

**Minnesota Department of Agriculture  
Food and Feed Safety Division**

Document FOOD.40.03	Page 1 of 8
Version #: 2.1	Effective Date: 2/15/2017
Title: Field Inspection Audit – Manufactured Foods SOP	

**Table of Contents**

1. PURPOSE
2. SCOPE
3. BACKGROUND
4. RESPONSIBILITY
5. DEFINITIONS
6. PROCEDURES
7. RELATED DOCUMENTS (includes References, Attachments)
8. EQUIPMENT/MATERIALS NEEDED
9. SAFETY
10. CIRCULATION
11. APPROVAL/DOCUMENT HISTORY

**1. PURPOSE**

This procedure describes the process used by the Minnesota Department of Agriculture (MDA) Food & Feed Safety Division (FFSD) for the periodic review of field inspections of manufactured food and wholesale food facilities. Audits are conducted to verify that inspections are consistently performed according to established policies and procedures by Inspection Staff. Audit results are then analyzed to determine program performance and identify trends for improvement.

**2. SCOPE**

This procedure applies to the auditing of manufactured food and wholesale food field inspections for completeness, accuracy, and compliance with FFSD manufactured field inspection procedures. The audit may pertain to routine MDA and/or FDA Contract inspections for manufactured food and wholesale food facilities. Field inspection audits will be conducted by qualified MDA or FDA auditors. This procedure will not be used for audits of Retail Food facility inspections.

**3. BACKGROUND**

Field inspection competencies are the basis for an inspector to properly evaluate a firm's conformance with applicable food regulations and food safety practices. Additionally, field inspections are typically the foundation of communication with regulated facilities and the main avenue for development of investigational evidence. Auditing is a tool utilized to assure a quality system exists within the Manufactured Food Program for the consistency and thoroughness of manufactured food and wholesale food inspections. Auditing can help to identify where deficiencies exist within the current system as well as assist in the initiation of necessary corrective actions when deficiencies are identified.

**4. RESPONSIBILITY**

**Minnesota Department of Agriculture  
Food and Feed Safety Division**

Document FOOD.40.03	Page 2 of 8
Version #: 2.1	Effective Date: 2/15/2017
Title: Field Inspection Audit – Manufactured Foods SOP	

**Manufactured Food Program Manager (Program Manager)** – The Manufactured Program Manager will identify staff required to be audited, review completed audit forms identified as overall “Needs Improvement”, communicate with the FDA District Office regarding overall “Needs Improvement” audit, and assist in the determination of appropriate corrective actions when needed.

**Manufactured Food Inspection Supervisor (Supervisor)** - The Supervisor will review completed audit forms and assist in the determination of appropriate corrective actions when needed.

**Manufactured Food Inspector (Inspector)** – The Inspector will complete the field audit as outlined in the procedure.

**MDA Auditor (Auditor)** –The Auditor will complete the field audit as outlined in the procedure, complete the audit form and submit the audit form to the Food Standards Coordinator and the Supervisor.

**Food Standards Coordinator** – The Food Standards Coordinator will review completed audit forms, communicate issues with audit forms to the Supervisor and Program Manager as needed, update appropriate worksheets and appendices, assist in monitoring of corrective actions, and maintain documentation related to field inspection audits.

## 5. DEFINITIONS

**Manufactured Food Field Inspection Audit** – a Manufactured Food Field Inspection Audit is an inspection in which an inspector is accompanied by a MDA Qualified Manufactured Field Inspection Auditor or FDA Auditor for the purpose of assessing the quality and performance of inspection either contract or state.

**Individual Performance Deficiencies** – An Individual Performance Deficiencies occurs when:

- a) The overall audit is rated as “Needs Improvement (NI)”. The overall audit is rated as “Needs Improvement” when four or more Performance Factors are marked as NI.
- b) Performance deficiencies are found during a verification audit of MDA auditors.

**MDA Qualified Manufactured Field Inspection Auditor (Auditor)** – a MDA Qualified Manufactured Field Inspection Auditor is someone who is recognized by the Manufactured Food Program Manager as having field experience and communication skills necessary to audit other inspectors and who has:

- a) Completed FFSD Basic Inspection Training Course list.
- b) Completed FFSD Advanced Inspection Training Course list (as applicable to the facility type that will be audited such as Juice HACCP, Seafood HACCP, Acidified Food, Low Acid Canned Foods).
- c) Completed 3 years of FFSD Manufactured Food Inspections or Relevant Manufacturing Industry or Auditing Experience.
- d) Completed training on the most current version of *FOOD.30.01 Inspection Protocol – Food Manufacturing* and *FOOD.30.19 FDA Contract Inspections* along with related documents.

