![neha logo] **National Environmental Health Association**

# Voluntary National Retail Food Regulatory Program Standards

## Standard 9 Guidance
## Completing a Risk Factor Study

# Contents

# Introduction

Conducting a Risk Factor Study is a key element of meeting the requirements of Standard 9: Program Assessment (hereafter "Standard 9") of the Voluntary National Retail Food Regulatory Program Standards.

According to the FDA, a Risk Factor Study is defined as:[A] study on the occurrence of foodborne illness risk factors within institutional, foodservice, restaurants, and retail food facility types under a jurisdiction's regulatory authority (U.S. Food & Drug Administration, 2022). The desired outcome of this Standard is to enable managers to measure their program against national criteria and to demonstrate improvement in food safety. The process identifies program elements that may require improvement or be deserving of recognition." (U.S. Food & Drug Administration, 2022)

This document covers the steps necessary to successfully complete the Risk Factor Study portion of Standard 9: Program Assessment.

# Why Complete a Risk Factor Study?

With a better understanding of why jurisdictions need to complete a Risk Factor Study for Standard 9, you will be better prepared to carry out the work required for a Risk Factor Study. To help you understand the goals of the study, it is necessary to first understand what information will be derived from the data obtained in the study and how it will be used to protect public health. When used properly, a Risk Factor Study can be used as a Public Health Metric (Institute for Health Metrics and Evaluation (IHME), n.d.).

The first Risk Factor Study completed by a jurisdiction will provide a baseline for the occurrence of foodborne illness Risk Factors. This baseline then becomes the unit of measurement from which a variety of data points can be obtained.

This data can be used to:

- Assess the strengths and gaps in a retail regulatory food safety program
- Aid in setting programmatic priorities
- Develop intervention strategies to address the out-of-control foodborne illness Risk Factors in a jurisdiction
- Justify the allocation of program resources and potentially help obtain additional resources
- Track improvement in the occurrence of foodborne illness Risk Factors over time, thus helping to gauge the effectiveness of the food safety program

# How to Complete a Risk Factor Study

## Contact the FDA Retail Food Specialist

Step one of a successful Risk Factor Study is to contact the FDA Retail Food Specialist (RFS) assigned to the jurisdiction. The RFS is a subject matter expert in a variety of subjects and can provide information to jurisdictions as they complete their Risk Factor Study.

As the subject matter expert, the RFS can provide:

- Support for decision making when jurisdictions must determine issues such as the type of study to perform or what a realistic scope of work looks like

- Training for staff in the appropriate inspection methodology for study data collection

- Materials for data collection and access to completed studies and documents on FoodSHIELD

- Data analysis through a web page that makes recording and analyzing data easier

Remember, the FDA Regional Food Specialist can be an amazing asset. To find a RFS for a specific jurisdiction, use the FDA's Directory of FDA Retail Food Specialists (U.S. Food & Drug Administration, 2022). A link to the directory is found in the Resources section of this document.

## Determine Method of Data Collection

There are two methods that can be used to collect data when completing a Risk Factor Study. Each method has advantages and disadvantages. Some of these are outlined in this document to help jurisdictions decide which option is most suitable.

The two methods are:

1. Using routine inspection data
2. Collecting a random sample

According to the Voluntary National Retail Food Regulatory Program Standards (U.S. Food & Drug Administration, 2022): A jurisdiction may use routine inspection data or may conduct a separate data collection in completing a RISK FACTOR STUDY. A data collection instrument like the FDA Model Data Collection Form using the IN, OUT, NA, and NO convention, is required. Failure to use this convention skews the data toward either IN compliance or OUT of compliance. The FDA data collection instrument is not intended as an inspection form. However, jurisdictions that have developed an inspection form using the IN, OUT, NA and NO convention may use that inspection form as a survey instrument. If the jurisdiction uses a different form, the data may be difficult to compare with the data from the FDA National Foodborne Illness Risk Factor Studies or with data from other Routine Inspection Data.  When utilizing Routine Inspection Data as the source of information for a Risk Factor Study, the format of the routine inspection report must follow

the IN, OUT, N/O and N/A format for the 5 Foodborne Illness Risk Factors. Routine inspection data is collected and analyzed, eliminating the need for developing a data collection tool, marking instructions, or providing any staff training.

