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1. **PURPOSE**

The purpose of this procedure is to define the coordination, completion, submission, and review of basic, and specialized/advanced joint training inspections (JTI) and evaluations of newly hired or assigned Food Inspectors, further referred to as Trainee, who will conduct Manufactured Food Inspections.

1. **SCOPE**

This procedure applies to basic and specialized/advanced (including preventive controls) joint training inspections and evaluations for the Manufactured Food Program (MFP) Food and Feed Safety Division (FFSD) of the Minnesota Department of Agriculture (MDA).

1. **BACKGROUND**

Standard 2 of the Manufactured Food Regulatory Program Standards (MFRPS) defines the minimum number of basic Joint Inspections and Field Evaluations needed to meet the basic training requirements. The Manufactured Food Program within FFSD requires inspectors to complete at least 10 Joint Field Training Inspections of High and Medium Risk Facilities and pass two (2) Field Evaluations.

Standard 2 of the MFRPS also requires that each inspector who will conduct specialized/advanced inspections (Seafood HACCP, Juice HACCP, Acidified Food (AF), Low Acid Canned Food (LACF) or Preventive Controls), must complete two (2) Joint Inspections and pass one (1) Evaluation prior to conducting independent specialized/advanced inspections. A second Field Evaluation or Field Inspection Audit must be successfully completed within one year of being released to conduct independent specialized food inspections. Seafood HACCP requires two (2) joint inspections prior to attending FD249 Seafood HACCP per the current FD249 Seafood HACCP prerequisite requirements.

1. **RESPONSIBILITY**

**Manufactured Food Program Manager:** The Manufactured Food Program Manager will sign off on the Training Affidavit and Training Approval forms and assist in determining the list of qualified trainers for joint inspections and evaluations.

**Manufactured Food Inspection Trainee:** The Manufactured Food Inspection Trainee will complete joint training inspections (as assigned); communicate with the Trainer, MFG Training Coordinator, and Supervisor; update SharePoint list information as needed; complete trainer feedback forms when needed; and initiate a Training Affidavit when required.

**Manufactured Food Inspection Trainer:** The Manufactured Food Inspection Trainer will respond to emails regarding joint training inspections; provide/update information about locations for joint training inspections as requested; conduct assigned joint inspections; complete Trainee field assessments and evaluation forms; and provide information on Training Affidavits as needed.

**Manufactured Food Supervisor:** The Manufactured Food Supervisor will assist in determining the list of qualified trainers, verify that staff members have completed joint inspections as required; review and sign Training Affidavits as required; review inspection reports; review field assessments and evaluation forms and provide timely feedback to Trainees and Trainers; and initiate and sign Training Approval forms.

**MFG Training Coordinator (MFG TC)** The MFG TC) will schedule joint inspections, retrieve inspection reports from USA Food Safety (USAFS), review field assessments and evaluations, track joint inspections in SharePoint, and follow procedures listed in this SOP and associated documents.

1. **DEFINITIONS**

**Assessment:** An appraisal of the trainee’s level of competency based on the training received as evaluated and documented by the trainer. The assessment will measure the trainee’s ability to: prepare for an inspection, participate in or conduct an inspection based on current level of training, follow procedures for the inspection type, and communicate during an inspection.

**Evaluation:** Inspection in which the ability of an inspector is appraised to determine if they are competent to complete independent inspections. The evaluation will measure the inspector’s ability to: prepare for an inspection, conduct an inspection, follow procedures for the inspection type, communicate during an inspection, and assess specialized processes (as applicable).

**Joint Field Training Inspection (JTI):** Inspection conducted jointly by FDA or Qualified Field Inspection Trainer for the purposes of training or enforcement. Used to provide training during an inspection of a firm and may be trainer or trainee led. An assessment form will be filled out by the Trainer after every JTI.

