Proposed Amendments to Standard No. 9 – Program Assessment

Due to the amount of formatting and editing changes made and to allow for ease of reading, the language proposed below does not include underline/strike-out format. A full text of the existing language contained in Standard No. 9 can be found beginning on page 6 of this document.

STANDARD NO. 9 PROGRAM ASSESSMENT

This Standard applies to the process used to measure the success of jurisdictions in meeting the *Voluntary National Retail Food Regulatory Program Standards 1 through 9* (hereafter referred to as the National Standards) and their progress in reducing the occurrence of foodborne illness risk factors. Additionally, it applies to the requirements for recognition by the Food and Drug Administration of those jurisdictions meeting the National Standards.

REQUIREMENT SUMMARY

To be an active participant in the *Voluntary National Retail Food Regulatory Program Standards* and to be listed on the FDA Roll of Participating Jurisdictions, a jurisdiction must assure that:

1. 1. The program manager, or a designated representative, conducts an initial SELF-ASSESSMENT against the criteria in each of the nine (9) National Standards within 12 months following the date of enrollment and every 60 months thereafter; and,

1. 2. The program manager, or a designated representative, requests a VERIFICATION AUDIT within 3 months following any SELF-ASSESSMENT in which one or more Standards is claimed as met. The VERIFICATION AUDIT is to be completed within 6 months of that SELF-ASSESSMENT; and,

1. 3. Reporting, using the *FDA National Registry Report* and *Release Record and Agreement -Permission to Publish in National Registry* (FDA Forms 3519 and 3520), will be completed and submitted to the appropriate FDA Regional Office within 30 days following a SELF-ASSESSMENT or an update to a SELF-ASSESSMENT and following any VERIFICATION AUDIT.

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

1. 1. A RISK FACTOR STUDY (SURVEY) 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,

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

DESCRIPTION OF REQUIREMENT

To be an active participant in the National Standards and to be listed on the FDA Roll of Participating Jurisdictions, a jurisdiction must assure that the following procedures for SELF-ASSESSMENTS, VERIFICATION AUDITS, and reporting are completed:

A. Self-Assessment

1. The program manager, or a designated representative, conducts an initial SELF-ASSESSMENT against the criteria in each of the nine (9) National Standards within 12 months of the date of enrollment and every 60 months thereafter.

   If it is determined that a Standard has been met, at that point the Appendix documents (hereinafter referred to as the worksheets) for that Standard(s) are to be completed in preparation of the VERIFICATION AUDIT.

   For any Standard(s) which are not met, it is recommended that any deficiencies in meeting the Standards criteria be identified in order to meet that Standard in the future. It is further recommended that priorities, action plans, and target dates be established to facilitate continuous improvement in the jurisdiction's program.

   The National Standards Edition to be used when completing the required 60-month SELF-ASSESSMENT is the most recent version of the *Voluntary National Retail Food Regulatory Program Standards* published on the FDA web site at http://www.fda.gov. Once at the FDA main web page, click on "Food," then "Food Safety," then "Retail Food Protection" and click on "Program Standards."

2. For any Standard a jurisdiction claims as met:
   a) The compliance status of the jurisdiction's program as measured against that Standard(s) is documented by completing the Appendix documents or documents containing equivalent summary information for that Standard; and,

   b) QUALITY RECORDS specified as requirements in each of the National Standards are established, identified, and maintained. The QUALITY RECORDS must be maintained in such a manner that an AUDITOR can be provided information necessary to verify that a Standard's criteria have been met.

3. This complete SELF-ASSESSMENT cycle must be repeated at a minimum every 60 months. However, a jurisdiction may, and is encouraged to complete a SELF-ASSESSMENT UPDATE at any time during the 60-month interval to reflect the most current information on its program accomplishments as reflected by comparison against one or more of the individual Standards. A SELF-ASSESSMENT UPDATE can be made using the edition of the National Standards effective at its last required SELF-ASSESSMENT or a more recent edition of the National Standards, at the jurisdiction's discretion.

4. Following a SELF-ASSESSMENT UPDATE, a jurisdiction completes the worksheets or equivalent forms to document compliance with any additional National Standard(s) met since the last required SELF-ASSESSMENT, establishes the QUALITY RECORDS, and forwards the *FDA National Registry Report* and *Release Record and Agreement*

-*Permission to Publish in National Registry* (FDA Forms 3519 and 3520) to the appropriate FDA Regional Office within 30 days following a SELF-ASSESSMENT UPDATE.