## Routine Inspection Data

Jurisdictions can use routine inspection data for their Risk Factor Study. This is sometimes called a "desktop audit" because it uses data already on file from routine inspections. This method has the potential to take less time and effort from the workforce. It may also be a lower cost option due to the minimal training needed and the lack of field work above and beyond routine inspections. However, this option may result in a lower level of accuracy in data due to possible inconsistencies in data collection.

## Random Sample (Field work)

If a random sample is used instead of routine inspection data, there may be a higher degree of accuracy in data due to consistency of data collection. This is because the staff is trained in data collection. However, this method may take longer to complete the data collection phase. It also has the potential for higher cost due to an increase in the number of employees needed for training and data collection.

## Develop the Data Collection Tool

When performing a Risk Factor Study, data will need to be recorded in a consistent manner. To that end, inspectional observations during the study need to be recorded on a form that includes:

- The 5 Foodborne Illness Risk Factors

- Food from Unsafe Sources

- Improper Holding Temperatures

- Inadequate Cooking

- Poor Personal Hygiene and

- Contaminated Equipment

- The IN, OUT, N/O, and N/A conventions that determine the compliance status of the 5 foodborne illness Risk Factors

- Optional areas that the jurisdiction may deem necessary such as:

- Comments section to address clarification of marking instructions, additional concerns, questions or similar

- Additional data points to support the items marked (e.g., an area to record temperatures)

- Other items as determined by jurisdiction (e.g., Certified Food Protection Manager or Handwashing)

Jurisdictions may add topics to the data collection tool. If a jurisdiction would like to remove information, however, this would need to be discussed with an FDA Retail Food Specialist. Links to the data collection tools developed by the FDA are available in the Resources section of this document.

## Establish Timeframes

According to Standard 9 of the Retail Program Standards, a jurisdiction's first Risk Factor Study is to be completed as soon as possible after completing its first self-assessment of all nine standards (U.S. Food & Drug Administration, 2022).  Subsequent studies should be completed every 60 months per the Retail Program Standards.

It is not necessary to complete the entire Risk Factor Study in one year. Jurisdictions may choose to focus on a portion of the study each year until the work is complete, provided the work is finished within the 60-month period. Different types of food establishments may be used for data collection throughout the 60 months, provided the study is complete within the necessary time frame.

For example, in a jurisdiction that inspects only schools and retail outlets, for the first year of the study, data collection may be performed in the schools. In the second or third year, data collection would be performed in retail outlets. As long as all the data collection is completed in the 60-month time frame, the types of food establishments can be split up in this way to make the process more convenient.

## Ascertain Types of Food Establishments

When choosing types of food establishments for the study, it is only necessary to collect data from food establishment types under the regulatory jurisdiction of the organization performing the study. If a jurisdiction does not regulate food safety in schools, for example, they do not need to collect any data from schools (U.S. Food and Drug Administration, 2015). The types of establishments are:

- **Healthcare**: Hospitals, Long Term Care
- **Schools**: Base Kitchen, On-Site Kitchen, Combination Kitchen
- **Restaurants**: Full-Service Restaurant, Fast Food Restaurant
- **Retail Food Stores:** Deli Department/Operation, Seafood Department/Operation, Produce Department/Operation

## Compute Sample Size

When determining sample size for the Risk Factor Study, a 95% confidence level and a 5% margin of error are reflective of those chosen by FDA CFSAN for The Study on the Occurrence of Foodborne Illness Risk Factors in Selected Retail and Foodservice Facility Types (U.S. Food and Drug Administration, 2015). Although jurisdictions have questioned the necessity of adhering to the 95% confidence level while completing a Risk Factor Study, the Clearinghouse Workgroup issued a response to this question in 2003. Their response was then updated in 2020 to say, in part:

