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COMMITTEE NAME: Program Standards Committee – Standard 8 Subcommittee

DATE OF FINAL REPORT: November 6, 2017 (Revised January 5, 2018)

COMMITTEE ASSIGNMENT: ☐ *Council I* ☒ *Council II* ☐ *Council III* ☒ *Executive Board*

REPORT SUBMITTED BY: Michael Schaffer & David Lawrence, Subcommittee Co-Chairs

COMMITTEE CHARGE(S):

Issue # 2016 II-020

1. Review the "Description of Requirements" for "Staffing Level" to ensure they are accurate, reasonable, and attainable for jurisdictions of all sizes.
2. Report back their findings and recommendation to the 2018 Biennial Meeting of the Conference for Food Protection.

COMMITTEE WORK PLAN AND TIMELINE:

This subcommittee was established by the PSC to address the specific charges in Issue 2016 II-020. Michael Schaffer is the submitter of Issue #2016 II-020. David Lawrence is the previous Chair of the PSC. In addition to the subcommittee co-chairs, who are both local regulators, membership included four (4) state regulators, one (1) industry representative, two (2) FDA consultants, and one (1) CDC consultant. Subcommittee activities have been conducted by conference calls and emails including the Program Standards Committee Chair and Co Vice-Chairs. A great deal of work was accomplished by Mr. Schaffer and his team with Harris County Public Health and Environmental Services. Their work included surveys of VNRFRPS enrollees, data compilation, statistical analysis, and providing graphic representations of data and data analysis to the subcommittee. Subcommittee documents were posted to the Issue 2016 II-020 – Reevaluation of FDA VNRFRPS 8 workgroup folder on FoodSHIELD for review during conference calls to form recommendations.

COMMITTEE ACTIVITIES:

1. *Dates of committee meetings or conference calls:*

   The Standard 8 Subcommittee met eight (8) times by conference call: October 11, 2016; October 28, 2016; November 22, 2016; January 10, 2017; April 17, 2017; August 15, 2017; October 11, 2017; and October 23, 2017. Mr. Schaffer, Mr. Lawrence, and the FDA consultants met by conference call on October 19 and November 2, 2017 to conduct a detailed review of the subcommittee's data, discuss what the subcommittee is proposing, and request FDA consultant feedback.

2. *Overview of committee activities:*

   Following a review the supporting documents attached to Issue #2016 II-020, the subcommittee commenced additional research to reach out to those jurisdictions enrolled in the Program Standards that are identified as meeting Standard 8 following a self-assessment and/or verification audit based on the current Standard 8 "Staffing Level" criteria. *See Voluntary National Retail Food Regulatory Program Standards – Standard 8.* When asked, the jurisdictions that responded were not able to provide their supporting data or documentation. This finding initiated a series of survey-based activities to collect and analyze data from Retail Program Standards enrollees.

   The subcommittee, with support from staff with Harris County Public Health & Environmental Services, distributed a total of three surveys to enrolled jurisdictions who have made progress with the Retail Program Standards except Standard 8. The intent was to:

   a. Help identify barriers to jurisdictions that have not met Standard 8 (including those beyond the current FTE/Inspection ratio);
   b. By comparing "highly performing" regulatory food program enrollees (those who have met six or more of the nine Standards) with enrollees who have met fewer than six Standards, develop an approach that maintains the goal of the Retail Program Standards to measure "where we want to be" rather than "where we are";
   c. Use data to drive and establish a more statistically sound logic model for the FTE/inspection ratio; and
   d. Devise a new formula to calculate Standard 8 "Staffing Level." The proposed calculation/formula will be very much like the calculations in the Manufactured Food Regulatory Program Standards. The variables will be based on an enrollee's inventory of establishments in each risk grouping. The constants will include the median inspection time based on survey data, a re-inspection rate, and a frequency of two (2) inspections each year (at least one every six months) for every food establishment [as prescribed in § 8-401.10(A) of the 2013 FDA Food Code].

3. *Charges COMPLETED and the rationale for each specific recommendation:*

a. Charge 1 was to review the "Description of Requirements" for "Staffing Level" to ensure they are accurate, reasonable, and attainable for jurisdictions of all sizes. This charge has been completed and the subcommittee provides a recommendation in Charge 2. The subcommittee initially revisited the supporting documentation provided by the submitter of Issue #2016 II-020 and decided to conduct additional follow-up with enrolled jurisdictions who are listed on the FDA Registry of Enrolled Jurisdictions as meeting Standard 8 (following a self-assessment and with or without a verification audit). The subcommittee felt that the self-assessment documentation for the FTE/Inspection Ratio requirement would help to identify in what ways conformance with the requirement was being achieved. Unfortunately, efforts to obtain the actual self-assessment documentation from the few enrolled jurisdictions listed on the FDA website as meeting Standard 8 were not successful. Therefore, the subcommittee stopped seeking out this information. The subcommittee quickly reached consensus that the current "Description of Requirements" for Standard 8 "Staffing Level" is neither reasonable nor attainable, even if the FTE/Inspection Ratio requirement was determined by the FDA to be accurate,. The opinion of subcommittee members, who have been a part of the NACCHO Program Standards Mentorship program and/or use the Manufactured Food Regulatory Program Standards, is that the current Standard 8 "Staffing Level" criteria lacks scalability to jurisdictions of various sizes and with varying levels of resources. There have also been significant innovations currently used in both the food industry and regulatory agencies that were not around when the FDA developed the Standard 8 "Staffing Level" FTE/Inspection Ratio criteria.