**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 an inspection either contract or state.

**Manufactured Food Inspection Trainee (Trainee):** A ManufacturedFood Inspection Trainee is a food inspector new or newly assigned to manufactured food inspections, or assigned Specialized/Advanced training after completion of basic training**.**

**Manufactured Food Training Start Date:** The date a food inspector is assigned to the Manufactured Food Program and begins manufactured food training.

**Qualified Field Inspection Trainer (Basic Trainer):** A Qualified Field Inspection Trainer is a food inspector or supervisor who has completed basic training, or received a waiver from training, and has field experience and communication skills necessary to train or supervisor other inspectors. The Basic Trainer is designated by the Manufactured Food Program to conduct training and/or evaluation inspections.

**Qualified Specialized/Advanced Field Inspection Trainer:** A Specialized/Advanced Field Inspection Trainer is a food inspector who has completed basic training or received a waiver from training, completed advanced classroom training (Seafood, Juice, Acidified Food, Low Acid Canned Food and Preventive Controls), and has field experience and communication skills necessary to train other inspectors or is a Consumer Safety Officer from the Food & Drug Administration (FDA). The Specialized/Advanced Inspection Trainer is designated by the Manufactured Food Program Manager to conduct advanced joint training inspections and/or evaluation inspections.

**Shadow Inspection:** Inspection conducted jointly by qualified field inspection trainer (basic, specialized/advanced trainer)and a manufactured food inspection trainee (trainee)for the purposes of exposure to general inspection procedures or Manufactured Food Program regulations. The inspections are trainer led.

1. **PROCEDURES**
   1. **Field Training Scheduling**

MFG TC

* + 1. Coordinate and assign shadow, basic, and specialized/advanced joint inspections and evaluations for manufactured food inspection trainees according to parameters established in Tables 1 and 2 below using the applicable SharePoint scheduling lists.
       1. Consult with Supervisors to determine trainers and firms to be used for Joint Inspections and evaluations to ensure a variety of products and processes are covered.
          1. Considerations for trainers:

Basic: Base the selection of the trainer on the list of designated trainers for each level of inspection. Refer to the definition of qualified field inspection trainer.

Specialized: Base this selection on advanced training completed and MFP Manager or supervisor recommendation. Refer to the definition of qualified specialized/advanced field inspection trainer.

Preventive Controls: Base this selection on advanced training completed and MFP Manager or supervisor recommendation. Refer to the definition of qualified specialized/advanced field inspection trainer.

* + - * 1. Considerations for facilities:

Basic: Select a variety of high or medium risk facilities for routine joint training inspections and evaluations. Joint Licensing, Sampling, and Reinspection/Follow-up Inspections may be at low risk facilities. Refer to *FOOD.30.08 – Manufacturer and Distributor Risk Category SOP.*

Preventive Controls: All facilities must be subject to Subpart C of 21 CFR 117 Subpart C, require a Food Safety Plan, and be high or medium risk.

Specialized/Advanced: All facilities must be high risk for Seafood HACCP, Juice HACCP, Low Acid Canned Food or Acidified Food.

* + - 1. evaluations will be conducted at firms that are representative of the firms that will be inspected by the inspector once training is complete. At least one evaluation will be conducted by the Trainee’s Supervisor.

**Table 1: Basic Field Training**

|  |  |  |  |
| --- | --- | --- | --- |
| **Type of Inspection** | **Minimum Number** | **Successful Evaluations** | **Timeframe** |
| Shadow Inspections | TBD | N/A | Prior to beginning joint training inspections or otherwise during training as applicable |
| Routine Manufacturing (High and Medium Risk firms) | 10 | 2 | Prior to conducting independent MFP inspections |
| Licensing | 1 | N/A | Prior to conducting MFP licensing inspections |
| Sampling | 1 | N/A | Prior to independent sample collection. |

