

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

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Title: <b>Retail Risk Factor Study SOP</b>	

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## **1. PURPOSE**

This procedure describes the process to be used by the Food and Feed Safety Division (FFSD) of the Minnesota Department of Agriculture (MDA) in conducting a Risk Factor Study in the Retail Food Inspection Program.

## **2. SCOPE**

This procedure applies to members of the FFSD and MDA delegated agencies whom will have a role in completing the Risk Factor Study including: designing the Study, determining establishments that will be included in the Study, training of staff, conducting data collections, entering and analyzing data, and designing and implementing an intervention strategy designed to address the occurrence of risk factors identified in the study.

## **3. BACKGROUND**

Standard 9 of the Voluntary National Retail Regulatory Program Standards (VNRFRPS) requires that a Risk Factor Study on the occurrence of the five foodborne illness risk factors is conducted and repeated at least once every 60 months to measure trends in the occurrence of the risk factors. The Standard requires that each facility type regulated by the jurisdiction be included in the study (as outlined in the Standard). An analysis of the data collected and a report on the outcomes and conclusions of the study must be written. The standard also requires that an intervention strategy is designed and implemented to address the occurrence of the risk factor(s) identified in the Risk Factor Study. The effectiveness of the intervention strategy is evaluated by a subsequent Risk Factor Study or similar tool.

## **4. RESPONSIBILITY**

**Retail Food Program Manager:** The Retail Food Program Manager will assist in designing the Study; assist in determining the inspection staff to conduct the data collections; assist in analyzing the collected data and composing the final report; and designing and implementing an intervention strategy.

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**Retail Food Program Supervisors:** The Retail Food Program Supervisors will assist in identifying inspection staff to conduct data collections; conduct data collections as assigned; submit completed forms per the procedure; assist in analyzing the collected data and composing the final report; and assist in designing and implementing an intervention strategy.

**Retail Food Program Inspectors:** The Retail Food Program Inspectors will conduct data collections as assigned and submit completed forms per the procedure.

**Food Standards Coordinator:** The Food Standards Coordinator will assist in designing the Study; request random list of establishments; assist in determining facility types in randomly pulled establishments; conduct training for inspection staff; assist in data entry as requested; assist in analyzing the collected data and composing the final report; and designing and implementing an intervention strategy.

**Business and Quality Management (BQM) Unit Supervisor:** The BQM Unit Supervisor will assist in designing the Study; identify BQM staff to assist in identifying facility types in randomly pulled establishments; and assist in analyzing the collected data and composing the final report; and assist in designing and implementing an intervention strategy.

**Training Coordinator (TC):** The TC will provide information about eligibility of inspection staff to conduct data collections.

**Training and Standards Administrator (TSA):** The TSA will assist with determining facility types found in randomly pulled establishments; enter data into the electronic database; and pull reports from the electronic database as requested.

**Electronic Systems Coordinator:** The Electronic Systems Coordinator will pull a list of active retail facilities from the electronic inspection system and randomize the list for the Study.

**Response, Training, and Outreach (RTO) Unit Supervisor:** The RTO Unit Supervisor will assist in analyzing the collected data and composing the final report.

**Study Workgroup:** The Study Workgroup will include at a minimum the Retail Food Program Manager, Food Standards Coordinator, and other support staff necessary to design a Risk Factor Study.

**Outreach Coordinator:** The Outreach Coordinator will assist in the design and implementation of the intervention strategy.

## 5. DEFINITIONS

**Risk Factor Study (Study):** a Risk Factor Study is a research activity to identify the occurrence of food safety practices and employee behaviors that may contribute to foodborne illness. Five risk factors are required to be measured during the study including: poor personal hygiene, food from unsafe sources, inadequate cooking temperatures, improper holding temperatures, and contaminated equipment/protection from contamination.

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**Facility Type(s):** a Facility Type is a specific department within an establishment including deli, meat, seafood, and produce departments.

