Minnesota Department of Agriculture
Dairy and Food Inspection Division

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Version #: **1**	Effective Date: 3/17/2015
Title: **FDA Contract Management SOP**	

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1. PURPOSE

The purpose of this procedure is to establish a uniform process for work planning, review of contract reports and entry of Food and Drug Administration (FDA) contract inspection information into eSAF (Electronic System to Access Field Accomplishments and Compliance Tracking System (FACTS)). This procedure also provides guidance regarding the quality assurance of eSAF submissions and the state contract reports.

2. SCOPE

This policy applies to all FDA Food contract inspection reports. This procedure does not cover Food Inspector procedures related to FDA Food Contract Inspections as this information is in FOOD.30.19.

3. BACKGROUND

The Dairy and Food Inspection Division of the Minnesota Department of Agriculture has a yearly contract with the FDA to conduct inspections of FDA regulated firms under State jurisdiction. FDA uses a database, electronic State Access to Field Accomplishments and Compliance Tracking System (FACTS) otherwise known as eSAF, for entry of state contract inspection data and tracking of inspections. The eSAF system allows FDA to automate the issuance of contract work assignments to the states and allows the states to enter and update inspection results electronically.

4. RESPONSIBILITY

Food Program Manager: The Food Program Manager will review all policies and procedures and issue final approval of all food program policies and procedures. The Food Manager will also attend all work planning meetings and act as a liaison between MDA Food Inspection Staff and the FDA.

FDA Food Contract Quality Assurance Coordinator (QAC): The QAC will manage the list of inspections, submit reports to the FDA, and review contract report and eSAF submissions.

Food and Dairy Inspection Supervisors: Food Inspection Supervisors will assign inspections, review inspection reports, upload the information into eSAF, and respond to any issues regarding firms or reports. The Food Supervisors will also attend all Work Planning meetings and other on-going meetings with the FDA Liaison, and hold yearly Food Contract Inspection training for inspectors.

Food Contract Lead: The FDA Contract lead is the Food Inspection Supervisor responsible for coordinating work planning and on-going FDA Contract meetings.

FDA State Liaison: The State Liaison will reconcile the MDA and FDA facility lists, create assignments in eSAF, review inspection reports, advise states on new procedures, and respond to any issues that may arise.

Data Management Coordinator (DMC): The Data Management Coordinator will provide technical support to the QAC. The DMC's activities may include creating SharePoint sites, troubleshooting issues, and exporting data.

Regulatory, Educational and Outreach Program Coordinator: The Regulatory, Educational and Outreach Program Coordinator will ensure that all staff are trained in carrying out the responsibilities of this SOP.

5. DEFINITIONS

Action Referred to FDA (RAI): This will appear as OAI in the system used by FDA. The use of this classification is extremely rare.

Assigned Inspection Types: The type of inspection assigned by FDA that designates the focus of the inspection. Inspection types include: GMP, Seafood HACCP, Juice HACCP, Low Acid Canned Food/ Acidified Food (LACF/AF), Environmental Sampling, and Audit.

eSAF: A database designed for entry of state contract inspection data that is integrated with the FDA's online automated Field Accomplishments and Compliance Tracking System (FACTS). eSAF allows FDA to automate the issuance of work requests to the states and allows the states to enter, update, and retrieve inspection results electronically.

FDA Inspection Contract Summary (FICS): A report prepared by MDA when a FDA Food Contract Inspection is conducted to document specific information gathered and to summarize inspectional findings and results. The report is provided to FDA (MIN-DO) as documentation of the work conducted during the inspection. The form is to be used for all GMP manufacturing, Seafood HACCP, Juice HACCP, LACF/AF, and Environmental Sampling Inspections except when the FICS-Visit or FICS - Warehouse form applies.

FDA Inspection Contract Summary (FICS) – Visit: A report prepared to document specific information gathered when an FDA Contract Visit is conducted.

