

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

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Title: Reinspection and Follow-Up Inspection SOP	

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1. PURPOSE

The purpose of this procedure is to provide direction for the determination of conducting reinspections and follow-up inspections including the assessment of reinspection fees as authorized in MN Statute 28A.085.

2. SCOPE

This procedure applies to all inspections conducted by Food Inspection staff and covers Manufacturing, Wholesale, and Retail Food facilities.

3. BACKGROUND

Per Policy.60.01 – Food Progressive Enforcement Policy, the Manufactured Food and Retail Food Programs use a progressive enforcement model that begins with outreach and education, includes field inspections and field compliance all the way through administrative, civil, and criminal enforcement. Follow-up inspections and Reinspections are considered part of the progressive enforcement continuum and considered a valuable field compliance tool.

Follow-up inspections and reinspections are conducted when the inspection staff, inspection supervisor, and/or program manager determine the need to verify continued compliance with orders that were corrected on site or to establish compliance with significant orders related to food safety outside of routine inspections. This determination can also be made in conjunction with the Compliance Unit. Follow-up inspection and reinspection are terms further defined in this procedure and are not interchangeable. A fee is only associated with a reinspection, not a follow-up inspection.

Minnesota Statutes 31.04, 31.08, 34A.04, 34A.12 (and any other applicable laws and regulations) provide the legal authority for Department staff to enter, inspect, copy records, take photographs and sample to determine compliance with the Minnesota laws including, but not limited to, MN Chapters 17, 28, 28A, 29, 30, 31, 31A, 32 and 34 and Agency rules promulgated there under.

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4. RESPONSIBILITY

Food Program Manager (Retail or Manufactured Food) – The Food Program Manager will assist in the determination of further action (reinspections, follow-up inspections, or referral to compliance) as requested.

Food Inspection Supervisor – The Food Inspection Supervisor will assist the Food Inspector in determining when further action is warranted; review request further actions and approve or deny the request following applicable procedures; and determine that further action is warranted if not done so by the inspector.

Food Inspector – The Food Inspector will determine the need for further action at the conclusion of each inspection; submit referrals for further actions to the Supervisor following applicable procedures; and conduct further actions following applicable procedures.

Compliance Supervisor – The Compliance Supervisor will assist in the determination of further actions and reinspection fees as requested.

Support Staff – Support Staff will assess reinspection fees following applicable procedures and send invoices as assigned.

5. DEFINITIONS

Critical Violation: is a Major Violation as defined by Minn. Stat. § 28A.03Subd.9 or a Critical Item as defined by MR 4626.0030 Subd.2 and includes violations of Minn. Stat. §§ 31.121, 31.123, 31.161, 31.165, 31.02, 34A.04 Subd.1, 34A.05, and 34A.11 Subd.1. Critical Violations are violations directly linked to public health risk, food adulteration, and/or known contributors to foodborne illness.

Follow-Up Inspection: is an inspection that is conducted if the firm has multiple violations of lower significance not directly related to public health or direct food contamination were observed and documented in the current inspection; significant administrative issues are identified such as incomplete HACCP records; the firm has a history of non-compliance; or the long term compliance must be verified for items corrected on site during the current inspection.

Food Code: is a rule (Minnesota Rules, Chapter 4626,) that applies to all retail food establishments and is the basis for safeguarding public health and provide to consumers food that is safe, unadulterated, and honestly presented.

Good Manufacturing Practices (GMP): is a set of federal regulations 21 CFR 110 and 21 CFR 117 (adopted by reference in MN Statute 31) that apply to all food processors, distributors, and warehouses. They are the basis for determining whether the practices, conditions, and controls used to process, handle or store food products are safe and whether the conditions in the facility are sanitary.

Hazard Analysis Critical Control Point (HACCP) Based Inspection: is an inspection conducted utilizing scientific knowledge and direct observation to evaluate a firm's food handling activities including processing, storage and distribution. An inspector identifies and then assesses

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hazardous 'points' in the process, the amount of control over those hazardous points, and documentation of the hazards, process, and any monitoring conducted by the firm.

Highly Susceptible Population: are persons who are more likely than other people in the general population to experience foodborne disease because they are:

- 1) Immunocompromised: pre-school to elementary school age children or older adults; and
- 2) Obtaining food at a facility that provides services such as custodial care, health care, or assisted living , such as a child or adult day care center, kidney dialysis center, hospital or nursing home, or nutritional or socialization services such as a senior center or school.