B. Verification Audit

1. The program manager, or a designated representative, requests a VERIFICATION AUDIT within three (3) months following any SELF-ASSESSMENT or SELF-ASSESSMENT UPDATE in which one or more Standard(s) is claimed as met. The VERIFICATION AUDIT is to be completed within six (6) months of that SELF-ASSESSMENT or SELF-ASSESSMENT UPDATE.

2. A complete SELF-ASSESSMENT of all Standards will be completed every 60 months after the initial SELF-ASSESSMENT. At each complete SELF-ASSESSMENT, a VERIFICATION AUDIT is to be conducted for any standard that is being claimed as met only if the Standard has been revised since the last VERIFICATION AUDIT.

3. An AUDITOR, as defined in the National Standards, shall complete the VERIFICATION AUDIT. VERIFICATION AUDITS confirm and report on the accuracy of a SELF-ASSESSMENT that claims one or more Standard(s) as met. During the VERIFICATION AUDIT, the auditor will:

   a) Review the QUALITY RECORDS and confirm that the SELF-ASSESSMENT accurately reflects the program's compliance status with each criterion for the version of the National Standards that was used when completing the SELF-ASSESSMENT or a SELF-ASSESSMENT UPDATE; and,

   b) Determine whether the QUALITY RECORDS specified as requirements in each of the National Standards have been established, identified, and maintained. If the quality records for a specific program element provide inadequate information upon which to make a determination of conformance with the Standard or to enable a VERIFICATION AUDIT, that Standard is not met.

C. Reporting Requirements for Self-Assessments and Verification Audits

1. Reporting, using the *FDA National Registry Report* and *Release Record and Agreement -Permission to Publish in National Registry* (FDA Forms 3519 and 3520), is completed and submitted to the appropriate FDA Regional Office within 30 days following a SELF-ASSESSMENT or a SELF-ASSESSMENT UPDATE and following any VERIFICATION AUDIT.

2. Submission of the *FDA National Registry Report* and *Release Record and Agreement -Permission to Publish in National Registry* is required following each 60-month SELF-ASSESSMENT regardless of whether any Standard(s) are claimed as met.

3. If a jurisdiction wishes to complete a SELF-ASSESSMENT UPDATE with its most current program information, a new *FDA National Registry Report* (FDA Form 3519) and *Release Record and Agreement -Permission to Publish in National Registry* (FDA

Form 3520) must be submitted. Any report form submitted is marked to show attainment of all applicable Standards achieved at the time of submission. Dates showing attainment for each Standard should be recorded on each submission in order to accurately reflect the program's history. Marking all applicable Standards with their most recent attainment dates ensures that accurate information is posted on the FDA List of Enrolled Jurisdictions.

4. The *FDA National Registry Report* (FDA Form 3519) and *Release Record and Agreement -Permission to Publish in National Registry* (FDA Form 3520) is submitted following a VERIFICATION AUDIT. The date of the audit and the date of the version for the Standard that is being audited should be included on the report forms so that information may be added to the FDA List of Enrolled Jurisdictions.

ACHIEVING STANDARD 9

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

A. A RISK FACTOR STUDY (SURVEY) and report on the occurrence of foodborne illness risk factors is completed. A RISK FACTOR STUDY (SURVEY) 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. A RISK FACTOR STUDY (SURVEY) includes all facility types under regulation by the jurisdiction.

It is recommended that a jurisdiction's first RISK FACTOR STUDY (SURVEY) 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 (SURVEY) information is to be updated at least once every five (5) years 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:

1 o Institutions – 1) Hospitals; 2) Nursing Homes; 3) Elementary Schools (K-5)
2 o Restaurants – 4) Full Service; 5) Fast Food
3 o 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.)

D. A jurisdiction may use routine inspection data or may conduct a separate data collection in completing a Risk Factor Study (Survey). A data collection instrument similar to the FDA Model Data Collection Form in Appendix J, 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. 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. 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. Achievement of Standard 9 is audited using the same procedures and reported using the *FDA National Registry Report* (FDA Form 3519) and *Release Record and Agreement -Permission to Publish in National Registry* (FDA Form 3520) in the same manner as achievement of the other eight National Standards as detailed under **DESCRIPTION OF REQUIREMENTS** in this document for Self-Assessment, Verification Audit, and Reporting.

OUTCOME

The desired outcome of this Standard is to enable managers to measure their program against national criteria. The process identifies program elements that may require improvement or be deserving of recognition.

