## Committee Final Reports are considered DRAFT until acknowledged by Council or accepted by the Executive Board

COMMITTEE NAME: Program Standards Committee (PSC)

DATE OF FINAL REPORT: October 31, 2019 Date amended: 12/3/2019

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

REPORT SUBMITTED BY: Angie Cyr, Chair; Amanda Douglas, Co-Vice Chair; Andre Pierce, Co-Vice Chair

#### **COMMITTEE CHARGE(S):**

#### Issue # 2018 II-013 Report - Program Standards Committee (PSC)

- 1. Examine whether there is an additional burden placed on enrollees or FDA (in time, money, or added complexity of the Standards) associated with development of a system to ensure that jurisdictions are uniformly recognized for partial achievement of the Standards (charge originally assigned via Issue 2016-II-009);
- 2. Continue work on a cost/benefit analysis for recognizing partial achievement of the VNRFRPS following clarification from the FDA (as noted above) (charge originally assigned via Issue 2016-II-009);
- 3. Identify inconsistencies in language between all Standards in the VNRFRPS; and
- 4. Report back the Committee's findings and recommendations to the 2020 biennial meeting.

# Issue # 2018 II-014 PSC 2 - Improvements to VNRFRPS (Note: These charges were assigned by the Executive Board at their meeting August 21 -22, 2018.)

- **1.** Work with the FDA to include plan review in the VNRFRPS. The committee recognizes that facility design and construction support behaviors that reduce the occurrence of foodborne illness risk factors.
- 2. For the Listing of Jurisdictions Enrolled in the VNRFRPS on the FDA's website: Work with the FDA to identify a means to recognize enrolled jurisdictions that are self-reporting partial achievement of a Standard. For example, place an asterisk (\*) by an agency's name under that particular VNRFRPS Standard to denote partial achievement and a footnote that states the reason why the jurisdiction cannot fully meet the Standard.

#### Issue # 2018 II-018 PSC 3 - Continue Revision of VNRFRPS Standard 8 Staffing Level Criteria

- 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 a more statistically sound logic model for the FTE (full-time equivalent)/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 findings and recommendations to the 2020 Biennial Meeting.

#### Issue # 2018 II-019 PSC 7 - Training of Food Safety Regulatory Professionals

- 1. Continue review of initiatives (existing, new or under development) involving the training, evaluation and/or certification of food safety inspection officers to ensure the sharing of information and eliminate unnecessary redundancy in the creation of work products or assignments of tasks/responsibilities.
- 2. Review the results of the PFP TCWG recommendations for the nationally recognized Retail Food Curriculum based on the Retail Food Competency and Curriculum Framework to determine if changes are needed in the Voluntary National Retail Food Regulatory Program Standards (VNRFRPS) Standard 2 curriculum; including, but not limited to: a) Identifying any gaps and recommendations for change; and b) Reviewing the time frame for completion of Standard 2, Steps 1 through 4, for new hires or staff newly assigned to regulatory retail food protection programs.
- 3. Continue to assess if any changes will be needed in VNRFRPS Standard 2 Trained Regulatory Staff to provide better alignment with Standard 4 of the VNRFRPS.
- 4. Report back the Committee's findings and recommendations to the 2020 biennial meeting.

#### Issue # 2018 II-020 PSC 8 - Approval & Posting of Updated Foodborne Illness Training Crosswalk

- 1. Maintaining the "Crosswalk Requirements for Foodborne Illness Training Programs" document as a resource for content baseline for foodborne illness training;
- 2. Evaluating the following references for inclusion in the Crosswalk document: a) CDC EHS e-Learning on Environmental Assessment of Foodborne Illness Outbreaks https://www.cdc.gov/nceh/ehs/elearn/ea\_fio/ b) FDA Food Related Emergency Exercise Bundle (FREE-B)

https://www.fda.gov/Food/FoodDefense/ToolsEducationalMaterials/ucm295902.htm[CA(1] (updated URL: https://www.fda.gov/food/food-defense-tools-educational-materials/food-related-emergency-exercise-bundle-free-b) c) IS-305: Environmental Health Training in Emergency Response (EHTER) Awareness Level https://training.fema.gov/is/ d) NEHA Certified Foodborne Outbreak Investigator Credential (CFOI) http://neha.org/professional-development/credentials/certified-foodborne-outbreak-investigator-cfoi-credential e) Integrated Food Safety Center of Excellence (CoE) Webinar Series https://www.coefoodsafetytools.org/AllCoEProducts.aspx (updated URL: https://www.coefoodsafetytools.org); and

3. Reporting back any findings and recommendations to each biennial meeting of the Conference for Food Protection.

## Issue # 2018 II-021 Amend VNRFRPS - Standard 4 - Uniform Inspection Program

# ...address the Voluntary National Retail Food Regulatory 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; and
- 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 attached Program Standards Committee Work Plan.
- 2. All subcommittee work was completed in October, 2019. The PSC final report and issue submittals were drafted and submitted to the Executive Director and Conference Chair for review on October 31, 2019.

#### **COMMITTEE ACTIVITIES:**

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

- a. PSC Committee chair and co-vice chairs met via conference call on September 11, 2018 to discuss PSC issues and subcommittee formation.
- b. PSC Committee chair participated in the Clearinghouse Work Group calls on September 25, 2018, February 14, 2019, May 7, 2019 and September 10, 2019.
- c. Full committee meetings were held via conference call or WebEx on October 5, 2018, August 8, 2019 and August 9, 2019.
- d. PSC subcommittee #1 (Issue 2018 II-013 & 2018 II-014) held conference calls on February 19, 2019, March 21, 2019, May 1, 2019, May 30, 2019 and June 27, 2019.
- e. PSC subcommittee #2 (Issue # 2018 II-018) held conference calls on February 19, 2019, March 19, 2019, May 13, 2019, June 18, 2019, October 17, 2019 and October 21, 2019.
- f. PSC subcommittee #3 (Issue # 2018 II-019) held conference calls on December 19, 2018, January 9, 2019, January 23, 2019, February 6, 2019, March 13, 2019, April 10, 2019, May 8, 2019, June 12, 2019, July 17, 2019, August 14, 2019, September 11, 2019 and October 2, 2019. Dates of electronic votes: February 16, 2019 and October 4, 2019.
- g. PSC subcommittee #4 (Issue # 2018 II-020) held a conference call on December 6, 2018. A second call was scheduled for January 23, 2019 but was postponed due to the federal government shutdown. The subcommittee chair reached out to team members individually to discuss progress on their assigned tasks throughout 2019.
- h. 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:

- a. A full committee meeting was held on October 5, 2018. The CFP Anti-trust statement was read and the CFP Master Calendar and committee charges were discussed. The committee has six issues with charges to be worked on. It was decided that a subcommittee will be formed to work on the charges for each issue.
- b. Amanda Douglas, co-vice chair, Andre Pierce, co-vice chair and Angie Cyr, chair, discussed subcommittee formation further on October 5, 2018. It was decided to combine Issue 2018 II-013 and Issue 2018 II-014 since they are closely related. Five subcommittees were formed to work on the assigned charges.
- c. The PSC chair sent an email on October 8, 2018, requesting that committee member's signup for the subcommittees that they are interested in. Co-chairs of the subcommittees were also solicited at that time.
- d. The committee chair created teams for each of the subcommittee's within FoodSHIELD on November 6, 2018 and then sent subcommittee rosters to each of the subcommittee co-chairs so they could begin scheduling subcommittee meetings.
- e. Due to the federal government shutdown, the subcommittees had limited dialogue with our FDA partners for part of the biennium. This had an impact on the subcommittee work on the assigned charges.

