

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

Document FOOD.40.06	Page 1 of 7
Version #: 2	Effective Date: 8/23/2017
Title: Inspection Report 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 and Feed Safety Division (FFSD) for the periodic review of inspection reports of manufactured food and wholesale food facilities. The audit is conducted to verify that appropriate inspectional information was obtained, inspection reports were properly and accurately completed, and reports are submitted according to established policies and procedures by inspection staff.

2. SCOPE

This procedure applies to the audit of manufactured food and wholesale food facility inspection reports for completeness, accuracy and compliance with FFSD field inspection procedures. The audit pertains to inspection reports completed for routine inspections conducted at manufactured food and wholesale food facilities inspected under MDA authority and those completed under FDA contract. This procedure does not apply to retail inspection report review.

3. BACKGROUND

Inspection reports serve multiple purposes including communication with regulated facilities, record-keeping for activities conducted by inspection staff and evidentiary development purposes. Proper use, completion, and submission of inspection reports are key components in assuring those purposes are adequately and consistently being met in the Manufactured Food Program. Auditing is a tool used to assure a quality system exists within the Manufactured Food Program for the consistency and maintenance of manufactured food and wholesale food inspection reports. Auditing can help to identify where deficiencies exist within the current system as well assist in the initiation of corrective actions which are necessary when deficiencies are identified. MDA is also required to audit inspection report annually per Standard 4 of the Manufactured Food Regulatory Program Standards (MFRPS).

4. RESPONSIBILITY

Manufactured Food Program Manager – The Manufactured Food Program Manager will, along with the Food Inspection Supervisors, review *Appendix 4.3 Performance Rating for the Inspection Report Audits* and identify and assign programmatic corrective actions as appropriate.

Food Inspection Supervisor - The Supervisor will review all *Appendix 4.6 Inspection Report Audit Forms* for their respective staff; assign corrective actions (*Appendix 4.8*) based on individual audit findings as appropriate; assist in reviewing the *Appendix 4.3 Performance Rating*

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

Document FOOD.40.06	Page 2 of 7
Version #: 2	Effective Date: 8/23/2017
Title: Inspection Report Audit – Manufactured Foods SOP	

for the Inspection Report Audits; assist in auditing inspection reports to the assigned procedures as requested; and assist in assigning programmatic corrective actions as appropriate.

Food Standards Coordinator – The Food Standards Coordinator will randomly select inspection reports to audit, audit inspection reports according to the assigned procedures, identify when corrective actions are needed, complete required worksheets and appendices, and communicate with the Food Inspection Supervisor and the Manufactured Food Program Manager regarding corrective action completion, verification, and monitoring.

5. DEFINITIONS

Individual Performance Deficiency – An Individual Performance Deficiency occurs when the overall audit is rated as “Needs Improvement” (NI) (less than 80% rating). An audit is rated as overall NI when three out of ten questions are marked as “Needs Improvement” on *Appendix 4.6*.

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 per *FOOD.40.03 - Field Inspection Audit – Manufactured Foods SOP*.

Program Performance Deficiency – A program performance deficiency occurs when:

- a) A single performance factor is below 80% or
- b) The overall audit performance rating is below 80 percent based on *Appendix 4.3* calculations.

Qualified Inspection Report Auditor (Auditor): A qualified inspection report auditor is someone who has:

- a) Completed the most current FOOD.30.05 Inspection Report Writing SOP Training.
- b) Completed 2 years of directly related inspection work in FFSD.
- c) Assigned by the Program Manager to conduct audits.

Wholesale Food Handler: Wholesale food handlers are persons who sell to others for resale.

Wholesale Food Processor or Manufacturer: Wholesale food processor or manufacturers are persons who process or manufacture raw materials and other food ingredients into food items, or who reprocess food items, or who package food for sale to others for resale, or who commercially slaughter animals or poultry.

6. PROCEDURES

6.1. Select Inspection Reports for Review

Electronic Systems Coordinator

- 6.1.1. Generate report in USAFS of submitted and approved routine GMP and 117 GMP Inspection Reports from previous month to be sent to the Food Standards Coordinator. The report will be generated by the first of each month.

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

Document FOOD.40.06	Page 3 of 7
Version #: 2	Effective Date: 8/23/2017
Title: Inspection Report Audit – Manufactured Foods SOP	

Food Standards Coordinator

- 6.1.2.** Randomize list of completed GMP and 117 GMP Inspection Reports within two (2) business days of receipt utilizing a random number generator.
- 6.1.3.** Randomly select at least six Wholesale Food Handler or Wholesale Food Processor or Manufacturer routine inspection reports to review per month. Specialized process inspection reports associated with the randomly selected routine reports will be audited in conjunction with the routine report. At a minimum, 70 inspection report audits must be completed each year.
 - a.** Select reports beginning with the first report on the random list. If an inspector will have a report selected more than once due to the order of the random list, move to the next inspector to avoid duplication.
 - b.** Select all inspection reports associated with MANUFACTURED FOOD FIELD INSPECTION AUDITS that have been completed by assigned inspection staff regardless of monthly total.