DOCUMENTATION

The quality records required for this Standard include:

1 1. The completed Appendices (worksheets) for each Standard and supporting records,
2 2. Written reports on the occurrence of RISK FACTOR STUDIES (SURVEYS),
3 3. VERIFICATION AUDIT reports,
4 4. FDA National Registry Report (FDA Form 3519), and
5 5. Affidavit of Permission to Publish (FDA Form 3520).

Existing language

STANDARD NO. 9 PROGRAM ASSESSMENT

This standard applies to the process used to measure the success of jurisdictions in meeting the *Voluntary National Retail Food Regulatory Program Standards 1 through 9* (hereafter referred to as the National Standards) and their progress in reducing the occurrence of foodborne illness risk factors. Additionally, it applies to the requirements for recognition by the Food and Drug Administration of those jurisdictions meeting the National Standards.

Requirement Summary

1. For listing on the FDA Roll of Participating Jurisdictions, a jurisdiction must assure:

   A. That the program manager conducts an initial *self-assessment* within 12 months of the date of enrollment in the National Registry and every 36 months thereafter; and,

   B. That a *verification audit* is conducted within 36 months of the initial *self-assessment*. Subsequent verification audits are conducted every 36 months thereafter.

2. For achievement of Standard 9, a jurisdiction must assure:

   A. That a survey and report on the occurrence of foodborne illness risk factors and the use of *Food Code* interventions is completed within the 36-month period between the self-assessment and the verification audit; and

   B. A survey on the occurrence of foodborne illness risk factors and *Food Code* interventions is conducted at least once every five years thereafter to measure trends specific to the occurrence of the risk factors and interventions.

3. Reporting by means of the FDA National Registry Report form.

Description of Requirement

For Listing on the FDA Roll of Participating Jurisdictions, a jurisdiction must assure that:

1. Self-Assessment

The program manager, or a designated representative, conducts an initial *self-assessment* of the retail food safety program within 12 months of the date of enrollment in the National Registry and every 36 months thereafter. The *self-assessment* will determine:

A. The compliance status with each of the National Standards by completing the Appendix documents (hereafter referred to as the worksheets) or documents containing equivalent summary information for each Standard, and

B. Whether the *quality records* specified as requirements in each of the National Standards have been established, identified, and maintained. If the quality records for a specific program element are incomplete or provide inadequate information upon which to make a determination or to enable a verification audit, that standard is not met.

2. Verification Audit

The first *verification audit* is conducted within 36 months the initial *self-assessment*. An individual as defined in the definitions shall complete the verification audit. Subsequent verification audits are conducted every 36 months thereafter. Verification audits confirm and report on the accuracy of the *self-assessment* and the occurrence of risk factors and *Food Code* interventions survey reports. During the *verification audit*, the auditor will:

A. Review the *quality records* and confirm that the *self-assessment* accurately reflects the current program compliance status in each of the program elements, and

B. Confirm that the occurrence of risk factors survey collection procedures and survey tools similar to Appendix J have been used and that the conclusions are supported by the data.

3. Achievement of Standard 9

A jurisdiction must assure that a survey and report on the occurrence of foodborne illness risk factors and the use of *Food Code* interventions is completed within the 36-month period between the self-assessment and the verification audit. The survey information is updated at least once in every 5 years to measure trends specific to the occurrence of the risk factors and *Food Code* interventions. The subsequent surveys and reports will determine whether there has been a net change in the occurrence of the risk factors and use *Food Code* interventions.

A data collection instrument similar to the FDA model form referenced in 2.B., 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. 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. 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 study or with data from other jurisdictions.

4. Reporting

The FDA National Registry Report (Appendix I) will be completed and submitted to the appropriate FDA Regional office within 30 days following completion of the self-assessment, survey report on the occurrence of foodborne illness risk factors and *Food Code* interventions, verification audits, and/or survey of risk factor occurrence updates. The FDA National Registry listing will be updated using data contained in this report. A current Release and Permission to Publish Form must accompany each FDA National Registry Report.

Outcome

The desired outcome of this Standard is to enable managers to measure their program against national criteria. The process identifies program elements that may require improvement or be deserving of recognition.

Documentation

The quality records required for this standard include:

1. The completed Appendices (worksheets) for each Standard and supporting records,
2. Survey reports on the occurrence of risk factors and *Food Code* interventions,
3. Verification audit reports,
4. FDA National Registry Report, and
5. Affidavit of Permission to Publish.