- f. Subcommittee #1 (Issue # 2018 II-013 & Issue # 2018 II-014) -The PSC co-vice chair, Andre Pierce took the lead on scheduling subcommittee meetings. His work got the subcommittee on track to complete the assigned charges by the deadline. Members of the committee developed a survey related to partial achievement that was sent to VNRFRPS enrolled jurisdictions in North Carolina and Texas. There were 47 respondents- 91% were local jurisdictions. The results showed that most jurisdictions would like some way to track their partial achievement of standards for internal purposes only. Only three of the 47 respondents wanted a public facing website to report. Nearly half (49%) of the respondents had not heard about the tracking spreadsheet. The committee used the data to develop the position that the tracking spreadsheet is a useful tool for internal self-reporting and needs to be marketed, rather than having a public website for reporting. The issue will reflect these discussions and will close this charge. Additionally, the subcommittee discussed the value of plan review to support behaviors that reduce the occurrence of risk factors associated with foodborne illness. The subcommittee developed draft criteria and is recommending that those ideas be explored further in the next biennium with the submittal of *PSC Issue #5 Continuation of Issue 2018 II—014 PSC2 Plan Review Incorporation in the Program Standards*. The subcommittee also discussed potential inconsistencies in the VNRFRPS. No changes were identified at this time.
- Subcommittee #2 (Issue # 2018 II-018) The work of the subcommittee and the subcommittee co-chairs team at Harris County Public Health 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 of the proposed additional method to determine compliance with the staffing levels in Standard 8. Subcommittee documents were posted to the Subcommittee #2 workgroup folder on FoodSHIELD for review during conference calls. The proposed model for Standard 8 staffing level assessment, developed by Mr. Schaffer's team at Harris County Public Health 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 assigned to work on this issue. See the attached Standard 8 Summary and Standard 8 PowerPoint PDF documents for additional information. 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 supported the proposed changes. Mr. Sudler, FDA CFSAN, 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, as of the due date of this report, we have not been notified of a meeting with an FDA statistician. A statistician with Harris County Public Health did review the pilot study methods and data.
  - In August 2019, Subcommittee #2 met with the voting members of the PCS 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 directed by the PSC. 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 study 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. The consensus was to move forward with an issue proposing an additional model for assessing staffing levels in Standard 8. The existing methods in Standard 8 are maintained and may be used to determine compliance with the staffing level rather than using the new proposed model.
- h. Subcommittee #3 (Issue # 2018 II-019) The conference call on December 19, 2018 was used to review the committee charges, determine the timeline for addressing the charges, and it was decided that FoodSHIELD will be used for document sharing. The conference call on January 9 addressed charge 1, and a list of training, evaluation and/or certification courses available to food safety inspection officers was developed. The conference call on January 23, 2019 addressed charge 3, and the committee started work on a document of the twenty Standard 4 Quality Assurance elements and associated trainings. The conference call on February 6, 2019 provided an overview of the Retail Food Competency and Curriculum Framework from International Food Protection Training Institute (IFPTI) and addressed the time frame for completion of Standard 2, steps 1 through 4. Conference calls March 13, 2019 through July 17, 2019 were to review the IFPTI framework courses. Four teams were assembled with one industry and one regulatory member. Each team was assigned four courses to review (one per month) for its usefulness, whether there is any missing content, and if it should be implemented as "pre" or "post" coursework in the current VNRFRPS Standard 2 curriculum in Appendix B-1. The conference call on August 14, 2019 reviewed the list of charge 1 initiatives for training, certification, and evaluation of food inspection officers, charge 2a, and the recommendations received at that point, i.e. add, replace, or no action and indicating "pre" or "post" coursework. The conference call on September 11, 2019 continued discussion of group recommendations and discussed charge 3. An insufficient number of voting members on the call prohibited voting. On October 2, 2019, the final conference call was held. The group voted on majority of potential issues for charge 2a and charge 3. Voting continued electronically on October 4, 2019. The results of the vote were emailed on October 14 and issue submittal documents compiled.

- i. PSC subcommittee #4 (Issue # 2018 II-020) The subcommittee had discussions regarding the use of the Crosswalk document for Standard #5. In addition, updating previous resources identified, such as CIFOR, occurred in 2019. EATS 102 was evaluated as a resource. EATS 101 is already a resource, so there was no need to review EATS 101. Subcommittee members continued to identify resources and report at the subcommittee meetings. Emphasis was on industry private sector courses. Four of the eight resources currently identified were reviewed for accuracy in order to maintain the Crosswalk document. Pending resources were reviewed against the Crosswalk document, to verify that the reference citations were still accurate. On February 11, 2019, the PSC committee chair reached out to FDA to request Pathlore access to non-regulatory subcommittee members for purposes of materials review related to the subcommittee charges. The subcommittee chair worked directly with the subcommittee members throughout the biennium as they worked on reviewing their assigned resources. The Crosswalk document was updated with the new resources that were reviewed.
- PSC subcommittee #5 (Issue #2018 II-021) Time has been spent reviewing Standard 4. Subcommittee members reached out to larger jurisdictions who are enrolled in the standards and have indicated that they have met Standard 4. Things explored with these agencies was the burden of conducting the 3 field exercises with applicable file review over the 5 year time period. The agencies that responded were Tri-County Health in Colorado and Florida Dept. of Business and Professional Regulation. The subcommittee reviewed the statistical methodology for Standard 4 and had a discussion with the FDA statistician about the percentage of each quality element in order for compliance to be 75%. The subcommittee also reached out to the original Issue submitter, Veronica Bryant, for further clarification on the Issue that was submitted. The subcommittee reviewed 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 exercise. Marc Boyer, CFSAN statistician attended the February 14, 2019 meeting and provided Statistical Methodology and Explanation of the Statistical Model for Standard 4.See the attached Standard 4-Statistical Methodology document provided by FDA. It was decided at the February 28, 2019 meeting, on advice of Robert Sudler, FDA consultant, to submit the issue via questions to the Clearinghouse Work Group (CWG) and to suspend meetings until the CWG was able to address the questions (see CFP PSC Subcommittee CWG Questions attached PDF). The subcommittee submitted the questions to the CWG and provided clarifying information after the May meeting of the CWG. A response was received from the CWG after the September meeting of the CWG. See attached CWG Standard 4 Response PDF. With regards to the charge 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.
- k. The PSC chair solicited feedback from the committee membership on the formation of a Retail Food Alliance due to a request from the Executive Director. The feedback was provided to the Executive Director on January 25, 2019.
- I. The PSC chair assisted the Executive Director with the development of a Supplemental Funding Proposal that was submitted to AFDO on July 24, 2019. The proposed use of the requested funding, should it be granted, is to hold a 2.5 day meeting in 2020 to focus on sharing information about the VNRFRPS.
- m. A full PSC meeting was held on August 9, 2019 to learn about and provide feedback on the FDA's proposed Flexible Funding Model. Maribeth Niesen, FDA, presented the information to the committee during the meeting.
- n. The PSC chair had a conference call with Robert Sudler, FDA, on August 12, 2019 to discuss the upcoming changes to the VNRFRPS. The majority of the changes were the result of previous CFP issue submittals, along with correcting typographical errors. Further action was not needed by the PSC.
- o. A subcommittee was formed to work on the VNRFRPS special session at the 2020 conference. The workshop will be hands on with stations set up for each of the standards. For each standard, a regulatory agency will showcase something they did related to conformance or continuous improvement with meeting the standard.

