

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

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Title: Sample Submission Report Audit – Manufactured Foods	

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1. PURPOSE

This procedure describes the process used by the Food & Feed Safety Division (FFSD) for the periodic review of Manufactured Food and Retail Food Program sample records for MANUFACTURED FOOD SAMPLE collection. The audit is conducted to verify that that samples were properly collected, identified, recorded, and submitted according to established procedures and policies and that appropriate information was recorded for samples collected by Food Inspection Staff.

2. SCOPE

This procedure applies to the audit of official MANUFACTURED FOOD SAMPLE records for completeness, accuracy, and compliance with the Food Programs sample collection and reporting procedures. The audit may pertain to sample records submitted for manufactured food samples collected for surveillance, compliance, complaint, foodborne illness/outbreak response or investigation purposes. This procedure does not apply to unofficial samples collected in relation to foodborne illness, response, and outbreak response or retail food samples (products produced at retail). The *2014 MFRPS-ISO Sampling Initiative Protocols* outlines which types of samples are acceptable under the sampling initiative and those that do not qualify.

3. BACKGROUND

Proper collection, identification records, and submission of samples are key components in the use of samples for evidentiary purposes. Auditing of the sample submission records is a tool utilized to assure a quality system within the Food Programs regarding the collection and handling of samples. Auditing can help to identify where deficiencies exist within the current system as well assist in the initiation of corrective actions necessary when deficiencies are identified.

4. RESPONSIBILITY

Food Standards Coordinator – The Food Standards Coordinator will select sample reports to audit, audit sample 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 Program Manager regarding corrective action completion, verification, and monitoring.

Manufactured Food or Retail Food Program Manager (Food Program Managers) – The Manufactured Food or Retail Food Program Manager will, along with the Food Inspection

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Supervisors, review *Appendix 4.4 Performance Rating for the Inspection Report Audits* and identify and assign programmatic corrective actions as appropriate.

Manufactured Food or Retail Food Inspection Supervisor (Food Inspection Supervisor) -

The Supervisor will review all *Appendix 4.7 Sample 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 4.4 Performance Rating for the Sample Report Audits*; and assist in assigning programmatic corrective actions as appropriate.

Sample Submission Report Auditor - The Auditor will complete audits as assigned.

5. DEFINITIONS

Individual Performance Deficiencies – An Individual Performance Deficiency occurs when the overall audit is rated as “Needs Improvement” (NI) (below 80%). An overall NI occurs when three or more performance factors are marked as NI on the audit form.

Manufactured Food Sample – a sample that meets the conditions for inclusion in State Sampling Agreements per the *2014 MFRPS–ISO Sampling Initiative Protocols*.

Program Performance Deficiencies – A program performance deficiency occurs when:

- a) A single performance factor is below 80% or
- b) The overall audit performance rating is below 80% based on *Appendix 4.4* calculations.

Qualified Sample Record Auditor (Auditor) – a Qualified Sample Record Auditor is someone who has:

- a) Completed the most current Sample Report Audit SOP training
- b) Been designated by the Food Program Managers

Sample Record – the complete documentation of the collection and analysis of a sample set submitted to the MDA Laboratory. This record is identified by the unique sample submission report but also includes the associated inspection report, the report of laboratory results and any associated documentation that was collected in relation to the sample such as the home sample release form or photographs of collection.

Sample Submission Report – the report generated by the collecting inspector to document the specific details of collected sample set. This report is generated through the USA Food Safety system or on form AG-01409-02.

6. PROCEDURES

6.1. Selection of Sample Records for Review – Auditor/Food Standards Coordinator Role

- 6.1.1. Export a list of all SAMPLE RECORDS associated with MANUFACTURED FOOD SAMPLES at the close of each quarter based on the year October 1st-September 30th.
- 6.1.2. Save the list of reports to the MFRPS SharePoint site. Enter the quarter and year for which the list was pulled in the naming convention.
- 6.1.3. Randomize the list of reports to be audited using a random number generator (VBA Macros, online random number generator, etc.)

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- 6.1.4. Select at least the first 10 SAMPLE RECORDS for MANUFACTURED FOOD SAMPLES to audit each quarter if available. The minimum number of SAMPLE RECORDS will be audited each year according to the table below:

Number of Samples in 12 months	Minimum Number of Records Required	Maximum Number of Records Required
Less than 40 records	All	All
40 – 800 records	40	40
More than 800	5% of records	70

6.2. Completion of Sample Report Audit Form (*Appendix 4.7*)

Food Standards Coordinator/Auditor Role

- 6.2.1. Complete *Appendix 4.7 Sample Report Audit Form* for each sample record electronically.
- 6.2.1.1. Refer to all applicable Sampling Procedures, Work Instructions and *Guidance for Completing Appendix 4.7* when completing the form.
- 6.2.1.2. Mark all program elements with “Satisfactory” or “Needs Improvement” as appropriate. All “Needs Improvement” markings must be described with an additional comment.
- 6.2.1.3. Submit completed *Appendix 4.7 Sample Report Audit Forms* to the assigned Food Inspection Supervisor of the inspector who wrote the report electronically upon completion. Identify audits that meet the definition of an INDIVIDUAL PERFORMANCE DEFICIENCY. Move to section 6.5.

Food Inspection Supervisor Role

- 6.2.2. Review the completed *Appendix 4.7 Sample Report Audit Form* received from the Food Standards Coordinator/Auditor within five (5) days of receipt. If a sample report audit has identified an INDIVIDUAL PERFORMANCE DEFICIENCY (refer to definition), move to section 6.5.1.

