Minnesota Department of Agriculture
Food and Feed Safety Division

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Version #: **3**	Effective Date: 12/29/2016
Title: **Inspection Report SOP**	

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1. PURPOSE

This document describes the procedures used by Minnesota Department of Agriculture (MDA) Food and Feed Safety Division (FFSD) staff for issuing the Notice of Inspection and writing an inspection report at a facility inspected by the Food Programs.

2. SCOPE

This applies to all reporting of inspections of Manufactured Food Program and Retail Food Program facilities. It applies to facilities that are licensed, unlicensed, or a license is not required (due to exclusions in MN Statute 28A). It is also applicable to special investigations of food establishments, food transportation vehicles, or as otherwise directed by Division Management or Supervisors.

3. BACKGROUND

The MDA has the authority to conduct inspections in accordance with Minnesota Statutes 17.984, 31.04, 31.08, 34A.04 or any other applicable legal authority of MDA to enter, inspect, copy records, take photographs, and sample to determine compliance with Minnesota laws including but not limited to MN Statutes and Rules promulgated thereunder.

Issuing the Notice of Inspection (NOI) to a firm at the beginning of an inspection provides the firm with information regarding the State's and Departments regulatory authority, their rights to appeal, and the use and availability of the data they provide as provided for under the Minnesota Government Data Practices Act.

Inspection reports are one of the most useful tools to assess and record findings during an inspection. Inspection reports must be clear and concise because they are used to identify ongoing facility issues and may be used in enforcement cases. Enforcement actions and future inspections can be affected if inspection reports are not completed properly and according to policy. Remember that inspection reports are public record and may be read by others in the MDA, attorneys, press, or anyone requesting a copy through the Minnesota Data Practices Act.

Critical violations and non-critical violations are directly identified in the MN Food Code (MN Rule 4626), however, they are not directly identified in 21 CFR regulation. The MDA therefore evaluated the regulation and identified critical and non-critical violations for 21 CFR citations in early 2016.

4. RESPONSIBILITY

Food Program Manager – The Retail or Manufactured Food Program Manager will assist in identifying and approving missing standard orders from the electronic inspection system as requested.

Food Supervisor - The Supervisor will assist the inspector in determining if extended compliance dates are warranted and will assist in identifying and approving missing standard orders from the electronic inspection system as requested.

Food Inspector – The Inspector will follow all applicable USAFS Guidance/Work Instructions related to inspection report writing and updating facility information, document orders, observations, and comments in the inspection report per the procedure.

Electronic Systems Coordinator – The Electronic Systems Coordinator will update or add standard orders to USAFS as requested.

5. DEFINITIONS

Corrected On Site (COS): is a violation that was corrected at the time of the inspection.

Credentials: include a state issued identification card or a state issued badge. It does not include only a business card.

Critical Violation: A Critical Violation is a Major Violation as defined by Minn. Stat. § 28A.03 Subd.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 Sudb.1.

Foodborne Illness Risk Factors (RF): are improper practices or procedures identified as the most prevalent contributing factors of foodborne illness or injury.

High Public Health Severity: Pose a clear and significant risk for potential foodborne illness or injury.

Inspection: includes routine inspection, re-inspection, special investigation, complaints, licensing, plan review, sampling, or consultation if data or information about a potential firm or operator is collected.

Low Public Health Severity: Pose a potential risk for foodborne illness or injury or is otherwise not in conformance with applicable food laws.

MRP/PIC: is an owner, operator, or agent who is present at the firm and is responsible for the operation at the time of inspection.

Non-Critical Violation: A Non-Critical Violation is a violation of Minnesota Statute or Rule that does not meet the definition of Critical Violation.

Public Health Interventions (PHI): are control measures to prevent foodborne illness or injury.

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

Good Retail Practices (GRP): are preventative measures to control the addition of pathogens, chemicals, and physical objects into foods.

6. PROCEDURES

6.1. Follow USAFS Guidance/Work Instructions

6.1.1. Complete inspection reports following the USAFS Guidance Documents/Work Instructions listed below or in an emergency, follow the *FOOD.WI.30.12 - Paper Inspection Report WI.*

Additional USAFS guidance can be found on the electronic server for specific inspection related activities.

6.1.1.1. Create a new facility in USAFS
6.1.1.2. Prepare for an inspection
6.1.1.3. Update information for an existing facility
6.1.1.4. Enter an Inspection

6.2. Create and Issue Notice of Inspection

6.2.1. Create the Notice of Inspection the day the inspection is conducted.

6.2.2. Identify the most responsible person available on-site at the firm upon arrival at the facility. Present your credentials and state the purpose of your visit (inspection, reinspection, complaint, investigation, etc.)