#### Charges COMPLETED and the rationale for each specific recommendation:

- a. Issue # 2018 II-013 charge #1 Examine whether there is an additional burden placed on enrollees or FDA (in time, money, or added complexity of the Standards) associated with development of a system to ensure that jurisdictions are uniformly recognized for partial achievement of the Standards (charge originally assigned via Issue 2016-II-009). The subcommittee's survey data indicated that most jurisdictions in the surveyed states wanted internal rather than external recognition. The subcommittee concluded there is an undue burden on volunteer auditors to audit components of a standard as well as for FDA to maintain a public facing website. The subcommittee recommended marketing the Self-Assessment tool (see attached *Draft 2017 VNRFRPS Self-Assessment Audit Form*) for internal self-reporting and will ask FDA to maintain it.
- b. Issue # 2018 II-013 charge #2 Continue work on a cost/benefit analysis for recognizing partial achievement of the VNRFRPS following clarification from the FDA (as noted above) (charge originally assigned via Issue 2016-II-009). The subcommittee's survey data indicated that most jurisdictions in the surveyed states wanted internal rather than external recognition. The Self-Assessment tool is an effective way to track partial achievement and report to internal auditors. Based on this information, a cost-benefit analysis of recognizing partial achievement is no longer necessary.

- c. Issue # 2018 II-013 charge #3 The subcommittee did not identify any changes for the VNRFRPS.
- d. Issue # 2018 II-013 charge #4 This report serves as completion of this charge.
- e. Issue # 2018 II-014 charge #2 Based on the survey that was done, the subcommittee feels that this external recognition is not necessary.
- f. Issue # 2018 II-018 charge #1 FDA has been consulted and has participated on subcommittee conference calls. See PSC Issue #2 Recommendation to include a new proposed assessment tool to Standard 8 of VNRFRPS Staffing Level Criteria which has been submitted to resolve this issue.
- g. Issue # 2018 II-018 charge #2 Use the supporting attachments listed in the 2016-2018 Program Standards Committee, Standard 8 Subcommittee report as the foundation to establish a more statistically sound logic model for the FTE (full-time equivalent)/Inspection ratio and provide the new calculation/formula to be used by a VNRFRPS enrollee to assess the Standard 8 "Staffing Level". A more statistically sound model for the FTE/inspection ratio has been developed along with a new formula for calculating staffing needs that may be used by enrollees to assess staff level. This model is proposed as an additional method that may be used to determine compliance with the staffing level in Standard 8. The existing methods in Standard 8 are maintained and may be used to determine compliance with the staffing level.
- h. Issue # 2018 II-018 charge #3 Amendments to Standard 8, the Standard 8 Staffing Level Assessment Workbook and accompanying Instruction Guide have been made and submitted as an Issue.
- i. Issue # 2018 II-018 charge #4 This report serves as the completion of this charge.
- j. Issue # 2018 II-019 charge #1 The committee discussed initiatives (existing, new, or under development) involving the training, evaluation and/or certification available to Food Safety Inspection Officers (FSIO) in their respective jurisdictions (see *PSC subcommittee #3 Charge 1 Training Evaluation and Certification Initiatives* attached PDF).
- k. Issue # 2018 II-019 charge #2a The Committee reviewed 26 Integrated Food Safety System Basic Curriculum courses for Food Protection Professionals provided by the International Food Protection Training Institute (IFPTI) (see attachments *PSC subcommittee #3 Charge 2 IFPTI Course Review and Integrated Food Safety System (IFSS) Food Protection Professionals Curriculum Framework*). Courses B7 Emergency Response and B19 Pest Control were under development and not available for review. After the team's review, the committee discussed the training and voted on whether to (1.) replace existing Standard 2 curriculum in appendix B-1 with the IFPTI course, (2.) add the IFPTI course to existing Standard 2 curriculum in appendix B-1, or (3.) do not include the IFPTI course in existing Standard 2 curriculum in appendix B-1 ("no action"). The committee recommends the following changes to existing Standard 2 (Appendix B-1):
  - i. Reformat Appendix B-1 into a table with training topics in one column and courses which fulfill the curriculum topics in another column. The current formatting implies the course listed is the only course that will fulfill the training requirement. The proposed format better shows that other courses may be used if deemed equivalent by the regulatory jurisdiction. It is anticipated that there may be accessibility issues with ComplianceWire courses in the future and other comparable courses may be needed as substitutions. Attachment *PSC subcommittee #3 Charge 2 Appendix B-1 Reformatted 1st Draft* demonstrates suggested changes to Appendix B-1 using current Standard 2 curriculum; Attachment *PSC subcommittee #3 Charge 2 Appendix B-1 Reformatted 2nd Draft* demonstrates suggested changes to Appendix B-1 with all proposed issues below incorporated.
  - ii. IFPTI Course B2 (CC8029W): Replace FD252, Allergen Management in "post" curriculum. This course is a significant upgrade in course content providing more relevant and up to date information.
  - iii. IFPTI Course B8 Environmental Hazards (CC8024W): Add to "pre" curriculum. The committee agrees this is an important topic, not currently covered in Standard 2 curriculum, necessary for new (Food Safety Inspection Officer's) FSIO's baseline knowledge.
  - iv. IFPTI Course B12 Integrated Food Safety System (CC8018W): Add to "post" curriculum. The committee agrees this is an important topic, not currently covered in Standard 2 curriculum, necessary for new FSIO's baseline knowledge.
  - v. IFPTI Course B15 Jurisdiction (CC8037W): Add to "pre" curriculum. The committee agrees this is an important topic, not currently covered in Standard 2 curriculum, necessary for new FSIO's baseline knowledge.
  - vi. IFPTI Course B16 Labeling (CC8038W): Add to "post" curriculum. The committee agrees this is an important topic, not currently covered in Standard 2 curriculum, necessary for new FSIO's baseline knowledge.