**Table 2: Specialized/Advanced Food Inspection Field Training**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Type of Inspection** | **Minimum Number of Joint Inspections** | **Minimum Number of JTIs prior to Evaluation (Trainee lead)** | **Minimum Number of Successful Evaluations Prior to Specialized/Advanced Independent Inspections** | **Minimum Number of Successful Evaluations or Field Inspection Audits post Specialized/Advanced Independent Inspections** |
| Seafood HACCP | 2 (High Risk) - prior to FD249 Seafood HACCP | 1 – after completion of FD249 Seafood HACCP | 1- (High Risk) after completion of FD249 Seafood HACCP | 1 – (High Risk) within one year of being released to conduct Seafood HACCP inspections |
| Juice HACCP | 1 – prior to FD219 Juice HACCP | 1 – after completion of FD219 Juice HACCP | 1– after completion of FD219 Juice HACCP | 1 – within one year of being released to conduct Juice HACCP inspections |
| Acidified Food | 1 – prior to FD202 Acidified Food | 1 – after completion of FD202 Acidified Food | 1 – after completion of FD202 Acidified Food | 1 – within one year of being released to conduct Acidified Food inspections |
| Low Acid Canned Food | 2 – prior to FD304 Low Acid Canned Food | 1 – after completion of FD304 Low Acid Canned Food | 1 – after completion of FD304 Low Acid Canned Food | 1 – within one year of being released to conduct Low Acid Canned Food inspections |
| Preventive Controls for Human Food | If available, not required | 2 – after completion of FD 254 Preventive Controls for Human Food for Regulators (Trainee leads only on second JTI) | 1 – after completion of FD 254 Preventive Controls for Human Food for Regulators | 1 – within one year of being released to conduct Preventive Controls inspections |

* + 1. Complete the following information in the basic manufacturing, preventive controls, or specialized joint training inspection SharePoint form. Update status to ‘Inspection Approved by TC – Pending Inspection’.
       1. **Inspection Number** – Pick the training number, or select the type of inspection such as reinspection or licensing based on previously completed or scheduled inspection(s).
       2. **JTI (Joint Training Inspection) Type (Specialized/Advanced Only):** enter the Joint Inspection Type: Seafood, Juice, Acidified, or LACF.
       3. **Inspection Type** –
          1. **For Manufactured Food Joint Training Inspections (Basic)**: Check all relevant types that apply to the firm.
          2. **For Specialized/Advanced and Preventive Controls:** Select Joint Inspection or Evaluation
       4. **Trainee Name**
       5. **Trainee’s Supervisor Name**
       6. **Trainer’s Name**
       7. **Trainer’s Supervisor**
       8. **Establishment Name**
       9. **City** - if preselected. Otherwise, this section is completed by the trainer based on type of firm and territory**.**
       10. **Risk Category**
       11. **Firm Size –** To be filled in by the trainer.
       12. **Lead** – Identify if the trainee is the inspection lead based on Appendix A Manufacturing Joint Training Inspection Expectations and Responsibilities.
       13. **# of Days –** To be filled in by the trainer.
       14. **Date of Inspection –** Base start date selection on trainer’s and trainee’s schedules including training, workload, vacations, and supervisor discretion.
       15. **Facility ID -** USAFS Facility ID
       16. **Inspection ID** - USAFS Inspection ID (added by trainer after the inspection)
       17. **Comments -** Provide any additional information about the inspection such as other dates available, additional requirements, or options to change the location.

Trainer

* + 1. Work with MFG TC to schedule joint training inspections and evaluations work assignments.
    2. Do not select facilities assigned for inspection under the FDA Food Contract until the trainee has received notification that their FDA Commission has been received.
    3. Add or update inspection type, name, city, firm size, date, and time to complete inspection if needed. Provide comments regarding any changes in the SharePoint form.
    4. Set up a meeting location and time as soon as possible prior to the inspection to allow trainee time to schedule travel and lodging.