b. Since efforts to obtain the actual self-assessment documentation from enrolled jurisdictions listed on the FDA website as meeting Standard 8 were not successful, there was a shift to consider similar criteria in Standard 8 of the Manufactured Food Regulatory Program Standards. Why not consider a model that looks at inspection time spent by food establishment risk categorization and considers technological advancements in industry, efficiency improvements within local and state food regulatory programs, methods to conduct risk assessment categorization of food establishments, and policies for establishing inspection frequency based on risk categorization (as listed in the description of requirements for Standard 3 of the Retail Program Standards)?

c. First, with support of staff at Harris County Public Health and Environmental Services, the subcommittee collected and analyzed raw data from enrolled jurisdictions on average inspection times as it related to risk categorizations for food establishments in their inventory. To address any concern about the quality of inspections, the subcommittee identified enrollees who have met six (6) or more of the nine (9) Retail Program Standards as being "highly performing" and most likely to have quality inspection activities. The subcommittee collected 12 data sets from local and state health departments across the country. This information was organized into line graphs that depict, excluding two outliers, the average inspection time spent for inspection for the most common food establishment risk categorization approaches (3 and 4 risk categories). *See Standard 8 - Average Inspection Time by Risk Categorization*. Additionally, there was developed an initial model that incorporated the data to easily calculate the number of employees needed to meet our proposed criteria. *See Standard 8 - Proposed Model Without Outliers and Standard 8 – Productive Hours Calculation Without Outliers*. In order to do regression modeling and other types of statistical analysis, the subcommittee needed at least 18 more data sets.

d. A second survey was conducted and included all Retail Program Standards enrollees. There were 148 respondents from the over 750 enrollees, with 101 enrollees providing sufficient data on total staff, staffing in terms of full-time equivalents (FTEs), number of establishments in their inventory, how establishments are grouped by risk (risk categorization), inspection frequency according to risk, and average inspection time for each risk assignment. When the second survey analysis was presented to the subcommittee, the CDC consultant recommended use of median inspection time and a comparison of the data from the first survey of "highly performing" enrollees to the second survey data to address a concern about quality of inspections. No relative standard deviation was found between enrollees who meet six (s) or more of the nine (9) Standards and those who meet fewer Standards. *See Standard 8 – FTE to Inspection Ratio Calculation (Using Median Inspection Time by Risk Categorization) and Standard 8 - Report Data Analysis Update.*

e. To be more consistent with what Standard 8 considers as "inspection activities" and with the calculation used in Standard 8 of the Manufactured Food Regulatory Program Standards, the subcommittee conducted a follow-up survey with the 101 enrollees requesting the rate at which, in terms of percentage of total inspections, foodborne illness complaint inspections/environmental assessments and follow-up inspections are conducted; and average travel time. *See Standard 8 – Survey Responses for Median Frequency Other Inspection Types & Travel Time.* As a demonstration of how the proposed model may work, Mr. Schaffer used data specific to Texas Department of State Health Services to provide a comparison of the Inspection/FTE Ratio result based on the current calculation and the proposed calculation. *See Standard 8 – Sample Comparison of Current to Proposed Inspection to FTE Calculation.* The FDA consultants requested additional time to review the subcommittee's findings and provide feedback.

f. On October 27, 2017, the FDA consultants provided their feedback for the subcommittee to consider as part of development of recommendation(s). The FDA consultants outlined their feedback as follows:

(1) The current FTE range requirement in Standard 8 represents a standard for jurisdictions to aspire to reach, it is not

necessarily reflective of the current staffing levels in many retail programs.

(2) Draft proposal presents current model as not data driven, however that is inaccurate. The explanation for the current ratio is included as a "*Note" in Standard 8. *See Voluntary National Retail Food Regulatory Program Standards – Standard 8 (page 8-4).* The CFP has also developed a tool for jurisdictions to use for making this calculation that is currently posted on the CFP website as the Standard 8 Staffing Level Assessment Workbook & Instruction Guide.

(3) Need clarification on several points:

i. Clearly define problem – is it that the current ratio is in need of change; is the 4 hours in need of change; other?

ii. Is the proposal to change the criteria from the current 280-320 inspections/FTE to 506-1052 inspections/FTE or is it for the use of a new tool that would have jurisdictions plug in their own numbers to determine if they meet the Standard?

iii. If the proposal is for a tool that jurisdictions would use by plugging in their own numbers:

1. What is the actual formula?
2. What are the components of the formula?
3. What is fixed within the formula and what are the variables?
4. If everything is variable, how can it be a standard? Also need to account for flexibility in jurisdictional categorization (Ex. some may have 1-2 or 1-5, etc.) What is the formula(s)? If it is the second, what is the proposed criteria to meet the Standard?