- vii. IFPTI Course B17 Laws, Regulations, Policies, & Procedures (CC8039W): Replace FDA35, Basic Food Law for State Regulators in "pre" courses. This course is a significant upgrade in course content providing more relevant and up to date information.
- viii.IFPTI Course B19 Pest Control: Add to "pre" curriculum. The committee agrees this is an important topic, not currently covered in Standard 2 curriculum, necessary for new FSIO's baseline knowledge.
- ix. IFPTI Course B20 Plumbing: Add to "pre" curriculum. The committee agrees this is an important topic, not currently covered in Standard 2 curriculum, necessary for new FSIO's baseline knowledge.
- x. IFPTI Course B22 Professionalism (CC8025W): Add to "pre" curriculum. The committee agrees this is an important topic, not currently covered in Standard 2 curriculum, necessary for new FSIO's baseline knowledge.
- xi. IFPTI Course B23 Public Health Principles (CC8026W): Replace FDA36, "Public Health Principles" in "pre" courses. The committee agrees this is an important topic, not currently covered in Standard 2 curriculum, necessary for new FSIO's baseline knowledge.
- xii. IFPTI Course B24 Recalls (CC8041W): Add to "post" curriculum. The committee agrees this is an important topic, not currently covered in Standard 2 curriculum, necessary for new FSIO's baseline knowledge.
- xiii.IFPTI Course B25 Sampling (CC8035W): Replace MIC13, Aseptic Sampling, in the pre-requisite curriculum. This course is a significant upgrade in course content providing more relevant and up to date information.
- xiv. IFPTI Course B26 Sanitation Practices (CC8032W): Replace MIC15, Cleaning & Sanitizing, in "pre" courses. This course is a significant upgrade in course content providing more relevant and up to date information.
- xv. IFPTI Course B27 Traceability (CC8042W): Add to "post" curriculum. The committee agrees this is an important topic, not currently covered in Standard 2 curriculum, necessary for new FSIO's baseline knowledge.
- xvi. IFPTI Course B28 Transportation (CC8036W): Add to "post" curriculum. The committee agrees this is an important topic, not currently covered in Standard 2 curriculum, necessary for new FSIO's baseline knowledge.
- I. Issue # 2018 II-019 charge #2b The committee reviewed the time frame for completion of Standard 2, Steps 1 through 4, for new hires or staff newly assigned to regulatory retail food protection programs. The committee voted on February 16, 2019 to increase the timeframe from 18 to 24 months to align with Standard 2 of the Manufactured Food Regulatory Program Standards and to provide adequate time for standardization of staff.
- m. Issue # 2018 II-019 charge #3 The committee reviewed the twenty quality assurance program elements in Standard 4 of the VNRFRPS. It was determined that all but three elements are contained in the CFP Field Training Manual, Training Plan and Log. To better align with training in Standard 2 (see *PSC subcommittee #3 Charge 3 Quality Elements Cross-referenced PDF attached*), the committee recommends adding the following three missing elements to the CFP Field Training Manual, Training Plan and Log:
  - i. Standard 4 Performance Element III: "Verifies that the establishment is in the proper risk category and that the required inspection frequency is being met. Informs the supervisor when the establishment is not in the proper risk category or when the required frequency is not met." Add "Reviewed establishment file for documentation indicating the assigned risk category" to CFP Training Manual Section I Pre-inspection, #2. Reviews establishment file for previous inspection report, complaints on file, and if applicable, required HACCP Plans or documents supporting the issuance of a variance by the agency. Also add "Verified the establishment is assigned the correct risk category, and when necessary, informs the supervisor when the establishment is not in the proper risk category." to CFP Training Manual Section II Inspection Observations and Performance, #3 Uses a risk-based inspection methodology to correctly assess regulations related to employee practices and management procedures essential to the safe storage, preparation, and service of food.
  - ii. Standard 4 Performance Element IX: "Discuss options for the long-term control of risk factors with establishment managers, when the same out-of-control risk factor occurs on consecutive inspections, in accordance with the jurisdiction's policies. Options may include, but are not limited to; risk control plans, standard operating procedures, equipment and/or facility modification, menu modification, buyer specifications, remedial training, or HACCP plans." Add "Discussed options for the long-term control of risk factors with establishment managers when the same out-of-control risk factor occurs on consecutive inspections (e.g., risk control plans, standard operating procedures, equipment and/or facility modification, menu modification, buyer specifications, remedial training, or HACCP plans)" to CFP Training Manual Section II Inspection Observations and Performance, #6 Verifies correction of out of compliance observations identified during previous inspection.
  - iii. Standard 4 Performance Element XVIII: "Documents that options for the long-term control of risk factors were discussed with establishment managers when the same out-of-control risk factor occurs on consecutive inspections. Options may include, but are not limited to, risk control plans, standard operating procedures, equipment and/or facility modification, menu modification, buyer specifications, remedial training, or HACCP

Plans." Add "Documented that options for the long-term control of risk factors were discussed with establishment managers when the same out-of-control risk factor occurs on consecutive inspections" to CFP Training Manual Section IV Written Communication, #1 Completes inspection form per jurisdiction's administrative procedures (e.g., observations; corrective actions; public health reason; applicable code reference; compliance dates).

- n. Issue # 2018 II-019 charge #4 This report serves as completion of this charge.
- o. Issue # 2018 II-020 charge #1 The materials in the current Crosswalk document have been reviewed and the Crosswalk document has been revised. The "Crosswalk Requirements for Foodborne Illness Training Programs" draft document is attached to this report.
- p. Issue # 2018 II-020 charge #2 The materials have been reviewed and the Crosswalk document has been revised. The "Crosswalk Requirements for Foodborne Illness Training Programs" draft document is attached to this report.
- g. Issue # 2018 II-020 charge #3 This report serves as completion of this charge.
- r. Issue # 2018 II-021 charge #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)
- s. Issue # 2018 II-021 charge #2 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.
- t. Issue # 2018 II-021 charge #3 This report serves as completion of this charge.

