Conference for Food Protection
2012 Issue Form

Internal Number: 071
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Council Recommendation:	Accepted as Submitted	_____	Accepted as Amended	_____	No Action	_____
Delegate Action:	Accepted	_____	Rejected	_____		

All information above the line is for conference use only.

Title:
Administrative Procedures for Retail Food Program Standards

Issue you would like the Conference to consider:
Jurisdictions that use the Voluntary National Retail Food Regulatory Program Standards would benefit from the availability of a document that describes the processes used by FDA to administer the Program Standards and the processes that FDA expects jurisdictions to follow to "enroll in" and "remain" an active participant. As an addendum to the Program Standards that is maintained by FDA, such a document would serve to consolidate items currently described in Program Standard No. 9 and elsewhere in supporting materials and on websites maintained by FDA.
Currently Standard No. 9 of the Voluntary National Retail Food Regulatory Program Standards contains many of the procedures that jurisdictions are expected to follow if they are to be considered "an active participant" in the Program Standards. Among other things, these procedures address the required frequency for completion of self-assessments and verification audits and how jurisdictions are expected to report progress to FDA for inclusion on FDA Listing of Enrolled Jurisdictions. FDA believes these broad "standards implementation" requirements should be moved from Standard No. 9 to the new addendum, so that Standard No. 9 requirements contain only requirements directly related to a jurisdiction's assessment of their own program.

Public Health Significance:
Currently Standard No. 9 requires jurisdictions to assess their programs by conducting a Risk Factor Study and analysis of the resulting data to track trends over time related to the occurrence of risk factors. The intent of this Standard is for enrolled jurisdictions to track and assess their program outcomes as demonstrated by the occurrence of foodborne illness risk factors over time and to develop and implement strategies to improve food safety in their jurisdiction.
In addition, Standard No. 9 includes administrative requirements related to the self-assessment and auditing of a program against the full set of Program Standards and establishes what must be reported to FDA in order for an agency to be recognized as an "active participant" in the Program Standards.
FDA believes such administrative requirements do not belong in a specific Program Standard and instead belong in an administrative procedures document that more fully

describes the roles and expectations of jurisdictions formally participating in the Program Standards and of FDA in administering the Program Standards. Having a separate procedures document that describes all that is required for active participation and recognition by FDA should make it easier for stakeholders to locate and understand all the procedures related to Program Standards participation. Further, having a separate administrative procedures document should provide FDA more flexibility to improve the ways it implements the Program Standards without changing a recognized Program Standard itself.

Among the items that FDA believes would be best moved to a separate administrative document are those currently in Program Standard No 9. related to:

- the frequency of self-assessments and audits;
- procedures for conducting self-assessments and audits;
- the qualifications of auditors; and
- the submission of forms to FDA for inclusion on the Listing of Enrolled Jurisdictions.

Also appropriate for inclusion in such a document are administrative procedures that are not contained in Standard No. 9 but that would address:

- Program Standards enrollment eligibility;
- Procedures for maintaining FDA's Listing of Enrolled Jurisdictions and other means of recognizing participating jurisdictions;
- Procedures for obtaining interpretations of Program Standards through FDA Program Standards Clearinghouse;
- Procedures for resolving disputes concerning the results of non-conforming verification audits.

Recommended Solution: The Conference recommends...:

that a letter be sent to FDA requesting that:

1. FDA develop and maintain an addendum to the Voluntary National Retail Food Regulatory Program Standards that describes the administrative processes used by FDA to implement the Program Standards and by jurisdictions that choose to be active participants in the Program Standards, and that the addendum address how, and with what frequency, to:
    - Enroll jurisdictions in the Program Standards;
    - Measure and report progress made by jurisdictions in assessing and auditing their programs for conformance with the Voluntary Retail Food Regulatory Program Standards 1 through 9 (including submission of specific forms);
    - Recognize those jurisdictions meeting the Standards, including how jurisdictions are listed on the FDA website;
    - Interpret the Standards and resolve disputes concerning the results of non-conforming audits; and
    - Otherwise successfully implement the Program Standards.
2. Upon availability of an administrative procedures document, FDA will amend Program Standard 9, as shown in Attachments A and B, to remove language that describes the administrative processes used by jurisdictions to demonstrate implementation of the Program Standards but that are not requirements for conformance with Program Standard 9-Program Assessment and to make necessary editorial changes, as needed;

3. During development of the administrative procedures document, FDA consult the CFP Program Standards Committee for input on its content and format and on the placement of such a document as an addendum to the Standards.

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Attachments:

- "Attachment A-EXAMPLE Proposed amendments to Standard 9 for Admin Procedures"
- "Attachment B-CLEAN COPY EXAMPLE Proposed amendments to Standard 9 - Admin"

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.

EXAMPLE of proposed text changes recommended for removal upon inclusion in 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. ~~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~~ Program management must ensure ~~assure~~ that:

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,~~
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,~~
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 a SELF-ASSESSMENT update and following any VERIFICATION AUDIT.~~

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

~~2.~~ 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 ~~risk factors~~; and,

~~3.~~ 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~~

~~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:~~

~~**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[1]. 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 (worksheets) 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 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 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, shall request a VERIFICATION AUDIT within three (3) months following any SELF-ASSESSMENT or SELF-ASSESSMENT 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-ASSESSMENTof 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 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), shall be 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 UPDATEwith 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 current 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.~~

Description of Requirement

Achieving Standard 9

To achieve the criteria of Standard 9 and claim Standard 9 as met, a jurisdiction must ensure ~~assure~~ 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. ~~A~~ 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 ~~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:

   - 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 ~~conduct~~ use a separate data methodology ~~collection~~ in completing a RISK FACTOR STUDY. A data collection instrument similar to the FDA Model Data Collection Form in the FDA Data Collection Manual ~~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. 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.

C. ~~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 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. ~~The completed Appendices (worksheets) for each Standard and supporting records,~~
2. Survey reports on the occurrence of risk factors and *Food Code* interventions;
3. Survey collection tools or inspection sheets used for data collection; and
4. Documentation that each facility type regulated is surveyed during the 60-month survey cycle.
5. ~~Verification audit reports,~~
6. ~~FDA National Registry Report, FDA Form 3519, and~~
7. ~~Affidavit of Permission to Publish, FDA Form 3520.~~

~~The Standard 9: Program Self-Assessment and Verification Audit Form, included as a file on this disk is designed to document the findings from the self-assessment and the verification audit process this Standard~~.

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

STANDARD 9
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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,

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Description of Requirement

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B. The RISK FACTOR STUDY includes all facility types under regulation by the jurisdiction.

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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.

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(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.

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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.

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The quality records required for this standard include:

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