

**Conference for Food Protection  
2016 Issue Form**

**Issue: 2016 II-013**

**Council Recommendation:** Accepted as Submitted \_\_\_\_\_ Accepted as Amended \_\_\_\_\_ No Action \_\_\_\_\_

**Delegate Action:** Accepted \_\_\_\_\_ Rejected \_\_\_\_\_

*All information above the line is for conference use only.*

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**Issue History:**

This is a brand new Issue.

**Title:**

Amend FDA VNRFRPS Standard 9 – Program Assessment

**Issue you would like the Conference to consider:**

Amend Voluntary National Retail Food Regulatory Program Standards (VNRFRPS) Standard No. 9 to adjust the required facility types for a Risk Factor Study, such that nine separate facility type assessments would no longer be a requirement. This would be consistent with FDA's approach to the current Risk Factor Study which no longer includes nine separate facility types.

**Public Health Significance:**

In order to achieve conformance with Program Standard No. 9, a jurisdiction must collect risk factor data every 60 months, write a report and analyze the data, and implement an intervention strategy based on the data collected in the risk factor study. Jurisdictions may collect risk factor data through a risk factor study, or through routine inspectional data. However, jurisdictions must collect data for each facility type identified in Program Standard No. 9, if the facility type is regulated by the jurisdiction. Program Standard No. 9 currently identifies nine (9) specific facility types:

- Institutions
  - Hospitals;
  - Nursing Homes;
  - Elementary Schools (kindergarten through grade 5)
- Restaurants
  - Full Service
  - Fast Food
- Retail Food Stores
  - Delis;

- Meat Departments;
- Seafood Departments;
- Produce Departments

After the completion of FDA's third Risk Factor Study and subsequent Trend Analysis Report, FDA embarked on a revised Risk Factor Study design that incorporates lessons learned from the first ten year study. One substantial modification to the current risk factor study design involves the facility types chosen for the data collection. Rather than collect data for each of the nine facility types, FDA modified its approach by adjusting the facility types within certain facility categories used for data collection. This new design allows for greater flexibility to collect meaningful data and identify trends.

FDA would like enrolled jurisdictions to use this new model, including the changes to the facility type categories, and have the changes incorporated into Program Standard No. 9 as described below. Jurisdictions would continue to be required to collect and analyze data from all facility categories under their regulation, but would incorporate the following new options;

1. Rather than specify the nine (9) facility types that must be included, Program Standard No. 9 would specify four (4) broad facility categories:
  - (1) Health Care;
  - (2) Schools (kindergarten through grade 12);
  - (3) Restaurants;
  - (4) Retail Food Stores.
2. In order to meet Standard 9, jurisdictions would be required to collect and analyze data for each facility category under regulation.
3. Jurisdictions would have flexibility to evaluate patterns and subcategories within each facility category. For instance, a jurisdiction could separate the restaurant category into the traditional 'full service' and 'fast food' type operations, or all restaurants could be evaluated together.

The proposed changes will provide greater efficiency and flexibility, and enable a risk-based approach when measuring the success of a program to reduce the occurrence of foodborne illness risk factors.

**Recommended Solution: The Conference recommends...:**

that a letter be sent to FDA requesting that the Voluntary National Retail Food Regulatory Program Standards (VNRFRPS), Standard Number 9 - Program Assessment, be amended to reflect the changes shown in *"Attachment A - Proposed Amendments to Program Standard No. 9 - Program Assessment."*

Those areas of the Standard with proposed changes are noted below (underline indicates language to be added; strikethrough format used to indicate language to be deleted)

STANDARD 9

PROGRAM ASSESSMENT

This Standard applies to the process used to measure the success of a jurisdiction's program in reducing the occurrence of foodborne illness risk factors to enhance food safety and public health in the community.

### Requirement Summary

Program management must ensure that:

1. 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;
2. An analysis is made of the data collected and a report on the outcomes and conclusions of the risk factor study is written; and
3. A targeted intervention strategy designed to address the occurrence of the risk factor(s) identified in their risk factor study is implemented and the effectiveness of such strategy is evaluated by subsequent risk factor studies or other similar tools.

### Description of Requirement

To achieve the criteria of Standard 9, a jurisdiction must ensure that:

A. A risk factor study and report on the occurrence of the five (5) foodborne illness risk factors must be completed. A risk factor study serves two purposes:

1. To identify risk factors most in need of priority attention in order to develop strategies to reduce their occurrence.
2. To evaluate trends over time to determine whether progress is being made toward reducing the occurrence of foodborne illness risk factors. Studies designed to measure trends require analysis of data over a period of time, and no single point in time can be used to derive trend conclusions.

B. The risk factor study includes all facility ~~types~~ categories under regulation by the jurisdiction.

It is recommended that a jurisdiction's first risk factor study be conducted as soon as possible following its first self-assessment, before programmatic changes are made. There is value in using the first study to establish a "baseline" against which future performance can be measured. Program improvements and changes may then be reflected in subsequent studies.

C. The risk factor study information is to be updated at least once every 60 months to measure trends specific to the occurrence of the five (5) foodborne illness risk factors.

The data collection and analysis ~~for the various facility types under regulation by the jurisdiction~~ may occur at various times over the 60-month period, as long as all facility ~~types~~ categories under regulation are included in the 60-month cycle. The 60-month study update is required to maintain achievement of Standard 9. The subsequent studies and reports will ~~determine whether or not indicate if~~ there has been a net change in the occurrence of the risk factors.