#### 3. Charges INCOMPLETE and to be continued to next biennium:

- a. Issue # 2018 II-013 charge #3 is a standing PSC charge
- b. Issue #2018 II-014 charge #1 see PSC Issue #5
- c. Issue #2018 II-019 charge #1 is a standing PSC charge
- d. Issue # 2018 II-020 charge #1 is a standing PSC charge

#### **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:

PSC Issue #1: Report - 2018-2020 Program Standards Committee

#### a. List of content documents submitted with this Issue:

- (a.1) Program Standards Committee Final Report (see attached PDF)
- (a.2) Program Standards Committee Roster (see attached PDF)
- (a.3) Program Standards Committee Work Plan (see attached PDF)
- (a.4) Crosswalk Requirements for Foodborne Illness Training Programs Based on Standard 5 2019 Final (attached Word document)
- (a.5) Standard 8 Proposed Model (see attached PDF)
- (a.6) Draft CFP Training Manual Revision
- (a.7) Draft Attachment A CFP Training Plan and Log Revision (attached Word document)

#### b. List of supporting attachments:

- **(b.1)** Program Standards Committee subcommittee #1 final report
- (b.2) Program Standards Committee subcommittee #2 final report
- (b.3) Program Standards Committee subcommittee #3 final report
- (b.4) Program Standards Committee subcommittee #4 final report
- (b.5) Program Standards Committee subcommittee #5 final report

- (b.6) Issue 2018 II-018 (see page 27 http://www.foodprotect.org/media/biennialmeeting/council-ii-final-issue-recommendations-1.pdf)
- (b.7) 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.
- (b.8) Standard 8 Summary (see attached PDF)

(b.9) Standard 8 PowerPoint (see attached PDF)

- (b.10) 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)
- (b.11) Standard 8 Re-Evaluation of Staffing Level Model Pilot Study Report (see attached PDF)
- (b.12) CFP PSC Subcommittee CWG Questions (see attached PDF)
- (b.13) CWG Standard 4 Response (see attached PDF)
- (b.14) Standard 4 Statistical Methodology (see attached PDF)
- (b.15) Partial Achievement Survey (see attached PDF)
- (b.16) CFP Plan Review Guide (see http://www.foodprotect.org/media/guide/2016-plan-review-manual.pdf)
- (b.17) Preliminary Plan Review Proposal (see attached Word document)
- (b.18) PSC subcommittee #3 Meeting #1 Minutes 12 19 2018
- (b.19) PSC subcommittee #3 Meeting #2 Minutes 1 09 2019
- (b.20) PSC subcommittee #3 Meeting #3 Minutes 1 23 2019
- (b.21) PSC subcommittee #3 Meeting #4 Minutes 2 06 2019
- (b.22) PSC subcommittee #3 Meeting #5 Minutes 3 13 2019
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- (b.29) PSC subcommittee #3 Meeting #12 Minutes 10 2 2019
- (b.30) PSC subcommittee #3 Charge 1 Training Evaluation and Certification Initiatives
- (b.31) PSC subcommittee #3 Charge 2 Appendix B-1 Reformatted 1st Draft
- (b.32) PSC subcommittee #3 Charge 2 Appendix B-1 Reformatted 2nd Draft
- (b.33) PSC subcommittee #3 Charge 2 IFPTI Course Review
- (b.34) PSC subcommittee #3 Charge 3 Quality Elements Cross-referenced
- (b.35) Integrated Food Safety System (IFSS) Food Protection Professionals Curriculum Framework
- (b.36) B2 Allergens IFPTI Course Profile
- (b.37) B17 Laws Regulations IFPTI Course Profile
- (b.38) B23 Public Health Principles IFPTI Course Profile
- (b.39) B25 Sampling IFPTI Course Profile
- (b.40) B26 Sanitation Practices IFPTI Course Profile
- (b.41) Standard 2 Appendix B-1 (see https://www.fda.gov/media/86752/download)
- (b.42) B8 Environmental Hazards IFPTI Course Profile
- (b.43) B12 Integrated Food Safety System IFPTI Course Profile
- (b.44) B15 Jurisdiction IFPTI Course Profile
- (b.45) B16 Labeling IFPTI Course Profile
- (b.46) B19 Pest Control IFPTI Course Profile
- (b.47) B20 Plumbing IFPTI Course Profile

- (b.48) B22 Professionalism IFPTI Course Profile
- (b.49) B24 Recalls IFPTI Course Profile
- (b.50) B27 Traceability IFPTI Course Profile
- (b.51) B28 Transportation IFPTI Course Profile
- (b.52) VNRFRPS, Standard 2 (see https://www.fda.gov/food/voluntary-national-retail-food-regulatory-program-standards/voluntary-national-retail-food-regulatory-program-standards-november-2019)
- (b.53) VNRFRPS, Standard 3 (see https://www.fda.gov/food/voluntary-national-retail-food-regulatory-program-standards/voluntary-national-retail-food-regulatory-program-standards-november-2019)
- (b.54) VNRFRPS, Standard 4 (see https://www.fda.gov/food/voluntary-national-retail-food-regulatory-program-standards/voluntary-national-retail-food-regulatory-program-standards-november-2019)
- **(b.55)** CFP Training Manual (see http://www.foodprotect.org/guides-documents/conference-for-food-protection-cfp-field-training-manual-for-regulatory-retail-food-safety-inspection-officers-5-31-13-cfp-update/)
- (b.56) Manufactured Food Regulatory Program Standards (see https://www.fda.gov/MFRPS)
- (b.57) Draft 2017 VNRFRPS Self-Assessment Audit Form

#### 2. 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: 

  No supporting attachments submitted
- (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 PDF)
- (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)

#### 3. PSC Issue #3 Posting updated Crosswalk

- 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: Crosswalk-Requirements for Foodborne Illness Training Programs Based on Standard 5 2019 Final (attached Word document)
- (2) See Issue titled: Report 2018-2020 Program Standards Committee; Attachment title: Program Standards Committee subcommittee #4 final report (attached PDF)
- 4. PSC Issue #4 Maintenance and Posting of the Self-Assessment Tool (SA Tool)
  - 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: Program Standards Committee subcommittee #1 final report (see attached PDF)

(2) See Issue titled: Report – 2018-2020 Program Standards Committee; Attachment title: *Draft 2017 VNRFRPS Self-Assessment Audit Form* (see attached PDF)

#### 5. PSC Issue #5 Continuation of Issue 2018 II-014 PSC2

- a. List of content documents submitted with this Issue:
- b. List of supporting attachments:
- (1) See Issue titled: Report 2018-2020 Program Standards Committee; Attachment title: Program Standards Committee subcommittee #1 final report (see attached PDF)
- (2) See Issue titled: Report 2018-2020 Program Standards Committee; Attachment title: Preliminary Plan Review Proposal (see attached Word document)
- (3) See Issue titled: Report 2018-2020 Program Standards Committee; Attachment title: *CFP Plan Review Guide* (see http://www.foodprotect.org/media/guide/2016-plan-review-manual.pdf)

#### 6. PSC Issue #6 Amend Standard 2 Appendix B-1 format

- 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: Program Standards Committee subcommittee #3 final report (see attached PDF)
- (2) See Issue titled: Report 2018-2020 Program Standards Committee; Attachment title: PSC subcommittee #3 Charge 2 Appendix B-1 Reformatted 1st Draft
- (3) See Issue titled: Report 2018-2020 Program Standards Committee; Attachment title: PSC subcommittee #3 Charge 2 Appendix B-1 Reformatted 2nd Draft
- (4) See Issue titled: Report 2018-2020 Program Standards Committee; Attachment title: Standard 2 Appendix B-1 (see https://www.fda.gov/media/86752/download)