(4) FDA supports the concept of using a formula that can be customized to reflect specific jurisdictional factors of number of high, med, low risk facilities in their inventory and travel time (maybe also various vacation, training, breaks, etc.) as these are factors that can vary greatly and programs cannot control. We would anticipate that time/frequency would need to be fixed #s and % risk categorization variable.

(5) To be an actual 'standard' the formula would need to include a constant such as agreed upon ideal to represent a 'best practice' value for the number of hours/facility and/or number of inspections/year. The proposed model suggests values based on a survey of the current times and inspectional frequencies, which are not necessarily 'best practice' values. To be a true 'standard' there must be a constant(s) that represents an agreed up ideal for the amount of time/inspection and number of inspections/year rather than the proposed formula that catalogs a jurisdiction's current situation but doesn't relate it to any actual 'standard' value.

(6) These ideal values for inspectional time and frequency need to be agreed upon before a formula that incorporates variations in number of facility risk types and travel are developed.

g. On November 2, 2017, Mr. Schaffer, Mr. Lawrence and the FDA consultants held a conference call to review the FDA consultants' feedback. The consultants are seeking out the source of the information used to determine the current inspections/FTE ratio criteria. The subcommittee stated that its proposed calculation/formula will be very much like the calculations in the Manufactured Food Regulatory Program Standards. *See Manufactured Food Regulatory Program Standards – Appendix 8.2*. The variables will be based on an enrollee's inventory of establishments in each risk grouping. The constants will include the median inspection time based on survey data, a re-inspection rate, and a frequency of two (2) inspections each year (at least one every six months) for every food establishment [as prescribed in § 8-401.10(A) of the 2013 FDA Food Code].

h. Charge 2 is to report back their (the subcommittee's) findings and recommendation to the 2018 Biennial Meeting of the Conference for Food Protection. This charge has been completed. The subcommittee has completed a great amount of work that will serve as the foundation for future progress on the Standard 8 "Staffing Level" requirement. The subcommittee has formed a recommendation to:

(1) Continue to collaborate with the FDA internal Program Standards working group on modifying the "Description of Requirements" for "Staffing Level" in Standard 8 of the FDA Voluntary National Retail Food Regulatory Program Standards (VNRFRPS);

(2) Use the findings of the 2016 – 2018 Program Standards Committee, Standard 8 Subcommittee as the foundation to establish a more statistically sound logic model for the FTE/Inspection ratio and provide the new calculation/formula to be used by a VNRFRPS enrollee to assess the Standard 8 "Staffing Level";

(3) Propose amendments to Standard 8 of the VNRFRPS and the CFP guidance document titled "Standard 8 Staffing Level Assessment Workbook" to incorporate the outcomes of Charges 1 and 2; and

(4) Report back committee outcomes and recommendations to the 2020 CFP Biennial Meeting.

4. *Charges INCOMPLETE and to be continued to next biennium:*

None

COMMITTEE REQUESTED ACTION FOR EXECUTIVE BOARD:

☒ *No requested Executive Board action at this time; all committee requests and recommendations are included as an Issue submittal.*

LISTING OF CFP ISSUES TO BE SUBMITTED BY COMMITTEE:

Issue #8: PSC – Recommendations from Issue 2016 II-020. A recommendation that the 2018 – 2020 Program Standards Committee and the FDA continue to work on changing the Standard 8 "Staffing Level" criteria using a new calculation/formula based on the findings of the 2016-2018 Program Standard Committee, Standard 8 Subcommittee.

List of content documents submitted with this Issue:

(1) none

b. List of supporting attachments: ☐*No supporting attachments submitted*

(1) See Issue titled: Report – 2016-2018 Program Standards Committee; Attachment title: Re-evaluation of VNRFRPS Standard 8 Subcommittee Report

(2) See Issue titled: Report – 2016-2018 Program Standards Committee; Attachment title: Voluntary National Retail Food Regulatory Program Standards – Standard 8

(3) See Issue titled: Report – 2016-2018 Program Standards Committee; Attachment title: Standard 8 - Average Inspection Time by Risk Categorization

(4) See Issue titled: Report – 2016-2018 Program Standards Committee; Attachment title: Standard 8 – FTE to Inspection Ratio Calculator (Using Median Inspection Time by Risk Categorization)

(5) See Issue titled: Report – 2016-2018 Program Standards Committee; Attachment title: Standard 8 – Productive Hours Calculation Without Outliers

(6) See Issue titled: Report – 2016-2018 Program Standards Committee; Attachment title: Standard 8 - Report Data Analysis Update

(7) See Issue titled: Report – 2016-2018 Program Standards Committee; Attachment title: Standard 8 – Proposed Model Without Outliers

(8) See Issue titled: Report – 2016-2018 Program Standards Committee; Attachment title: Standard 8 – Survey Responses for Median Frequency Other Inspection Types & Travel Time

(9) See Issue titled: Report – 2016-2018 Program Standards Committee; Attachment title: Manufactured Food Regulatory Program Standards, Appendix 8.2