Trainee

* + 1. Notify MFG TC and Supervisor if there are any issues with completing the assigned inspection.
    2. Contact the assigned trainer prior to the scheduled inspection via email regarding meeting time and location.
  1. **Conduct Joint Training Inspections/Evaluations**

Trainee and Trainer

* + 1. Review and use the following applicable field assessment forms, evaluation forms, and instructions listed in Table 3 and Table 4:

**Table 3: Forms and Instructions for Trainers**

|  |  |
| --- | --- |
| **Type** | **Forms and Instructions** |
| Basic Manufacturing Joint Inspection 1 & 2 | * Appendix A – Manufacturing Joint Training Inspection Expectations and Responsibilities |
| Basic Manufacturing Joint Inspection 3 & 4 | * Manufactured Food Inspector Field Assessment – Short Form * Food Inspector Field Assessment/Evaluation - Food Manufacturing Inspections Instructions * Appendix A – Manufacturing Joint Training Inspection Expectations and Responsibilities |
| Basic Manufactured Joint Inspection 5-10 | * Manufactured Food Inspector Field Assessment/Evaluation Form * Food Inspector Field Assessment/Evaluation – Food Manufacturing Inspections Instructions * Appendix A – Manufacturing Joint Training Inspection Expectations and Responsibilities |
| Basic Manufacturing Inspection Evaluation | * Manufactured Food Inspector Field Assessment/Evaluation Form * Food Inspector Field Assessment/Evaluation - Food Manufacturing Inspections Instructions |
| Seafood and Juice Evaluation | * Food Inspector Field Evaluation - Seafood and Juice HACCP Manufacturing Inspections |
| LACF Evaluation | * Food Inspector Field Evaluation – Low Acid Canned Foods Manufacturing Inspections |
| Acidified Food Evaluation | * Food Inspector Field Evaluation – Acidified Foods Manufacturing Inspections |
| Preventive Controls Evaluation | * Food Inspector Field Evaluation –Preventive Controls Inspections |

**Table 4: Forms and Instructions for Trainees**

|  |  |
| --- | --- |
| **Type** | **Evaluation Form and Instructions** |
| Basic Manufacturing Joint Inspection | * Manufacturing Field Trainer Feedback Form (optional) * Appendix A – Manufacturing Joint Training Inspection Expectations and Responsibilities |

* + 1. Complete the joint training inspection at the assigned facility on the date(s) scheduled. Both trainer and trainee need to be present for the entire inspection, report writing and exit interview. If there is a scheduling issue that may not allow the trainee to be present for a portion of the inspection, contact the Supervisor to discuss options.

Trainer

* + 1. After the inspection is completed, enter the Inspection ID number(s), review the inspection information in SharePoint (as referenced Section 6.1.2.), and update if required. Update status to ‘Pending Review of Report by TC’.
    2. Complete the applicable Manufactured Food Inspector Field Assessment/Evaluation Form for JTIs and email a PDF to the MFG TC within four (4) business days of the close of the inspection. Refer to Table 3 for further information based on the type of inspection. Name the document using the following format: Date\_Firm Name\_City\_Trainee Name.
    3. Complete the Manufactured Food Inspector Field Assessment/Evaluation Form for Evaluations and email a PDF to the trainee’s Supervisor within four (4) business days of the close of the inspection. Refer to Table 3 for further information based on the type of inspection. Name the document using the following format: Date\_Firm Name\_City\_Trainee Name.

Trainee

* + 1. Optional: Complete Manufacturing Field Trainer Feedback Form and email a PDF of the evaluation to the MFG TC within four (4) business days for applicable joint inspections. Refer to Table 4. Verbal feedback to the trainee supervisor would also be acceptable. Examples of situations that may result in the completion of a form include:
       1. the trainer communicating well during the inspection, providing support and feedback in a constructive manner, and reinforcing training points throughout the inspection; or
       2. the trainer did not communicate well during the inspection, provided incomplete or unclear answers to questions, or did not use division procedures.

MFG TC

* + 1. Review trainee assessments and evaluations and if applicable, Trainer feedback forms, within five (5) business days after receiving the document via email from the Trainer or trainee.
    2. Verify all questions were answered and comments were completed (as required). If any information is missing or the incorrect form was used, return to the sender and request an update.
    3. Upload all complete and correct assessments and evaluations to the correct folder on the SharePoint Training site. SharePoint will notify the supervisor that the assessment and/or evaluation has been added.