#### 7. PSC Issue #7 Amend Std 2 curriculum to replace select courses with updates

- 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: Program Standards Committee subcommittee #3 final report (see attached PDF)
- (2) See Issue titled: Report 2018-2020 Program Standards Committee; Attachment title: *B2 Allergens IFPTI Course Profile* (see attached PDF)
- (3) See Issue titled: Report 2018-2020 Program Standards Committee; Attachment title: *B17 Laws Regulations IFPTI Course Profile* (see attached PDF)
- (4) See Issue titled: Report 2018-2020 Program Standards Committee; Attachment title: *B23 Public Health Principles IFPTI Course Profile* (see attached PDF)
- (5) See Issue titled: Report 2018-2020 Program Standards Committee; Attachment title: *B25 Sampling IFPTI Course Profile* (see attached PDF)
- (6) See Issue titled: Report 2018-2020 Program Standards Committee; Attachment title: *B26 Sanitation Practices IFPTI Course Profile* (see attached PDF)

#### 8. PSC Issue #8 Amend Standard 2 to include additional "pre" and "post" topics

- 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: Program Standards Committee subcommittee #3 final report (see attached PDF)
- (2) See Issue titled: Report 2018-2020 Program Standards Committee; Attachment title: *B8 Environmental Hazards IFPTI Course Profile* (see attached PDF)
- (3) See Issue titled: Report 2018-2020 Program Standards Committee; Attachment title: *B12 Integrated Food Safety System IFPTI Course Profile* (see attached PDF)
- (4) See Issue titled: Report 2018-2020 Program Standards Committee; Attachment title: *B15 Jurisdiction IFPTI Course Profile* (see attached PDF)
- (5) See Issue titled: Report 2018-2020 Program Standards Committee; Attachment title: *B16 Labeling IFPTI Course Profile* (see attached PDF)
- (6) See Issue titled: Report 2018-2020 Program Standards Committee; Attachment title: *B19 Pest Control IFPTI Course Profile* (see attached PDF)
- (7) See Issue titled: Report 2018-2020 Program Standards Committee; Attachment title: *B20 Plumbing IFPTI Course Profile* (see attached PDF)

- (8) See Issue titled: Report 2018-2020 Program Standards Committee; Attachment title: *B22 Professionalism IFPTI Course Profile* (see attached PDF)
- (9) See Issue titled: Report 2018-2020 Program Standards Committee; Attachment title: *B24 Recalls IFPTI Course Profile* (see attached PDF)
- (10) See Issue titled: Report 2018-2020 Program Standards Committee; Attachment title: *B27 Traceability IFPTI Course Profile* (see attached PDF)
- (11) See Issue titled: Report 2018-2020 Program Standards Committee; Attachment title: *B28 Transportation IFPTI Course Profile* (see attached PDF)

#### 9. PSC Issue #9 Amend Std 2 to increase the time for completion of Steps 1-4

- 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: Program Standards Committee subcommittee #3 final report (see attached PDF)
- (2) See Issue titled: Report 2018-2020 Program Standards Committee; Attachment title: *VNRFRPS, Standard* 2 (see https://www.fda.gov/food/voluntary-national-retail-food-regulatory-program-standards/voluntary-national-retail-food-regulatory-program-standards-november-2019)
- (3) See Issue titled: Report 2018-2020 Program Standards Committee; Attachment title: *Manufactured Food Regulatory Program Standards* (see https://www.fda.gov/MFRPS)

#### 10. PSC Issue #10 Amend CFP Training Manual to add Quality Program Elements

- 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: Program Standards Committee subcommittee #3 final report (see attached PDF)
- (2) See Issue titled: Report 2018-2020 Program Standards Committee; Attachment title: PSC Subcommittee #3 Charge 3 Quality Elements Cross-referenced (attached Word document)
- (3) See Issue titled: Report 2018-2020 Program Standards Committee; Attachment title: Draft Attachment A CFP Training Plan and Log Revision (attached Word document)
- (4) See Issue titled: Report 2018-2020 Program Standards Committee; Attachment title: VNRFRPS, Standard 2 (see https://www.fda.gov/food/voluntary-national-retail-food-regulatory-program-standards/voluntary-national-retail-food-regulatory-program-standards-november-2019)
- (5) See Issue titled: Report 2018-2020 Program Standards Committee; Attachment title: VNRFRPS, Standard 4 (see https://www.fda.gov/food/voluntary-national-retail-food-regulatory-program-standards/voluntary-national-retail-food-regulatory-program-standards-november-2019)
- (6) See Issue titled: Report 2018-2020 Program Standards Committee; Attachment title: CFP Training Manual (see http://www.foodprotect.org/guides-documents/conference-for-food-protection-cfp-field-training-manual-for-regulatory-retail-food-safety-inspection-officers-5-31-13-cfp-update/)
- (7) See Issue titled: Report 2018-2020 Program Standards Committee; Attachment title: *Draft CFP Training Manual Revision*

Last Name	First Name	Position (Chair/Member)	Constituency	Employer	City	State	CFP Region	Telephone	Email
Cyr	Angie	Chair	State Regulator	Minnesota Department of Health	St. Paul	MN	Midwest	651-201-5634	Angie.cyr@state.mn.us
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Sweet	Bridget	Member	Academia	Johnson & Wales University	Providence	RI	Northeast	401-598-5171	bsweet@jwu.edu
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Willis	Richard	Member	Food Service Industry	Mandalay	Las Vegas	NV	Pacific	702-587-2675	rwillis@mandalaybay.com
Edsall	Jean	Member	Food Service Industry	Compass Group	Charlotte	NC	Southeast	704-328-5893	Jean.edsall@compass-usa.com
Lindholm	Jeffrey	Member	Food Industry Support	iCertainty	Chevy Chase	MD	Mid-Atlantic	443-452-1950	Jeff.lindholm@icertainty.com

Click	Krista	At-Large Non- Voting Member	Local Regulator	Hendricks County	Danville	IN	Midwest		kclick@co.hendricks.in.us
Pearson	Peri	Member	State Regulator	Virginia Department of Health	Richmond	VA	Mid-Atlantic	804-864-7692	Peri.pearson@vdh.virginia.gov
Walker	Matthew	Member	State Regulator	Idaho Food Protection Program	Boise	ID	Pacific	208-334-5946	Matthew.walker@dhw.idaho.gov
English	Amber	Member	Local Regulator	Washoe County Health District	Reno	NV	Pacific	775-328-2629	aeenglish@washoecounty.us
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Sylvis	Christine	Member	Local Regulator	Southern Nevada Health District	Las Vegas	NV	Pacific	702-759-0507	sylvis@snhd.org
Pohjola	Carrie	Member	State Regulator	WI DATCP	Galesville	WI	Midwest	715-579-9487	Carrie.pohjola@wisconsin.gov
Speltz	Mark	Member	Elective (State Regulator)	lowa Department of Inspections and Appeals	Des Moines	IA	Southwest	515-669-3266	Mark.speltz@dia.iowa.gov
Straughn	Ki	Member	Elective (Local Regulator)	Public Health Seattle & King County	Bellevue	WA	Pacific	206-718-9241	kstraughn@kingcounty.gov