## **6. PROCEDURES**

### **6.1. Design Risk Factor Study**

#### Study Workgroup

6.1.1. Review the current *Developing a Baseline on the Occurrence of Foodborne Illness Risk Factors Data Collection Instruction Manual* from the FDA, and other applicable resources, to assist in the determination of the following:

- a. Availability of resources to conduct the STUDY;
- b. Data analysis capabilities;
- c. Determining facility types to include in the STUDY;
- d. Determining sample size based on the current establishment inventory

6.1.2. Determine personnel that will lead the STUDY based on resource availability.

### **6.2. Select Facilities to Include in the Study**

#### Electronic Systems Coordinator

6.2.1. Upon request from the Food Standards Coordinator, pull a list of active retail establishments from USA Food Safety (USAFS) to include in the STUDY based on the following:

- a. High- or medium-risk categorization based on the current version of *FOOD.30.16 – Retail Risk Category SOP*;
- b. Do not include establishments with an active enforcement case

6.2.2. Export list of active retail establishment into Microsoft Excel and combine with the list(s) provided by delegated agencies if needed.

6.2.3. Obtain list of active enforcement cases from SharePoint.

6.2.4. Combine list of retail establishment with the list of active enforcement cases in Microsoft Access and remove establishments with active enforcements.

6.2.5. Assign a number to each establishment (ranging from 1 to the last establishment listed).

6.2.6. Use the RANDBETWEEN function in Microsoft Excel and generate random numbers within the range used in section 6.2.5.

6.2.7. Use Microsoft Access to pull out the first 500 establishments based on the random numbers generated in section 6.2.6.

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- 6.2.8. Compile the list of 500 randomly selected establishment and email to the Food Standards Coordinator and Business and Quality Management (BQM) Unit Supervisor.

Food Standards Coordinator

- 6.2.9. Save the list of randomly selected establishments to the VNRFPS SharePoint site.

**6.3. Determine Eligibility of the Facilities for Inclusion in the Study**

Food Standards Coordinator/TSA/BQM Unit

- 6.3.1. Review list of randomly selected facilities and verify the available FACILITY TYPES located within each establishment on a continuous basis. This verification may take place by:
- a. Reviewing the facility details found in USAFS; and/or
  - b. Discussion with the area inspector or an inspector with first-hand knowledge of the establishments' departments; and/or
  - c. Telephone call to the establishment to obtain department information.
- 6.3.2. Document the available FACILITY TYPES for each establishment on the list.
- 6.3.3. Verify that at least 87 of each FACILITY TYPE is documented on the list (some establishments may contain more than one FACILITY TYPE).
- 6.3.4. Contact delegated agencies as needed if an establishment which falls into their jurisdiction is identified for inclusion in the STUDY.

**6.4. Prepare for Data Collection**

Food Standards Coordinator/TC/BQM Unit

- 6.4.1. Consult with the Retail Food Program Manager and Retail Food Supervisors to identify the inspection staff whom will be responsible for conducting the data collections based on the following considerations:
- a. Location of establishments; and
  - b. Lead inspector is currently approved to conduct independent inspections
- 6.4.2. Determine general timeline for completion of the data collections based on the estimated timeframes for completing each data collection form, entering collected data into the online database, analyzing and reviewing the data, and designing and implementing an intervention strategy.

BQM Unit/Retail Food Program

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- 6.4.3. Conduct training with identified Retail Food Program and delegated agency staff on the use and completion of the data collection form prior to conducting data collections.

## **6.5. Conduct Data Collection**

### Retail Food Program Inspectors/Supervisors

- 6.5.1. Issue a Notice of Inspection (NOI) per *FOOD.30.20 – Inspection Protocol-Retail Food* at the beginning of each data collection.
- 6.5.2. Conduct the data collection visit at the assigned establishment. A routine regulatory inspection should be conducted in conjunction with the data collection according to *FOOD.30.20 – Inspection Protocol-Retail Food* if:
- a. Establishment is high-risk and has not been inspected in the last 6 months; or
  - b. Establishment is medium-risk and has not been inspected in the last year
- 6.5.3. Complete a separate *MDA Data Collection Form* for each FACILITY TYPE identified at the establishment.
- 6.5.4. Reference the *FDA Marking Instructions for Data Collection Form – Short Version, Chapter 2 – Employee Health FDA Model Food Code, Equipment Type Options for the Data Collection Form*, and other resources as needed throughout the data collection.
- 6.5.5. Complete a Retail Inspection Report (and other inspection report types if applicable) in USAFS per *FOOD.30.05 – Inspection Report SOP* for routine regulatory inspections. Use the standard comment language related to the data collection visit in the comments section of the report.
- 6.5.6. Complete a General Regulatory Inspection Report per *FOOD.30.05 – Inspection Report SOP* if the data collection is NOT conducted during a routine regulatory inspection. Use the standard comment language related to the data collection visit in the comments section of the report.