Most Responsible Person (MRP): is an owner, operator, or agent who is present at the firm and is responsible for the operation at the time of inspection.

Person-In-Charge (PIC): is the individual present at a food establishment who is responsible for the operation at the time of inspection.

Quality Control Operation: is a planned and systematic procedure for taking all actions necessary to prevent food from being adulterated.

Ready-to-Eat (RTE): means food that is in a form that is edible without additional washing, cooking, or other preparation by the firm or the consumer to achieve food safety, and that is reasonably expected to be consumed in that form. It may receive additional preparation for palatability or aesthetic, epicurean, gastronomic, or culinary purposes.

Reinspection: is an inspection that may be conducted when the firm has displayed an overall lack of control over their process; significant and/or critical violations (e.g. not an isolated occurrence); multiple repeat violations related to public health or direct food contamination were observed; or public health risk in relation to the violations observed is substantial (including sanitary notice).

Repeat Violation (Chronic Violation): is a specific violation observed and documented during at least two (2) inspections in a row, also known as a chronic violation.

Risk Factors: are practices or procedures that pose the greatest potential for foodborne illness during a retail inspection. Risk factors as determined by the CDC and FDA are Food Source, Inadequate Cooking, Improper Holding Temperatures, Cross Contamination, Poor Personal Hygiene, and Environmental Contamination.

Specialized Process: Manufactured Foods produced under 21 CFR, parts 113 Low Acid Canned Food (LACF), 114 Acidified Food (AF), 120 Juice, and 123 Seafood or as defined in the Food Code.

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6. PROCEDURES

6.1 Determine Need for Further Actions – Inspector Role

6.1.1. Determine the need for further actions at the conclusion of each inspection in consultation with the Food Supervisor or Food Program Manager as needed. Options for further action include, but are not limited to, the following:

- a. REINSPECTION; or
- b. FOLLOW-UP INSPECTION; and/or
- c. Refer to the Compliance Unit. See *FOOD.60.10 – Enforcement Trigger and Assessment SOP*. Examples of when to refer a facility to the Compliance Unit include, but are not limited to, endangerment of public health, overall lack of process control at the facility, and multiple repeat violations.

6.1.2. Assess the firms' overall compliance based on inspectional observations and documented violations on the inspection report using the following documents as guidance:

- a. For Manufactured Food or Wholesale facilities refer to *Appendix A-MFG Reinspection and Follow-Up Inspection Violative Condition Examples*.
- b. For Retail Food facilities refer to *Appendix B-Retail Reinspection and Follow-Up Inspection Violative Condition Examples*.

6.2 Refer Inspection for Supervisor Review – Inspector Role

6.2.1. If a further action is identified, select the appropriate further action(s) in USAFS. Refer to the applicable USAFS Guidance/Work Instructions for instructions on submitting an inspection for a follow-up, reinspection, or Refer to Compliance.

6.3 Review Referred Inspection – Supervisor Role

6.3.1. If further action is identified by the inspector in USAFS, review inspection report and assess the nature of the violations and make one of the following determinations within two (2) business days:

- a. Concur with the inspector recommendation; or
- b. Determine that further action or different further action from the recommendation is needed.

6.3.2. Approve or deny the inspector's reinspection, follow-up inspection, or Refer to Compliance request in USAFS per the applicable guidance. If the inspector's original request is being denied, add an internal note in the inspection with explanation.

6.3.3. Refer the facility to the Compliance Unit if deemed necessary upon review if not done so by the inspector per the applicable USAFS guidance. Refer to *FOOD.60.10 – Enforcement Trigger and Assessment SOP*.

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6.4 Conduct Further Action(s) – Inspector Role

6.4.1. Conduct REINSPECTION

6.4.1.1. Conduct the REINSPECTION within 2-14 business days following the conclusion of the current inspection. Extended timeframes may be approved by the supervisor for conducting a REINSPECTION under certain circumstances such as the following:

a. Cease and Desist Order is written and firm is not operating when due for the REINSPECTION to take place.

b. Facility and equipment-related issues requiring further correction than what is possible by the firm itself (i.e.-major roof leak, new equipment on back order from the manufacturer, etc.). Written documentation must be obtained from the firm to support an extended timeframe for compliance.

c. Sample or test results are not available within the REINSPECTION timeframe.

d. Other enforcement actions: Embargo/Condemnation – awaiting further information from the firm, courts, or other investigative information to make the final determination.

e. Firm is a seasonal operation and will be discontinuing operations or will be unable to make certain corrections within the REINSPECTION timeframe.

