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ADMINISTRATION

Retail Food Risk Factor Study Guidance

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What is a Risk Factor Study?

A Risk Factor Study is a public health metric that tracks food safety in your community by measuring the occurrence of foodborne illness risk factors. Your department can use these data to identify food safety priorities, and design and implement interventions to improve food safety. You can then evaluate these interventions using later studies and track trends.

Why do a Risk Factor Study?

There are many reasons to do a Risk Factor Study. Completing a study will help your department work towards meeting Standard 9 of the Voluntary National Retail Food Regulatory Program Standards (Program Standards). Additionally, as discussed above, it also gives you a way to measure food safety in your community, identify priority areas, design targeted intervention strategies, and track trends.

However, the benefits of doing a Risk Factor Study go beyond Standard 9. A Risk Factor Study gives you the tools to make data-driven decisions for your program. You can use these data to assess strengths and gaps in your food safety program and evaluate how you deliver services. The results can set performance metrics and outline program priorities. You can also leverage these data to support policy changes, food safety initiatives, and resource allocations when talking with decision makers, partners, and stakeholders. Simply put, a Risk Factor Study provides the tools you need to make strategic decisions, get buy-in, and show the value of the work that you do.

Study Design

Two Main Approaches

There are two main approaches to conducting a Risk Factor Study—a data collection and a file review of inspection data.

The Food and Drug Administration (FDA) uses the data collection approach for the national study. This approach estimates the occurrence of risk factors using observational visits to randomly selected establishments, while a file review uses routine inspection data to retroactively assess occurrence.

Pros and Cons – Data Collection vs. File Study

As one can imagine, each approach has its pros and cons. The file study approach uses fewer field resources since you don't need to complete separate observational visits; however, inspections can have competing priorities. A data collection's sole focus is the observation of food safety behaviors tied to risk factors. While a risk-based inspection should prioritize these items, there are additional elements to observe and an inspector may need to focus on a specific area to get compliance, leading to missed observations. Having a separate, optional

visit can give the operator facetime with you in a non-regulatory capacity and you may get more robust data. Another consideration is the quality of the data you're getting. With a data collection, you can train experienced staff to ensure consistency. If you use inspection data, you may have uniformity concerns, particularly if your department is still working to meet Standards 2 and 4 (trained staff and uniform inspections) or if you've experienced staff turnover.

You should also consider how easy it is to access your inspection data. For example, if you have paper inspection forms, you will need a database and data entry resources to use that information, which may be expensive and time consuming. However, if you do electronic inspections, and your system provides the data you need in easy-to-use reports, using inspection data may be an easier option.

In addition to looking at resources, think about what you want to accomplish with your Risk Factor Study. Are there questions you want the data to answer? Are there other aspects you're interested in such as Certified Food Protection Manager status, the development of Food Safety Management Systems, or local code provisions? Are you trying to draw associations between observations and things like Food Safety Management Systems? Are you trying to follow the design of the national study? It's incredibly important to identify your goals at the beginning as they can drive your study design. You may find that a separate data collection provides you more opportunity and flexibility depending on what you need from your data.

Hybrid Approach

A third approach combines elements of the first two—combining the data collection with a routine inspection. With the hybrid approach, you would still sample your facility categories, but as you complete the data collections, staff also complete a routine inspection.

This method would help conserve resources while trying to capture the benefits of doing a data collection. With this approach, you could limit the data collection to experienced staff to increase quality and consistency of the data, and you could add in other study elements like the Food Safety Management Systems assessment. Additionally, depending on your statutes, you'd have fewer refusals. However, you would need to balance the competing priorities of regulatory visit with the goals of the study. Something to consider is having the inspector fill out a separate data collection form after completing inspection report. This way, they can verify that they observed all pertinent practices and mark the sheet using the study protocols, which might be different than how they mark inspections, depending on your policies and study design.

Collection Schedule

An important consideration during the design phase is your timeline. Standard 9 gives you flexibility in this area. You do not have to collect data on all facility categories at once and you can decide if you want to space out the collections to better fit your resources. You have five years to complete your data collections, analyze the data, write your report, and design and implement an intervention. How you manage that work is up to you.

Data Collection Form

The form used to collect your observations is critical. The design must accurately capture observations and provide checks for quality assurance.

Information Collected

The form must collect observations of food safety practices and behaviors tied to the five foodborne illness risk factors:

- Poor personal hygiene,
- Improper holding time and temperatures,
- Inadequate cooking temperatures,
- Contaminated equipment/protection from contamination, and
- Unsafe sources.

