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COMMITTEE NAME: Program Standards Committee subcommittee #5

DATE OF FINAL REPORT: October 24, 2019 Date amended: 12/3/2019

COMMITTEE ASSIGNMENT: Council I X Council II Council III X Executive Board

REPORT SUBMITTED BY: Carrie Pohjola and Bridget Sweet, Co-Chairs

COMMITTEE CHARGE(S):

Issue # 2018 II-021 Amend VNRFRPS-Standard 4-Uniform Inspection Program. The Program Standards Committee was charged to address the Voluntary National Retail Program Standards (VNRFRPS), Program Standard No. 4-Uniform Inspection Program to:

- 1. Research a new model, solution and/or recommendation that will allow large and small jurisdictions to have the same statistical compliance requirements
- 2. Amend audit requirements to include randomized selection of files to be reviewed
- 3. Report back to the 2020 Biennial meeting of the Conference for Food Protection its findings and recommendations.

COMMITTEE WORK PLAN AND TIMELINE:

1. See the Program Standards Committee Work Plan

COMMITTEE ACTIVITIES:

- 1. Dates of committee meetings or conference calls: PSC subcommittee #5 (Issue #2018 II-021) held conference calls on January 2, 2019, January 30, 2019, February 14, 2019, and February 28, 2019 with biweekly calls scheduled from this date on.
- 2. Overview of committee activities:

The committee has met via conference call twice (1-2-2019 and 1-1-30-2019). Conference calls are now scheduled bi-weekly beginning 2-14-2019. Time was spent reviewing Standard 4. Committee members reached out to larger jurisdictions who are enrolled in the standards and have indicated that they have met Standard 4 and the burden of conducting the 3 field exercises with applicable file review over the 5 years. Those agencies that responded were Tri-County Health in Colorado and Florida Dept. of Business and Professional Regulation. The committee is also reviewing the statistical methodology for Standard 4 as well as discussing with the FDA statistician the percentage of each quality element for compliance to be 75%. The committee also reached out to the original submitter, Veronica Bryant, for further clarification on the issue submitted which she provided. Finally, the committee will be reviewing the instructions for auditors and the possibility of random sampling and a randomly selected sample size as opposed to the auditor reviewing all records for each applicable field exercises. The committee met again via phone conference on 2-14-2019 and 2-28-2019 to further discuss the issue. Marc Boyer, CFSAN math statistician, joined the call on 2-14-19 and provided Statistical Methodology and Explanation of the Statistical Model for Standard 4 which is attached. It was decided at the 2/28/2019 meeting by Robert Sudler to submit the issue via questions to the Clearinghouse and to suspend meetings until the Clearinghouse was able to address the questions. The questions submitted can be found in the attached document, Clearinghouse Submission.

On 6/21/1019, further clarification of the Clearinghouse Submission questions were provided to Robert Sudler by Carrie Pohjola (Clearinghouse Submitter) to bring forth to the Clearinghouse group for consideration. Clarification provided for Question 1 was the requirements for the person completing the field exercises and applicable file review to assess the 20 Quality Elements. In addition, clarification for Question 2 was provided on file review of the auditor of an agencies self-assessment and the required file review involved assessing if Standard 4 is being met by an agency. Clarification was provided from the Clearinghouse on Standard 4 and the response is attached.

With regard to the issue of file review of all files during the self-assessment audit of Standard 4 the committee discussed and interpreted, after extensive review of the standard documentation, that file review is not required by the auditor but can be requested upon discretion.

3. Charges <u>COMPLETED</u> and the rationale for each specific recommendation:

a. Čharge 1 – Based on the information provided by the FDA Statistician, small and large jurisdictions already have the same statistical compliance requirements. (See Standard 4 – Statistical Methodology attached PDF)

b. This charge was related to the review of files during an audit. This was discussed and interpreted, after extensive review of the standard documentation, that file review is not required by the auditor. The auditor can request a random number of files to review, upon their discretion. c. Charge 3 – this report serves as completion of this charge.

4. Charges INCOMPLETE and to be continued to next biennium: None

COMMITTEE REQUESTED ACTION FOR EXECUTIVE BOARD:

X 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: None

ATTACHMENTS:

- 1. Content Documents: No draft content documents submitted at this time
- 2. Supporting Attachments
 - a. See Issue titled: Report 2018-2020 Program Standards Committee; Attachment title: CFP PSC Subcommittee CWG Questions (see attached PDF)

b. See Issue titled: Report – 2018-2020 Program Standards Committee; Attachment title: CWG Standard 4 Response (see attached PDF)

c. See Issue titled: Report – 2018-2020 Program Standards Committee; Attachment title: Standard 4 – Statistical Methodology (see attached PDF)