Mack	James	At-Large Non- Voting Member	State Regulator	WI Department of Agriculture, Trade & Consumer Protection	Madison	WI	Midwest	608-224-4691	James.mack@wisconsin.gov
Copeland	Deanna	At-Large Non- Voting Member	Local Regulator	Harris County Public Health	Dacadona	TX	Southwest	713-274-6443	Deanna.copeland@phs.hctx.net
Mickiewicz	Courtney	Member	State Regulator	Virginia Department of Agriculture and Consumer Services	Virginia Beach	VA	Mid-Atlantic	757-363-3840	courtney.mickiewicz@vdacs.virginia.gov
Read	David	At-Large Non- Voting Member	Food Industry Support	IFPTI	North St. Paul	MN	Midwest	651-485-8905	David.read@ifpti.org
Sudler	Robert	Non-Voting Member	Federal Consultant	FDA				240-402-1943	Robert.sudler@fda.hhs.gov
Kennedy	Katey	Non-Voting Member	Federal Consultant	FDA				503-671-9711, ext. 16	Katey.kennedy@fda.hhs.gov
Kramer	Adam	Non-Voting Member	Federal Consultant	CDC				404-498-1228	Ank5@cdc.gov

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## Crosswalk - Requirements for Foodborne Illness Training Programs Based on Standard 5

#### Introduction:

The 2014 – 2016 Interdisciplinary Foodborne Illness Training Committee (IFITC) was charged with developing a Crosswalk that would identify areas where training programs could be compared to Standard 5 of the Voluntary National Retail Food Regulatory Program Standards. Using the FSMA 205 C (1) Phases of a Food Incident Response CIFOR/RRT/MFRPS/VNRFRPS Crosswalk as a base, the Committee revised the Crosswalk to compare additional training programs that were identified. In addition to the training programs identified in the CIFOR/RRT/MFRPS/VNRFRPS Crosswalk, the IFITC also reviewed:

- 1. National Environmental Health Association (NEHA) course "I-FITT-RR"
- 2. National Environmental Health Association (NEHA) Epi-Ready Foodborne Illness Response Strategies, June 2006

The resulting Crosswalk now identified the content of all the training programs and indicated, using a table format, how these compared to Standard 5. This Crosswalk is called Crosswalk – Requirements for Foodborne Illness Training Programs Based on Standard 5.

The Committee also recognized that in the process of determining gaps the Crosswalk could now have an expanded purpose of (1) identifying available resources related to Foodborne Illness Training; (2) setting a content baseline for the development of Foodborne Illness Training Programs; (3) establishing some consistency for training programs as a whole. The Committee considered this a more powerful interpretation of the first Charge and as such did not include any references to best practices.

The Committee also agreed that this document will be useful to regulators, academics and NGO's when new training programs are being considered especially as it would introduce consistency, a much needed component in Foodborne Illness Training Programs.

In 2016-2018, the Program Standards Committee (PSC) was now charged with maintaining the document. The document was updated with current references for the training materials.

In 2018 – 2020, the PSC used this Crosswalk to identify essential education content of foodborne disease outbreak training programs and update the Crosswalk with additional information. Courses added to the document are CDC EHS e-Learning on Environmental Assessment of Foodborne Illness Outbreaks, FDA Food Related Emergency Exercise Bundle (FREE-B0, IS-305: Environmental Health Training in Emergency Response (EHTER) Awareness Level, NEHA Certified Foodborne Outbreak Investigator Credential (CFOI) and Integrated Food Safety Center of Excellence (CoE) Webinar Series.

The resulting Crosswalk now identifies the content of all the training programs as indicated, using a table format, comparing them to Standard 5. In the interest of saving space, identified "Tools" that did not have a correlating "Reference" to the Standard 5 element being evaluated were removed from the Standard 5 element listing.

### **Industry Related Sources**

The PSC reached out to 50 industry food safety professionals to determine whether or not any companies had developed their own internal training system for investigating foodborne illnesses. We were unable to find any company that have developed their own comprehensive internal training system for investigating foodborne illnesses. There are a variety of documents from public resources, such as from state and federal agencies to teach the basics of investigations. For the most part, the PSC feels that industry needs to be knowledgeable enough to determine if the illness was related to the food that was served or sold and if there was a breakdown in safe food handling practices. Additionally, the industry needs to be as informed as the sanitarians or epidemiologists investigating the outbreak.

#### Acronyms Used:

RRT: Rapid Response Team

**CIFOR**: Council to Improve Foodborne Outbreak Response

MFRPS: Manufactured Food Regulatory Program Standards

IAFP: International Association of Food Protection

**NASDA**: National Association of State Departments of Agriculture – Food Emergency Response Plan Template https://www.nasda.org/policy/issues/food-safety/emergency-management/food-emergency-response-plans

NEHA Epi-Ready: National Environmental Health Association

NEHA I-FITT-RR: Industry-Foodborne Illness Investigation Training and Recall Response

**CDC** – Center for Disease Control

**VNRFRPS**: Voluntary National Retail Food Regulatory Program Standards – Standard 5

CDC EHS: Centers for Disease Control Environmental Health Specialist

**NEHA (CFOI)**: National Environmental Health Association Certified Foodborne Outbreak Investigator credential \*NOTE: The CFOI procedures relate to policies that are part of the exam for purposes of obtaining the credential. Therefore the applicability of the CFOI to Standard 5 is limited.

**IFSCOE**: Integrated Food Safety Center of Excellence

CoE: Center of Excellence

**EATS**: Environmental Assessments Training Series - EATS 102 is a training program designed to reinforce the lessons learned in EATS 101 by providing 4 additional scenarios. The training does reinforce how to perform an environmental investigation and the roles for different team members. It does not necessarily provide written guidelines for a program to incorporate into their procedures.

**EHTER**: Environmental Health Training in Emergency Response \*\*NOTE: EHTER is a face-to-face introductory course designed to provide an overview of potential environmental health topics and guidance that an EH professional may encounter in a disaster situation (primarily focused on natural disasters). It does not address foodborne illness.

### STANDARD 5 - Voluntary National Retail Food Regulatory Program Standards

- 1. Investigative procedures.
- a. The program has written operating procedures for responding to and /or conducting investigations of foodborne illness and food- related injury\*. The procedures clearly identify the roles, duties and responsibilities of program staff and how the program interacts with other relevant departments and agencies. The procedures may be contained in a single source document or in multiple documents.