You can do this using a data collection approach like the FDA where each risk factor is assessed by data items and their associated information statements, or you can identify violations on your inspection form that measures the occurrence of the risk factors. In both cases, ensure that the form has spaces for field staff to describe their OUT observations. This will help with quality assurance.

Form Design

Form design is essential regardless of the study design you choose. Field staff need a document that captures their observations accurately. Standard 9 requires that you use a form that allows field staff to mark items as IN, OUT, NO (not observed), or NA (not applicable) unless the practice is expected to occur during each visit such as proper handwashing.

Without the ability to record unobserved items, you will not be able to adjust your data appropriately, and items that were not observed or not applicable will be counted as IN or OUT depending on your marking protocols. This will skew your results and render your analysis inaccurate. For example, if you had 100 establishments in your study, five of them don't cool foods (NA), 15 do cool foods but were not doing so at the time of the visit (NO), and you marked 60 establishments OUT, you would have to take into account the 20 establishments where cooling wasn't observed. Without adjustment, you would have a 60% out-of-compliance percentage; however, cooling is actually out of compliance in 75% of the establishments where you observed the practice. This difference could affect the intervention you choose and how you're able to track trends and impacts over time. The importance of NO and NA holds true whether you do a data collection or use inspection data. The form must accurately capture observations so you can properly analyze the data.

You should also consider how your data collectors/inspectors will record temperature observations. The FDA data collection form has tables for cold and hot holding, cooking, reheating, and cooling. You do not have to use separate tables for each of these items, but you will want a section on your form where your staff can clearly capture this information. Additionally, FDA's form includes documentation of the actual temperatures to better understand the range of out of compliance temperatures which is valuable when determining priorities and interventions. You may also want to include this on your form if you do not use FDA's document.

Marking Instructions

In conjunction with a well-designed form, you should consider providing field staff with marking instructions that outline how you want them to mark different items. While this is not required per Standard 9, it is a quality assurance and training tool. If you don't have marking instructions, you will want some other way to ensure staff mark items consistently.

The marking instructions can serve a second role as well—a road map for quality assurance. The people checking data for consistency need to know what you expect. These instructions, coupled with the notes and temperature observations noted by field staff, provides the information needed to assess quality assurance.

Optional Assessments

Standard 9 requires that you collect data to measure the occurrence of the five foodborne illness risk factors and track trends. However, depending on your goals, you may want to include other food safety areas, one of the FDA's optional assessments, or collect data specific to your state or local interests.

Additional Data Items

In addition to measuring the five foodborne illness risk factors using Data Items 1-10 and 17, FDA looks at other data items such as allergen awareness, stocked hand sinks, proper use of the consumer advisory, time as a public health control, and more. If there are additional areas of interest to your department, consider adding those data items to your data collection form, or pulling that inspection data. Again, ensure that your staff can record their observations using the IN, OUT, NO, and NA conventions for accurate analysis.

Handwashing Frequency

As part of the FDA's study, data collectors tally the number of times that they observe employees wash hands correctly, miss a required hand wash, or wash their hands improperly. This assessment is a broad-based indicator of handwashing practices in the facility and may inform intervention strategies.

Employee Health Policy

The FDA uses a series of questions to evaluate employee health policies. These questions assess employee awareness of when to report and management's use of exclusion, restriction, and reinstatement procedures. You can use the FDA's questions or design your own based on your state or local requirements.

Certified Food Protection Manager

The Certified Food Protection Manager (CFPM) assessment collects information on whether an establishment has a CFPM employed, present, and whether they are the person in charge. The FDA analyzed CFPM data from recent data collections and found that establishments with a person in charge who was a CFPM had stronger Food Safety Management Systems.

Food Safety Management Systems

Food Safety Management Systems (FSMS) are specific actions and procedures put in place to achieve active managerial control. FSMS include food safety procedures that staff are trained to perform and methods to monitor activities to ensure staff follow those procedures. FDA has developed a way to assess the strength of these systems and have assessed the correlation between the strength of FSMS and the control of risk factors. The FDA has also analyzed the relationship between the strength of FSMS and CFPM status (none, employed, present, person in charge). Recent studies show FSMS are stronger in establishments where the person in charge is the CFPM than in establishments with no CFPM (https://www.fda.gov/food/retail-food-protection/retail-food-risk-factor-study).