FDA Inspection Contract Summary (FICS) – Warehouse: A report prepared when an FDA Food Contract Inspection is conducted to document specific information gathered and summarize inspectional findings and results. The report is provided to FDA (MIN-DO) as documentation of the work conducted during the inspection. The form is to be used for all warehouse GMP Inspections EXCEPT that when a warehouse is subject to the Seafood HACCP regulation (21 CFR 123), the main FICS must be completed.

No Action Indicated (NAI): Inspection conclusion for no significant violations or violative conditions found during the inspection that closely link to public health risk and/or product adulteration (Refer to FOOD.30.01 Inspection Protocol –Food Manufacturing Section 6.4. 8 & 9).

Not an Official Establishment (NOE): An establishment that no longer manipulates product or is otherwise engaged in activities subject to FDA regulation, but still remains in business.

Out of Business (OOB): 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 records research.

State Action Indicated (SAI): Inspection conclusion for significant violations found and documented warranting some type of regulatory action be taken by MDA. MDA Supervisor notifies the FDA State Liaison within three working days regarding the type of follow-up action proposed by MDA. Violations of state law or regulations that are not actionable under current FDA policy are not to be used to support this inspection conclusion.

Visit: An inspection was attempted and the establishment was found to be: "Out Of Business" (OOB), not an official establishment (NOE) as defined by FDA, not subject to coverage under the food contract (i.e. retail only), relocated outside of the State of Minnesota, or when a complete inspection cannot be accomplished during the contract period of performance for unforeseen circumstances. Perform all reasonable efforts to locate firms that have moved or relocated.

Voluntary Action Indicated (VAI): Inspection conclusion for significant violations or violative conditions found and documented during the inspection that the firm identified corrective actions to address. (Refer to FOOD.30.01 Inspection Protocol –Food Manufacturing Section 6.4. 8 & 9). Violations of state law or regulations that are not actionable under current FDA policy are not to be used to support this inspection conclusion.

Wish List: The state's desired firms for contract inspections. Selections are made from FDA provided list of their inventory. These selections should represent approximately 30-50 % of total contract assignments for the year.

6. Procedure

6.1. Prior to Work Planning Meetings

QAC

6.1.1. Export list of firms from USAFS via business program area to capture firms with Mfg/Processor, Mfg/Processor – USDA, Wholesale/Distributor, and Food Broker licenses. Additionally, firms with another type of license, such as Retail, but having an operation classification representing Manufacturing or Wholesale/Distributor activities, may be added to the list.

6.1.2. Submit a complete excel spreadsheet list of MDA firms including firm name, address, risk category, and last inspection date to the FDA State Liaison by April 1st of each year.

6.1.3. Once final reconciled list is received from the FDA State Liaison, post the list on SharePoint in the Food Contract Folder within 5 business days of receipt and notify Supervisors.

6.1.4. Investigate firms missing from MDA's Firm List and note findings on the excel spreadsheet. Some entities are not licensed and/or inspected by MDA but may show up on FDA's list. Examples: grain elevators and packaging material manufacturers.

6.1.5. Notify Supervisors about firms that do not have an MDA license.

6.1.6. Send the Wish List to the FDA State Liaison within 5 business days of completion (by Supervisors).

FDA State Liaison

6.1.7. Once the MDA facility list has been received, compare MDA and FDA lists.

6.1.8. Identify any FDA firms missing from MDA's list on a separate tab in the excel sheet.

6.1.9. Send the reconciled list, separated by type of firm (Seafood, LACF/AF, GMP, Juice, and Environmental Sampling) to the QAC by approximately July 1st.

6.1.10. Provide a list of potential firms (from the FDA inventory) for current years' contract assignments to MDA Food Contract Lead by approximately August 1st.

Food Supervisors

6.1.11. When notified by QAC, review names of firms on FDA list that do not have an MDA license and assign to inspection staff for further follow up as appropriate.

6.1.12. Based on criteria established by Food Contract Lead, select possible firms to be inspected under the current year's Contract into a Wish List by August 31st.