## **6.6. Submit Data Collection Forms**

### Retail Food Program Inspectors/Supervisors

- 6.6.1. Upon completion of each *MDA Data Collection Form*, review the form for completion and scan and upload the form to the SharePoint site. The following naming convention should be used to identify each form:
- Name of Establishment\_Date of Collection\_Facility Type

## **6.7. Enter Data into Online Database**

### TSA/BQM Unit

- 6.7.1. Obtain completed *MDA Data Collection Forms* from SharePoint on a continuous basis.

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- 6.7.2. Enter information from each form into the online database.
- 6.7.3. Notify the Food Standards Coordinator, Retail Food Program Manager, and the BQM Unit Supervisor when at least 87 forms have been completed for each FACILITY TYPE.

**6.8. Compile and Analyze Study Results**

BQM Unit/Retail Food Program Manager/RTO Unit Supervisor

- 6.8.1. Compile STUDY data from the online database when all data collection forms have been entered.
- 6.8.2. Analyze the STUDY data using the report tools located in the online database.
- 6.8.3. Identify the risk factor (s) most often found out of compliance during the data collection visits.

**6.9. Design and Implement Intervention Strategy**

BQM Unit/Retail Food Program/Outreach Coordinator

- 6.9.1. Utilize the risk factor occurrence information found in section 6.8.3 to design an intervention strategy to improve the control of the risk factor. Such strategies may include, but are not limited to:
  - a. Brief synopsis of the STUDY results and suggested strategies for improvement mailed with license renewals to all Retail Food Handlers;
  - b. Communication of STUDY results and improvement strategies to inspection staff for further education through inspections;
  - c. Posting of STUDY results and improvement strategies on pertinent websites; and
  - d. Communication of STUDY results and improvement strategies through educational outreach sources working with the Outreach Coordinator.

**6.10. Compose Report of STUDY Outcomes**

BQM Unit/Retail Food Program

- 6.10.1. Gather all pertinent data related to the outcome of the STUDY including reports to compose a final report of the STUDY. The final report should contain at least the following information:
  - a. Introduction including background, purpose, and study design
  - b. Methodology including selection of facilities, selection of data collectors, data collection form used, etc.
  - c. Results and summary of data related to each FACILITY TYPE
  - d. Intervention strategy design and implementation.

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**6.11 Documentation – All Staff**

6.11.1 Retain all training documentation, data collections forms, reports, and other documentation related to the Risk Factor Study in an electronic file.

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

VNRFRPS Standard 9

MDA Data Collection Form

FDA Marking Instructions for Data Collection Form – Short Version

2016-2017 MDA Risk Factor Study Training

Chapter 2 – Employee Health FDA Model Food Code

Equipment Type Options for the Data Collection Form

FOOD.30.05 – Inspection Report SOP

FOOD.30.20 – Inspection Protocol-Retail Food SOP

Gathering Facility Type Information for the Risk Factor Study handout

**8. EQUIPMENT/MATERIALS NEEDED**

N/A

**9. SAFETY**

N/A

**10. CIRCULATION**

This policy will be circulated to the following: Retail Food Program Manager, Retail Food Program Supervisors, Retail Food Program Inspection Staff, BQM Unit Supervisor, RTO Unit Supervisor, Food Standards Coordinator, TSA, Electronic Systems Coordinator, Training Coordinator, Outreach Coordinator, Assistant Division Director, and Division Director.

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**11. APPROVAL/DOCUMENT HISTORY**

<b>Document History</b>		
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<b>1</b>	<b>I</b>	Initial procedure drafting.
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I = Initial document; R = Revised document