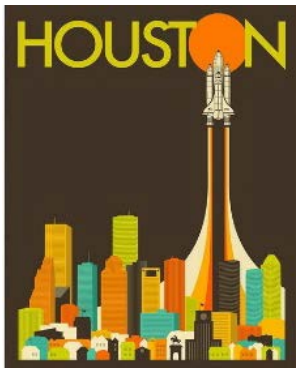

8th MFRPAlliance (MFRPA) meeting

&

5th Governmental Food and Feed Laboratory Accreditation Meeting

April 8-11, 2019

Hyatt Regency

Houston, TX

Launching the 2019-20 Human Food Contract

Navigating the changes in the 2019-20 Statement of Work (SOW)

DATE: Wednesday, April 10, 2019 - Roundtable Speed Dating - LOCATION: Arboretum I-V – Second Level

NOTE: This document is provided as a guidance document and does not replace the official Statement of Work

Previous referenced information regarding FDA Training requires further clarification and has been removed to avoid confusion.

- FDA training will be referenced in the 2019-20 Human Food contract Statement of Work (SOW)
- During the annual technical conference call to discussion changes in the Statement of Work with the States, further clarification regarding FDA Training required under the Human Food contract will be provided.

FDA Training – Additional Information

Domestic AF and LACF inspections are not stand-alone inspections

- will always be part of a Seafood HAACP or GMP/Limited Scope or Full Scope PCHF inspections
- must also meet the training requirements of those programs.

PC for Human Food Regulators Course, FD254, is now a prerequisite to attend FD202 (Conducting Acidified Food Inspections) & FD304 (Low Acid Canned Food Inspections).

- State inspectors who have already completed FD202 and FD304 and currently conducting these contract inspections are not required to complete FD254.
- For future, training requirement for FD254 to conduct AF and LACF inspections may be further adjusted**.**

PC Rule inspections

Prior to conducting contract inspections, State inspectors

- shall successfully complete
    - all pre-requisites and FD 254, Preventive Controls for Human Food Regulators course
    - a joint inspection or other in-field training experience at a PCHF regulation firm completed with a qualified State or FDA field inspection trainer

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Inspections

Food Inspections (Basic work) reference firm types below:

- **GMP inspections**
  - at facilities that are not required to register are subject to GMP Subparts A, B, F
    - GMP not tied to registration
  - at facilities that are required to register are subject to Preventive Controls Subparts C & G
    - Preventive Controls are tied to registration
  - at warehouses that are solely engaged in the storage of unexposed packaged food (ambient, frozen, refrigerated but not for safety)

NOTE: Facility as defined in the FD& C Act, please see below
Facility means a domestic facility or a foreign facility **that is required to register** under section 415 of the Federal Food, Drug, and Cosmetic Act, in accordance with the requirements of part 1, subpart H of this chapter.
(21 CFR 117.3)
For further details, please see **The Food Facility Biennial Registration Fact Sheet** located via the link below
https://www.fda.gov/Food/GuidanceRegulation/FoodFacilityRegistration/default.htm
Stroll down to Quick Links to access the Fact Sheet.

- **GMP/modified requirements**
  - for qualified facilities
  - at warehouses that are solely engaged in the storage of unexposed packaged food that requires refrigeration for safety

- **GMP/Limited Scope PCHF inspections, depending on commodity, may also include LACF or Acidified component**

Bottled water plants

- are not exempt from the GMP PCHF regulations.
- will either be conducted as GMP Limited or Full Scope PC
- shall also be inspected for any provisions in the bottled water GMP regulation, 21 CFR 129 that are not included in the GMP PCHF regulation including testing requirements

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Inspections

Seafood HACCP and Juice HACCP
Foods covered by 21 CFR 123 Fish & Fishery Products and 21 CFR 120 Hazard Analysis & Critical Control Point Systems