> [i]n a nutshell, the statistics show that although you may be able to reduce sample size somewhat, your ability to measure trends over time is greatly compromised. You will lose precision to a degree that you may not be able to detect increases or decreases in compliance of risk factors in future surveys. (U.S. Food & Drug Administration Clearinghouse Work Group , 2021)

Additional information can be found in the Clearinghouse Work Group Questions and Answers on the Implementation of the Retail Program Standards. A link to this document is found in the Resources section of this document. The Clearinghouse Work Group was developed to provide answers to questions about the implementation of the Retail Program Standards and is comprised of various stakeholders from Federal, State, Local, Tribal and Conference for Food Protection (CFP) partners.

The RFS can help a jurisdiction determine the number of observations needed to conduct a statistically significant analysis of the jurisdiction's food establishments. Free sample size generators can also be found online by searching for "free sample size generators."

### Sample Size Example

Below is an example of a free sample size generator. When you link to the generator, 3 fields are prefilled and one is blank. The first two prefilled boxes meet the requirements of a 95% confidence level and a 5% margin of error for a Risk-Factor Study and can remain.

The calculator automatically populates a population proportion of 50%. Using the population proportion of 50% could have a jurisdiction completing too many or too few data collections than needed. For accuracy, the population proportion will need to be changed from 50% after the new proportion is calculated in the next steps. The blank box is for the total population being studied.

## Using a free generator to determine sample size

1. You will need to know the number of total food establishments in the jurisdiction and the number of food establishments in each risk category.

   In this example, we'll use a generator to determine the sample size for Coffee County. (Coffee County does not regulate food safety in schools or healthcare facilities, as those are handled by a state agency.) Coffee County has:
   - 1588 total food establishments in the jurisdiction
   - 955 are retail food stores
   - 633 are restaurants

2. Coffee County will be using retail food stores for the first year of their study. Now they need to determine the population proportion of their total food establishments that are retail food stores.

   We will use the formula for finding the population proportion (p=x/n), where:
   "x" is the number of items you're interested in, and
   "n" is the total number of items in the population.

   Note: "p" is usually used as the symbol for the population proportion

When we input Coffee County's numbers for the variables (p = 955 [x=total number of retail food stores]/1588 [n=total number of establishments]), our result becomes the fraction 955/1588.

Convert the fraction to a percentage to use in the sample size calculator: 955/1588 or 955÷1588 expressed as a decimal is .603 or 60%

This means that 60% of all establishments inspected by Coffee County are retail food stores.

3.      After you determine the population proportion of 60%, you can enter it in the sample size calculator to obtain an accurate number of food establishments where data can be collected.



4.      Repeat the previous steps to determine the population proportion for any other food establishments being used for data collection.

## Pull a Random Sample of Food Establishments

Once the types of food establishments and sample size have been determined, select a random sample of food establishments regulated by the jurisdiction for the study. In our hypothetical jurisdiction, Coffee County has 955 retail food stores being used for this portion of their Risk Factor Study and will need a sample size of 300 food retail food stores.

Selecting food establishments for data collection must be a random selection process. There are several ways to carry out a random selection, but for the purposes of this document a random number generator will be used.

1. The first step in pulling the sample is to organize the data in a manner that can be used with a random number generator. Unfortunately, permit numbers have changed over the years and can't be used with a random number generator. In this situation, Coffee County can use a program like Microsoft Excel (or a similar spreadsheet program). Using a spreadsheet, each establishment has a row number and the numbers start on number 2. The Program Manager was able to do this by exporting data from their inspection system into Excel.

| | A | B | C | D |
|---|---|---|---|---|
| 1 | Permit # | FE Name | | |
| 2 | 133 | Homecookin Kitchen | | |
| 3 | 6259 | Bob's Burgers | | |
| 4 | 3566 | Fiona's Restaurant | | |
| 5 | 1235 | Tilly's Tacos | | |
| 6 | 365 | ABC Eatery | | |
| 7 | 799 | Cafeteria 123 | | |
| 8 | 845 | Mama's Pizzeria | | |
| 9 | 1239 | Delicious Deli | | |
| 10 | 9251 | Sam's Seafood Raw Bar | | |
| 11 | 5568 | Hot Dog Heaven | | |
| 12 | 3639 | Coffee Café and Bakery | | |
| 13 | 2547 | Bristol Bar and Grill | | |
| 14 | 323 | Coconuts on the Beach | | |

2. Choose which random number generator you'll be using. Any random number generator can be used. A link to one can be found in the Resources section of this document.