Supervisors

* + 1. Within ten (10) days of notification from SharePoint, review all trainee and trainer assessments and evaluations. Identify strengths and opportunities for improvement.
    2. Provide feedback to trainees, based on assessments and evaluations on a regular basis throughout their training period regarding the evaluations. This can be done via email, phone, or meeting, depending on evaluation results.
    3. Provide feedback to trainers, based on the Manufactured Field Trainer Feedback Forms, as needed through email, phone, or meetings. Trainer feedback may also be given at annual reviews.
  1. **Inspection Review and Approval**

MFG TC

* + 1. Within five (5) business days of receiving the inspection completion notification from SharePoint, review inspection information including date, location, and inspection report. Update any inspection information in SharePoint as required.
    2. Contact the trainee’s supervisor if there are any concerns about the inspection. Contact the trainee to initiate a training affidavit per *FOOD.WI.20.01 – Training Affidavit WI* if they were present at the inspection, but their name does not appear on the report*.*
    3. Approve or deny the joint inspection based on review of the information. If approved, the inspection will be sent to the Inspector’s Supervisor for review and final approval. If denied, the inspection report will not count toward the total number of training inspections required. Contact the supervisor prior to denial to discuss and determine that the missing information would prevent the inspection from being counted in the total number of training inspections. Choose the appropriate status ‘Report approved by TC – Pending Review by Supervisor’ or ‘Report rejected by TC – New inspection required’.

Supervisor

* + 1. Within ten (10) business days of receiving the completion notification from the MFG TC, review inspection information and inspection report (when written by the trainee).
    2. Provide specific feedback to the trainee regarding the report such as well written orders or missing information. The more feedback given to the inspector, the more they will learn from the training inspections. Refer to *FOOD.30.05 – Inspection Report – Manufactured Food SOP*.
    3. Approve or deny the joint inspection based on review of the information. If approved, the inspection will be counted toward the total number of training inspections required. If denied, the inspection report will not count toward the total number of training inspections required. Choose the appropriate status ‘Report approved by Supervisor – Complete’ or ‘Report rejected by Supervisor – New Inspection Required’.