Facility Categories and Risk Categories

Facility Categories to Include

Standard 9 says that you must include establishments in health care (hospitals, long-term care), schools, restaurants (fast food and full-service), and retail food stores (particularly delis) over which you have jurisdiction. That said, it is up to you to define the categories in Standard 9 that fit your jurisdiction's framework, and it might be worth writing down a description of each one for consistency from study to study. If there is a category that you do not regulate, you do not have to include it in your study. Additionally, you are not limited to these categories. If you wish to look at mobiles or temporary food establishments, you can add them to your study.

You can also choose to drill-down into each category such as breaking restaurants down into full-service and fast food like the FDA does with the national study. The risk factors at play can be different in the subcategories, and depending on your study's goals, this approach could answer some additional questions or help direct your chosen intervention strategy.

Risk Categories

Something to consider, while not required by Standard 9, is to assign risk categories to each establishment as required by Standard 3. You can use the table in Annex 5 or create your own system. You can then remove lower-risk establishments like hot dog carts, convenience stores, and packaged food vendors from your establishment list before sampling. These operations have fewer food safety practices to see, leading to more NO and NA markings, and you want your data collectors to make the most observations possible.

Sampling

Approach—Facility Categories and Collections

The FDA samples each facility category or subcategory (e.g., fast food, full-service) separately and treats each as a distinct data collection. This approach allows for the most robust data analysis possible, and we encourage you to use this method.

Before deciding your approach, list the questions that you want your data to answer, identify your long-term goals, and then think about how to design your study to meet your needs. If you have questions or would like to discuss strategies with the resources you have, contact your Retail Food Specialist.

Curating Your Establishment Lists

Having a sorted, accurate list of establishments is an important preparation step before figuring out your sample size and pulling your random sample. First, pull a list of your establishments and assign them to your defined facility categories. If you choose to eliminate lower-risk establishments, assign risk categories, and remove those establishments that do not qualify for your study. Double-check your list for accuracy, operational status, and remove those going through your compliance and enforcement process. After you've curated the list, sort by category. Divide the categories into separate lists and alphabetize.

If you curate your list in Excel, this not only makes data manipulation easy, but each row assigns a number to each establishment. These numbers will be important when you pull your random sample. Additionally, you can use the row numbers to tell you how many establishments you have, which you will need to calculate your sample size.

Sample Size

If you are doing a data collection, you will need a representative sample that is large enough to support meaningful statistical analysis. The sample size depends on three inputs: the number of establishments, the confidence level desired, and the margin of error you deem acceptable. With a higher confidence level and a lower the margin of error, the more certain you can be that the estimates reflect the occurrence of risk factors in the population. However, this means a larger sample size and more resources. The FDA uses a 95% confidence level and a 5% margin of error for each category in our national studies. You are welcome to use different benchmarks so that your sample size better fits your resources. However, remember the lower the confidence level and the wider the margin of error, the less representative your sample may be and the more likely you are to miss trends over time.

The good news is that you do not have to understand all the math that goes into figuring out the sample size for your chosen confidence level and margin of error. There are resources available on the internet.

https://www.surveymonkey.com/mp/sample-size-calculator/

http://www.raosoft.com/samplesize.html

https://www.checkmarket.com/sample-size-calculator/

https://www.calculator.net/sample-size-calculator.html

A couple of closing notes on sample size. First, if you are a small jurisdiction with 30 or fewer establishments, or if you have less than 30 in any facility category, don't sample—do all of them. Otherwise, there will not be enough to ensure a normal distribution, and you cannot use parametric tests for statistical significance. Second, if you are using existing inspection data, you do not have to pull samples. Remember that sampling is done to approximate what is going on when you cannot test the entire population. If you have routine inspection data for all your

eligible establishments, you have a population metric. That said, if you decide to do a hybrid approach and combine the data collection with routine inspections, you will need pull a random sample to determine which establishments participate in the hybrid visit.

Pulling a Random Sample

Distribution of Work

It is up to you how you divide the work across your field staff. However, if you want to divide the work evenly, you should talk to a statistician before pulling your sample to ensure that you accomplish this without impacting the integrity of the sample. Adjusting establishments after you pull the sample compromises the study. For example, if you want each collector to do 20 collections, and Collector A has 30 randomly pulled in her area and Collector B only has 10, you can't throw out 10 from A's list and hand pick another 10 for B. However, if you want things assigned evenly and within the existing bounds of staff assignments, talk to a statistician about your options.