3. Fill in the data in the random number generator. Remember, Coffee County has:

   - 955 retail establishments
   - 300 sample size needed

| Prompt | Input |
|---|---|
| How many sets of numbers do you need to generate? | 2* |
| How many numbers per set? | 300 |
| Number range (e.g., 1-50) | 1-955 |
| Do you wish each number in a set to remain unique? | Yes |
| Do you wish to sort the numbers that are generated? | Any answer choice |
| How do you wish to view your random numbers? | Any answer choice |

*For the Retail Program Standards, you will always generate 2 sets of numbers. The second set is a backup set to account for substitutions.

4. When you run the generator with this input, your two sets of unique numbers will be generated.

5.  Match the numbers from first set produced by the randomizer to the rows on the spreadsheet. (The second set of numbers is a backup in case a food establishment from the first set has closed or can't be used during the data collection process.) In matching up the first three numbers generated by the site (4, 5, and 7), we can see that Fiona's Restaurant, Tilly's Tacos, and Cafeteria 123 will all be used for data collection because they are found on rows 4, 5, and 7 of the spreadsheet.

| | A | B | C | D |
|---|---|---|---|---|
| 1 | Permit # | FE Name | | |
| 2 | 133 | Homecookin Kitchen | | |
| 3 | 6259 | Bob's Burgers | | |
| 4 | 3566 | Fiona's Restaurant | | |
| 5 | 1235 | Tilly's Tacos | | |
| 6 | 365 | ABC Eatery | | |
| 7 | 799 | Cafeteria 123 | | |
| 8 | 845 | Mama's Pizzeria | | |
| 9 | 1239 | Delicious Deli | | |
| 10 | 9251 | Sam's Seafood Raw Bar | | |
| 11 | 5568 | Hot Dog Heaven | | |
| 12 | 3639 | Coffee Café and Bakery | | |
| 13 | 2547 | Bristol Bar and Grill | | |
| 14 | 323 | Coconuts on the Beach | | |

## Prepare for Fieldwork

It is important that the data collection methodology be consistent to ensure that the study is not adversely affected or skewed by improper data collection. The RFS can provide training to the food safety staff performing data collection on the tools to be used and how to gather data properly.

## Conducting Fieldwork/Data Collection

Having determined the correct sample size and pulled the random sample of the required food establishment types, a jurisdiction can begin the data collection process. Data collectors will need to have an ample supply of documents available to use and/or hand out to food establishments.

Examples of documents that may be beneficial to carry or have links for:
- Data Collection Letter of Introduction

- Retail Food Protection: Employee Health and Personal Hygiene Handbook (2022)

- Assorted Food Safety Guidance: proper handwashing, cooling methods, hot holding, reheating, cold holding, etc.

A letter of introduction can be given to food establishments prior to data collection. The letter provides key information about the data collection process, study objectives, and whether the visit is being done specifically for data collection or if it is part of a routine inspection. Additional information on the letter of introduction can be found in the U.S. Food and Drug Administration; Study on the Occurrence of Foodborne Illness Risk Factors in Selected Retail and Foodservice Facility Types (2013-2024), Protocol for the Data Collection.

### Unannounced Visits

Unannounced data collection visits are preferred because announced visits may not provide accurate inspectional data for the study. Using unannounced allows inspection staff to see food establishments operating as they normally would.

### Introductions/Communication

Introductions are a critical part of the inspection process as they are an opportunity to explain the purpose of the visit and begin building a rapport with the management and staff of the food establishment. It is important that inspectors work to put establishment staff at ease for what can be an intimidating process.