Food Contract Lead

6.1.13. Post the list of potential contract firms to SharePoint and provide instructions by August 1st for Food Supervisors to create Wish List. Base instructions based on priorities established during communication with the FDA Liaison. Criteria may include the following:

a. New firms including any firms found on the FDA reconciled list but not known by MDA

b. Previous contract assignments

c. Compliance history

d. Inspection delinquency

e. Specialized Processes (Seafood, LACF/AF, and Juice)

f. Balanced distribution by geographic and inspector territories

g. Risk Level – balance of high, medium and low risk manufacturers and warehouses.

h. Firms where Environmental Sampling may be conducted.

Firms that are NOT to be selected include Grade A milk facilities where only Grade A products are processed, and firms that solely engage in the manufacture and distribution of Dietary Supplements.

6.1.14. Notify QAC when the *Wish List* has been completed (no later than August 31st.)

6.1.15. Schedule the Work Planning Meetings with FDA to be held during September and October. This scheduling is completed by September 1st.

6.1.16. Create an agenda for the Work Planning meetings and circulate it to MDA Supervisors, Management, QAC, and the FDA State Liaison for comments.

6.2. Work Planning Meeting(s)

MDA Supervisors, Management, QAC, FDA State Liaison and other MIN-DO Management

6.2.1. Attend Work Planning meeting(s) and participate in discussions regarding assignments, training, and issues regarding the previous contract.

6.2.2. Finalize firm selections of all types of contracted inspections (numbers of inspection types based on current years contract), joint inspections and audit selections. Refer to the Contract and the Statement of Work. Inspection priorities are to be based on FDA criteria including

High Risk firms, performance goals, and FDA inspection frequency mandates established by FSMA and as identified by MIN-DO.

6.2.3. Select replacement firms that may be substituted for an already assigned firm. These firms would become Assignments when it is determined that the contracted number of inspections cannot be met because of conversion to a Visit or other unforeseen circumstance. The number of replacement firms should approximate the number of Visits allowed under the current year's contract.

6.2.4. Discuss any contract up-dates, identify training needed for staff, audits, joint inspections, issues identified from the previous year's contract, and other issues identified in the Statement of Work.

6.3. Contract Assignments

QAC

6.3.1. Once received from FDA, post the Master Work Plan to SharePoint and notify Supervisors and Management by October 5th. Keep this list updated if there are future changes with the assignments.

6.3.2. When the FDA Liaison issues the eSAF assignments complete the following steps:

a. Confirm assignments entered by the FDA State Liaison in eSAF are on the Master Work Plan.

b. If the firm is on the list, enter the assignment number to the Master Work Plan on SP

c. If the firm is not on the list, send an email to the FDA State Liaison regarding the assignment.

d. Throughout the contract year, if FDA adds an assignment, inform supervisors and update the Master Work Plan.

6.3.3. Create a SharePoint Document Set for each assigned firm by November 15th

a. Fill in the required metadata.

b. Upload the eSAF cover sheet (password protected).

c. Save Assignment.

d. Start the SharePoint work-flow (assignment to Supervisor)

Food Supervisors

6.3.4. Once the Master Work Plan is posted, enter a supervisor name for each assignment on the Excel spreadsheet by October 15th.

6.3.5. Assign inspections in SharePoint after receiving the SharePoint workflow notification. Assignments should be made no later than December 1st. Inspector assignments should take into consideration the inspectors experience and training certifications (e.g. no assigned Seafood HACCP Contract inspections if the inspector is not certified by FDA), work load, complexity of an operation, etc. Due dates are to be assigned based on the following:

a. Inspector workload

b. Seasonality of the firm

c. General balancing of the workload

d. Supervisor availability

e. FDA Performance Goals- quarterly percentages based on FDA Liaison request.

6.3.6. Provide training to staff by November 15st on the FICS, Contract Inspection SOP and any other updates for the contract year.

Food Contract Lead

6.3.7. Create FDA Contract Sampling Work Plan with by the assigned Agriculture Consultant. This Work Plan includes specific environmental and other sampling inspectional requirements, analysis requirements, and specific assignments of inspectors and dates for the FDA assigned inspections.