6.2.3. Issue the NOI to the most responsible person present.

6.2.4. One inspector must print and sign their name on the NOI.

6.2.5. Each MDA employee present during the inspection must show their credentials.

6.2.6. The most responsible person at the firm does not need to sign the NOI.

6.2.7. Issue a Notice of Inspection any time an inspection report is issued.

6.2.8. For an inspection that continues over multiple days, only one notice of inspection needs to be issued (not one each day). Leave the NOI at the start of the inspection, even if you may not leave an inspection report that day.

6.3. Start the Inspection Report

6.3.1. Select the appropriate inspection type in USAFS, using the following table for reference. Use two inspection types when orders are issued from multiple regulations. For example, if a retail inspection is conducted but wholesale violations are also documented, the necessary wholesale orders must be issued in an associated GMP inspection report.

Table 1: Inspection Report Types

USAFS Inspection Type	**When to Use for Inspection**
General Regulatory Inspection	For Out of Business (OOB), licensing, investigations, complaints, consultations, and sampling inspections. If orders are issued during any of these inspections, use the specific inspection type.
Retail Food	For retail food handler inspections
GMP Inspection Report	For inspections of wholesale food handlers, brokers, and manufacturer processors that are currently subject to 21 CFR 110. Used in addition to specialized reports, resulting in two reports for Seafood HACCP, Juice HACCP, acidified foods, etc.
117 GMP Inspection Report	For inspections of wholesale food handlers, brokers, and manufacturer processors that are currently subject to 21 CFR 117 Part A, B & F. Used in addition to specialized reports, resulting in two reports for Seafood HACCP, Juice HACCP, acidified foods, etc.
Prepackaged Retail Food Establishment	For retail establishments that sell prepackaged food only.
Retail Food Establishment Vending	For food vending machine inspections.
Acidified Foods Inspection Report	For manufacturers producing acidified foods regulated by 21 CFR 108 & 114.
LACF and Aseptic Inspection Report	For manufacturers producing Aseptic foods.
Retail Food HACCP System Routine Audit	For approved HACCP plans, complete for every routine inspection.
Retail Food HACCP System Audit	For when a plan has been significantly changed since approval (formal review), has been in use more than 3 years since approval, and has not been fully reviewed (by inspector using 4-page form) within 3 years
Water Bottler Inspection Report	For manufacturers of bottled water.
Juice HACCP Inspection Report	For manufacturers of products regulated by 21 CFR 120.
LACF Inspection Report	For manufacturers producing LACF foods regulated by 21 CFR 108 & 113.
Seafood HACCP Inspection Report	For manufacturers and wholesalers producing or selling foods that are regulated under 21 CFR 123.
Preventive Controls (PC) Inspection Report	For manufacturers and wholesalers producing or selling foods that are regulated under 21 CFR 117 Part C.

6.4. Update Facility and Inspection Maintenance Pages

6.4.1. Complete, add, or update the required information using the applicable USAFS Guidance/Work Instructions. This information includes:

Facility Account Maintenance Page	**Inspection Maintenance Page**
Name	Inspection Reason
Contact Information	License Information
Physical Address	Facility Reference Data
Mailing Address	Validation Questions
Facility Classification/Facility Reference Data	Regulatory Line Items
FSMA PC Compliance Data (applicable to Mfg/Processor and WFH firms only)	Prior Violations
Water Supply	Regulatory Code Comments
Sewage Disposal	Prior Violations
Refuse	Inspection Published Comments
Hours of Operation	Food Temperatures
	Food Disposal
	Administration
	Visit Information

6.5. Write Professionally

6.5.1. Document violations and observations clearly, legibly, and concisely.

6.5.2. Use proper grammar, proper use of words, proper spelling, and complete sentences.

6.5.3. Always write in third person tense, never use first or second person tense.

6.5.4. Complete the inspection report completely and accurately.

6.5.5. Use acronyms only if they are spelled out on the inspection report and explained. For example: Person In Charge (PIC), Most Responsible Person (MRP), and Corrected on Site (COS).

6.6. Document Orders Issued at the Firm

6.6.1. Issue orders for regulation or code violations per the current Minnesota Food Code or other applicable food regulations. Orders are a statement of specific regulation or rule in the form of an action.

6.6.2. Based on the identified regulation in violation, select the appropriate order from the standard orders in USAFS.

6.6.3. Modify the standard order or create a new order if the standard order does not fit the situation or is missing. Contact your Supervisor (or the Program Manager if Supervisor is unavailable) for approval prior to creating a new order. Contact the Electronic Systems Coordinator if an order is missing in USAFS.

