

Conference for Food Protection – Committee FINAL Report

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COMMITTEE NAME: Program Standards Committee – Subcommittee #2 (Re-evaluation of Standard 8 Staffing Levels)

DATE OF FINAL REPORT: October 21, 2019 **Date amended:** 12/3/2019

COMMITTEE ASSIGNMENT: Council I Council II Council III Executive Board

REPORT SUBMITTED BY: Michael Schaffer & Peri Pearson, Subcommittee Co-Chairs

COMMITTEE CHARGE(S):

Issue # 2018 II-018

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 supporting attachments listed in the 2016-2018 Program Standards Committee, Standard 8 Subcommittee report as the foundation to establish as 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” and accompanying “Instruction Guide” to incorporate the outcomes of Charges 1 and 2; and
4. Report back committee finding and recommendations to the 2020 Biennial Meeting.

COMMITTEE WORK PLAN AND TIMELINE:

The Standard 8 Subcommittee was established by the Program Standards Committee to address the specific charges in Issue #2016 II-020. Michael Schaffer is the submitter of Issue #2016 II-020. The 2018-2020 subcommittee is continuing the work started in 2016. Mr. Schaffer is a local regulator and Ms. Pearson is a State Regulator, other members of this subcommittee include one (1) local regulator, two (2) industry representatives, two (2) FDA consultants, and one (1) CDC consultant. Subcommittee activities have been conducted by conference calls and emails. A great deal of work was accomplished by Mr. Schaffer and his team with Harris County Public Health. Their work included surveys of Retail Program Standards enrollees, data compilation, statistical analysis, and providing graphic representations of data and data analysis, as well as conducting a Pilot Study to the subcommittee. Subcommittee documents were posted to the Subcommittee #2 workgroup folder on FoodSHIELD for review during conference calls.

COMMITTEE ACTIVITIES:

1. Dates of committee meetings or conference calls:

Subcommittee #2 met eight (6) times by conference call: February 19, 2019; March 19, 2019; May 13, 2019; June 18, 2019; October 17, 2019; and October 21, 2019.

2. Overview of committee activities:

The proposed model for Standard 8 staffing level assessment, developed by Mr. Schaffer’s team with assistance from this (and the 2016-2018) PSC subcommittee, was presented for Subcommittee review. The proposed change provides three options for assessing staffing levels including one which removes the range (280-320 inspections/FTE) and is based on data obtained through surveys conducted by the 2016-18 Subcommittee. The presentation and document are available in the Food Shield Subcommittee #2 Folder. FDA continues to express concern that the proposed changes to Standard 8 staffing levels do not adhere to the “Best Practice” approach that the Standards promote and does not present a uniform staffing level standard. The voting members of Subcommittee #2 support the proposed changes. Mr. Sudler, FDA CIFSAN, agreed to contact a FDA statistician and set up a meeting with Mr. Schaffer to further evaluate the most appropriate use of the data (primarily data related to times assigned to inspection categories). However, we have not been notified of a meeting with an FDA statistician to date.

In August 2019, Subcommittee #2 met with the Program Standards Committee to discuss the work that had been completed to date. A key decision made on the call was to pilot the proposed model with a pool of health departments across the nation. In September 2019, Subcommittee #2 conducted a pilot study of a proposed staffing level evaluation model as decided by the Program Standards Committee. The study consisted of sending a survey to health departments in order to obtain staffing level data and use the proposed model to analyze this data. Harris County Public Health led the study. The Subcommittee shared the result of the Pilot Results with the subcommittee members to get their feedback before drafting an issue requesting modification of the criteria for assessing staffing levels in Standard 8 for consideration by the 2020 CFP.