6.3.8. Initiate review and changes to the FICS Templates with revisions complete by approximately November 1st. Changes should be based on new or revised information as requested by FDA, clarifications, or changes to SOPs.

6.3.9. In consultation with the Training Coordinator, provide a list of inspectors that are expected to conduct contract inspections, inspection types assigned, information about the inspectors' training, and training received by State auditors.

FDA State Liaison

6.3.10. Send the final Master Work Plan of assignments to the QAC by approximately October 1st, including pre-selected replacement firms

6.3.11. Create all eSAF assignments by approximately November 1st with 20% assigned by Oct 1 and balance by Oct 31

6.3.12. Send FDA Complaints associated with contracted firms to Food Contract Lead, as they become available

6.4. Inspection Results and eSAF Entry

Food Supervisors

Results of all inspections are to be reported to MIN-DO within 20 business days per the FDA Contract. This includes supervisory review, eSAF entry, review by QAC, and submission of reports to MIN-DO. If there are extreme circumstances such as resource limitations or food emergencies, report all inspections no later than October 10th after each contract year.

6.4.1. Once the inspection report and FICS and other required documents are uploaded to SharePoint, review the documents using the following criteria:

a. All required forms and documents have been uploaded to SharePoint and are the most current versions.

b. Verify that all data has been appropriately and accurately captured in USAFS including the overall risk category for the firm.

c. Ensure that the FICS fully captures the required information in the FDA Contract Inspections SOP FOOD.30.19.

d. Determine the appropriate State Compliance Follow Up based on inspector recommendation, review of reports and discussion with inspector. Reinspections or Follow Up Inspections are to be conducted per SOP FOOD.30.02 Conducting Reinspections and Follow Up Inspections. Mark the appropriate State Follow up on the FICS. See also 6.4.13 regarding submission of additional information and reports to FDA.

e. If samples were collected, enter narrative summary about final lab results. List the MDA sample numbers (a range is acceptable) in the Summary section. Additionally, a copy of the complete final lab report is to be posted to the Document Set. This information may not have been available when the inspector completed and submitted the FICS.

f. Ensure correct language, grammar and spelling usage.

g. Ensure that appropriate actions have been taken when significant violations have been identified, e.g. potentially violative products are embargoed, reinspections or other enforcement action is initiated.

6.4.2. If corrections are needed to the submitted documents (errors, information is incomplete, etc.), request changes from the assigned inspector; the documentation must be revised or added to SharePoint by the inspector within two working days of receiving the notification. If the errors become a pattern, identify a corrective action for the inspector.

6.4.3. Determine the Inspection Conclusion NAI, VAI, or SAI (as defined above) based on violations, product adulteration, etc. and enter on the FICS. The inspection conclusion may be different for the different PAC codes, product codes, etc. For example, a Seafood HACCP Inspection may have the GMP portion rated as NAI, but the Seafood portion as VAI, depending on the violations.

6.4.4. If there are significant violations found during the inspection including those resulting in potentially violative product, discuss the situation with the inspector(s) and assess if the inspection will be classified as SAI. If it will be classified as SAI, notify the FDA Liaison within 3 days of the completion of the inspection and continue to provide updates as appropriate.

6.4.5. Notify MIN-DO State Liaison under the following additional circumstances:

a. Any additional State enforcement actions are planned or completed such as embargo, condemnation, warning letters, license revocations, etc. information is to be communicated and actions coordinated with MIN-DO, providing updates as appropriate.

b. A firm states that they do not intend to register with FDA as required under the BT Act or FSMA.

c. Significant positive laboratory results, presumptive positive laboratory results, or when a sample confirms as positive. MIN-DO FDA Liaison and FDA Office of Regulatory Science ORAHQORSMANAGEMENT@fda.hhs.gov shall be notified within one (1) business day. Sample reports of final determination for positive (violative) samples are to be submitted to MIN-DO FDA Liaison within three (3) business days. Sample reports for negative (non-violative) samples are to be submitted

with the other inspection documents (posted in Document Set) within the usual 20 business day time frame.

