. Corrective Action Plan for Contract Performance

The contractor shall submit a corrective action plan if 90% of the deliverables do not successfully meet any given requirement as stated in this contract or presented during the workplanning meeting. The corrective action plan shall identify the responsible parties, actions required, dates of completion, and other information needed to ensure the contract requirements and obligation will be met during the contract period of performance. The contractor shall submit the corrective action plan as described in Section F of this contract to the Contracting Officer's Representative (COR), District Technical Advisor, and Contracting Officer. The inability to meet the requirements of the contract may result in adverse actions, including termination of the contract.

ix. Delay in Contract Payments

If FDA finds an inspection record, sample report, quarterly report, or invoice to be unacceptable, the Contractor will be advised and given an opportunity to correct and/or resubmit the required documentation. Each instance whereby the Contractor fails to submit or correct the required report shall result in the delay of invoice payment until the corrected document(s) are received and accepted by the FDA.

8. Electronic State Access to Field Accomplishments (eSAF) and Compliance Tracking System

The FDA has an automated Field Accomplishment and Tracking System (FACTS) in which all food firm inspection data is captured and tracked. To automate some processes and to streamline communications between the States and FDA, the eSAF concept was developed.

The eSAF system automates the issuance of work requests to the State food firm contractors and allows the contractors to enter and update inspection results electronically. Additionally, the contractors will have access to the firm’s data that FDA has maintained in FACTS for the past several years. This data will enable the contractors to identify firms considered to be “high risk” and to obtain information about past inspections and violations for firms within their jurisdictional area. Attachment 2, “Electronic State Access to Field Accomplishments (eSAF) and Compliance Tracking System,” represents the requirements associated with eSAF.

Guidance on FDA product codes and OEI development and maintenance procedures may be found in FMD-130 (Attachment 18, or most recent version when notified by FDA)..

The FDA Product Code Builder may be found at:
<http://www.accessdata.fda.gov/SCRIPTS/ORA/PCB/PCB.HTM>

Inspections should be classified using the guidance found in FMD-86 Establishment Inspection Reports and Decisions and provided by the District (Attachment 19, or most recent version when notified by FDA).

Inspection conclusions found in eSAF may transfer differently into FACTS. The table below summarizes the eSAF classifications that may be chosen and the final inspection conclusion found in FACTS. Guidance from the District on the proper use of eSAF inspection classification will be provided to the State.

eSAF Classification	eSAF Code	Transfer Code	FACTS Code	FACTS Classification	Definition excerpted from FMD-86
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No action indicated	NAI	N	NAI	No Action Indicated (NAI)	No objectionable conditions or practices were found during the inspection, or the objectionable conditions found do not justify further action.
No action/follow-up inspection	NFI	N	NAI	No Action Indicated (NAI)	
Voluntary action indicated	VAI	E	VAI	Voluntary Action Indicated (VAI)	Significant objectionable conditions and practices were observed, but the District is not prepared to take or recommend any regulatory action.
Violation/follow-up inspection	VFI	E	VAI	Voluntary Action Indicated (VAI)	
Action referred to FDA	RAI	A	OAI	Official Action Indicated (OAI)	Significant, objectionable conditions or practices warrant a Warning Letter, seizure, injunction, recall or other regulatory actions listed in FMD-86.
State/Title action indicated	SAI	I	RTS	Refer to State (RTS)	Significant objectionable conditions or practices are present, but the Agency either does not have jurisdiction over the apparent violation in question or it is determined that state action is the most efficient method of obtaining the establishment's compliance with applicable federal laws, regulations or administrative requirements.
			RTC	Refer to Center only	Significant objectionable conditions or practices appear to warrant regulatory action, but the apparent violations noted constitute a compliance area for which no clear policy has been established or there are significant technical issues which require Center review and decision.

i. eSAF

All contractors shall enter inspection information into the eSAF system. Contractors shall use an Internet browser that is compatible with eSAF and have the other resources required for eSAF usage. Training may be obtained through FDA/ORM/DHRD or provided by the District.

ii. eSAF Support

After training has been successfully completed, the Contractor shall contact the ORA Applications Helpdesk for technical assistance via e-mail at APPSDESK@fda.hhs.gov or at 866-807-3742. The Helpdesk operates 24hrs/daily.

iii. Change in eSAF Users

The Contractor shall notify APPSDESK@fda.hhs.gov with a courtesy copy to the District Technical Advisor at least twenty-four (24) hours prior to an eSAF user departing from State employment or transferring/reassignment to a position that does not require the use of eSAF.

9. National Food Safety Data Exchange (NSFDX)

FDA is currently working with a limited number of State contractors on using a new system, the National Food Safety Data Exchange (NSFDX). Its purpose is to facilitate and automate data transfers and increase sharing of accurate, timely, complete, and relevant food safety data to improve the efficiency and efficacy of FDA inspections and fulfill the FSMA mandate. It provides regulatory partners involved in ensuring the safety of the nation's food supply an investigative tool that will allow sharing and exchange of food safety information, such as inspection findings and facility information, on a national and international basis. In addition, the NSFDX offers analysis and collaboration tools to assist investigators and regulatory partners working collaboratively with other agencies.

Participating States may use the NSFDX to submit inspection reports in lieu of eSAF. States shall work with the FDA District State liaison to ensure all data submission requirements are met and the submitted inspection reports are equivalent to reports submitted through eSAF.

10. Use of eLEXNET and Data Entry

The Contractor shall ensure that all laboratory analysis result data associated with product and environmental samples collected under this contract are entered into eLEXNET through the eLEXNET Data Entry Module within ten (10) business days of final results determination for negatives and three (3) business days for confirmed positive samples.

DATA ENTRY INFORMATION: To enter data into eLEXNET, the Contractor shall identify the person(s) that shall have an eLEXNET account. The account can be created using the "New Account Request Form". On this form, the prospective user would mark the following roles: eLEXNET member, eLEXNET data entry, eLEXNET reporting. Data entry is performed using the 'eLEXNET data entry' community in eLEXNET, and

training for data entry is available in the 'portal training' community of eLEXNET. The contractor will contact Solomon Tadele, FDA/ORR/Office of Regulatory Science, at Solomon.Tadele@fda.hhs.gov or 202-430-3132 for New Account Request Forms or if you have any questions related to eLEXNET and eLEXNET data entry.

b. Electives

1. Seafood HACCP Inspections

The Contractor shall conduct inspections of seafood processors under the guidance of FDA's Domestic Fish and Fishery Inspection Program (Attachment 10), including the use of the appropriate forms.

This program includes coverage to determine compliance with the Seafood HACCP regulation as well as to address violations of the FD&C Act and other regulations under the Act that relates to food sanitation, wholesomeness, and labeling including nutritional content labeling.

FDA is aware that there may be economic incentives for some seafood producers and retailers to misrepresent the identity of the seafood species they sell to buyers and consumers, and we have conducted DNA testing on fish that have a history of being misidentified, to combat seafood fraud. In June 2014, President Obama issued a Presidential Memorandum, "Establishing a Comprehensive Framework to Combat Illegal, Unreported, and Unregulated Fishing and Seafood Fraud." State and local authorities play a key role in detecting and preventing seafood fraud.

Based on recent seafood fraud initiatives, seafood HACCP inspections performed under contract shall include detailed product label reviews to evaluate more closely the possibility for seafood substitution. Incoming invoices, product and package labeling and outgoing invoices should be reviewed for consistency and any discrepancies noted for further follow up.

Additional information on seafood species substitution fraud may be found at: <http://www.fda.gov/food/guidanceregulation/guidancedocumentsregulatoryinformation/seafood/ucm071528.htm>

All Seafood HACCP inspections conducted under contract shall only be performed by State inspectors that have successfully completed FDA's FD249 Conducting Seafood Inspections Training Course, including passing the course assessments/examinations and all course prerequisites. FDA's Compliance Program (CPGM 7303.842) requires that inspectors successfully complete the training prior to conducting independent inspections. In addition, a joint inspection at a seafood HACCP firm shall be completed with a qualified State or FDA trainer prior to the inspector conducting inspections independently under contract.