Supervisor Role: Create an internal note must be made in USAFS in the Inspection ID of the REINSPECTION when it occurs by the providing rationale for an extension in REINSPECTION timeframes.

6.4.1.2. Document in the introductory statement of the report that the inspection was conducted as a REINSPECTION. Include the date(s) of the previous inspection.

6.4.1.3. Document the compliance status of each violation being reviewed during the REINSPECTION on a GMP or Retail Inspection Report type in USAFS per *FOOD.30.05 – Inspection Report SOP* and applicable USAFS Guidance/Work Instructions.

6.4.2. Conduct FOLLOW-UP INSPECTION

6.4.2.1. Conduct the FOLLOW-UP inspection during the timeframe identified as appropriate by the inspector and the supervisor.

a. The maximum timeframe for a FOLLOW-UP INSPECTION is the half-way point based on current inspection frequency. For example, a follow up for a high-risk firm should not exceed 6 months, since this would be the half-way point between the annual routine inspections.

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Supervisor Role: If a timeframe of more than maximum listed above, document why time frame was chosen in the internal notes on the FOLLOW-UP INSPECTION in USAFS.

6.4.2.2. Document in the introductory statement of the report that the inspection was conducted as a FOLLOW-UP INSPECTION. Include the date(s) of the previous inspection.

6.4.2.3. Document the compliance status of each violation being reviewed during the FOLLOW-UP INSPECTION on a GMP or Retail Inspection Report type in USAFS per *FOOD.30.05 – Inspection Report Writing SOP* and applicable USAFS guidance.

6.4.3. Assess the need for further action at the close of the current inspection. If the firm is still unable to demonstrate compliance with documented violations as determined by the inspector, return to section 6.1. Consult with supervisor as needed.

6.5 Assess Reinspection Fees – Support Staff

6.5.1. Assess appropriate fee for all REINSPECTIONS (and subsequent REINSPECTIONS) per the fee schedule described in Minnesota Statute 28A.085. The appropriate fee is determined based on the number of REINSPECTIONS and the firms' gross annual food sales.

6.5.1.1 Consult with the Compliance Supervisor and applicable Food Program Manager if a firm is unlicensed to determine next steps for assessing the REINSPECTION fee.

6.5.2. Create invoice for REINSPECTION fee and mail to the firm within 2 (two) business days of notification from USAFS or Food Inspection Supervisor.

6.5.3 Contact licensing staff to notify that the firm's license is to be put on-hold.

7. RELATED DOCUMENTS (includes References, Attachments)

Appendix A - MFG Reinspection and Follow-Up Inspection Violative Condition Examples

Appendix B - Retail Reinspection and Follow-Up Inspection Violative Condition Examples

FOOD.30.05 – Inspection Report Writing SOP

FOOD.60.10 – Enforcement Trigger and Assessment SOP

USAFS Guidance/Work Instructions

8. EQUIPMENT/MATERIALS NEEDED

N/A

9. SAFETY

All MDA employees must follow the personal protective equipment requirements and field safety guidelines outlined in the initial and annual Food Inspector safety training. Never enter an area or perform any job task that you think will result in injury or illness. If you do identify any unsafe conditions – STOP the inspection immediately and consult with the facility management or your

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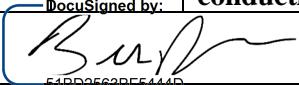
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supervisor regarding a corrective action for the hazard(s). Lastly, stick to the specific focus of your position and as always – THINK SAFETY!

10. CIRCULATION

This document is circulated to the following: Manufactured and Retail Food Inspection Staff, Food Inspection Supervisors, Compliance Unit, Food Program Managers, Support Staff, and the Food Standards Coordinator. 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	I	Initial Policy Drafting-02/28/2013
2	R	Updated and clarified procedure to provide specific guidance for determination of further actions by moving this information out of the procedure into Appendices A and B. Provided more instruction for staff in regards to conducting further actions and applicable documentation.
DocuSigned by:  <small>51DD2563BF5444D...</small>		12/28/2016
Approved By:		Date
Approved By:		Date

I = Initial document; R = Revised document