- are exempt from 21 CFR 117 Subparts C and G.
- Observations regarding any CGMP requirements from Subpart B, except for training requirements and human food being diverted to animal food
    - should be cited under 21 CFR 123.11 Sanitation Control Procedures (Seafood) & 21 CFR 120.6 Sanitation Standard Operating Procedures (Juice)
- Inspectional hours for coverage of subparts A (training and training records), B (only for human food being diverted to animal food), and F (general record keeping requirements) must be reported appropriately
    - 03S903 (GMP - Part 117 Subparts, A, B and F)
    - and/or 03S002 (State Contract Seafood HACCP) PAC codes or 03S004 (State Contract Juice HACCP) PAC codes
- Firm's Seafood HACCP Plan, only to support significant observations.
    - Do not collect routinely

Low-acid canned foods (LACF)

- are **not** exempt from the Subparts C and G
- Assessment of the thermal processes is covered by
    - 21 CFR 113 Thermally Processed Low-Acid Foods Packaged in Hermetically Sealed Containers (LACF)
    - Hazards requiring a control not controlled by processing requirements (21 CFR 113) are covered by 21 CFR 117 Subparts C and G

Acidified foods

- are not exempt from the CGMP & PCHF rule
- AF facility's Food Safety Plan (FSP)
    - must include a preventive control program covering C. botulinum and other public health significance microorganisms & any chemical or physical hazards that may require preventive controls
    - acceptable to reference and/or incorporate the scheduled processes, operating procedures, and records established and maintained in accordance with 21 CFR 114
- Hours should be reported under
    - 03803A for requirements specific to 21 CFR 108 Emergency Permit Control
    - 21 CFR 113 Thermally Processed Low-Acid Foods Packaged in Hermetically Sealed Containers (LACF)
    - 21 CFR 114 Acidified Foods
- Hours for coverage of the CGMP & PCHF rule should be reported under the appropriate PAC(s)

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Samples Elective

- Samples must be analyzed using FDA recommended methods and procedures, or other current validated and fit-for-purpose food testing methodologies.
- FDA will provide additional guidance on product sampling to include product selection and analyses under the sample elective.
- Analytical data packages may be requested for review
- Environmental sampling may be requested as part of an assignment.
    - The assignment instructions, including sample collection and laboratory methodology, must be followed.
- Environmental sampling zone must be identified for contract work

COR and Project Manager responsibilities

COR located in Office of Management (OM)/Contracts & Grants (C&G) – financial oversight

- Ensures the Government receives the work funded under the contract within the specified timeframes in collaboration with technical experts
- Participates in the development of the Statement of Work (SOW) in conjunction with the Project Manager, Center Technical Advisor, Division Technical Advisor, or other technical experts
- Processes invoices in a timely manner with input from technical experts and notifies Project Manager when invoices are rejected
- Completes reporting requirements for the Contractor Performance Assessment Reporting System (CPARS) as required
- Initiates closeout process in conjunction with OAGS

Project Manager located in Office of Partnerships (OP) – technical/program oversight

- Leads oversight of the contractor's technical performance, in conjunction with the COR and the Division Technical Advisor
- Leads efforts in the development of the contract Statement of Work (SOW) and Independent Government Cost Estimate (IGCE)
- Reviews RFP solicitation in concert with the COR where required
- Participates in contract negotiations with the COR as appropriate
- Leads contract issue resolution

Invoices

RECOMMENDATION to avoid confusion at close out of contract when invoices have not been submitted. FDA will equally be committed to processing submitted invoices in a timely manner.

To facilitate more timely submission and processing of invoices, the States are requested to submit:

- signed invoices within fifteen (15) business days after receipt of the Division approval of the Quarterly Summary Report to Department of Payment Services at FDAVendorPaymentsTeam@fda.hhs.gov, and Contracting Officer Representative (COR) via email

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Information required from top firm management

The name, title, physical address, and **email address** of the top management official shall be obtained during the inspection.

Definitions/Clarification

- State or FDA field inspection trainer
  - as defined in the Manufactured Food Regulatory Program Standards
- GMP/Limited Scope PC inspections are PC inspections
  - are limited in scope coverage for Subparts A, B, and F of 21 CFR Part 117 and broad-based assessment of preventive control programs
- The FDA Food Safety Modernization Act (FSMA) Preventive Controls for Human Food Rule is now final, and as of September 2018
  - all food businesses are subject to the new rule unless exempt or qualify for modified requirements.