The PAC code for Seafood HACCP inspections is 03S002. If the Contractor performs Seafood HACCP inspections, they shall split the time recorded in eSAF between PACs when a food inspection covers both food safety (03S014) and Seafood HACCP (03S002).

The inspectors that perform Seafood HACCP Inspections shall complete and submit Form FDA 3501 in eSAF (or other FDA-approved systems, such as NFSDX). Contractors with questions regarding the FDA 3501 should contact the District.

2. Juice HACCP Inspections

The Contractor's Juice HACCP inspections are to be performed under the current Juice HACCP Compliance Program (CPGM 7303.847) (Attachment 11), including the use of the appropriate forms. If the Contractor performs Juice HACCP inspections, they shall split the time recorded in eSAF (or other FDA-approved systems, such as NFSDX) between PACs when a food inspection covers both food safety (03S014) and Juice HACCP (03S004).

All Juice HACCP inspections conducted under State contract shall be performed by State inspectors who have successfully completed FD219 Juice HACCP and Conducting Juice Inspections Course and all prerequisites. In addition, a joint inspection at a juice HACCP firm shall be completed with a qualified State or FDA trainer prior to the inspector conducting inspections independently under contract. The inspections shall be HACCP based and consistent with the methods included in the FD219 Juice HACCP and Conducting Juice Inspections Course.

3. Acidified/ LACF Inspections

As directed or approved by the District Technical Advisor, the contractor shall perform inspections under CPGM 7303.803A (Attachment 12), including the use of the appropriate forms.

Domestic AF inspections shall be performed by State inspectors who have successfully completed and passed FD202, Conducting AF Inspections. Domestic LACF inspections shall be performed by State inspectors who have successfully completed and passed FD304, (previously FD203) Conducting LACF Inspections training courses. In addition, a joint inspection at a LACF or AF firm shall be completed with a qualified State or FDA trainer prior to the inspector conducting inspections independently under contract. The State Inspectors shall have knowledge of the applicable LACF and AF regulations.

The appropriate State personnel should request the firm's filed processes from the District Technical Advisor prior to conducting the inspection.

The PAC for AF/LACF inspections under State contract is 03S005. If the Contractor performs AF/LACF inspections, they shall split the time recorded in eSAF (or other FDA-approved systems, such as NFSDX) between PACs when a food inspection covers both food safety (03S014) and AF/LACF (03S005).

4. Samples

Samples shall consist of sufficient units, size, etc., necessary for the official laboratory methodology to be used. FDA will make appropriate Sample Schedules (Attachment 20) available to the contractor upon request. Samples shall be collected in accordance with currently recognized sampling procedures and analyzed using analytical methods that are appropriately validated and fit-for-purpose for the required analysis of the sample. For more information on method validation and fit-for purpose methodology, please refer to the “Food/Feed Testing Laboratories Best Practices Manual” (Attachment 28). The contractor may also be requested to collect interstate documentation on a sample if FDA is considering pursuing regulatory action based upon the State’s sample results.

i. Compliance Samples

A Compliance Sample is collected on a selective basis as the result of an inspection, complaint, or other evidence of a problem with a product. Compliance Samples shall be collected to support inspectional observations made during a contract inspection. The Contractor shall collect samples as outlined in this contract, or as directed by the FDA District Office.

ii. Surveillance Samples

A Surveillance Sample is collected on an objective basis where there is no inspectional or other evidence of a problem with a product identified during the inspection. Surveillance Samples are selected based on product risk categorization. The contractor shall collect Surveillance Samples based on the plans established during the workplanning session.

iii. Reporting

The Contractor shall submit sample reports upon final results determination to the FDA District Office and enter the results into eLEXNET. The sample reports should include a description of the product and sample (e.g., brand name, name of product, packaging, weight, and other identifying information), location of sample collection, sample collection technique, sample shipment procedures, and name and address of laboratory. Additional information, including the data laboratory package, may also be requested by the District.

The Contractor shall document the sample collection and analytical results in the Establishment Inspection Report submitted in eSAF.

The District and FDA/ORR/Office of Regulatory Science (ORAHQORSMANAGEMENT@fda.hhs.gov) shall be notified within one (1) business day of potentially significant positive laboratory results, preliminary positive

(Can't Rule Out (CRO)) pending confirmation, or when a sample is determined to be confirmed positive. Sample reports for positive (violative) samples shall be submitted to the District within three (3) business days of final determination. Sample reports for negative samples (non-violative) shall be received by the District within thirty (30) business days of final determination.

All samples analyzed shall be reported to the FDA on forms used by the State. Additionally, worksheets or other more detailed information on the analyses shall be submitted to the FDA for those samples found not to comply with current FDA administrative guidelines, or where a question exists whether a sample is violative.

5. Environmental Sample Collection and Analysis

i. Introduction

This sampling option encourages collaboration on food safety capacity building between FDA District Offices and State regulatory partners. The goal of the program is to establish and promote quality surveillance systems on a regional and national level. Recent foodborne outbreaks serve to highlight the importance of being able to quickly isolate, analyze, and identify a food contaminant and rapidly trace it back to its source. Samples shall be collected in accordance with currently recognized sampling procedures and analyzed using analytical methods that are appropriately validated and fit-for-purpose for the required analysis of the sample. For more information on method validation and fit-for purpose methodology, please refer to the "Food/Feed Testing Laboratories Best Practices Manual" (Attachment 28).

ii. Scope

The Contractor shall perform microbiological analyses of environmental samples collected during contracted inspections as directed and selected during work planning by the District office and State. The environmental samples shall be collected during the inspection. The Contractor shall perform sample collection during the contract inspection and analysis at their State lab at approximately 10 directed facilities. The facilities for environmental sampling should be identified during the work planning session. For *Salmonella* environmental sampling collect at least 100 subs and ideally 300 subs if there are a sufficient number of promising sample sites. For *Listeria* environmental swabbing, collect at least 50 swabs and ideally 100 or more subs if there are a sufficient number of promising sample sites. For purposes within the scope of this contract, one sample will equal one swab/sponge. Analysis shall be performed within 24 hours of collection of samples.

iii. Technical Standardization Recommendations

The samples shall be analyzed using the following resources and guidelines:

- Current food testing methodologies

- The Association of Official and Analytical Chemist (AOAC) methodology.
- FDA's DFI Field Bulletin No. 30, No. 32 and its related documents (Attachments 21-24).

iv. Reporting Requirements

Upon completion of sample analysis, sample information shall be entered into eLEXNET and into the facility's eSAF cover sheet with the following clearly stated line items:

- Environmental sample taken: Y
- Number of Samples: XX
- Results: Data

The Contractor shall ensure that all laboratory analysis result data associated with product and environmental samples collected under this contract are entered into eLEXNET through the eLEXNET Data Entry Module within ten (10) business days of final results determination for negatives and three (3) business days for confirmed positive samples. The environmental samples will be identified as being collected under the contract in eLEXNET.

The Contractor shall also notify the District office and FDA/ORR/Office of Regulatory Science (ORAHQORSMANAGEMENT@fda.hhs.gov) when a confirmed positive sample is identified within one (1) business days and submit the sample reports to the District within (3) business days of final determination. Sample results for negative samples (non-violative) shall be received by the District within 30 business days of final determination.

6. Elective Work to Add Imported Products to Routine Food Inspections

During a contract activity, the Contractor may identify a violative situation for an imported food and determine further investigation and possible regulatory action is necessary. The Contractor shall work with the District to determine the criteria for a violative situation for an imported food. The District shall be notified within three (3) business days after completion of an examination of an imported food and all regulatory actions must be coordinated with the District.