## Quick Walk Through

The quick walk through is critical for determining which areas have processes involving the Five Foodborne Illness Risk Factors and if the process is a dynamic one that needs to be evaluated early or a static process that can be addressed later. This is done through asking questions on processes occurring, conducting a menu review, and walking through all the processing areas. The quick walk through is an opportunity to efficiently assess as many Foodborne Illness Risk Factors as possible and prioritize the inspection and aid in determining everything from when to take temperatures of a cooling food or if a process is static and can be addressed at the end of the visit.

## Focus on Primary Data Items

Once the quick walk through has been completed, it is important to focus on the primary data items on the collection form. These items are all based on the Five Foodborne Illness Risk Factors. It is easy to become sidetracked by other processes happening during the data collection process. The ten items to evaluate during the data collection process are:

Risk Factor–Poor Personal Hygiene
- Employees practice proper handwashing
- Food Employees do not contact ready-to-eat foods with bare hands

Contaminated Equipment / Protection from Contamination
- Food is protected from cross-contamination during storage, preparation, and display
- Food contact surfaces are properly cleaned and sanitized

Improper Holding / Time and Temperature
- Foods requiring refrigeration are held at the proper temperature
- Foods displayed or stored hot are held at the proper temperature
- Foods are cooled properly
- Refrigerated, ready-to-eat foods are properly date marked and discarded within 7 days of preparation or opening

Inadequate Cooking
- Raw animal foods are cooked to the required temperature
- Cooked foods are reheated to required temperatures

Additional information on properly collecting study data can be found in the Protocol for the Data Collection. This is also where the Risk Factors and the 10 items listed above are pulled from.

## Questions During Data Collection

Questions from data collection staff may arise on specific violations or issues observed during the visit. Examples include questions on how to mark an item on the Data Collection Tool or how to handle specific violative situations while in the food establishment. It may be beneficial for jurisdictions to assign a knowledgeable individual, from within their jurisdictions, as the point of contact to answer questions. This will help ensure the answers and information are consistent for the study..

## Quality Assurance for Process/Inputting Data

Your jurisdiction's RFS can arrange to have a FoodSHIELD website designed specifically for data collection in place. To promote consistency, data collection staff and anyone who will be inputting data into the FoodSHIELD system will need to be trained in how to use the website. This database in FoodSHIELD has a series of quality checks built into the program.

Examples of the type of quality assurance checks programmed into the database include:

- Notifications when any data entry field has been left blank

- Standard drop-down screens for consistent responses

- Automatic calculation of the results of the overall data based on what was entered for the information statements under the data items

- Cross-checks to ensure that compliance marking for data items requiring temperature measurements were consistent with the temperatures recorded in the temperature charts;

- Automatic calculations for food product temperature summary tables based on the actual temperature recorded in the temperature chart as compared to the required food safety temperature for the data item; and

- Notifications via dialogue boxes that ensure the FSMS assessment was entered for the selected Risk Factor area.

The staff who performed the data collection will enter their data with the assistance of an assigned point of contact for questions and using the checks and balances built into the FoodSHIELD System. FoodSHIELD will compute the data to either build a baseline or added information that can then be used to track risk factor trends over time. (U.S. Food & Drug Administration, 2022)

# Data Analysis

## Building the Baseline

The first Risk Factor Study a jurisdiction completes provides a baseline for the occurrence of Foodborne Illness Risk Factors in that jurisdiction. This baseline then becomes the unit of measurement from which a variety of data points can be obtained. The "Why Complete a Risk Factor Study?" section of this document explains how the baseline data can be used to strengthen a food safety program.

## Trends

Once the first Risk Factor Study is completed and the baseline data has been obtained, future data collections will show trends in violations over time. Interventions can then be put in place for the most common out-of-compliance risk factor(s). After each subsequent collection, the data can be analyzed to determine which out-of-compliance risk factor is the most cited and an intervention plan can be developed to address this risk factor across the jurisdiction. The data may show that one particular risk factor is out of compliance, or several risk factors may need to be addressed.