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

- a. Charge 1 has been completed. We have continued to discuss the proposed model with various FDA members. The FDA members agree that the current assessment tool for staffing level was designed on unrealistic logic based on no known data, making the ratio that passes or fails a jurisdiction in the tool inappropriate. However, there is no consensus on if the new proposed model that has been designed with real data and statistical robustness should modify and/or replace the ratio of the current tool. One main concern is that it does not represent “best practice” from their perspective as the proposed model is derived from real world data of what jurisdictions “currently” do and not what they “should” do. To try to alleviate this concern we’ve demonstrated that the methodology creating the proposed model sought to use data focused more heavily from high performing jurisdictions (i.e., ones that met more standards) but statistical testing verified that high performing jurisdictions had no significantly different data than lower performing ones. To keep the effort to make the proposed model something for jurisdictions to strive to meet, we discussed best practices with high performing jurisdictions and used data from our research that sought to capture what jurisdictions should aim for. The FDA members continue to be hesitant if the proposed model should be used to modify and improve the current assessment tool.
- b. Charge 2 has been completed. In order to verify that the proposed model was statistically sound, Subcommittee #2 worked with Dr. Matthew Koslovsky, a Post-Doctoral Research Associate from Rice University focusing in Biostatistics. He reviewed and approved the below methodology used to create the proposed model. This model was created by using data provided by 105 health departments. The logic behind the proposed model requires that food establishments be categorized by risk level (low, moderate, and high). The first step in creating the proposed model was to analyze if the inspection times and frequencies provided by the health departments were significantly related to the number of standards a health department had met. This was important, since the number of standards a health department met was the only information indicating their performance level. If health departments that met more standards had significantly different inspection times and frequencies than those that did not, it would have been better to only use those values. Statistical analysis demonstrated that there was no significant relationship between the number of standards a health department met and their responses related to inspection time and frequency. Due to this, it was considered sufficient to use either the average or median inspection time and frequency values of all respondents. Further statistical analysis confirmed that the average and median inspection frequency and time values were significantly different for each risk category. In other words, inspection time and frequency was lower for low-risk establishments and was higher for high-risk establishments. Lastly, it was decided that the median, not the average, should be used to remove the effects of extreme values. This was important as the median prevents outliers such as jurisdictions that are inspecting establishments fewer times a year than the FDA recommends, or conducting inspections too fast or too slow as deemed reasonable, from influencing the standardized values in the model. The proposed model works by removing the inspection-to-FTE ratio and instead calculates how many FTEs a health department should have. It does this by first using a formula based on standardized inspection times and frequencies based on risk categories to calculate the total inspection hours for each jurisdiction. It automatically divides this total by the FTE productive hours calculated in the current model to obtain the number of FTEs the health department should have. Lastly, it “passes” the health department if the number of FTEs they currently have is greater than or equal to the number of FTEs the jurisdiction should have. If the health department currently has an equal or greater number of FTEs, as calculated by the proposed model, then the health department would be considered sufficiently staffed; consequently, that health department would meet Standard 8. In order to determine if the proposed model would work in a self-audit, we conducted a pilot study from August to September 2019. The details of the pilot can be reviewed in the supporting document “Standard 8 Re-Evaluation of Staffing Level Model Pilot Study Report”.
- c. Charge 3 has been completed. On October 21, 2019, the members of Subcommittee #2 held a vote to determine the proposed amendments to the Standard 8 of the VNRFRPS and the CFP guidance document. The voting members decided to recommend including both the current and proposed amendment tool to assess compliance for Standard 8. The jurisdiction conducting the self-audit will have the option of using either of the assessments tools to determine compliance for staffing level resources.
- d. Charge 4 has been completed. The subcommittee has devised a recommendation to propose an amendment to the Standard 8 “Staffing Level” FTE/Inspection Ratio criteria. The majority of the subcommittee voting members decided to amend Standard 8 to include the proposed model assessment tool as a secondary option to determine compliance. The intent of the recommendation will not be to weaken the Standard but to provide a secondary assessment tool that measures practical performance of the enrollee against the Standard.

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

- a. 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:

1. PSC Issue #2 New assessment tool for Standard 8 Staffing Level Criteria.

a. List of content documents submitted with this Issue: None

b. List of supporting attachments:

- (1) See Issue titled: Report – 2018-2020 Program Standards Committee; Attachment title: Standard 8 – Proposed Model (see attached PDF)
- (2) See Issue titled: Report – 2018-2020 Program Standards Committee; Attachment title: *Program Standards Committee subcommittee #2 final report* (attached Word)
- (3) See Issue titled: Report – 2018-2020 Program Standards Committee; Attachment title: *2018 Issue* (see page 27 <http://www.foodprotect.org/media/biennialmeeting/council-ii-final-issue-recommendations-1.pdf>)
- (4) See Issue titled: Report – 2018-2020 Program Standards Committee; Attachment title: *2018 Program Standards Committee Final Report* http://www.foodprotect.org/issues/packets/2018Packet/issues/II_013.html. See the Re-evaluation of VNRFRPS Standard 8 Subcommittee Report and supporting attachments for Standard 8.
- (5) See Issue titled: Report – 2018-2020 Program Standards Committee; Attachment title: *Standard 8 Summary* (see attached PDF)
- (6) See Issue titled: Report – 2018-2020 Program Standards Committee; Attachment title: *Standard 8 PowerPoint* (see attached PDF)
- (7) See Issue titled: Report – 2018-2020 Program Standards Committee; Attachment title: Voluntary National Retail Food Regulatory Program Standards – Standard 8 (see <https://www.fda.gov/food/voluntary-national-retail-food-regulatory-program-standards/voluntary-national-retail-food-regulatory-program-standards-november-2019>)
- (8) See Issue titled: Report – 2018-2020 Program Standards Committee; Attachment title: *Standard 8 Re-Evaluation of Staffing Level Model Pilot Study Report* (see attached PDF)