Conference for Food Protection
Committee FINAL Report

COMMITTEE NAME: **Program Standards Committee**

COUNCIL (I, II, or III): **II**

DATE OF REPORT: **11/15/11**

SUBMITTED BY: **Nicole Grisham**

COMMITTEE CHARGE(s):

Issue #: 2010 II-026

Charge: The Conference recommends re-creating the Program Standards Committee to work on the following charges:
1. Serve as a stakeholder group to provide input to an FDA internal working group which will be considering administrative functions such as:
    - Criteria for verification auditors
    - Recommending additional changes or improvements to the Program Standards
2. Formulate resolutions to issues brought before the committee.
3. Report back to Conference at the 2012 CFP Biennial Meeting.

COMMITTEE ACTIVITIES AND RECOMMENDATIONS:

The 2010-2012 Program Standards Committee (PSC) has met on a monthly basis by conference call to provide feedback to the FDA internal working group and to discuss additional changes and improvements to the Program Standards as identified in the committee charge.

Charge 1A – Criteria for verification auditors

Background:

FDA would like feedback on suggested criteria for verification auditors. Currently in Standard No. 9 it states that "an AUDITOR, as defined in the National Standards, shall complete the VERIFICATION AUDIT." An auditor is defined as "any authorized city, county, district, state, federal, tribal, or other third party person who has no responsibilities for the day-to-day operations of that jurisdiction and is charged with conducting a verification audit, which confirms the accuracy of the self-assessment." Additionally, a verification audit is defined as "a systematic, independent examination by an external party to confirm the accuracy of the self-assessment."

Committee work and discussion:

At the time the PSC commenced, a review of Standard No. 9 by the FDA internal working group and steering committee was underway. After discussing the scope of the work that the working group was focused on related to Standard No. 9, the PSC placed evaluating criteria for verification auditors and additional work on hold to avoid duplicating any efforts. The working group identified the need to separate the administrative sections of the Standard from the requirements of the Standard and desired the input of the PSC on these final documents as our direction. This separation was addressed partly to follow the format and logic of the other Standards and to provide better guidance to jurisdictions and auditors. Additionally, the separation allowed for a reevaluation of the components of Standard 9 which identified the possibility that a jurisdiction could conduct repeated Risk Factor Studies without ever implementing any activities designed to reduce the occurrence of foodborne illness risk factors and still meet Standard No. 9 by simply collecting the data. Thus, proposed language was added to the Standard to provide needed grammatical corrections, but more importantly, to ensure that enrolled jurisdictions develop a targeted intervention strategy or strategies designed to address the occurrence of the risk factors identified in their Risk Factor Study; identify procedures to ensure that these strategies are implemented; and evaluate the effectiveness of such strategies by subsequent Risk Factor Studies or other similar tools. The PSC received the draft of the proposed Standard No. 9 language with the administrative sections removed in October 2011 and provided feedback. This feedback was shared with the FDA internal working group in November 2011.

Currently, Standard No. 9 requires jurisdictions to conduct a Risk Factor Study and analysis of the resulting data to track trends over time related to the occurrence of risk factors. What is currently lacking is a requirement for jurisdictions to attempt to improve the compliance rates for the risk factors identified as having a high out of compliance rate in their Risk Factor Study. Although one of the objectives of the Program Standards is to track the results of regulatory efforts over time, as currently written, it is possible that a jurisdiction could conduct repeated Risk Factor Studies without ever implementing any activities designed to reduce the occurrence of foodborne illness risk factors and still meet Standard No. 9 by simply collecting the data.

The proposed additional language as submitted by the Program Standards Committee provides needed grammatical corrections, but more importantly, would ensure that enrolled jurisdictions develop a targeted intervention strategy or strategies designed to address the occurrence of the risk factors identified in their Risk Factor Study, that these strategies are implemented, and the effectiveness of each strategy is evaluated by subsequent Risk Factor Studies or other similar tools.

The proposed language does not require that interventions result in a reduction in the occurrence of the risk factors, simply that it is attempted and measured. It encourages innovative approaches by suggesting jurisdictions consider various types of interventions such as code changes, educational and training activities, enforcement and compliance strategies, etc. The purpose of the proposed intervention strategy is to attempt to effect improvement in reducing priority risk factor occurrences, between measurement intervals and to assess the strategy's effectiveness.

These proposed changes have been included as part of the amendments to Standard 9 as attached (submitted as Issue titled: Amendments to Program Standard No. 9 – Program Assessment).

The FDA internal working group and the PSC have discussed issues and the future work needed on the separation of the administrative pieces from Standard No. 9. Through these discussions, it was determined

that the FDA Center for Food Science and Applied Nutrition will consider submitting an issue to the CFP on the development of an administrative procedures document for the Standards. The PSC supports this concept and proposes the re-created PSC serves as a stakeholder group on the development of this administrative procedures document as part of the PSC charges listed under the submitted issue titled: Re-create Program Standards Committee. The following components of the potential issue from the FDA internal working group are acknowledged and supported by the PSC:

1. The CFP Program Standards Committee recommends that the Food and Drug Administration develop a document that describes the administrative processes it uses to:
   - enroll jurisdictions in the program standards;
   - measure the success of the jurisdictions in meeting the Voluntary Retail Food Regulatory Program Standards 1 through 9;
   - recognize jurisdictions that meet the Standards including how these jurisdictions are listed on the FDA website; and
   - address issues and resolve disputes concerning the results of non-conforming audits.