## Intervention Strategy

When developing an intervention strategy to address the most common out-of-compliance risk factor(s) from the study, it is important to take into consideration the types of establishments that were assessed. If it is predominantly small, independent stores, the intervention will need to be geared to a smaller location, not a major retailer with many programs already in place. The intervention also needs to be manageable for the jurisdiction. A handout with some key points addressing the issue or a link to a web page with similar information and with a quick explanation at the end of an inspection may be easier than putting together a training video.

Regardless of the intervention strategies chosen, once it's implemented, the efficacy can be evaluated during the next study cycle.

Examples of intervention strategies (not all inclusive):

- Distribute guidance pertaining to the out-of-compliance (OOC) risk factor and educate at the end of all inspections for a set period, even when writing new permits or during survey sampling. Send weekly reminders to all field staff with facts and updates on the OOC risk factor.

- Email guidance on the intervention to be implemented to the POC for all food establishments in the jurisdiction.

- Post videos pertaining to the OOC risk factor on the portions of the jurisdictions website that is commonly used by operators.

- Speak to local industry and food safety groups about the jurisdiction's efforts to reduce the occurrence of foodborne illness through addressing the OOC risk factors.

- Offer to deliver free training to industry on the specific OOC violation and provide support materials.

- Form alliances with industry to work on realistic methods to address OOC risk factor(s).

# Risk Factory Study Checklist

1.    Reach out to FDA Retail Food Specialist
2.    Determine time frames of study
3.    Determine type of study
4.    Develop study instrument
5.    Determine food establishments to be utilized in study
6.    Determine appropriate sample size of food establishments
7.    Pull random sample of food establishments included in study
8.    Determine staff
9.    Train staff
10.    Set up FDA data collection website with FDA
11.    Perform field work
12.    Input collected data/compile data
13.    Analyze trends
14.    Compile report
15.    Determine appropriate interventions to address out of compliance Risk Factors

# Resources

**Websites**

- [FoodSHIELD](#)

- [FDA Risk Factor Study Webpage](#)

- [Voluntary National Retail Food Regulatory Program Standards – Standard 9: Program Assessment](#)

- [NEHA-FDA RFFM Grant Program Home](#)

- [Survey Sample Size Calculator](#)

- [Random number generator](#)

- [Directory of FDA Retail Food Specialists](#)


**Data Collection Forms**

- [Retail Food Store Data Collection Form](#)

- [Restaurant Data Collection Form](#)

- [Marking Instructions for the Data Collection Form](#)


**Clearinghouse Work Group Questions and Answers**

- [Link to the Clearinghouse Q&A](#)

# Glossary

**Baseline Study**: Initial Risk Factor Study. A baseline study measures the situation at the beginning of the project. This can then be compared to the situation after the end of the intervention, to establish what change has occurred (World Food Progamme, May 2011 ) .

**Confidence Level**: The percentage of all possible samples that are expected to include the true population parameter (Zach, 2021).

**Population**: Every possible individual element that we are interested in measuring (Wasserthiel-Smoller, 1990).

**Population Proportion**: In statistics, a population proportion refers to the fraction of individuals in a population with a certain characteristic (Wasserthiel-Smoller, 1990).

**Public Health Metric**: A quantitative assessment of population health. The Risk Factor Study provides a quantitative assessment of the occurrence of Foodborne Illness Risk Factors in food establishments (Institute for Health Metrics and Evaluation (IHME), n.d.).

**Random Sample**: Simple random sampling is a sampling technique in which each member of a population has an equal chance of being chosen, using an unbiased selection method. Each subject in the sample is given a number and then the sample is chosen by a random method (Simkus, 2022).

**Sample**: A portion of the population (Wasserthiel-Smoller, 1990).

**Risk Factor Study**: A study on the occurrence of foodborne illness risk factors within institutional, foodservice, restaurants, and retail food facility types under a jurisdiction's regulatory authority.

**Sample size**: The number of units (persons, animals, patience, specified circumstances, etc.) in a population to be studied. The sample size should be big enough to have a high likelihood of detecting a difference between the two groups.

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