6.6.4. Document repeat violations observed during the inspection. Issue the same order as was initially issued to the firm, unless the order was cited incorrectly on the initial inspection report. Do not issue a new compliance date.

6.6.4.1. Write "Repeat order" in the observation statement and the date the order was originally issued. If the order was issued more than once, include all report dates when the order was issued.

Example:

Label all packaged foods with a complete list of ingredients, including a breakdown of any multi-ingredient items in descending order of predominance. (Write the observation statement). Repeat order. Previous order issued on 4-4-16 and 5-15-16 with an initial compliance date of 5-4-16.

6.6.4.2. Re-issue the original compliance date from the initial inspection report when the order was written in USAFS.

6.6.5. For GMP inspections only, verify that USAFS default critical violations continue to meet the definition of critical violation based on the specific observation noted at the firm.

6.7. Document Observations

6.7.1. Document observations for each order cited. The observation is specifically how the firm was observed to be out of compliance with the identified regulation.

6.7.2. Write observations that are specific and fact-based. They must portray how the violation and observation could result in unsafe and unsanitary conditions in regards to food receipt, handling, processing/preparation, storing and/or shipping.

6.7.3. Do not base observations on opinion or inference. In all cases tie the observation directly to potential or actual contamination of a specific food product observed. Examples of this include the following:

6.7.3.1. Condensate was observed dripping onto a processing line where unprotected cheese balls were in production.

6.7.3.2. A gap under a warehouse door large enough to allow pest entry was observed approximately 10 feet from pallets of open bags of bulk flour.

6.7.4. In the observation, provide the following information: who (including pertinent position descriptor but not employee name), what, where, when, and how in relation to products or processes being inspected. For example:

6.7.4.1. A sandwich processing line employee was observed handling ready to eat sandwiches during production without gloves.

6.7.4.2. The deli manager stated they wash, rinse and sanitize their utensils and spatulas once per shift, which is over the 4 hour limit. The utensils were observed on a counter in the deli which was noted at 68 °F ambient air temperature

6.7.5. Use language and descriptions that are familiar to the firm. If the inspector is unfamiliar with an area, room, piece of equipment, process, etc., ask the firm how they would refer to a particular piece of equipment or area. Use the description given on the inspection report.

6.7.6. Write all observations in a manner that clearly distinguishes one from another if more than one observation was noted for an order.

6.7.7. Document any corrective action(s) taken by the firm during the inspection after the observation for each order issued. Documentation may include the firm's immediate corrections in addition to the firm's long term correction plan. Examples include:

Provide appropriate handwash sinks as necessary for convenient use by food employees. (The firm assembles, heats, packages, and hot holds pizzas in the convenience store area of the large grocery store, but no handsink is available in this area. Food employees are therefore not able to wash hands prior to handling food products and utensils, which could lead to contamination of the food products. The Store Manager stated the firm will utilize the deli department which has adequate facilities to assemble, cook, and package the pizzas until the firm installs the proper handwashing facilities in the convenience store.)

Maintain all cold potentially hazardous food at 41° F or below, under mechanical refrigeration. (Raw salmon and tilapia in the meat department's retail display cooler were noted with internal temperatures of up to 47° F. These items had been placed in the display cooler 2 hours prior to the temperature being taken. The manager immediately contacted a refrigeration technician who completed the repairs prior to the exit interview. Additionally, the meat department manager relocated the affected product to the walk in cooler to bring the temperature down to 41° F, which was verified by the inspector approximately half an hour later.)

6.7.8. Document any intended corrective actions discussed or stated by the MRP/PIC including details on the timeframe and extent of action.

6.7.9. Indicate that Voluntary Destruction of products has occurred when a firm chooses to discard food, equipment, or utensil that is in violation of a statute, rule or other law and may be adulterated in lieu of embargo, seizure, or condemnation. The voluntary destruction statement and order observations must reference products involved and must tie together products listed in the Food Disposal section. Include the method of destruction (such as placed in firm's trash compactor).

Examples of voluntary destruction include:

6.7.9.1. An owner/agent chooses not to further evaluate products involved in a truck accident when there was physical damage, exposure to contamination or temperature abuse.

6.7.9.2. Violations of MN Rule 4626 regarding date marking of food (no dates or beyond 7 days), hot or cold holding or cooling violations (where food is at improper temperatures) and there is no remedy for bringing the food back into a safe condition.