During the contract food inspection if a violative situation is determined with an imported ingredient(s) or imported finished product, the contractor shall:

- Conduct field examinations of imported goods while in either import or domestic status at establishment being inspected.
- Collect samples of imported goods while in either import or domestic status if indicated.

- Analyze samples of imported goods by FDA approved methods and procedures.
- Supervise destruction or exportation, including marking activities, of imported products refused entry by FDA.
- Conduct traceback investigations of imported goods related to consumer complaints, adverse events, recalls, or other reports indicating significant health and safety problems associated with the products. The tracebacks will attempt to identify the foreign source or origin of the implicated product(s). The tracebacks will consist of paper review only at establishment.

7. Elective Work to Add Domestic and/or Import Sample Collection to Routine Food Inspections or Special Non-Routine Sample Collection Requests for Extraordinary Circumstances

A contract modification may be requested for the cost of collecting, preparing, and shipping the sample as the need is identified or determined.

i. Introduction

FDA may request that the Contractor collect samples to protect the public health under the auspices of this contract for emergencies and other special purposes. Samples may be collected from domestic or import samples from a specific food firm, warehouse or retail location. The samples will vary by assignment.

The reason for the collection may be, but not limited to, special sampling assignments as a result of targeting of specific commodities because of intelligence (BT surveillance), the result of possible contamination, other violations of the Federal FD&C Act or other extraordinary circumstances.

The sample would normally be collected during an inspection of an assigned firm. However, FDA could request a sample of a specific project, or intelligence regarding a specific commodity, which may not be associated with an inspection.

The contractor shall collect samples in accordance with FDA procedures outlined in the FDA Inspectors Operations Manual (IOM). The Contractor shall contact the FDA District office for instructions on maintaining “chain of custody”, location of the testing laboratory and other special instructions.

These special sample collection requests do not affect routine sample collections that are currently in your contract.

ii. Scope

The Contractor shall collect frozen, refrigerated and non-refrigerated food samples as directed by the District office. At each site, there shall be a minimum and maximum

number of samples collected as directed by the District. For purposes within the scope of this contract, one sample will be one of any product such as one can, box, carton, or case. If the request is for one sample and ten sub-samples, each sub will be calculated as one sample.

All samples collected shall be shipped to the analytical laboratory as designated by FDA. The requested sample analysis, as defined by the sampling assignment, will be completed by the designated lab.

8. Elective Work to Add the Audit Program

Phases II and III of the Audit Program are offered to the Contractor as an elective. The requirements for Phases II and III of the audit program are described in FMD-76 (Attachment 17, or most recent version when notified by FDA). FMD-76 requires audits of the inspectors and auditors (verification audits) to be performed by both the State and FDA.

Successful completion of FD320 State Food Contract Audit Course is required by the Contractor (supervisory inspector, team leader, or senior inspector) to participate in this elective. The State auditors shall understand the relevant compliance programs and regulations and have experience in conducting inspections in the specific program area. In addition, the State auditors shall complete the training courses described in this contract. State auditors can only audit a Seafood HACCP, Juice HACCP, or LACF/AF inspection if they have completed the training that is required to conduct a Seafood HACCP, Juice HACCP, or LACF/AF contract inspection in addition to meeting the training and verification audit requirements.

The State auditor shall complete at least one training audit and one verification audit for each type of inspection that the auditor will be responsible for auditing. For example, to conduct audits for GMP and Seafood HACCP, the State auditor must complete at least one training audit and one verification audit for GMP and one training audit and one verification audit for Seafood HACCP.

During Phase II of the audit program, the minimum required audit rate is achieved through a combination of audits conducted by the District and the State agency.

During Phase III, the State agency assumes the responsibility for conducting audits at the rate specified in the most recent version of FMD-76. The State agency must have a quality assurance program (QAP) that requires correcting performance deficiencies found during an inspection or an audit. A minimum of two qualified auditors is required for the State agency to implement Phase III to meet the verification audit requirements.

If the Contractor bids on this elective, an agreement as defined in FMD-76 must be signed by the FDA District Director and the Director of the State inspection program.

The signed agreement must be submitted with the State's contract quote/proposal prior to award of the contract.

9. Elective Work to Add Manufactured Food Regulatory Program Standards (MFRPS)

i. Description

The Manufactured Food Regulatory Program Standards (MFRPS) (Attachment 25) are intended to ensure that State programs develop and maintain best practices for a high-quality regulatory program. The goal is to enhance food safety by establishing a uniform basis for measuring and improving the performance of manufactured food regulatory programs in the United States. The development and implementation of these program standards will help Federal and State programs better direct their regulatory activities at reducing foodborne illness hazards in plants that manufacture, process, pack, or hold foods.

The ten standards describe the critical elements of a regulatory program designed to protect the public from foodborne illness and injury. These elements include the State program's regulatory foundation, staff training, inspection, quality assurance, food defense preparedness and response, foodborne illness and incident investigation, enforcement, education and outreach, resource management, laboratory resources, and program assessment. Each standard has corresponding self-assessment worksheets, and certain standards have supplemental worksheets and forms that will assist State programs in determining their level of implementation with the standard. The Contractor is not required to use the forms and worksheets contained herein; however, alternate forms should be equivalent to the forms and worksheets in the draft program standards. These program standards do not address the performance appraisal processes that State agency may use to evaluate individual employee performance. FDA will use the program standards as a tool to improve contracts with State agencies.

The FDA will assist the State program during its implementation of the program standards. Both parties will meet annually to discuss, review, and evaluate the implementation of the program standards. The FDA will assess the State program's implementation of the program standards at 18, 36 and 60 months during the program's development of its MFRPS program. After 60 months, FDA will conduct an assessment every 2 years.

Option

Under this option, eventually, the State program achieves conformance with the MFRPS. The Contractor has the option to conclude implementation of the program standards after the first year.

The Contractor shall conduct a baseline self-assessment and verification audit described in Standard 9 of its manufactured food program against all criteria in each program standard in the first contract year. These self-assessments are designed to identify the strengths and weaknesses of the State program by determining the level of implementation with the program standards. The results of the baseline self-assessments are used to develop a strategic improvement plan that moves the State program toward conformance with each of the program standards and it establishes timeframes for making improvements. Subsequent assessments are conducted by FDA after completion of the initial self-assessment at 18, 36, 60 months, and then every 2 years.

In subsequent years, the Contractor shall implement their strategic improvement plans in accordance with Standard 9. If the elements of a program standard are not met, the improvement plan shall contain specific strategies and timeframes for achieving conformance and maintaining an acceptable level of performance. The improvement plan shall also contain reviews of the State program's progress in implementing the plan. Continued funding will be based on the subsequent self-assessments and improvement plans that will track the State program's progress toward meeting and maintaining conformance with the program standards.

Contractors receiving funds under the Conformance with the Manufactured Food Regulatory Program Standards (MFRPS) or Flexible Funding Model - Infrastructure Development and Maintenance for State Manufactured Food Regulatory Programs Cooperative Agreements are not eligible to enroll in this option.

Deliverables

To receive reimbursement for participation, the Contractor must complete and submit a copy of the MFRPS Appendix 9.1 (Self-Assessment and Improvement Plan Report) (Attachment 25). MFRPS Appendix 9.1 must be emailed to MFRPS@fda.hhs.gov for review and acceptance prior to invoicing. After the first year, the program must submit an updated copy of their self-assessment forms (Appendix 1, 2.1, 3.1, 4.1, 5.1, 6.1, 7.1, 8.1, 9.1 and 10.1) along with an updated copy of their strategic improvement plan.