6.3. Completion of Performance Rating for Sample Submission Record Audit (*Appendix 4.4*) – Food Standards Coordinator Role

- 6.3.1. Verify auditor is qualified based on the QUALIFIED SAMPLE REPORT AUDITOR definition (see above).
- 6.3.2. Enter the data from all completed *Appendix 4.7 Sample Report Audit Forms* into *Appendix 4.4 Performance Rating for the Sample Report Audits* or electronic database on an on-going basis.
- 6.3.3. Notify the Food Program Managers immediately at any time that the *Appendix 4.4 Performance Rating for the Sample Report Audits* reveals a Performance Rating below 80% (refer to definition of PROGRAM PERFORMANCE DEFICIENCY).

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- 6.3.4. Verify that the minimum number of SAMPLE RECORDS have been audited according to the table in Section 6.1.4.
- 6.3.5. Calculate the final ratings for *Appendix 4.4 Performance Rating for the Sample Report Audits* annually.
- 6.3.6. Send *Appendix 4.4* results to the Food Program Managers and Supervisors when completed.

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

- 6.4.1. Within thirty (30) days of receipt, review *Appendix 4.4 Performance Rating for the Sample Report Audits* to determine the effectiveness of the sampling program, recognize trends in inspectional coverage, and identify best practices used to achieve quality reports. If the review identifies a PROGRAM PERFORMANCE DEFICIENCY, move to section 6.5.

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

6.5.1. Individual Sample Report Audit

Food Inspection Supervisor Role

- 6.5.1.1. Complete *Appendix 4.8 Corrective Action Plan* for any individual Sample Record audit identified as an INDIVIDUAL PERFORMANCE DEFICIENCY. Corrective Actions activities must include (but are not limited to):
 - a) Review of applicable Sampling Procedures and Work Instructions OR completion of remedial Sample Collection Training,
 - b) Completion of joint sampling inspections with assigned inspection staff,
 - c) Successful completion of an additional Sample Report Audit.
- 6.5.1.2. Include an approximate timeframe for the expected completion of all activities identified in the *Appendix 4.8*.
- 6.5.1.3. Submit completed *Appendix 4.8* form to Food Standards Coordinator within five (5) working days of receiving the audit report.
- 6.5.1.4. 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*. Documentation must include:
 - 6.5.1.4.1. An email stating that the inspector reviewed applicable sampling procedures and work instructions, completed remedial Sample Collection Training, or other information to support the corrective action.
 - 6.5.1.4.2. The Sample ID for the report from USAFS to be used as the corrective action sample report audit follow-up.

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Food Standards Coordinator Role

- 6.5.1.5. 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.
- 6.5.1.6. 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.
- 6.5.1.7. Complete a follow-up sample report audit using the *Appendix 4.7 Sample Report Audit Forms* within five (5) business days of receiving the Sample ID from the Supervisor.
- 6.5.1.8. Update the individual *Appendix 4.8* form with the completion date of the corrective action(s) and the follow-up sample report audit and sign the form.

6.5.2. Overall Program Performance Factor Ratings

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 that a PROGRAM PERFORMANCE DEFICIENCY has been identified.
- 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

- 6.5.2.3. Review the *Appendix 4.8* upon receiving notification from the electronic system. Contact the applicable Food Program Manager or Supervisor if there are questions or concerns with the corrective action(s) proposed.
- 6.5.2.4. Review the supporting documentation provided by the Food Program Manager or Supervisor to verify that the corrective action(s) have been completed as outlined in the *Appendix 4.8* form.
- 6.5.2.5. 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/appendices and documentation related to the Audits and Corrective Actions in an electronic file per *FFSD.POLICY.90.07 – Record Management and Data Practices Policy*.

7. RELATED DOCUMENTS (includes References, Attachments)

2014 MFRPS–ISO Sampling Initiative Protocols
Appendix 4.7 Sample Report Audit Form
Appendix 4.8 Corrective Action Plan

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FOOD.30.10 – Environmental Sampling-Food Manufacturing SOP
 FOOD.30.23 – Investigation Sampling-Inspector Initiated SOP
 FOOD.30.26 – Surveillance – Routine Sampling SOP
 FOOD.30.32 – Response, Complaint, and Enforcement Sampling SOP
 FOOD.WI.30.46 – Creating food samples in USAFS WI
 FFSD.POLICY.90.07 – Record Management and Data Practices Policy
 Guidance for Completing the Sample Submission Record Audit Form
 Standard 4 Appendix 4.4

8. EQUIPMENT/MATERIALS NEEDED

N/A

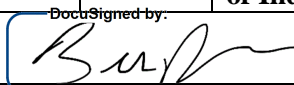
9. SAFETY

N/A

10. CIRCULATION

This policy will be circulated to the following individuals: the Manufactured Food and Retail Food Program Manager, Manufactured Food and Retail Food Program Supervisors, Compliance Supervisor and Officers, Manufactured Food and Retail Food Program Inspectors, Food Standards Coordinator, Business and Quality Management Unit Supervisor, RRT Staff, and MDA Laboratory Services Division. The current version will be stored electronically on the FFSD document control site.

11. APPROVAL/DOCUMENT HISTORY

Document History		
Version #	Status (I, R)	Change History
1	R	Initial Policy Drafting. Updates made to original SOP (FOOD.40.01) to meet 2016 MFRPS requirements and additional corrective action plan initiation and monitoring language added.
1.1	R	Updated procedure to audit sample records on a quarterly basis and added the table from the 2016 Manufactured Food Program Regulatory Program Standards outlining the number of sample reports to audit. Updated definition of Individual Performance Deficiency.
DocuSigned by: 		10/2/2017
Approved By: <small>51662583BF5444D...</small>		Date
Approved By:		Date

I = Initial document; R = Revised document