Sample List

Using a random number generator, pull a list of numbers for each sample. Go to your file with your curated lists. Save a copy of the file to indicate that it's your primary sample. This way, you can retain your clean, original list. Then, in the primary sample file, go down the list, highlighting or otherwise indicating which establishments were identified by the random number generator. Repeat this process for each category. Then, delete the establishments not identified and save the file.

https://www.random.org/integers/

https://www.calculator.net/random-number-generator.html

Substitution List

As field staff collect data, they may find establishments that have closed, refuse to participate, or have changed their business in a way the disqualifies them from the study. If this happens, you want to replace these establishments while maintaining the integrity of your sample. You could overestimate with your original sample and build in some cushion, but this may not guarantee that you are able to meet your sample size. A better way is to create a substitution list using random sampling.

There are two ways to go about creating your substitution list. The first way is the easiest. Pull another list of random numbers for each category, label each list with the category, and save them. Then, if you need a back-up, go to the correct list for the category, find the first number pulled, go to your original list and find the matching establishment. If this establishment was not pulled for your original sample, you have your replacement, and you can cross the number off the random number list. If it was included in the original sample, cross the number off the random number list and go to the next number and repeat the process. With the substitution list, use the numbers in order.

The second way to do this is more work up front. You still run a random number list for each category, but you sort through things ahead of time, going down the number list, in order,

figuring out which establishments are eligible back-ups. If you do this option, consider saving the back-up list under another name to maintain your original curated list.

Training

If you are going to do a data collection, you should train your field staff on the goals of the study, the data collection approach, your collection form and marking procedures, and if applicable, your study database. Going over the different priorities, marking, or interpretations they need to know will improve the quality of the data and make their jobs easier. That said, this process works best if the field staff taking part in the study have inspection experience. It's recommended to use standardized staff, but it is not required by Standard 9. However, at minimum, consider staff who have completed Steps 1-3 of Standard 2.

If you use the FDA's form, marking instructions, and database, your Retail Food Specialist has resources to help you with training. They can also work with you to provide training to your staff regardless of your approach.

After you train your data collection staff, you may want to consider having weekly check-in for data collectors to ask questions, review any discrepancies quality assurance staff have identified, or go out in the field with them for a few collections to see how things are going.

Field Work

Introductions

If you decided to do a voluntary data collection, field staff, after introducing themselves, will need to explain the purpose of the visit and get permission to proceed. They should explain the benefits of the visit—free consultation, not regulatory, participation in a study that helps their community—and explain how participation will not affect their compliance status or grade. You might consider using a letter like the FDA's that outlines the purpose of the visit and benefits. Your Retail Food Specialist can provide you a copy of this letter that you can adapt to your jurisdiction's needs.

If you chose to combine a data collection with a regulatory inspection, check your policies and decide if you want field staff to mention that their observations will be used in a local study.

Walkthrough

Your data collectors should complete a quick walkthrough just as they would for a risk-based inspection. They should ask strategic questions of the person in charge to gauge what procedures are happening, if there is food being reheated, cooked, or cooled. The collector should develop an approach that prioritizes risky and dynamic processes.

Data Collection

The collector should work through the facility starting with the high-priority items identified during the walkthrough. They should focus on the practices that measure the risk factors (Data Items 1-10 and 17 on the FDA's form). When items are out of compliance, they should work to get

corrective action. If the data collection is voluntary and not combined with a routine inspection, this may take finesse, but in the FDA's experience, most operators take voluntary corrective action. If you combine the data collection with a routine inspection, you may have additional tools for compliance. However, the hybrid approach may complicate how the collection works. Again, a routine inspection has competing priorities. Collectors will need to satisfy the elements of their routine inspection while keeping the goals and focus of the data collection as a top priority.

Data Entry

Whether you use your inspection system, the Risk Factor Study Database, or another program to capture your data, ensure data collectors or your data entry team are trained on the system and enter the information promptly. This will not only help with data entry fatigue but will help with quality assurance. If there are questions about how a collector marked an item, the data collection visit will be fresher in the collector's mind. Additionally, it could help manage the workload for the quality assurance team.

Quality Assurance

Quality assurance measures should weave through the study from start to finish. From your study design all the way to data entry, each element acts as an integrity check. This includes elements that you may not consider to be part of quality assurance including the experience of your data collection team, the training you provide them, the tools you create for uniform marking and collection, verifying establishment information, and determining the correct sample size. Additionally, ensuring a random sample and following proper replacement procedures is imperative.

Data entry and review can be one of the most intensive aspects of quality assurance. It is important to go through each form to ensure data collectors completed them and marked each item according to your marking rules. Train your quality assurance staff so they understand your procedures. Make sure field staff write why something was marked out and that they record temperatures to support their conclusions for cold and hot holding, cooking, cooling, and reheating.