6.7.9.3. Accidental adulteration of food where the firm recognizes the contamination.

6.7.10. Refer to *FOOD.30.27 – Field Compliance Actions SOP* for required documentation related to field compliance actions taken during the inspection.

6.8. Issue a Compliance Date

6.8.1. Issue compliance dates for every order issued that are reasonable to mitigate the public health hazard in a timely fashion. Document in the observation statement a short-term corrective action taken or planned by the firm to mitigate orders that have high public health severity or other high risk behaviors as defined below.

6.8.2. Use the following table as a guide for Compliance Dates:

Order	**Compliance Date**
High Public Health Severity (Bare hand contact with ready to eat food, not washing and sanitizing food contact surfaces)	Correct on Site (whenever possible). An actual date must be written in addition to COS. Issue compliance date as the date the violation was observed for multi-day inspections.
Other High Risk Behaviors (Provide an approved sanitizer)	1-3 days to comply
Low Public Health Severity (Non critical or lower risk violations such as stained or scored cutting boards, spots that allow pest entry)	2-14 days to comply
Non critical or lower risk (facility and equipment repair violations such as refinishing worn floors, or repairing a frayed conveyor belt.)	Up to 6 months to comply

6.8.3. Document corrective actions taken by the firm in the observation statement for any order that is marked as COS or corrected on site. All observations related to the order must be corrected during the inspection to be documented as COS. For multi-day inspections, the violation must be corrected on the day it was observed.

6.8.4. Time frames can be extended in consultation with supervisor. This may require the firm to submit additional documentation as evidence such as a work order, procedure, or purchase order. The requirement for the submission should be included in the inspection report.

6.9. Document Inspection Report Comments

6.9.1. Write the following required comments on all inspection reports:

6.9.1.1. A Notice of Inspection was issued on (date) to (person issued to), (title).

6.9.1.2. The firm is a (size) (firm type) that conducts the following activities: (activities). During the inspection, the following products were being produced: (products) and the firm was conducting the following processes: (processes).

6.9.2. When applicable, write additional comments covering the following areas:

6.9.2.1. A description of complaint follow up (See *FOOD.30.15 – Public Complaint SOP*)

6.9.2.2. If the inspection is being conducted as a follow up inspection OR reinspection; include the dates of previous inspections.

6.9.2.3. A description of the samples collected (See applicable USAFS Sample Documentation work instruction)

6.9.2.4. If the inspection was conducted under contract with the US Food and Drug Administration (FDA). (See current version of *FOOD.30.19 – FDA Contract Inspection SOP* for all required comments on FDA inspections).

6.9.2.5. If the firm is a manufacturing or repackaging for wholesale distribution, document the lot coding system used and include a brief description. If no lot coding system is in use, write a comment to that effect. For example:

a. This firm uses Julian dates with a 2 digit year for lot coding.

b. This firm does not use any lot coding for finished products.

c. This firm applies a best buy date combined with a four digit code. The best buy date is two years from production, and the four digit code represents the shift and packaging line. Best by 1/30/2017 0114.

6.9.3. Document applicable actions, assessments or discussions that occurred during the inspection to assess the overall food handling system in the facility. This may include but is not limited to product sourcing, recall capability, control point monitoring, traceability, sanitation practices, employee training and oversight, thermometer accuracy checks, etc. Additional comments must be are clear and descriptive. For example: "Reviewed pest control system in place", "Sanitation procedures and conditions were reviewed", etc.

6.9.3.1. Do not include any specific supplier or company names unless they are relevant to the inspection.

6.9.3.2. Avoid making generalized statements that conditions observed within the firm were "satisfactory", "acceptable", or "proper" in the Comments Section. For example, do not comment "general sanitation is acceptable".

6.9.3.3. Document a thermometer verification check of the inspector's thermometer during the inspection as needed according to *FOOD.30.09 – Temperature Measuring Device Use and Accuracy SOP*.

6.9.4. Document names and dates of any records that were reviewed during the inspection. Examples of records include: pest control, sanitation monitoring, firm policies and procedures, results of mock recall, training, temp monitoring logs, cooling logs, meat grinding logs, HACCP plans (voluntary or mandatory), etc.

6.9.5. Document any actions that have been taken by the firm since the previous inspection to address orders issued. Include descriptions of how orders are now in compliance, specific machinery that is fixed, facility maintenance or repairs that are complete, or include a statement that no orders were issued in the previous report.