The ~~nine (9)~~ four (4) facility ~~categories~~ types are:

- ~~Institutions~~
  - ~~Hospitals;~~

- ~~Nursing Homes;-~~
  - ~~Elementary Schools (K-5)-~~
  - Restaurants
    - ~~Full-Service-~~
    - ~~Fast-Food-~~
  - ~~Retail Food Stores~~
    - ~~Delis;-~~
    - ~~Meat Departments;-~~
    - ~~Seafood Departments;-~~
    - ~~Produce Departments-~~
1. Health Care:
  2. Schools (K-12):
  3. Restaurants;
  4. Retail Food Stores.

D. A jurisdiction may use routine inspection data or may conduct a separate data collection in completing a risk factor study. A data collection instrument similar to 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 jurisdictions.

E. A jurisdiction must ensure that a targeted intervention strategy designed to address the occurrence of the risk factor(s) identified in their Risk Factor Study is implemented and the effectiveness is evaluated by subsequent Risk Factor Studies or other similar tools. Jurisdictions are encouraged to incorporate various types of interventions such as code changes, educational and training activities, enforcement and compliance strategies, etc. The purpose of the intervention strategy is to attempt to affect improvement in reducing priority risk factor(s) occurrence rates between measurement intervals and assess their effectiveness.

#### Outcome

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.

#### Documentation

The quality records required for this standard include:

1. Survey reports on the occurrence of risk factors and *FDA Food Code* interventions,

2. Survey collection tools or inspection sheets used for the data collection,
3. Documentation that each facility ~~category type under regulated~~ is surveyed during the 60-month survey cycle,
4. Documentation of performed interventions, actions or activities designed to improve the control of risk factors,
5. Documentation that the effectiveness of performed interventions is evaluated.

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**Content Documents:**

- "Attachment A-Proposed Amendments to Program Standard No. 9 - Program Assess"

*It is the policy of the Conference for Food Protection to not accept Issues that would endorse a brand name or a commercial proprietary process.*

## **STANDARD 9 PROGRAM ASSESSMENT**

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## **STANDARD 9 PROGRAM ASSESSMENT**

This Standard applies to the process used to measure the success of a jurisdiction's program in reducing the occurrence of foodborne illness risk factors to enhance food safety and public health in the community.

### **Requirement Summary**

Program management must ensure that:

1. 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;
2. An analysis is made of the data collected and a report on the outcomes and conclusions of the RISK FACTOR STUDY is written; and
3. A targeted intervention strategy designed to address the occurrence of the risk factor(s) identified in their RISK FACTOR STUDY is implemented and the effectiveness of such strategy is evaluated by subsequent RISK FACTOR STUDIES or other similar tools.

### **Description of Requirement**

To achieve the criteria of Standard 9, a jurisdiction must ensure that:

- A. A RISK FACTOR STUDY and report on the occurrence of the five (5) foodborne illness risk factors must be completed. A RISK FACTOR STUDY serves two purposes:
  1. To identify risk factors most in need of priority attention in order to develop strategies to reduce their occurrence.
  2. To evaluate trends over time to determine whether progress is being made toward reducing the occurrence of foodborne illness risk factors. Studies designed to measure trends require analysis of data over a period of time, and no single point in time can be used to derive trend conclusions.
- B. The RISK FACTOR STUDY includes all facility ~~types~~ categories under regulation by the jurisdiction.

It is recommended that a jurisdiction's first RISK FACTOR STUDY be conducted as soon as possible following its first SELF-ASSESSMENT, before programmatic changes are made.

There is value in using the first study to establish a “baseline” against which future performance can be measured. Program improvements and changes may then be reflected in subsequent studies.

- C. The RISK FACTOR STUDY information is to be updated at least once every 60 months to measure trends specific to the occurrence of the five (5) foodborne illness risk factors.

The data collection and analysis ~~for the various facility types under regulation by the jurisdiction~~ may occur at various times over the 60-month period, as long as all facility types categories under regulation are included in the 60-month cycle. The 60-month study update is required to maintain achievement of Standard 9. The subsequent studies and reports will ~~determine whether or not~~ indicate if there has been a net change in the occurrence of the risk factors.

The ~~nine (9)~~ four (4) facility categories types are:

- ~~Institutions~~
    - ~~Hospitals;~~
    - ~~Nursing Homes;~~
    - ~~Elementary Schools (K-5)~~
  - ~~Restaurants~~
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    - ~~Meat Departments;~~
    - ~~Seafood Departments;~~
    - ~~Produce Departments~~
1. Health Care;
  2. Schools (K-12);
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  4. Retail Food Stores.

- D. A jurisdiction may use routine inspection data or may conduct a separate data collection in completing a RISK FACTOR STUDY. A data collection instrument similar to 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 jurisdictions.

- E. A jurisdiction must ensure that a targeted intervention strategy designed to address the occurrence of the risk factor(s) identified in their Risk Factor Study is implemented and the effectiveness is evaluated by subsequent Risk Factor Studies or other similar tools. Jurisdictions are encouraged to incorporate various types of interventions such as code changes, educational and training activities, enforcement and compliance strategies, etc. The purpose of the intervention strategy is to attempt to affect improvement in reducing priority risk factor(s) occurrence rates between measurement intervals and assess their effectiveness.

### **Outcome**

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.

### **Documentation**

The quality records required for this standard include:

1. Survey reports on the occurrence of risk factors and *FDA Food Code* interventions,
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3. Documentation that each facility ~~category type under regulation~~ is surveyed during the 60-month survey cycle,
4. Documentation of performed interventions, actions or activities designed to improve the control of risk factors,
5. Documentation that the effectiveness of performed interventions is evaluated.