CLEAN COPY EXAMPLE Proposed amendments to Program Standard 9 recommended for removal upon inclusion in an Administrative Procedures Addendum.

STANDARD 9
PROGRAM ASSESSMENT

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Standard 9

Program Assessment

This Standard applies to the process used to measure the success of the enrolled 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. 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; and,

2. An analysis is made of the data collected and a report on the outcomes and conclusions of the RISK FACTOR STUDY is written.

Description of Requirement

Achieving Standard 9

To achieve the criteria of Standard 9 and claim Standard 9 as met, a jurisdiction must ensure that:

A. A RISK FACTOR STUDY and report on the occurrence of the five (5) foodborne illness risk factors is 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 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 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 there has been a net change in the occurrence of the risk factors.

The nine (9) facility types are:

- Institutions – 1) Hospitals; 2) Nursing Homes; 3) Elementary Schools (K-5)
- Restaurants – 4) Full Service; 5) Fast Food
- Retail Food Stores – 6) Delis; 7) Meat Departments; 8) Seafood Departments; 9) Produce Departments

(See the FDA's Data Collection Manual for additional information regarding facility types and help with Risk Factor Studies.)

B. A jurisdiction may use routine inspection data or may use a separate data methodology in completing a RISK FACTOR STUDY. A data collection instrument similar to the FDA Model Data Collection Form in the FDA Data Collection Manual, 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. Refer to the Data Collection manual to understand the statistical limitations and restrictions if using an inspection form or a data collection form different from the FDA data collection instrument.

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 *Food Code* interventions;
2. Survey collection tools or inspection sheets used for data collection; and
3. Documentation that each facility type regulated is surveyed during the 60-month survey cycle.