10. Investigative Elective Work: Official Establishment Inventory (OEI) Improvement and Direct Recall Audit Checks

1. OEI Improvement

This OEI Improvement option encourages collaboration to improve the data in the FDA inventory database and to increase consistency between FDA District Offices and state regulatory partners. The goal of this elective option is to conduct investigational work to improve the accuracy of FDA Official Establishment Inventory (OEI) by implementing standardized criteria for verifying that a firm is no

longer subject to FDA jurisdiction and should be removed from the database or is recorded with erroneous data. This will reduce the number of attempted inspections of firms that have closed, moved, or are no longer engaged in FDA regulated activities to enhance the utilization of Government resources.

The Contractor will be assigned firms that the FDA District Offices suspect are no longer subject to FDA jurisdiction and are erroneously listed in the Official Establishment Inventory (OEI).

Examples of types of firms that may be assigned:

- Firms with a workload status of Bioterrorism (B) or Potential (P)
- Firms that have moved without proper notification to FDA
- Firms with other inaccurate registration information
- Firms that have failed to renew their registration
- Operational firms with no inspectional history, or have not been inspected in several years
- Firms that are no longer operational (OOB), subject to FDA inspection (NOE), or no longer considered a workload obligation
- Inactive firms
- State licensing records do not include the firm

If a firm is found to be operational and subject to inspection under the contract, a complete inspection should not be performed until approval from the District is obtained. The firm may be assigned at a later date for inspection under the contract.

This elective work shall be documented on the form provided by the FDA. This form shall serve as a record of all efforts made by the Contractor to verify the operational status, location, and activities of the firm. The Contractor shall perform all reasonable efforts to locate firms that have moved or relocated. The Contractor shall refer to FMD-130 (Attachment 18) for guidance.

The PAC for OEI Improvement investigations under State contract is 03S876.

Additional guidance and policy will be provided by the District.

As directed by the District, the State shall perform a combination of the following activities to verify the operational status, activities, and location of the firm:

- Physical visit
- Interviews with neighboring firms
- Telephone call
- Email
- Request forwarding address from US Postal Service
- Duns & Bradstreet (D&B) records
- Internet searches

- Records searches of other government and regulatory agencies, such as the secretary of state, state department of agriculture, state department of health, and municipal or county licensing or health agencies

A comprehensive report on the firm will include the following elements:

- Firm legal name and any additional trade names, doing business as (DBA) names, or alias
Name Change for any reason including due to change in ownership
- Address, including zip code and county
- Phone number, email address, web site and other contact information
- Firm point of contact
- Legal status (e.g. corporation, limited liability corporation, partnership, sole proprietorship, government entity)
- Information on changes in ownership, if available
- Operational status and hours; if seasonal, months of operation
- Number of employees
- Establishment size/approximate dollar volume of gross sales
- Type of operations (manufacturer, warehouse, repacker, distributor, etc.)
- Establishment type(s) and related industry code(s)
- List of products being manufactured, processed, distributed, and repacked
- Percent (%) Interstate sales
- Percent (%) Wholesale sales
- Export sales
- Registration status
- Efforts made to determine the operational status, activities, and location of the firm

The supplied form shall be used unless otherwise directed by the District (Attachment 26).

Because this work is administrative and fact-gathering, it constitutes an investigation and is distinct and separate from any inspection assignments.

2. **Direct Account Recall Audit Checks (RACs)**

Food producers recall their products from the marketplace when the products are mislabeled or when the food may present a health hazard to consumers because the food is contaminated or has caused a foodborne illness outbreak. The State will conduct Direct Account RACS at in-state food distributors, wholesalers, and distribution center recalls already in progress where the distribution extends beyond the wholesale level. RACs at the retail level shall not be performed under this contract.

The contractor is required to perform the following:

- Conduct the Direct Account RAC within 48-72 hours of receipt.

- Verify the firm has received the recall notice and has followed through with recall instructions.
- Collect customer sub-distribution list from the firm. Identify and report whether the contact list consists of ONLY those subaccounts that are known to have received the specific lot(s) of recalled product or those who may have received the recalled lot of product. If the direct account does not track the lot numbers of the products they sub-distributed, the State will determine how the firm developed the recall list.
- Collection of date and method of sub-recall notification, including obtaining copies of notifications sent.
- Determine if any product manipulation or creation of new product prior to distribution occurred.
- Witness destruction of recalled products as assigned by FDA. The report will document date and time of destruction, where the destruction occurred, who performed the destruction, how the product(s) was destroyed, the quantity and estimated value of product(s) destroyed, and specific product(s) destroyed. Documentation serving as proof of destruction should also be provided.
- Submission of RAC information on an e-3177 within 48 hours of completion.

The PAC code and further instructions for submitting the direct account recall audit check reports will be provided by the FDA District.

11. Elective Work to Inspect Firms Subject to the Preventive Controls (PC) Rule

The FDA Food Safety Modernization Act (FSMA) Preventive Controls for Human Food Rule is now final, and compliance dates for some businesses began in September 2016 based on firm size. For the first time, FDA has a legislative mandate to require comprehensive, prevention-based controls across the food supply to prevent or significantly minimize the likelihood of problems occurring. Requiring preventive measures at facilities that produce human food is an important step in reducing foodborne illness for humans.

PC Rule inspections shall be performed by State inspectors who have successfully completed and passed FD 254, Preventive Controls for Human Food Regulators Course. In addition, a joint inspection or other in-field training experience at a firm subject to the PC Rule must be completed with a qualified State or FDA trainer prior to the inspector conducting inspections independently under contract. Inspectors must be able to interpret 21 CFR Part 117 and other applicable regulations. FDA strongly encourages States to propose upon a minimum of 1 to 3 inspections per qualified inspector to maintain proficiency.

The PAC for Human Food PC inspections under State contract is 03S015.

12. Inspections of Sprouters

The Contractor shall conduct inspections of sprouters under the requirements of the Produce Safety Rule (21 CFR part 112), as applicable, and Subpart M of the produce rule using the appropriate forms to include the sprout intelligent questionnaire.

This program includes coverage to determine compliance with the produce rule as well as to address violations of the FD&C Act and other regulations under the Act that relate to food sanitation, wholesomeness, and labeling.

All inspections of sprouters conducted under contract shall only be performed by State inspectors that have successfully completed FDA's Sprout Regulator Training, including passing the course assessments/examinations and all course prerequisites. FDA's regulatory strategy requires that inspectors successfully complete the training prior to conducting independent sprouter inspections. In addition, a joint inspection at a sprouter must be completed with a qualified State or FDA trainer prior to the inspector conducting inspections independently under contract.

The sprout intelligent questionnaire shall be completed either electronically or in hard copy and submitted simultaneously with the finished report to the district.

The PAC code for Sprout inspections is 03S879.

Contractors using funds under the State and Territory Cooperative Agreement to Enhance Produce Safety in Preparation of Implementation of FDA's Rule: Standards for the Growing, Harvesting, Packing, & Holding of Produce for Human Consumption to conduct sprout inspections are not eligible to enroll in this option.

SECTION D – PACKING AND MARKING

This section is not applicable to this solicitation/contract.

SECTION E – 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 at the Food and Drug Administration, State Contracts Branch, HFA-500, 5630 Fishers Lane, Rockville, Maryland 20857.

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 times and places during the term of the contract. The Government shall perform inspections and tests in a manner that will 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 reperformance, 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 of this contract is from: September 30, 2018 through September 29, 2019 (base year). There are four (4) 12 month Option Years. (See Article B-2). The Government may extend the period of performance for four (4) additional option years in accordance with **52.217-9 Option to Extend the Term of the Contract (MAR 2000)**.