6.9.6. Document that additional inspections may be conducted if deemed necessary based on inspection findings. Do not use the words follow up or reinspection. Refer to *FOOD.30.02 – Reinspection and Follow-Up Inspection SOP* for further guidance. For example:

6.9.6.1. An additional inspection may be conducted to assess compliance with orders issued.

6.9.7. Record any comments specifically required by other applicable procedures, work instructions or inspection assignment details. For example:

6.9.7.1. Labels collected for review, a description of sample locations, details of a complaint follow up, etc.

6.9.7.2. Document any other information pertinent to the inspection. This includes:

6.9.7.2.1. Statements made by the MRP/PIC on future capital improvements or scheduled training,

6.9.7.2.2. Future product changes, etc.

6.9.8. Document any supplemental materials related to the inspection according to the applicable guidance or work instruction. Supplemental materials are collected or generated to support findings recorded in the inspection report. The following are examples of supplemental materials:

6.9.8.1. Photos taken during the inspection

6.9.8.2. Product Embargo

6.9.8.3. Risk Control Plan

6.9.8.4. Copies of records

6.9.8.5. Flow charts

6.9.8.6. HACCP plans

6.9.8.7. Plan review materials.

6.9.8.8. Record all educational material or literature provided to the firm.

6.10. Report Review and Delivery

6.10.1. Review the report with an employee of the firm, preferably the MRP/PIC, at the conclusion of the inspection. The employee receiving the report does not need to be the MRP/PIC referenced on the notice of inspection.

6.10.2. Review of the report can occur from a hard copy on paper or using a print screen on the computer. When using the USAFS inspection system, submit the inspection report in front of the MRP or firm representative.

6.10.2.1. Use additional means such as demonstrations, diagrams, or timing for interpreter availability (within reason) as necessary to aid in the communication of orders issued.

6.10.3. For multi-day inspections, a report can be left at the end of each inspection day if there are orders to be issued for observations significant to public health that need to be addressed immediately. However, a summary report at the end of one inspection n day does not constitute a close-out of the inspection. This information must be communicated to the firm and documented in the report accordingly. Otherwise, one inspection report at the conclusion of a multi-day inspection is sufficient.

6.10.4. Identify all inspectors present during the inspection. If an inspector who participated in the inspection is not present at the exit interview, document the name(s) of the other inspectors

in the published comments of the report including the dates they participated in the inspection.

6.10.5. Instruct the MRP or person the report was reviewed with to sign and date the inspection report. If the firm's policies do not allow for employees to sign inspection reports, document that this is the case.

6.10.6. Provide a copy of complete and signed inspection report at the conclusion of the review, or as soon as circumstances allow. Refer to the applicable USAFS guidance document for instructions for providing the completed inspection report to the firm if there is a printer failure when at the facility.

6.10.7. Provide contact information and be available if any questions arise regarding the inspection report.

6.10.8. Sync USAFS as required in *FOOD.WI.30.32 – USAFS Syncing WI* to ensure timely report submittal.

6.11. FDA Contract Inspections

6.11.1. Following the current version of *FOOD.30.19 - FDA Contract Inspection SOP*, complete all applicable sections of the FDA Template in addition to the inspection report for FDA Contract Inspections.

7. RELATED DOCUMENTS (includes References, Attachments)

FOOD.30.19 – FDA Contract Inspection SOP

FOOD.WI.30.12 – Paper Inspection Report WI

FOOD.30.27 – Field Compliance Actions SOP

FOOD.30.02 – Reinspection and Follow-Up SOP

Relevant Minnesota Statutes and Regulations including Chapters 17, 28, 28A, 29, 30, 31, 31A, 32 and 34.

FOOD.WI.30.32 – USAFS Syncing WI

USAFS Guidance/Work Instructions

8. EQUIPMENT/MATERIALS NEEDED

USAFS electronic inspection system

9. SAFETY

N/A

10. CIRCULATION

This policy will be circulated to the following individuals: Food Program Managers, Food Program Supervisors, Compliance Supervisor, Compliance Officers, Inspectors, and the Training and Outreach 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
2	**R**	Revised document based on new electronic inspection system (USAFS) and clarifications required by the audit and inspection protocol. This document is a combined procedure using FOOD.30.04 – Notice of Inspection SOP and FOOD.30.05 – Inspection Report Writing SOP into a single document.
3	R	Updated division name from DFID to FFSD; 117 GMP Inspection Report and PC Inspection Report added to table in 6.3; FSMA PC Compliance data added as required information in table in section 6.4; added documentation of repeat violations to 6.6; added further guidance regarding documenting corrective actions taken by the firm in section 6.7; updated all section headers to be action-oriented.

DocuSigned by: 51BD2563BF5444D...	12/29/2016
Approved By:	**Date**
Approved By:	**Date**

I = Initial document; R = Revised document