## **Addition of Joint Training Inspections and Approval to Conduct Independent Inspections**

Supervisor

* + 1. Basic Training assessments:
       1. If a trainee is receiving low marks on field assessments and trainers and/or supervisors are concerned with the performance in the field, assess if the trainee will require additional JTIs in consultation with the trainee, MFG TC, Supervisor, and the Manufactured Food Program Manager.
       2. If a trainee requires additional JTIs to successfully perform independent inspections, coordinate additional training with the MFG TC. Additional JTIs may be needed if the trainee needs more experience with inspection procedures, regulations, communication with the firm, etc.
    2. Basic Training Evaluations:
       1. Review evaluations and make a determination whether the trainee is prepared to conduct independent inspections based on completion of minimum field training requirements.
       2. Assign additional joint training inspections (as needed) and evaluation(s) if one or more of the initial evaluations was unsuccessful. Refer to requirements found in *FOOD.30.01 – Inspection Protocol – Manufactured Foods SOP* and *FOOD.30.05 – Inspection Report – Manufactured Food SOP* and other applicable SOPs to determine if the evaluation was unsuccessful. The supervisor will make this determination based on the discussion with the trainer(s), review of the evaluation, inspection report, and supporting documentation.
          1. Mark ‘Yes’ or ‘No’ under the Pass determination property on the SharePoint item where the evaluation form is located on SharePoint.
          2. Contact the MFG TC when an evaluation has been deemed unsuccessful to discuss additional JTIs or evaluations.
          3. Create a Training Corrective Action Form including additional JTIs and training required. Refer to *FOOD.WI.20.02 – Training Corrective Actions WI* for more information on completing a Training Corrective Action Form.
       3. Complete an approval form for the trainee when the joint training inspections are complete and the evaluations are acceptable.
          1. Refer to *Training Approval Form – Template* on SharePoint.
          2. Add all inspection types listed on Table 1 that have been completed or update the approval form as needed. Sign and date the form and update the status to notify the MFG TC.
          3. Verify all required classroom courses, online training, and required JTIs have been completed based on discussions with the MFG TC and the Training & Standards Administrator.
    3. Specialized/Advanced Inspections:
       1. Review the evaluation and make a determination whether the trainee is prepared to conduct independent inspections. Assign additional joint inspections (as needed) and an evaluation when the initial evaluation was unsuccessful.
       2. Refer to requirements found in *FOOD.30.01 – Inspection Protocol – Manufactured Foods SOP* and *FOOD.30.05 – Inspection Report-Manufactured Food SOP* and other applicable SOPs to determine if the evaluation was unsuccessful. The supervisor will make this determination based on the overall review of the evaluation, inspection report, and supporting documentation.
          1. Mark ‘Yes’ or ‘No’ under the Pass determination property on the SharePoint item where the Evaluation form is located on SharePoint.
          2. Contact the MFG TC when an evaluation has been deemed unsuccessful.
          3. Create a Training Corrective Action Form including additional JTIs and training required. Refer to *FOOD.WI.20.02 – Training Corrective Actions WI* for more information on completing a Training Corrective Action Form.
       3. Complete an approval form for the trainee when the joint training inspections are complete and the evaluations are acceptable.
          1. Refer to *Training Approval Form – Template* on SharePoint.
          2. Add all inspection types listed on Table 2 that have been completed or update as needed. Sign and date the form and update status to notify the MFG TC.
          3. Verify all required classroom courses, any online training, and required JTIs have been completed based on discussions with the MFG TC and the Training & Standards Administrator.

MFG TC

* + 1. Review the training approval form when notification is received from SharePoint.
       1. Verify all records are complete and all required JTIs have been completed and records are provided. Work with the Training & Standards Administrator to ensure that online and classroom trainings have been completed. Refer to *FOOD.20.07 – Training Assignments and Records-Manufactured Foods SOP* for more information regarding classroom and online training completions.
       2. If changes are required, reroute the approval form to the supervisor for updates.
    2. When complete, sign and date the form and update the status to notify the Training & Standards Administrator.

TSA

* + 1. Review the training approval form when notification is received from SharePoint. Verify that online and classroom trainings have been completed. Sign and date the form and update the status to notify the trainee.

Trainee

* + 1. Review the training approval form when notification is received from SharePoint. Sign and date the form and update the status to notify the Manufactured Food Program Manager.

Manufactured Food Program Manager

* + 1. Review the training approval form when notification is received from SharePoint. Sign and date the form and update the status to notify the Manufactured Food Program Manager.

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

Appendix A – Manufacturing Joint Training Inspection Expectations and Responsibilities

Food Inspector Field Assessment/Evaluation - Food Manufacturing Inspections Instructions

Food Inspector Field Evaluation – Acidified Foods Manufacturing Inspections

Food Inspector Field Evaluation – Low Acid Canned Foods Manufacturing Inspections

Food Inspector Field Evaluation – Seafood and Juice HACCP Manufacturing Inspections

Food Inspector Field Evaluation – Preventive Controls Inspection

FOOD.30.01 – Inspection Protocol – Manufactured Foods SOP

FOOD.30.05 – Inspection Report SOP

FOOD.40.03 – Field Inspection Audit – Manufactured Food SOP

FOOD.WI.20.01 – Training Affidavit WI

Manufactured Food Inspector Field Assessment/Evaluation Form

Manufactured Food Inspector Field Assessment - Short Form

Manufactured Food Field Assessment Form Instructions

Manufacturing Field Trainer Feedback Form

Training Affidavit (complete in SharePoint)

Training Approval Form (complete in SharePoint)

**8. EQUIPMENT/MATERIALS NEEDED**

SharePoint

**9. SAFETY**

N/A

**10. CIRCULATION**

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