F-2 – Reports/ Deliverables

Inspection Reports, HACCP Reports, and Compliance Action Reports	No significant violations: Received by the District within thirty (30) business days
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	<p>after completion of the inspection.</p> <p>Significant violations have been identified and/or State regulatory action has been conducted or is being considered: District shall be notified within 3 business days and the EIR received by the District within thirty (30) business days after the completion of the inspection.</p>
Audit forms, memorandums, and other documents required for the audit program (for States in Phase II and III of the audit program)	Refer to FMD-76 (most recent version) for the reporting requirements.
Responses received from the firm detailing corrective actions	Receipt of the firm's response by the FDA District office within thirty (30) days of receipt.
Sample Reports	<p>Negative (non-violative) sample results: Submission of the report within thirty (30) business days of final determination to the District unless otherwise requested.</p> <p>Positive (violative) sample results: Notification within one (1) business day of potentially significant positive laboratory results, preliminary positive (Can't Rule Out (CRO)) pending confirmation, or when a sample is determined to be confirmed positive. Receipt of report within three (3) business days of final determination by the District and FDA/ORR/ORS</p>
eSAF (Electronic Reporting) (or other FDA-approved systems, such as NFSDX)	Receipt by the FDA District Office within thirty (30) business days after completion of the inspection.
eLEXNET (Electronic Reporting)	<p>Negative (non-violative) sample results: Entered within ten (10) business days after completion of the inspection.</p> <p>Positive (violative) results: Entered within three (3) business days after completion of the inspection.</p>
Quarterly Summary Reports	Received no later than thirty (30) business days after the end of each ninety (90) day reporting period by the District for approval

<p>Corrective Action Plan for Contract Performance</p>	<p>with a courtesy copy to the COR. Received by the FDA District Office no later than ten (10) business days after notification that such a plan is required as described in Section C. Three (3) copies shall be submitted with one each to the Contracting Officer, Contracting Officer's Representative (COR) and District Technical Advisor.</p>
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a. Inspection and Compliance Actions Reports (CARs)

In accordance with contract requirements, the contractor shall conduct assigned initial inspections, necessary re-inspections and visits within the State. The contractor shall submit inspection findings to the District Office as follows:

1. For Inspections without significant violations and not requiring State regulatory actions (generally rated as “No Action Indicated (NAI)” or “Voluntary Action Indicated (VAI)”), the inspection reports shall be received by the District office within thirty (30) business days after completion of the inspection.
2. For any inspection that has violations and/or a State regulatory action has been conducted or is being considered, the State shall **NOTIFY** the District Office via email within three (3) business days after completion of the inspection and provide updates on the status of the firm. The State shall submit the complete inspection report, including the Compliance Action Report and compliance documents (e.g., warning letters, embargo forms, license revocation, etc.), within thirty (30) business days after the completion of the inspection.

Note (1): The above time frames will not apply for inspections conducted in September of each year as those inspections shall be entered into the FDA data system prior to October 15th to be counted in the FDA’s fiscal year data. As a result, State contract inspections conducted in September shall be entered into eSAF and reports shall be received by the District office no later than October 10th of each year. At least ninety percent (90%) of all notifications and submitted inspection reports shall be timely, accurate, complete and acceptable for date entry, analyses and processing.

Note (2): For the purposes of the reporting timelines established in this contract, a sample result is considered confirmed after the contractor has completed all analytical, managerial, and quality control activities related to the sample analysis.

b. Inspection Report

The Contractor’s inspection reports (Establishment Inspection Report (EIR) or State equivalent) shall detail the conditions found with sufficient narrative and documented evidence to enable an assessment of the significance of any objectionable conditions or

practices found. Where microbiologically oriented inspections are conducted, the contractor shall provide a more detailed description of the manufacturing process and routes of contamination, as a minimum.

The contractor shall complete a detailed inspection report for the appropriate industry. The Contractor and District shall work together to determine the appropriate report elements and format. Appropriate inspection report elements may be found in the Investigations Operations Manual (IOM), Section 5.10.4, available on the FDA website; (<http://www.fda.gov/ICECI/Inspections/IOM/ucm122529.htm>).

NOTE: The HACCP component (Program Assignment Code (PAC) 03S002) and the non-HACCP component (PAC 03S014) are to be accounted for separately in eSAF. For Seafood HACCP inspections, the Contractor shall submit Form FDA 3501. The Contractor shall use the FDA Product Code List to complete the appropriate sections of eSAF. The Contractor shall record the corrective actions taken by the firm in response to identified significant violations, including the firm's response to the Contractor, in the summary section of the inspection report and eSAF. The contractor shall forward responses submitted by the firm detailing corrective actions to the FDA District office within thirty (30) days of receipt.

c. HACCP Inspections

For all seafood inspections performed under "Domestic Fish and Fishery Products Inspection Program" (CPGM 7303.842), the contractor shall submit the following documents to the FDA District Office to support violations of the HACCP Regulations:

- Form FDA 3501
- Inspection Report (Establishment Inspection Report (EIR) or State's equivalent form)
- List of Observations (Form FDA 483) or State's equivalent form
- Inspection Cover Sheet
- Products Covered Form
- Firm's HACCP Plan
- Inspector's hazard analysis of the firm
 - For inspections of facilities that do not have a HACCP Plan or have an inadequate plan, a flow chart of the product(s) being evaluated shall be submitted.
 - For these cases, the submitted report shall also identify the significant hazards and Critical Control Points (CCP's) and determine if the CCP's are being adequately monitored, per Compliance Program 7303.842, Part III.

For inspections of facilities that do not have a HACCP Plan or have an inadequate plan, a flow chart of the product(s) being evaluated shall be submitted. For these cases, the submitted report shall also identify the significant hazards and Critical Control Points (CCP's) and determine if the CCP's are being adequately monitored, per Compliance Program 7303.842, Part III.

d. Sample Reports

Notification within one (1) business day to the District and submission of the report within three (3) business days to the District and FDA/ORR/Office of Regulatory Science (ORR@ORSMANAGEMENT@fda.hhs.gov) of potentially significant positive laboratory results, preliminary positive (Can't Rule Out (CRO)) pending confirmation, or when a sample is determined to be confirmed positive. Receipt of the report within thirty (30) business days by the District unless otherwise directed by the District for negative (non-violative) sample results. All samples analyzed shall be reported to the FDA on forms used by the State. Additionally, worksheets or other more detailed information on the analyses shall be submitted to the FDA, upon request, for those samples found not to be in compliance with current FDA administrative guidelines.

e. Electronic Reporting

1. eSAF (or other FDA-approved system, such as NFSDX): The contractor shall input complete inspection information into the eSAF system within thirty (30) business days after completion of the inspection.
2. eLEXNET: The contractor shall submit confirmed negative (non-violative sample results into eLEXNET within ten (10) business days and confirmed positive (violative) sample results into eLEXNET within three (3) business day.

f. Quarterly Summary Report

The contractor shall submit a Quarterly Summary Report (Form FDA 2684; Attachment 27) to the District for approval with a courtesy copy to the COR. The report shall be submitted via email no later than thirty (30) business days after the end of each ninety (90) day reporting period of the contract. In those periods where no inspections were performed, a report showing no inspection IS REQUIRED.