6.2. Complete the Inspection Report Audit Form (*Appendix 4.6*)

Food Standards Coordinator/Assigned Auditor Role

- 6.2.1.** Complete the *Appendix 4.6 Inspection Report Audit Form* electronically for each inspection report.
 - a.** Refer to the most current versions of *FOOD.30.01 Inspection Protocol – Food Manufacturing SOP*, *FOOD.30.02 Conducting Reinspections and Follow-Up Inspections SOP*, *FOOD.30.05 Inspection Report Writing SOP*, *FOOD.30.19 FDA Contract Inspection SOP*, *FOOD.30.27 – Field Compliance Actions SOP*, applicable USAFS Guidance or Work Instructions and the most current version of the *Guide for Completing Appendix 4.6-Inspection Report Audit Form* when completing the form.
 - b.** Mark all program elements with “Acceptable” or “Needs Improvement” as appropriate and include comments to support the marking. Comments are required for any “Needs Improvement” markings.
- 6.2.2.** Submit completed *Appendix 4.6 Inspection Report Audit Forms* and any associated documentation electronically to the assigned Supervisor of the inspector who wrote the Inspection Report upon completion. Identify audits that meet the definition of an INDIVIDUAL PERFORMANCE DEFICIENCY.

Food Inspection Supervisor Role

- 6.2.3.** Review the completed *Appendix 4.6 Inspection Report Audit Form* received from the Food Standards Coordinator within five (5) days of receipt. If an inspection report audit has identified an INDIVIDUAL PERFORMANCE DEFICIENCY, refer to section 6.5.1.

6.3. Complete *Appendix 4.3 Performance Rating for the Inspection Report Audit - Food Standards Coordinator Role*

- 6.3.1.** Enter the data from all *Appendix 4.6 Inspection Report Audit Forms* (except those audit forms completed as a corrective action) into *Appendix 4.3*

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

Document FOOD.40.06	Page 4 of 7
Version #: 2	Effective Date: 8/23/2017
Title: Inspection Report Audit – Manufactured Foods SOP	

Performance Rating for the Inspection Report Audits or electronic database on an on-going basis.

- 6.3.2.** Notify the Manufactured Food Program Manager immediately at any time that the *Appendix 4.3 Performance Rating for the Inspection Report Audits* reveals a PROGRAM PERFORMANCE DEFICIENCY.
- 6.3.3.** Verify at least 70 inspection reports are reviewed annually and that all reports from the Manufactured Food Field Inspection Audits have been reviewed.
- 6.3.4.** Calculate the final ratings for *Appendix 4.3 Performance Rating for the Inspection Report Audits* annually.
- 6.3.5.** Send *Appendix 4.3* results to the Manufactured Food Program Manager and Supervisors.

6.4. Review Annual Performance Ratings – Supervisor and Manufactured Food Program Manager Roles

- 6.4.1.** Within thirty (30) days of receipt from the Food Standards Coordinator, review the completed *Appendix 4.3 Performance Rating for the Inspection Report Audits* to determine the effectiveness of the inspection program, recognize trends in inspectional coverage, and identify best practices used to achieve quality inspection reports. Use the following guidance in this review:
 - a.** All associated documentation including inspection reports and completed *Appendix 4.6* forms should be available for reference during the discussion.
 - b.** Applicable report writing procedures, work instructions and the electronic inspection program manual should also be considered during the discussion.
 - c.** Document the discussion and submit to the Food Standards Coordinator when completed.
 - d.** If the review identifies a PROGRAM PERFORMANCE DEFICIENCY, move to section 6.5.2.

6.5. Complete Corrective Action Plans (*Appendix 4.8*)

6.5.1. Individual Performance Deficiency Audit

Supervisor Role

- 6.5.1.1.** Complete *Appendix 4.8 Corrective Action Plan* for any individual inspection report audit identified as an INDIVIDUAL PERFORMANCE DEFICIENCY. Corrective Actions must include (but are not limited to):
 - i.** Review of *FOOD.30.05 – Inspection Report SOP* OR completion of remedial report writing training.
 - ii.** Successful completion of an additional inspection report audit.
- 6.5.1.2.** Submit *Appendix 4.8* form to the Food Standards Coordinator electronically within five (5) working days of receiving the audit report.