**Minnesota Department of Agriculture  
Food and Feed Safety Division**

Document FOOD.40.03	Page 3 of 8
Version #: 2.1	Effective Date: 2/15/2017
Title: Field Inspection Audit – Manufactured Foods SOP	

- e) Completed FD320 State Food Contract Auditing.
- f) Completed joint training audit with FDA or MDA staff.
- g) Completed and successfully passed a joint verification audit inspection with FDA or MDA staff.

**Qualified Date:** qualified date begins when an inspector has completed all basic course and field elements and has been signed off to do independent inspections. This date may be estimated for experienced staff that records are not available.

**Program Performance Deficiencies** – A program performance deficiency occurs when:

- a) A single performance factor rated as “Needs Improvement” occurs in four or more audits as defined by the FDA contract process. If fewer than four audits are conducted, a performance deficiency may be considered for a single performance factor rated as “Needs Improvement” at the discretion of the District or the State agency; or
- b) A single performance factor for the program falls below 80 percent; or
- c) The overall audit performance rating is below 90 percent based on *Appendix 4.2* calculations.

**Verification Audit Inspection** – a Verification Audit Inspection is an inspection in which a qualified FDA or State auditor observes a qualified auditor performing an audit of a State inspector conducting an inspection.

## 6. PROCEDURES

### 6.1. Field Inspection Audit Scheduling – Manufactured Food Program Manager Role

- 6.1.1. As part of the annual FDA Contract work planning process, identify staff required to be audited based on the FDA Contract and the requirements in the Manufactured Food Regulatory Program Standards.
  - a. Verify assigned staff are audited at the required frequency of at least twice every 36-month period based on QUALIFIED DATE.
  - b. Audits may be completed by FDA staff or MDA Auditor and can address FDA Contract and/or MDA based routine manufacturing inspections.
  - c. For an FDA Contract based audit, communicate the MDA staff needing audits during FDA Contract planning period and if FDA auditors are needed to conduct those audits.
  - d. For an MDA based inspection audit, identify MDA Auditor availability and make audit assignments in consultation with Manufactured Food Supervisors.
- 6.1.2. Approve all field inspection audit facility selections prior to audits being conducted based on recommendations from inspection staff, MDA Auditors, supervisors, and the FDA State Liaison. Inspections selected for audits should include the highest risk firms that the inspector is trained for including specialized inspections. This may be a high or medium-risk facility based on *FOOD.30.08 - Manufacturer and Distributor Risk Category SOP* and selected by the Manufactured Food Program Manager.

**Minnesota Department of Agriculture  
Food and Feed Safety Division**

Document FOOD.40.03	Page 4 of 8
Version #: 2.1	Effective Date: 2/15/2017
Title: Field Inspection Audit – Manufactured Foods SOP	

**6.1.3.** Create audit assignments utilizing the electronic inspection system or SharePoint workflows as applicable.

**6.2. Completion of Field Audit (FDA Contract Audit or MDA Audit) – Inspector Role**

**6.2.1.** Respond to communications from FDA Contract Auditor or MDA Auditor to coordinate scheduling of audit inspection.

**6.2.2.** Do not enter the facility or conduct any aspects of the inspection at assigned audit facility until the FDA Auditor or MDA Auditor is present.

**6.2.3.** Complete the inspector related responsibilities identified in *FMD 76 Appendix A*.

**6.2.4.** Follow all applicable MDA policies and procedures for the inspection.

**6.2.5.** Mark the name of all MDA auditor(s) in USAFS and write an explanation in the published comments of the inspection report documenting that the auditor was present for the inspection and their role as auditor

**6.3. Completion of Field Inspection Audit Form (Appendix 4.5) – MDA Auditor Role**

**6.3.1.** Contact the inspector to be audited to coordinate the scheduling of the audit inspection.

**6.3.2.** Complete the auditor related responsibilities identified in *FMD 76 Appendix A*.

**6.3.3.** Complete and submit *Appendix 4.5 Contract Audit* form within five (5) business days of inspection completion.

**a.** Refer to all applicable manufacturing SOPs and *Guidance for Completing the Field Inspection Audit Form* when completing the Field Inspection Audit Form.