F-3 - Reports/Deliverables Submission Requirements**a. Quarterly Summary Report**

Included with the report shall be an electronic document (i.e. Word or Excel, as agreed to by the District) of the establishments inspected, samples, and any regulatory actions, specifying the following:

- Inspections
 - Number each inspection listed per inspection type (1,2,3,)
 - FEI#, name, address, and city of the firm inspected
 - Inspection date and classification in eSAF(NAL, VAL, etc.)
 - Type of inspection conducted (GMP, Seafood HACCP, Juice HACCP, low-acid and/or acidified foods) based on elective in contract

- State actions pursued and taken (e.g., warning letters, embargoes, license revocation, hearings, penalties, etc.) during each inspection, if applicable
- Audits
 - Number each audit listed (1,2,3, etc.)
 - Information for the inspection as identified above
 - Type of audit performed (audit, training audit, verification audit)
- Visits
 - Number each visit listed (1,2,3, etc.)
 - FEI#, name, address, and city of the firm assigned
 - Type of visit (OOB, NOEI, inactive, not subject to inspection under the contract)
 - Date visit was performed
- Samples
 - Number each sample listed (1,2,3, etc.)
 - Collection location (firm name), type of sample (such as produce or environmental), number of samples/subsamples and sample controls, eLEXNET sample ID# sample product name, sample description
 - Analyses performed method used, sample classification, and regulatory action pursued, if applicable
- Any other work performed and authorized by the contract.

b. Quarterly Summary Report Approval

A review of the Quarterly Summary Report will be conducted by the District and a notification provided to the contractor on the acceptability of the Quarterly Summary Report within ten (10) business days of receipt. If questions exist regarding the Quarterly Summary Report, the State will have ten (10) business days to respond to the District by providing additional information or submitting a revised Quarterly Summary Report. Following the review and confirmation of acceptance of all work detailed on the Quarterly Summary Report, the District will provide the contractor (via email with copy to the COR) approval of the Quarterly Summary Report.

Approval of the Quarterly Summary Report by the District is required prior to submission of the invoices. Invoices shall not be submitted to OAGS nor will invoices be paid without District approval of the Quarterly Summary Report. Documentation of District approval of the Quarterly Summary Report shall be submitted with the invoice and Quarterly Summary Report to OAGS and the COR.

c. Submission

Copies of the District approved Quarterly Summary Report shall be provided as follows:

- One copy to:

Food and Drug Administration
ORA/Office of Partnerships
ATTN: Teresa Bills
Email: Teresa.Bills@fda.hhs.gov

AND

FoodProgram@fda.hhs.gov

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

- One copy to:

Food and Drug Administration/OAGS/DSAAG
State Contracts Branch
ATTN: Contract Specialist, Cynthia Martin
5630 Fishers Lane, HFA-500
Rockville, MD 20857
Fax: 301-827-7106

****Acceptable methods of delivery include mail, hand delivery, fax, and email.****

NOTE (1): District approval of the MFRPS elective is not required. The MFRPS elective invoiced to the contract shall have received prior approval by OAGS and ORA/OP.

NOTE (2): Once the Quarterly Summary Report is approved by the District, the Quarterly Summary Report and district approval notification shall be submitted with all invoices submitted for payment to OAGS and ORA/OP.

d. Quality Control Plan

The Offeror shall submit a Quality Control Plan with its Technical Proposal that meets all requirements outlined in Section C.

SECTION G – CONTRACT ADMINISTRATION DATA

G-1 – Administrative Personnel

- a. The following personnel will represent the Government for the purpose of this contract:**

1. Contracting Officers Representative (COR):

Teresa Bills
Food and Drug Administration
ORA/Office of Partnerships
12420 Parklawn Drive
Rockville, MD 20857
Phone: 615-854-0019
Email: Teresa.Bills@fda.hhs.gov

FDA District:

Julie Vosilus
913-495-5134
julie.vosilus@fda.hhs.gov

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

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

1. 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.
2. 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.

d. The responsibilities and limitations of the District Technical Advisor are as follows:

1. The District Technical Advisor is responsible for the final inspection and acceptance of all reports and such other responsibilities as may be specified in the contract.
2. The District Technical Advisor is not empowered to issue or approve changes; enter into any agreement or contract modification; or any other matter which may affect the cost, period of performance, or terms and conditions of the contract.
3. The additional responsibilities of the District Technical Advisor include:
 - Communication and collaboration with State management

- Meet with State management twice a year with one meeting dedicated to work planning (*per FMD-50*)
- Ensure information provided by states is properly entered into FDA systems
- Review and provide feedback to state management on work products submitted to FDA
- Verify information on Quarterly Summary Reports within 10 working days of report receipt
- Work with OP to address discrepancies and to ensure work is completed in accordance with the contract

G-2 – Key Personnel (HHSAR 352.242-70)

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

The individual cited below is key personnel & Official with Agency Authorized to Sign the Non-Disclosure Agreement (NDA)

Project Director

Name: Eric Hueste
 Title: Bureau Chief, Bureau for Environmental Health Services
 E-mail: Eric.Hueste@health.mo.gov
 Phone: 573-751-6111

Official with Agency for (NDA)

Name: Tonya R. Loucks
 Title: Director, Division of Administration
 E-mail: Grants@health.mo.gov
 Phone: 573-751-6014

G-3 – Quarterly Invoice Submission

- A. The contractor shall submit all invoices to:
1. U.S. FOOD AND DRUG ADMINISTRATION

Attn: Vendor Payments
Division of Payment 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

2. One courtesy copy to the Contracting Officer Representative (COR)
US. Food and Drug Administration
Office of Partnerships | Contracts and Grants
Attn: Teresa Bills
Email: Teresa.Bills@fda.hhs.gov and FoodProgram@fda.hhs.gov

(Required method of delivery is via email)

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 official to whom payment is to be sent (must be the same as that in the purchase order/award, 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 Contracting Officer Representative (COR) or other Program Center/Office point of contact, as referenced on the award;

(xii) For all Inspections, Time-and-Materials and Labor-Hour Awards, 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;

(xiii) Any other information or documentation required by the award.

An electronic invoice is acceptable if submitted in adobe acrobat (PDF) format. All items listed in (i) through (xiii) 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.

Questions regarding invoice payments should be directed to the FDA Payment Office at the e-mail address provided above in Section A.

All payments will be made by Electronic Funds Transfer (EFT) and the State Contractor shall be responsible for providing any changes to the System for Award Management (SAM) database.

G-4 – Government Furnished Materials and Information

The following forms may be required for use in the performance of the services required hereunder and are made available by the Government at www.FDA.gov.

- Form FDA 2679 - Food Warehouse Inspection Report
- Form FDA 2681 – Bakery Inspection Report
- Form FDA 2682 – Beverage Plant Inspection Report
- Form FDA 2684 – Quarterly Summary Report
- Form FDA 2966 – Food GMP Inspection Report

- Form FDA 3501 – Domestic Seafood HACCP Report
- “What you Need to Know About Registration of Food Facilities” brochure
- Security Preventive Measure Guidance

In addition to the applicable Government Property Clause in Part II, Section I, the contractor shall comply with the provisions of DHHS publication, Contractor’s Guide for Control of Government Property, which is incorporated by reference. This Handbook is available on the HHS website:

http://www.hhs.gov/hhsmanuals/logisticsmanual/Appendix%20Q_HHS%20Contracting%20Guide.pdf

G-5 – Post Award Evaluation of Contractor Performance

a. Contractor Performance Evaluations

Interim and final evaluations of Contractor performance will be prepared on this contract in accordance with FAR 42.15. The final performance evaluation will be prepared at the time of completion of work. In addition to the final evaluation, interim evaluation(s) shall be submitted annually.

Interim and final evaluations will be provided to the Contractor as soon as practicable after completion of the evaluation. The Contractor will be permitted thirty days to review the document and to submit additional information or a rebutting statement. If agreement cannot be reached between the parties, the matter will be referred to an individual one level above the Contracting Officer, whose decision will be final.

Copies of the evaluations, Contractor responses, and review comments, if any, will be retained as part of the contract file, and may be used to support future award decisions.

b. Electronic Access to Contractor Performance Evaluations

Contractors that have Internet capability may access evaluations through the Contractor Performance Assessment Reporting System (CPARS) web site, which is managed by the Department of Defense (DOD). Details regarding CPARS training and on-line registration can be found at <http://www.cpars.gov/>.

The registration process requires the Contractor to identify an individual that will serve as a primary contact and who will be authorized access to the evaluation for review and comment. In addition, the Contractor will be required to identify an alternate contact who will be responsible for notifying the FDA contracting official in the event the primary contact is unavailable to process the evaluation within the required 30-day time frame.