2. The CFP Program Standards Committee recommends the "active participant" portions of the current Standard 9 in the National Standards be moved to this administrative procedure document. This includes:
   - Self-Assessment
   - Verification Audit
   - Reporting Requirements for Self-Assessment and Verification Audit

3. The CFP Program Standards Committee recommends that the FDA internal working group utilizes this committee as a stakeholder group in the development of the recommended administrative procedures document.

Charge 1B - Recommending additional changes or improvements to the Program Standards

Background:

FDA requested general feedback on the use and implementation of the individual Standards and whether changes are needed to the requirements of one or more of the Standards. If the PSC believes that changes or improvements can be made to one or more of the Standards, please give a brief summary of the changes needed and the reason why.

Committee work and discussion:

The PSC reviewed the Standards and focused efforts on improving applications related to Standard No. 8. The current language of the Standard is felt to be unachievable for many jurisdictions. The PSC reviewed and discussed feedback and concerns expressed by the Standard No. 8 pilot audit conducted at Santa Clara County Department of Environmental Health as a primary baseline for a discussion starting point. The PSC members shared their respective agency's approach to assessing the inspection frequency of retail food establishments, program logistics, and method of determining the number of staff required to execute the program. Additionally, the PSC reviewed data and information from the *2009 FDA Report on the Occurrence of Foodborne Illness Risk Factors in Selected Institutional Foodservice, Restaurant, and Retail Food Store Facility Types* since it was a validated study containing information related to our discussions. From these discussions, it was determined that the PSC would reevaluate the section of Standard No. 8 pertaining to Staffing Levels and the method for determining the number of full-time equivalent staff needed to properly execute a program.

The true intent of Standard No. 8 was discussed and the PSC focused on the section pertaining to Staffing Levels. This part of the Standard recommends "a staffing level of one full-time equivalent (FTE) devoted to food for every 280 – 320 inspections performed". While the PSC believes that this Standard as it applies to staffing level is unachievable for most jurisdictions and does not provide a realistic measurement that can be applied across various retail food regulatory programs across the nation, the majority agreed that if the PSC focused on a resource to assist in assessing the staffing level that valuable information pertaining to the challenges in meeting this Standard could be identified, which in the future could lead to a more attainable staffing level load. This would take additional research and quantitative validations which the PSC, due to limited time and resources, would not be able to adequately achieve. Thus the PSC agreed to focus on the development of a new resource to assist jurisdictions in assessing their staffing levels rather than addressing the current language in Standard No. 8 pertaining to staffing levels at this time. The developed tools are the most logical initial task, and language for staffing levels would be revisited and addressed as part of the PSC charges listed under the submitted issue titled: Re-create Program Standards Committee. The PSC chose to develop a new staffing level assessment resource in an Excel format through discussions and research on how our respective jurisdictions currently attempt to assess this part of the Standard, and revisiting the current guidance provided through the *2011 Self Assess and Audit Disk* for the Standards. The PSC developed the Excel resource to compliment the *Guide to Self Assess* for Standard No. 8.

Additionally, the PSC members utilized the draft Standard No. 8 Assessment Workbook to assess their staffing levels within their respective inspection programs and test the applicability of the new Excel resource. The PSC unanimously agreed that the new Excel resource greatly assisted in interpreting and applying the concepts in this section of the Standard. Through this testing application within the PSC, it was identified that an instruction guide would be a useful element to accompany the new Excel resource. The PSC developed the instruction guide for the new Excel resource to compliment the *Guide to Self Assess* for Standard No. 8 and recommends that both resource documents are made available to enrolled jurisdictions on the FDA web site and on upcoming versions of the *Self Assess and Audit Disk*.

Through the PSC's work, the PSC is recommending the addition of a new resource, Standard No. 8 Assessment Workbook and Instruction Guide (submitted as Issue titled: Standard No. 8 - Assessment Workbook and Instruction Guide).

Recommendation(s) for future charge:

The Program Standards Committee be re-created following the 2012 CFP Biennial Meeting with the following charges:

1. Serve as a stakeholder group to provide input to an FDA internal working group to:
    a. Collaborate on the development of an Administrative Procedures Document to support the Voluntary National Retail Food Regulatory Program Standards; and
    b. Recommend additional changes or improvements to the Program Standards.
2. Explore, assess, and reevaluate Staffing Levels language within Standard No. 8 and recommended any changes.
3. Formulate resolutions to issues brought before the committee and report back at the 2014 CFP Biennial Meeting.

REQUESTED ACTION:

The Program Standards Committee will submit four issues at the 2012 CFP Biennial Meeting based on the recommendation of the committee. These issues are titled:

1. Report - Program Standards Committee
2. Amendments to Standard No. 9 - Program Assessment
3. Standard No. 8 - Assessment Workbook and Instruction Guide
4. Re-Create - Program Standards Committee

Attachments:

- 2010-2012 Program Standards Committee Final Report
- 2010-2012 Program Standards Committee Roster
- Proposed Amendments to Standard No. 9
- Standard No. 8 - Assessment Workbook
- Standard No. 8 - Assessment Workbook Instruction Guide

COMMITTEE MEMBER ROSTER:

- *See attachment titled "2010-2012 Program Standards Committee Roster."*