**b.** Mark all program elements with “Acceptable” or “Needs Improvement” as appropriate. All “Needs Improvement” markings must be described with an additional comment. *Comments for “Acceptable” markings are strongly encouraged when it helps clearly identify actions that were completed by the inspector during the field audit.* These comments will serve to provide context as well as areas for needed improvement to supervisors and program management.

**c.** Identify audits with four (4) or more “Needs Improvement” ratings and mark the overall rating as “Needs Improvement” on the audit form.

**6.3.4.** Submit completed and signed *Appendix 4.5 Contract Audit* form and any associated documentation electronically to the Food Standards Coordinator and the Supervisor assigned to the Inspector audited.

**6.4. Review of Individual Audit Findings**

**Food Standards Coordinator Role**

**6.4.1.** Within two (2) working days of receiving the completed *Appendix 4.5 Contract Audit* form, review the audit findings including comments, Needs Improvement markings, and any audits identified as overall “Needs Improvement” (Individual Performance Deficiency).

**Minnesota Department of Agriculture  
Food and Feed Safety Division**

Document FOOD.40.03	Page 5 of 8
Version #: 2.1	Effective Date: 2/15/2017
Title: Field Inspection Audit – Manufactured Foods SOP	

- 6.4.2.** Communicate to the inspector’s supervisor and the Manufactured Food Program Manager if there are auditor comments that need further review or if an Individual Performance Deficiency is identified.

**Food Inspection Supervisor Role**

- 6.4.3.** Within five (5) working days of receiving the completed *Appendix 4.5 Contract Audit* form, review the audit findings with the identified inspector.

- 6.4.4.** Document information from the review including date, method of review and any specific “Needs Improvements” ratings follow-up information, as applicable, in the electronic system where the audit forms are stored.

**6.5. Completion of Performance Rating for Field Inspection Audit and Overall Audit Rating Forms - Food Standards Coordinator Role**

- 6.5.1.** For audits completed by MDA staff, verify that the auditor meets the definition of MDA QUALIFIED MANUFACTURED FIELD INSPECTION AUDITOR.

- 6.5.2.** Within five (5) working days of receiving the completed *Appendix 4.5*, enter the data from all *Appendix 4.5 Contract Audit* forms into *Appendix 4.2 Summary of Field Inspection Audit Findings* or electronic database.

- 6.5.3.** Notify the Manufactured Food Program Manager and the Supervisors if a single performance factor or the overall performance rating for the program falls below 90% at any time.

- 6.5.4.** Calculate the final ratings for *Appendix 4.2 Summary of Field Inspection Audit Findings* annually.

- 6.5.5.** Complete the Field Inspection Audit section of the *Worksheet 4.1: Performance Rating Summary Worksheet* annually after the final ratings for *Appendix 4.2 Summary of Field Inspection Audit Findings* have been completed.

- 6.5.6.** Send *Worksheet 4.1* and *Appendix 4.2* results to the Manufactured Food Program Supervisors and Manager.

**6.6. Review of Ratings – Supervisors and Manufactured Food Program Manager Roles**

- 6.6.1.** Meet and review *Appendix 4.2 Summary of Field Inspection Audit Findings* within two weeks of completion by Food Standards Coordinator to determine the effectiveness of the inspection program, recognize trends in inspectional coverage, and identify best practices used to achieve quality inspection reports.

- 6.6.2.** If two (2) or more “Needs Improvement” markings are noted within a single Performance Factor, add comments from review to *Appendix 4.2* and return to Food Standards Coordinator.

- 6.6.3.** Assess and evaluate trends in program performance using the *Worksheet 4.1: Performance Rating Summary Worksheet* annually.

**6.7. Completion of Corrective Action Plans (Appendix 4.8).**

- 6.7.1. Individual Field Inspection Audit – Manufactured Food Program Manager Role**

**Minnesota Department of Agriculture  
Food and Feed Safety Division**

Document FOOD.40.03	Page 6 of 8
Version #: 2.1	Effective Date: 2/15/2017
Title: Field Inspection Audit – Manufactured Foods SOP	

- a. If an Individual Performance Deficiency is identified, notify the FDA District Office within 10 business days unless the audit is not associated with the FDA Contract.
- b. Working with the Supervisor, identify proposed corrective actions as appropriate using *Appendix 4.8 Corrective Action Plan* within 10 business days. Corrective Actions must include:
  - a) Restriction from completing independent manufacturing and/or distributing inspections including FDA Contract inspections
  - b) Completion of joint inspections with assigned inspection staff
  - c) Successful completion of an additional Field Inspection Audit – this additional audit CANNOT be conducted at an FDA Contract inspection.
- c. Review and finalize Corrective Actions with the District Office unless the audit is not associated with the FDA Contract.
- d. Submit completed *Appendix 4.8* forms electronically to the Food Standards Coordinator and FDA District Office if applicable.
- e. Verify Corrective Actions are completed and submit associated documentation of completed corrective actions such as joint inspection reports and additional audit forms to the Food Standards Coordinator electronically as they are finalized.