SECTION H – SPECIAL CONTRACT

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 following:
- 2) **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.
 - a. **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.
- 3) **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:

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.

4) **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 Categories*, 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 Moderate High
Integrity: Low Moderate High
Availability: Low Moderate High
Overall Risk Level: Low 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 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 Moderate High

5) **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

- 6) **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 purposes 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. 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);
 - a. 18 U.S.C. 1905 (Criminal Code: Disclosure of Confidential Information); and
 - b. 44 U.S.C. Chapter 35, Subchapter I (Paperwork Reduction Act). 7) **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)*.
- 8) **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.

- 9) **Contract Documentation.** The Contractor shall use FDA-provided templates, policies, forms and other agency documents to comply with contract deliverables as appropriate.
- 10) **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.
- 11) **Contractor Non-Disclosure Agreement (NDA).** The Contractor shall have the FDA non-disclosure agreement signed by the Agency Official authorized to sign the form. Any subcontractors assigned to the contract must also sign the form. A copy of the signed and witnessed NDA form shall be submitted to the CO and COR prior to performing any work under the acquisition. (Section J – Attachment 3).
- 12) **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 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)*.
- 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*.
- 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.
- 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, 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.

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.

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

- (1) an authorized user accesses or potentially accesses personally identifiable information for another 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:

- 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: 4

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.asp>

- 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 returned or 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*.

HHS EA requirements may be located here:

<https://www.hhs.gov/about/agencies/asa/ocio/index.html>

- 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 COMMISSIONING OF INSPECTORS

The Government requires that certain Contractor personnel be commissioned by the Government to enable the Contractor to conduct activities under this Contract including, but not limited to, undertaking examinations, inspections, and investigations, and related activities to protect the public health in accordance with federal law, such as the provisions of "Public Health Security and Bioterrorism Preparedness and Response Act of 2002" (Public Law 107-188).

The Government has an established procedure to commission the Contractor's employees to perform certain functions pursuant to the FD&C Act such as conducting FDA examinations,

inspections, and investigations, collecting and obtaining samples, copying and verifying records, and receiving and reviewing official FDA documents.

H.3 FEDERALLY FUNDED RESEARCH AND DEVELOPMENT CENTERS AND SUPPORT CONTRACTORS

The Government may contract with federally Funded Research and Development Centers (FFRDC) and support contractors for services to support in technical and management oversight of the Contractor's efforts and products under this Contract. Employees of these FFRDCs and support contractors may attend meetings between the Contractor and the Government, may observe and participate with Government personnel in function and performance tests, may review all documentation and underlying data supporting work performed under this Contract, and may have access to the Contractor's facilities as related to any effort under this Contract. No employee of an FFRDC or support contractor has the authority to issue directions to the Contractor or effect changes to the Contract.

The Contracting Officer will identify to the Contractor the FFRDCs and support contractors who will be supporting this Contract. The Contractor shall be provided the names of the FFRDC and support contractor personnel who will be covered by the appropriate non-disclosure and conflict of interest statements. The Contractor agrees to cooperate with the FFRDCs and support contractors by engaging in technical discussions with their personnel, and permitting access to information and data relating to technical, cost, and schedule matters concerning this Contract to the same degree such access is accorded to Government personnel.

H.4 Contractor Personnel Security Clearance Standards and Residency Requirements

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.

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

A roster of contractor employee names, identifying Key Personnel and Tier designation(s);

Confirmation all individual employee security information has been submitted properly; Contractor's Non-Disclosure Agreement has been signed the Agency head.

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 exception of costs associated with fingerprinting Contractor employees outside of the FDA Personnel Security Office, the

Government will conduct all required background investigations at no cost to the Contractor. The cost of fingerprinting Contractor employees at any location other than the FDA Personnel Security Office will be borne by the Contractor. Employees who hold or have previously held a Government security clearance must advise the FDA Personnel Security Staff of the details of such clearance.

Note: Background investigations will be conducted by the Office of Personnel Management (OPM) 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 gain access to DHHS-owned or leased property without an escort. (See Section 6 for details on the PIV Card process) However, in the event the work must commence before a security screening can be completed, contractor employees will be considered visitors, as described above, and allowed onto DHHS-owned or leased property, but must be escorted at all times.

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

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

The Risk Designation(s) for this contract is/are Tier(s): 2

There are two (2) potential position risk designations, which are:

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

In order to access the e-QIP system, Contractor employees must provide the appropriate FDA Personnel Security Specialist with the following information: (a) full name; (b) position title; (c) social security number; (d) date of birth; (e) place of birth; (f) email address; and (g) phone number. This information will be provided on the e-Qip form that will be electronically sent to the employee. The FDA Personnel Security Specialist will use this information to enter each contractor employee into the e-QIP system. Once this is done, each Contractor employee will receive an email that contains a web link to access the e-QIP system, as well as instructions and

additional forms needed to initiate the background investigation.

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

2. 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 an abuse, destruction, defacement, unauthorized transfer or withholding (e., failure to return to the Government) may be punishable to the greatest extent of the 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 Appendix A, provided below. An individual who receives an unfavorable report may appeal that finding by submitting a written request to the FDA Personnel Security Specialist.

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

- Review of prior Government/military personnel records;

- Review of FBI records and fingerprint files;
 - Searches of credit bureaus;
 - Personal interviews; and
 - Written inquiries covering the subject's background.
3. **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.**
4. **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
1 0903 New Hampshire Avenue Building 32,
Room 1205, Silver Spring, MD 20993
No appointment necessary
Telephone: (301) 796-4000

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
		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:			
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		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 – 52.252-2 Clauses Incorporated by Reference (FEB 1998)

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

<https://www.acquisition.gov/far/>

<http://www.hhs.gov/policies/hhsar/>

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

Reg	Clause	Date	Clause Title
FAR	52.202-1	Nov-2013	Definitions
FAR	52.203-3	Apr-1984	Gratuities
FAR	52.203-5	May-2014	Covenant Against Contingent Fees
FAR	52.203-6	Sep-2006	Restrictions on Subcontractor Sales to the
FAR	52.203-7	May-2014	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
FAR	52.203-12	Oct-2010	Limitation on Payments to Influence Certain Federal Transactions
FAR	52.203-13	Oct-2015	Contractor Code of Business Ethics and Conduct
FAR	52.203-17	Apr-2014	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	52.204-4	May-2011	Printed or Copied Double-Sided on Recycled Paper
FAR	52.204-9	Jan-2011	Personal Identity Verification of Contractor
FAR	52.204-7	Oct-2016	System for Award Management
FAR	52.204-14	Oct-2016	Service Contract Reporting Requirements
FAR	52.209-6	Oct-2015	Protecting the Government's Interests When Subcontracting With Contractors Debarred, Suspended, or Proposed for Debarment
FAR	52.209-9	Jul-2013	Updates of Publicly Available Information Regarding Responsibility Matters
FAR	52.215-2	Oct-2010	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
FAR	52.215-19	Oct-1997	Notification of Ownership Changes
FAR	52.216-5	Oct-1997	Price Redetermination – Prospective Fill ins: 12 months, 12 months, 180 days, 30 days,
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	Oct-2015	Equal Opportunity for Veterans

