

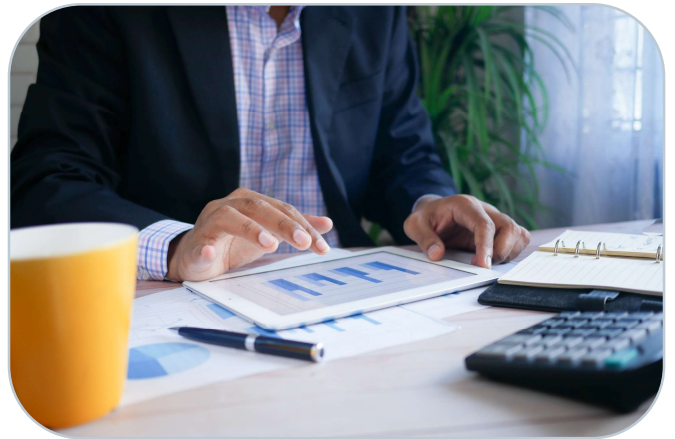
Standard 9: Program Assessment

Public Health Metric and Risk Factor Study

The goal of both the NEHA-FDA Retail Flexible Funding Model (“RFFM”) Grant Program and the Voluntary National Retail Food Regulatory Program Standards (“Retail Program Standards”) is to reduce the foodborne illness factors found in food establishments so that foodborne illness occurs less frequently. Completing the Standard 9: Program Assessment (“Standard 9”) with the required Risk Factor Study is one key component of achieving this goal.

The NEHA-FDA RFFM Grant Program provides funding so that jurisdictions can comply with Standard 9, which includes completing a Risk Factor Study and implementing intervention strategies to address out of compliance risk factors.

According to the FDA, a Risk Factor Study is “...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. The desired outcome of [Standard 9] 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.” (FDA, 2022)



Completing a Risk Factor Study

A Risk Factor Study includes data collection, analysis of the data, and a written report. The data collection instrument pertaining to the 5 foodborne illness risk factors must be included, using the IN/OUT/NA/NO convention. Only the facility types that the jurisdiction has regulatory authority over need to be included.

The first study is the “baseline study.” Once the baseline study is complete, jurisdictions implement intervention strategies aimed at the out of compliance risk factors that the baseline study identified as most common. Further studies are repeated at 5-year intervals to evaluate the efficacy of the intervention strategies.



Examples of interventions:

- Sharing [educational materials, such as posters and videos](#). Posters are available in nine languages.
- Providing on-site training.
- Assisting food establishments in developing their Food Safety Management System, such as assisting them in developing Prerequisite Programs.
- Assisting in the development/teaching of Process HACCP for menus.
- Reviewing type and placement of food equipment.

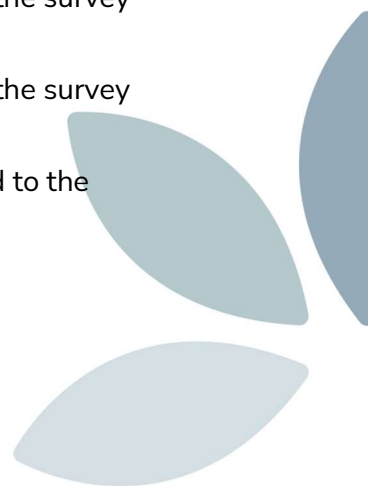
Additional information pertaining to Standard 9: Program Assessment can be found at on the website for the [Voluntary National Retail Food Regulatory Program Standards](#).

Scope of Work

Jurisdictions should determine what can be accomplished during the timeframe of the grant and only request funding for an appropriate scope of work. However, it is highly recommended to develop a strategy that includes full completion of a five-year Risk Factor Study cycle (included in your Comprehensive Strategic Improvement Plan/CSIP).

An example of a full, **five-year Risk Factor Study cycle** appropriate for a Track 2 Development Base Grant or a Track 3 Maintenance and Advancement Base Grant would be:

- **Year 1** – Establish a baseline survey through data collection using random sample of food establishments
 - Or - Establish a baseline survey using routine inspectional data.
 - Or - If the jurisdiction's inspection forms do not include IN, OUT, NA, and NO, update inspection forms to include data and begin baseline study.
- **Year 2** – Develop intervention strategies aimed at mitigating the occurrence of out-of-control risk factors and begin implementing them.
 - Or - If the intervention strategies have already been developed, continue to add data to the survey instrument using expectations found in Standard 9 of the Retail Program Standards.
- **Year 3** – Continue to use the results of collected inspectional data to improve the survey instrument.
- **Year 4** – Continue to use the results of collected inspectional data to improve the survey instrument.
- **Year 5** – Statistically measure the outcomes of newly collected data compared to the outcomes from the baseline survey.



Protocols for establishing a Risk Factor Study based on the FDA model can be found on [FoodSHIELD](#), at FDA's [Retail Food Risk Factor Study](#) website, and the Standard 9 Risk Factor Study Guidance Document.

Track 2 Development Base Grant: Work on Elements of Standard 9 in Pursuit of a Public Health Metric

Track 2 Development Base Grants are **one-year grants** to begin or continue work on elements of Standard 9 such as the Risk Factor Study.

In the application process, a jurisdiction can choose to work on one or more of the following options, each of which works toward meeting at least one of the elements of Standard 9:

- implement a Risk Factor Study or equivalent protocol to develop a baseline survey;
- develop and implement one or more intervention strategies aimed at mitigating the occurrence of out-of-control risk factors;
- continue to use the results of collected inspectional data to improve the survey instrument; or
- statistically measure the outcomes of new information compared to the baseline.

Track 3 Maintenance and Advancement (M&A) Base Grant (no new awards will be given in 2023)

If your jurisdiction has already been awarded a Track 3 M&A Base Grant, you would have been awarded funding for one these:

- Work on Elements of Standard 9 in Pursuit of a Public Health Metric
- Track 3 Maintenance and Advancement Base Grant
 - This three-year grant enables grantees to make significant progress on the Retail Program Standards. Because of the importance of the work encompassed by Standard 9, incorporating a Risk Factor Study into the proposed project is a requirement for any jurisdiction that has not already achieved Standard 9 (with audit passed and required paperwork approved by FDA). Applicants who have not already met Standard 9 must include one of the two Risk Factor Studies (routine inspection data or a separate data collection) in their proposed projects, and they must work on the metric for the full three-year cycle of the awarded grant.

This Public Health Metric project allows grantees to participate in the FDA Risk Factor Study, helping to standardize the data collected across the country. Protocols for establishing a Risk Factor Study based on the FDA model can be found on [FoodSHIELD](#), FDA's [Retail Food Risk Factor Study](#) website, and the Standard 9 Risk Factor Study Guidance Document.

Refer to the Standard 9 Risk Factor Study Guidance Document for additional information.