6.4.6. If the assigned inspection becomes a Visit, identify replacement firm(s) during the monthly meeting or via email communication with the FDA Liaison.

6.4.7. If a Specialized Process Inspection type becomes only a GMP inspection (e.g. the specialized process is no longer conducted by firm), notify the QAC to delete the appropriate Specialized Process type in eSAF (or QAC will request FDA to do so). Identify a replacement firm(s) for the deleted PAC during the monthly meeting or via email communication with the FDA Liaison.

6.4.8. Once the documents are complete and correct, input the required information into eSAF using *FOOD.WI.30.11 – eSAF Entry WI*. Do not enter Visits in eSAF because this is completed by the QAC.

6.4.9. Verify/Update/Edit the properties for the SharePoint Document Set to include the following information:

i. Risk Level (overall risk category assigned to the firm)

ii. Firm Type (based on how the firm is licensed)

iii. Inspection Type (update to include all that were completed as assigned under the contract during this inspection)

iv. Inspection Classification. If for a Specialized Inspection Type, and the Inspection Conclusion is different for the specialization versus the GMP portion, the most violative conclusion should be entered.

v. Hours (inspection time as reported on the FICS). Be sure to update as necessary when additional time is spent by inspectors for report corrections, sample follow up, etc.

vi. FDA Complaint Follow Up (for FDA assigned complaints)

vii. State inspectional follow up planned to include Reinspection and Follow Up inspection.

viii. Enforcement Compliance Actions (check any/all that are applicable). Actions taken at a later date should also be captured here when at all possible.

1. Warning Letters - Include all letters and notices sent to a firm's management informing or warning them of adverse conditions found during an inspection.

2. Embargoes - Number of actions taken in conjunction with inspections, which withhold or remove merchandise from the market.

3. Hearings Conducted - Number held as a result of inspections.

4. Prosecutions/Injunctions - Include court actions, i.e., prosecutions, and injunctions. Report number, when action filed. Include summary of results on continuation sheet upon completion

5. Other Actions - Actions not fitting above categories (i.e., recalls, license suspensions, or administrative penalties) should be reported here and type of action(s) should be specified.

6.4.10. Approve the inspection in SharePoint by completing the workflow task in SharePoint generated emails. This step will notify the QAC that an inspection is complete and ready for her review.

6.4.11. If the QAC identifies errors and is unable to correct them, review the issue and identify a corrective action. The inspector may need to assist or provide additional information to make the correction.

Correct and revise the documents in SharePoint and update the SharePoint work flow task. Include notes of the corrections that were made to any documents or in eSAF in the workflow task.

6.4.12. Submit to MIN-DO any responses received by the firm detailing corrective actions in response to a contract inspection as well as any results of a state conducted reinspection or follow up inspection (copy of state inspection report). These results can be posted to the Document Set, or if after the initial inspection has been submitted to FDA, they can be emailed to the FDA Liaison within 20 days of receipt (include firm name and FEI number in the subject line of the email).

<u>QAC</u>

6.4.13. Review all documents submitted by the supervisor and compare the documents to the information entered in eSAF.

6.4.14. Generate new assignments in SharePoint for replacement firms, such as Visits or when an assigned Specialized Process no longer exists (i.e. dropped), or an assigned inspection must be dropped for any other reason.

6.4.15. Assess if the QAC or the Supervisor will need to fix the error. The QAC can update the following errors:

a. Transcription Errors

b. Spelling Errors

c. Grammar Errors

6.4.16. If the error is not one listed above, return to supervisor for correction through the SharePoint workflow, noting the corrections that are needed.

6.4.17. After all errors have been corrected, complete the following tasks within 20 days of the inspection:

a. ‘Submit’ the inspection to FDA in eSAF

b. Send paper copies of the inspection documents to the FDA Liaison at MIN-DO via Certified Mail. Documents include the eSAF Cover Sheet, FICS, State Inspection Report, and other supporting documentation including HACCP plans, photographs, lab results, etc.

c. In the SharePoint Document Set, complete the date the reports were submitted to FDA and then complete the Workflow Task.