If you use your inspection data, you will still need a quality assurance check to review the same elements as with a data collection. You can use or adapt your procedures from Standard 4, Uniform Inspections, to support this effort.

This might sound like a lot of work—and it can be. However, there are resources available. The Risk Factor Study Database has built-in checks that help data collectors review information as they enter it. These features can help you decrease quality assurance resources while maintaining high-quality data. If this interests you, contact your Retail Food Specialist for more information or a demonstration.

Data Analysis and Report

Standard 9 requires that you measure the occurrence of risk factors for the facility categories you regulate, write a report describing outcomes and conclusions, and repeat this process at least every five years. In addition, it requires that you assess the impact of interventions implemented between studies and analyze trends.

Baseline

Your first risk factor study is your baseline which you will measure future progress against. If you are new to the Standards and just finished your self-assessment, you could tackle a Risk Factor Study to see how things change as you meet more elements of the Program Standards. However, if you do a Risk Factor Study before meeting Standards 2 and 4, your planning, training, and quality assurance elements will be even more important. If you use inspection data for this first baseline, you may not have a uniform inspection approach or a training program that ensures consistency in your data. You will need to determine how to address these challenges, so your conclusions are meaningful.

Analysis

When your quality assurance checks are complete, you're ready to start the analysis. Standard 9 requires that you look at the occurrence of risk factors for your facility categories; however, you can do additional analysis and drill down into individual data items or violations depending on your study design.

As touched upon during the discussion of the form conventions, how you calculate your % out-of-compliance for risk factors, data items, and violations is important. Items marked NO or NA are not observations. When you're trying to figure out the percentage, you will need to divide the number of times something was marked OUT, by the total number of observations, IN and OUT. Another way to look at this is to figure out the total number of markings for an item and subtract the number of NOs and NAs to get the denominator. If you don't make this adjustment, you essentially count the NOs and NAs as IN, which won't give you an accurate measure of occurrence.

If you use this method, it's important to recognize how to interpret your findings. The % out-of-compliance is a proportion, not a rate. If you find a risk factor is 80% out-of-compliance, that doesn't mean that it is out 80% of the time. It means that in 80% of the facilities where you could observe that risk factor, you observed at least ***one practice*** related to the risk factor that was OUT.

Report

After your analysis, write a report covering the outcomes and conclusions of the study. You do not need to provide a narrative, but you must outline your findings and identify the risk factors in need of priority attention. If you implemented an intervention between studies, you should discuss its impact per your chosen evaluation method. Once you get to your third and subsequent studies, include your trend analysis.

Trend Analysis

Standard 9 requires that you assess trends to determine if there has been a meaningful net change in the occurrence of risk factors. After you establish your baseline with the initial risk factor study, subsequent studies should measure if progress is made. That said, it's important to remember that you cannot use a single point in time to derive trends. While it may be tempting to draw conclusions between studies, it takes at least three studies (points in time) to assess change.

That said, Standard 9 does not require a reduction in occurrence. If your study and report provide quantitative measurements, you can still meet the Standard. However, you can set internal goals and performance metrics and measure progress using your studies.

Intervention

An important piece of Standard 9 is using the data obtained through your study to identify a risk factor in need of attention and design and implement an intervention to decrease that risk factor's occurrence. This data driven approach allows you to pin-point where attention is most needed, and where you may have more public health impact. You can test the effectiveness of your intervention with your next risk factor study or another approach.

Retail Risk Factor Study Database

As an enrolled jurisdiction, you can request access to the same data collection and analysis program that the FDA uses for the national study. The Risk Factor Study Database provides cloud storage for your data, as well as a customizable data collection form. The database has built-in quality assurance checks, saving you time and decreasing errors, and the system provides several reporting options, including some that do the heavy lift for your analysis.

Resources

The FDA has a number of resources available to help you from the initial planning phases through your data analysis. Your Retail Food Specialist is a great connection to get access to these tools, get advice, as well as receive training support. Here are some resources they can provide:

- FDA Data Collection Form
- FDA Marking Instructions
- FDA workshops and custom training
- Program Standards Resource Center
- Clearinghouse Interpretations
- Retail Risk Factor Study Database

Here are some helpful websites:

1. FDA's Risk Factor Study: https://www.fda.gov/food/retail-food-protection/retail-food-risk-factor-study
2. Retail Risk Factor Study Database: https://www.retailfoodriskfactorstudy.net/member/login/
3. FDA's Program Standards Clearinghouse: https://www.fda.gov/media/119309/download
4. Program Standards Resource Center: https://www.foodshield.org/