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

Document FOOD.40.06	Page 5 of 7
Version #: 2	Effective Date: 8/23/2017
Title: Inspection Report Audit – Manufactured Foods SOP	

6.5.1.3. Provide supporting documentation related to the *Appendix 4.8* form to verify that corrective action assignment(s) have been completed to the Food Standards Coordinator, along with the completion date, within thirty (30) days (unless otherwise approved by the Manufactured Food Program Manager) of submitting the *Appendix 4.8*. Documentation must include:

- i. An email stating that the inspector reviewed *FOOD.30.05 Inspection Report Writing*, completed remedial Report Writing Training, or other information to support the corrective action.
- ii. The Inspection ID for the report from USAFS to be used as the corrective action inspection report audit follow-up.

Food Standards Coordinator Role

6.5.1.4. Review the *Appendix 4.8* upon receiving notification from the electronic system. Contact the Supervisor if there are questions or concerns with the corrective action(s) proposed.

6.5.1.5. Review the supporting documentation provided by the Food Inspection Supervisor to verify that the corrective action(s) have been completed as outlined in the individual *Appendix 4.8* form.

6.5.1.6. Complete a follow-up inspection report audit using the *Appendix 4.6 Inspection Report Audit Form* within five (5) business days of receiving the Inspection ID from the Supervisor. Check the box on the form that signifies that the audit was conducted as a corrective action follow-up audit. Do not enter this audit in *Appendix 4.3 Performance Rating for the Inspection Report Audits*. This audit is considered outside the scope of the required annual audits.

6.5.1.7. Update the individual *Appendix 4.8* form with the completion date of the corrective action(s) and the follow-up inspection report audit and sign the form.

6.5.2. Overall Program Performance Factor Ratings

Manufactured Food Program Manager Role

6.5.2.1 Working with the Food Inspection Supervisors, identify and assign corrective actions as appropriate using *Appendix 4.8 Corrective Action Plan* within two (2) weeks of notification from the Food Standards Coordinator that a PROGRAM PERFORMANCE DEFICIENCY has been identified based on the following:

- i. Corrective actions for PROGRAM PERFORMANCE DEFICIENCIES identified throughout the year will be determined on a case-by-case basis.
- ii. Corrective actions for PROGRAM PERFORMANCE DEFICIENCIES identified upon review of the completed *Appendix 4.3 Performance Rating for the Inspection Report Audits* are required.

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

Document FOOD.40.06	Page 6 of 7
Version #: 2	Effective Date: 8/23/2017
Title: Inspection Report Audit – Manufactured Foods SOP	

6.5.2.2 Provide supporting documentation related to the *Appendix 4.8* form to verify that corrective action assignment(s) have been completed to the Food Standards Coordinator, along with the completion date, within thirty (30) days (unless otherwise approved) of submitting the *Appendix 4.8*.

Food Standards Coordinator Role

6.5.2.2. Review the *Appendix 4.8* upon receiving notification from the electronic system. Contact the Manufactured Food Program Manager or Supervisor if there are questions or concerns with the corrective action(s) proposed.

6.5.2.3. 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.

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

6.6. Documentation – Food Standards Coordinator Role

6.6.1. Retain all Worksheets and documentation related to the audits, corrective actions, and program reviews in an electronic file.

7. RELATED DOCUMENTS (includes References, Attachments)

Appendix 4.3 Performance Rating for the Inspection Report Audits
Appendix 4.6 Inspection Report Audit
Guidance for Completing Appendix 4.6 Inspection Report Audit Form
Appendix 4.8 Corrective Action Plan
FOOD.30.01 – Inspection Protocol – Food Manufacturing SOP
FOOD.30.02 – Reinspections and Follow-Up Inspections SOP
FOOD.30.05 – Inspection Report SOP
FOOD.30.19 – FDA Contract Inspection SOP
FOOD.30.27 – Field Compliance Actions SOP
FOOD.40.03 – Field Inspection Audit – Manufactured Foods SOP
USAFS Guidance/Work Instructions

8. EQUIPMENT/MATERIALS NEEDED

N/A

9. SAFETY

N/A


10. CIRCULATION

This policy will be circulated to the following individuals: the Manufactured Food Program Manager, Manufactured Food Program Supervisors, Manufactured Food Program Inspectors, BQM Unit Supervisor, and the Food Standards Coordinator. The current version will be stored electronically on the FFSD document control site.

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

Document FOOD.40.06	Page 7 of 7
Version #: 2	Effective Date: 8/23/2017
Title: Inspection Report Audit – Manufactured Foods SOP	

11. APPROVAL/DOCUMENT HISTORY

Document History		
Version #	Status (I, R)	Change History
1	R	Initial Policy Drafting. Updates made to original SOP (FOOD.40.02) to meet 2016 MFRPS. Reduced minimum number of inspection reports to audit to 70. (11/23/2016)
2	R	Added more defined randomization language to Section 6.1 and removed the requirement to not audit a report from an inspector more than once in a 2 month period. Added language to Section 6.5 to clarify when corrective actions are required for Program Performance Deficiencies. (8/23/2017)
Document Signed by: 		8/23/2017
Approved By:		Date
Approved By:		Date

I = Initial document; R = Revised document