**6.7.2. Single Performance Factor Rating or Overall Program Rating –  
Manufactured Food Program Manager Role**

- a. If a Program Performance Deficiency is identified, notify the FDA District Office within ten (10) business days.
- b. Working with the Food Inspection Supervisors, identify proposed corrective actions as appropriate using *Appendix 4.8 Corrective Action Plan* within 10 business days. Refer to *FMD76 Section 5.8.3.* for appropriate program corrective actions.
- c. Review and finalize corrective actions with the District Office if applicable.
- d. Submit completed *Appendix 4.8* forms electronically to the Food Standards Coordinator and FDA District Office if applicable.
- e. Verify corrective actions are completed and submit associated documentation of completed corrective actions such as joint inspection reports and additional audit forms to the Food Standards Coordinator electronically as they are finalized.

**6.7.3. Monitor Corrective Actions – Food Standards Coordinator Role**

- 6.7.3.1.** Review the *Appendix 4.8* upon notification from the Manufactured Food Program Manager.

**Minnesota Department of Agriculture  
Food and Feed Safety Division**

Document FOOD.40.03	Page 7 of 8
Version #: 2.1	Effective Date: 2/15/2017
Title: Field Inspection Audit – Manufactured Foods SOP	

**6.7.3.2.** Review the supporting documentation provided by the Manufactured Food Program Manager or Supervisor to verify that the corrective action(s) have been completed as outlined in the *Appendix 4.8* form.

**6.7.3.3.** Update the *Appendix 4.8* form with the completion date of the corrective action(s) and sign the form.

**6.8. Documentation – Food Standards Coordinator Role**

**6.8.1.** Retain all Worksheets and documentation related to the Audits and Corrective Actions in an electronic file.

**7. RELATED DOCUMENTS (includes References, Attachments)**

Worksheet 4.1 Performance Rating Summary Worksheet  
 Appendix 4.2 Summary of Field Inspection Audit Findings  
 Appendix 4.5 Contract Audit Form  
 Appendix 4.8 Corrective Action Plan  
 FOOD.30.01 - Inspection Protocol – Food Manufacturing SOP  
 FOOD.30.08 – Manufacturer and Distributor Risk Category SOP  
 FOOD.30.19 - FDA Contract Inspections SOP  
 FMD 76 State Contracts - Evaluation of Inspectional Performance  
 FMD 76 Appendix A Instructions for Evaluating Contract Inspections  
 Guidance for Completing the Field Inspection Audit Form

**8. EQUIPMENT/MATERIALS NEEDED**

N/A

**9. SAFETY**

N/A

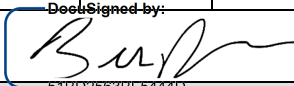
**10. CIRCULATION**

This policy will be circulated to the following individuals: Manufactured Food Program Staff and the Food Standards Coordinator. The current version will be stored electronically on the FFSD document control site.

**11. APPROVAL/DOCUMENT HISTORY**

**Minnesota Department of Agriculture  
Food and Feed Safety Division**

Document FOOD.40.03	Page 8 of 8
Version #: 2.1	Effective Date: 2/15/2017
Title: Field Inspection Audit – Manufactured Foods SOP	

Document History		
Version #	Status (I, R)	Change History
1	I	Initial Policy Drafting.
2	R	Updated definitions of Manufactured Food Field Inspection Audit and MDA Qualified Manufactured Field Inspection Auditor (Auditor). Added Food Standards Coordinator role to review of submitted audit forms prior to Supervisor review with inspector and monitoring of corrective actions.
2.1	R	Clarification added to Section 6.1.2 for facility selection for audits.
DocuSigned by: 		2/15/2017
<b>Approved By:</b>		<b>Date</b>
<b>Approved By:</b>		<b>Date</b>

I = Initial document; R = Revised document