6.4.18. Enter Visits in eSAF.

6.4.19. By approximately October 31st after the contract year, prepare a year-end report to be reviewed by Food Supervisors and Food Program Manager, listing the number and types of FDA rejections that need to be revised and re-submitted.

6.5. FDA Review

FDA State Liaison

6.5.1. Review all inspection reports within the quarter when the inspections occurred.

6.5.2. Send all questions and issues by email to the QAC to assess corrective actions.

6.5.3. In consultation with Food Supervisors, select replacement firms for Visits and Specialized Processes that are no longer operational; and issue new assignments

QAC

6.5.4. When FDA requests corrections, assess the questions or issues and forward to the Supervisor if the update is not listed under 6.4.13.

6.5.5. When corrections have been made, QAC will re-Submit in eSAF and send any revised documentation to the FDA State Liaison.

Food Supervisors

6.5.6. When requested by QAC, review FDA questions and issues and identify a corrective action plan. This may involve: revisiting the firm, updating staff on procedure, re-entering information in eSAF, clarification of information in the FICS, etc.

6.5.7. Notify the QAC of the corrective action and provide any documentation required.

6.6. Quarterly and Yearly Reports

QAC

6.6.1. Complete and submit Quarterly Summary Report (Form FDA 2684), in accordance with the FDA Contract, no later than 20 business days after end of each 90 day reporting period to the FDA Liaison via email for approval along with a courtesy copy to FDA's "Contracting Officers Representative" (COR). Copy MDA's designated accountant in Finance and Budget to ensure notification of FDA approval. In periods when no inspections were performed, a report showing 'No Inspections' is required.

6.6.2. Complete a detailed list (Excel spreadsheet) of firms inspected during the 90 day reporting period to include the following information:

a. FEI#, name, address, city of firm inspected;

b. inspection date and classification in eSAF;

c. type of inspection conducted (GMP, Seafood HACCP, Juice HACCP, LACF/AF);

d. State action(s) if applicable (warning letters, embargoes, license revocations);

e. Sample information (number, type);

f. If an Audit was performed and what type (training etc.);

g. Visits (include number of hours);

h. Other work performed and authorized by the contract.

6.6.3. Review, collect, and re-submit the quarterly report as required per the FDA Liaison and/or Supervisors.

6.6.4. On an annual basis, QAC will review corrective actions required in Quarterly Summary Reports. This information will be reported to and reviewed by the Food Program Manager and Food Inspection Supervisors.

FDA Liaison

6.6.5. Conduct a review of Quarterly Summary Report and report to MDA, within 10 business days of receipt, of acceptability of report.

6.6.6. Request further information or clarification as needed.

6.6.7. Following acceptance of all work detailed on the Quarterly Summary Report, provide MDA, (via e-mail, with a copy to the COR and MDA Finance and Budget) approval of the Quarterly Summary Report. Approval of the Quarterly Summary Report by the District is required prior to submission of the invoices. MDA Finance and Budget Division is responsible for invoicing for FDA Contract work.

Supervisor

6.6.8. Provide information and review documents as required by the QAC and FDA Liaison.

7. RELATED DOCUMENTS (includes References, Attachments)

FDA Contract Management Flow Diagram

FDA Inspection Contract Summary (FICS) Template

FICS Warehouse Template

FICS Visit Template

FOOD.WI.30.11 - eSAF Entry WI

FOOD.30.19-FDA Contract Inspection SOP

FDA Food Contract and Statement of Work

FDA Contract Sampling Work Plan

8. EQUIPMENT/MATERIALS NEEDED

N/A

9. SAFETY

N/A

10. CIRCULATION

11. This documented is circulated to Food Inspection Supervisors, Food Program Manager, Training Coordinator, and QAC. The document is also provided to the FDA. An electronic version of this document is stored in the SOP library. **APPROVAL/DOCUMENT HISTORY**

Document History			
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