FAR	52.222-36	Jul-2014	Equal Opportunity for Workers with Disabilities
FAR	52.222-37	Feb-2016	Employment Reports on Veterans
FAR	52.222-40	Dec-2010	Notification of Employee Rights Under the National Labor Relations Act
FAR	52.222-50	Mar-2015	Combating Trafficking in Persons
FAR	52.222-54	Oct-2015	Employment Eligibility Verification
FAR	52.223-6	May-2001	Drug-Free Workplace
FAR	52.223-18	Aug-2011	Encouraging Contractor Policies to Ban Text Messaging While Driving
FAR	52.227-1	Dec-2007	Authorization and Consent
FAR	52.227-2	Dec-2007	Notice and Assistance Regarding Patent and Copyright
FAR	52.229-4	Feb-2013	Federal, State and Local Taxes (State and Local Adjustments)
FAR	52.232-1	Apr-1984	Payments
FAR	52.232-8	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	52.232-23	May-2014	Assignment of Claims
FAR	52.232-25	Jan-2017	Prompt Payment
FAR	52.232-33	Jul-2013	Payment by Electronic Funds Transfer—System for Award Management
FAR	52.232-39	Jun-2013	Unenforceability of Unauthorized Obligations
FAR	52.232-40	Dec-2013	Providing Accelerated Payments to Small Business Subcontractors
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	52.242-1	Apr-1984	Notice of Intent to Disallow Costs
FAR	52.242-13	Jul-1995	Bankruptcy
FAR	52.243-1	Aug-1987	Changes - Fixed-Price, Alternate I (Apr 1984)
FAR	52.245-1	Jan-2017	Government Property – Alternate I (Jun 2007)
FAR	52.245-9	Apr-2012	Use and Charges
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 (Fixed-Price Supply and Service)
FAR	52.253-1	Jan-1991	Computer Generated Forms

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

Reg	Clause	Date	Clause Title
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HHSAR	352.203-70	Dec-2015	Anti-Lobbying
HHSAR	352.222-70	Dec-2015	Contractor Cooperation in Equal Employment Opportunity Investigations
HHSAR	352.224-70	Dec-2015	Privacy Act
HHSAR	352.227-70	Dec-2015	Publications and Publicity

I-2 – Clauses in Full Text

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 State Contractor within thirty (30) days.

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 within 15 days; 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 66 months.

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.

SECTION J – LIST OF ATTACHMENTS

The following attachments are incorporated into this solicitation/contract:

- Attachment 1 – Guidelines for State Coverage of NLEA Under Food Inspection Contracts



Attachment 1.doc
(32 KB)

- Attachment 2 – Electronic State Access to Field Accomplishments and Compliance Tracking System (eSAF)



Attachment 2.doc
(743 KB)

- Attachment 3 – 8 Single Signature Non-Disclosure Agreement (NDA) Form



NDA Single
Signature.pdf

Attachment 4 – FDA Regulatory Procedures Manual, Ch. 3, Commissioning and Work Sharing
<http://www.fda.gov/ICECI/ComplianceManuals/RegulatoryProceduresManual/ucm176712.htm>

- Attachment 5 – Disclosure of Lobbying Activities



Attachment 5
Disclosure of Lob...

- Attachment 6 – Pathlore Job Aid



PathloreStateUserJob
Aid.pdf

- Attachment 7 – FSMA Preventive Control Rule Fact Sheet
<https://www.fda.gov/downloads/Food/GuidanceRegulation/FSMA/UCM584807.pdf>



Attachment 7 (PC
Rule).pdf

- Attachment 8 – FSMA Sanitary Transportation Final Rule Fact Sheet
<http://www.fda.gov/downloads/Food/GuidanceRegulation/FSMA/UCM383764.pdf>



Attachment 8
(Sanitary Transport).p

- Attachment 9 – FSMA Intentional Contamination Final Rule Fact Sheet
<http://www.fda.gov/downloads/Food/GuidanceRegulation/FSMA/UCM379548.pdf>



Attachment 9
(Intentional Contaminat

- Attachment 10 – CPGM 7303.842 Domestic Seafood Processor Inspection Program
<http://www.fda.gov/downloads/Food/ComplianceEnforcement/ucm073125.pdf>



CPGM 7303.842..pdf

- Attachment 11 – CPGM 7303.847 Juice HACCP Inspection Program
<http://www.fda.gov/Food/ComplianceEnforcement/FoodCompliancePrograms/ucm236946.htm>



Attachment 11 (Juice
HACCP CPG).pdf

- Attachment 12 – CPGM 7303.803A Domestic Acidified and Low-Acid Canned Foods
<http://www.fda.gov/downloads/Food/.../ucm072975.pdf>



CPGM
7303.803A.pdf

- Attachment 13 – CPGM 7303.803 Domestic Food Safety Program
<http://www.fda.gov/downloads/Food/ComplianceEnforcement/ucm072848.pdf>



CPGM 7303.803.pdf

- Attachment 14 – CPGM 7303.037 Domestic and Imported Cheese
<http://www.fda.gov/downloads/Food/ComplianceEnforcement/FoodCompliancePrograms/UCM>

456592.pdf



Attachment 14
(Cheese CPG).pdf

- Attachment 15 – CPGM 7321.005 Domestic and Import NLEA, Nutrient Sampling and Analysis, and General Food Labeling Program



Attachment 15
(NLEA CPG).pdf

<http://www.fda.gov/Food/ComplianceEnforcement/FoodCompliancePrograms/ucm238066.htm>

- Attachment 16 – Guidance for Industry: Control of *Listeria monocytogenes* in Refrigerated or Frozen Ready-To-Eat Foods, February 2008

<http://www.fda.gov/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/FoodProcessingHACCP/ucm073110.htm>

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- Attachment 17 – FMD-76 State Contract Evaluation of Inspectional Performance

<http://www.fda.gov/downloads/ICECI/Inspections/FieldManagementDirectives/UCM384257.pdf>



FMD-76 V 2.0.pdf

- Attachment 18 – FMD-130 (OEI) Development and Maintenance Procedures

<http://www.fda.gov/ICECI/Inspections/FieldManagementDirectives/ucm096034.htm>

- Attachment 19 – FMD-86 EIR Conclusions and Decisions

<http://www.fda.gov/downloads/ICECI/Inspections/FieldManagementDirectives/UCM382035.pdf>



Attachment 19
(FMD-86).pdf

- Attachment 20 – FDA Investigations Operations Manual, Chapter 4. Sample Schedules

<http://www.fda.gov/downloads/ICECI/Inspections/IOM/UCM123507.pdf>

- Attachment 21 – FDA DFI Bulletin 32 Internal Testing Programs and Environmental Sampling



Attachment 21 (DFI
32).pdf

- Attachment 22 –Environmental Sampling for Salmonella



Attachment 22
(Salmonella ES).pdf

- Attachment 23 –Environmental Sampling for Listeria



Attachment 23
(Listeria ES).pdf

- Attachment 24 – FDA DFI Bulletin 30 Food Program Instructions for Environmental Sampling



Attachment 24 (DFI
30).pdf

- Attachment 25 – Manufactured Food Regulatory Program Standards (MFRPS), 2016 Version
<http://www.fda.gov/downloads/ForFederalStateandLocalOfficials/PartnershipsContracts/Overview/UCM377447.pdf>



MFRPS 2016.pdf

- Attachment 26 – OEI Improvement Form



Attachment 26 (OEI
Form).pdf

- Attachment 27 – FDA Form 2684 Quarterly Report

<http://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/Forms/UCM071296.pdf>



Attachment 27
(Quarterly Report).px

- Attachment 28 - Best Practices for Submission of Actionable Food and Feed Testing Data Generated in State and Local Laboratories



Attachment 28 - Lab
Best Practices.pdf

- Attachment 29 – FDA FSMA Rule on Foreign Supplier Verification Programs (FSVP)

<https://www.fda.gov/downloads/Food/GuidanceRegulation/FSMA/UCM472890.pdf>



Attachment 29 -
FSVP.pdf

- Attachment 30 – Representations and Certifications if SAM is not utilized (see Section H) per FAR 52.204-8 (Jan 2014)



Microsoft Word
Document

Attachment 31 - Class Deviation 18-01 Whistleblower Protection for Contractor Employees



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