Tool	Reference
RRT	II. A. Chapter 1
CIFOR	3.1
MFRPS	5.3
IAFP	Page 3-4
NASDA Version 4.0 August 2011	III, V, VI, VII, IX, X
NEHA Epi-	Modules 1, 2,
Ready. Foodborne Illness Response	3, 4,5, 6, 7
Strategies. Edition 2012	
NEHA	Module 1 Building a Partnership: Who and Why?
I-FITT-RR	
NEHA (CFOI)	*Performing Environmental Assessment
IFSCOE	The CoE's are integral to quantitative analysis of foodborne illness investigation. The
	Crosswalk does more than simply identify the content of the training content but makes it easy to access track and verify through certification.
EATS	Lessons 1-4. All four scenarios provide information on the roles and responsibilities of the
	investigation team in an outbreak. The material is presented in an e-learning formatted and
	participants are not provided with written guidelines for further use.
Food Related Emergency Exercise Bundle	Information contained in the Resource, Lead planner and Facilitator's guidelines are
(FREE)	provided depending on scenario.

b. The program maintains contact lists for individuals, departments, and agencies that may be involved in the investigation of foodborne illness, food-related injury\* or contamination of food.

Tool	Reference
RRT	II.B.
	Chapters 2&3
CIFOR	3.6.2.1
MFRPS	5.3.1.2.6
IAFP	Page3-4
NASDA Version 4.0 August 2011	VI, XIV

NEHA Epi-	Module 1
Ready. Foodborne Illness Response	
Strategies. Edition 2012	MALLA A D. T. I. D. A. L. I. MII. A. D. A. L. MIII. A
NEHA	Module 1 Building a Partnership: Who and Why?
I-FITT-RR	NELLA: III C. 31 ODOLE : C.L.II. III O. : D. L. II. N.C. L.
EATS	NEHA, in collaboration with CDC's Environmental Health Services Branch, the National
	Network of Public Health Institutes (NNPHI), EATS provides training on the role of
	environmental assessments in the broader context of outbreak investigations and the food safety system.
Food Related Emergency Exercise Bundle	Several of the scenarios provide contact lists for appropriate contacts on federal level,
(FREE)	websites where key information can be gathered.
	rocedure or a Memorandum of Understanding (MOU) with the appropriate epidemiological
	podborne illness investigations and to report findings. The operating procedure or MOU clearly
identifies the roles, duties, and responsibilities	
Tool	Reference
RRT	II.A.
	Chapter 1
CIFOR	3.1
MFRPS	5.3.1.1
NASDA Version 4.0 August 2011	V, VI, IX, XIII
NEHA	Module 1 Building a Partnership: Who and Why?
I-FITT-RR	Module 4 Epidemiologic Investigation
IFSCOE	The trainings are subject based.
Food Related Emergency Exercise Bundle	The modules would help a jurisdiction to develop the MOU's with the appropriate
(FREE)	program/department.
	r all complaints or referral reports from other sources alleging food-related illness, food-
	n. The final disposition for each complaint is recorded in the log or database and is filed in or
linked to the establishment record for retrieval	
Tool	Reference
RRT	II.E.
	Chapter 11
CIFOR	4.3.4.9
MFRPS	5.5
IAFP	Page 2,3,4 Example logs: page 139-140
NASDA Version 4.0 August 2011	
NEHA Epi-	Module 2
Ready. Foodborne Illness Response	

Strategies. Edition 2012	
NEHA	Module 2 How Do You Recognize a Foodborne Illness?
I-FITT-RR	
IFSCOE	Yes
EHTER	
Food Related Emergency Exercise Bundle	Similar logs or databases are used to facilitate discussion throughout several of the
(FREE)	scenarios presented.
e. Program procedures describe the disposition	n, action or follow-up and reporting required for each type of complaint or referral report.
Tool	Reference
RRT	Chapter 9, 10, 11 & 13
CIFOR	Chapter 4, 4.3, Chapter 5
MFRPS	5.5
IAFP	Page 3-11
NASDA Version 4.0 August 2011	VI, IX
NEHA Epi-	Module 2
Ready. Foodborne Illness Response	
Strategies. Edition 2012	
NEHA	Module 2 How Do You Recognize a Foodborne Illness?
I-FITT-RR	
IFSCOE	Yes the methodologies are covered in the COE
Food Related Emergency Exercise Bundle (FREE)	Similar procedures are referenced throughout the scenarios
	on or follow-up on each complaint or referral report alleging food-related illness or injury within
24 hours.	
Tool	Reference
RRT	Chapters 9, 10, 11 & 13 (pg.212)Subsection D
CIFOR	Chapter 4,5
MFRPS	5.5
NEHA (CFOI)	Detecting Outbreaks
	nd guidance for collecting information on the suspect food's preparation, storage or handling
	ess, food-related injury*, or outbreak investigations.
Tool	Reference
RRT	Chapters 9,10, 11 & 13 (Page 212) Subsection D
CIFOR	Chapter 4, 5
MFRPS	5.5
IAFP NEHA Epi-	Pages 41-45 Module 3, 5, 8

Ready. Foodborne Illness Response	
Strategies. Edition 2012	
NEHA	Module 3 Environmental Assessment Exercise
I-FITT-RR	
CDC	Lesson 4, 5
Foodborne Illness Outbreak Environmental	
Assessments	
NEHA (CFOI)	Performing Environmental Assessment
IFSCOE	Step 1: Detect a Possible Outbreak.
	Step 2: Define and Find Cases
	Step 3: Generate Hypotheses about Likely Sources
	Step 4: Test Hypotheses
	Step 5: Solve Point of Contamination and Source of the Food
	Step 6: Control an Outbreak
	Step 7: Decide an Outbreak is Over
EATS	Lessons 1-4 provides guidance on what information to collect during on site evaluations.
Food Related Emergency Exercise Bundle	The established procedures are referenced and explained throughout several of the
(FREE)	scenarios.
h. Program procedures provide guidance for in	mmediate notification of appropriate law enforcement agencies if at any time intentional food
contamination is suspected.	
Tool	Reference
RRT	Chapter 6, 10
CIFOR	3.1, 3.10, 6.3
MFRPS	
	5.5
IAFP	5.5 Pages 99-103
NASDA Version 4.0 August 2011	
NASDA Version 4.0 August 2011 NEHA Epi-	Pages 99-103
NASDA Version 4.0 August 2011 NEHA Epi- Ready. Foodborne Illness Response	Pages 99-103 V, VI, IX
NASDA Version 4.0 August 2011 NEHA Epi- Ready. Foodborne Illness Response Strategies. Edition 2012	Pages 99-103 V, VI, IX
NASDA Version 4.0 August 2011 NEHA Epi- Ready. Foodborne Illness Response Strategies. Edition 2012 Food Related Emergency Exercise Bundle	Pages 99-103  V, VI, IX  Module 7  The established procedures are referenced and explained throughout several of the
NASDA Version 4.0 August 2011 NEHA Epi- Ready. Foodborne Illness Response Strategies. Edition 2012 Food Related Emergency Exercise Bundle (FREE)	Pages 99-103 V, VI, IX Module 7  The established procedures are referenced and explained throughout several of the scenarios.
NASDA Version 4.0 August 2011 NEHA Epi- Ready. Foodborne Illness Response Strategies. Edition 2012 Food Related Emergency Exercise Bundle (FREE)	Pages 99-103  V, VI, IX  Module 7  The established procedures are referenced and explained throughout several of the
NASDA Version 4.0 August 2011 NEHA Epi- Ready. Foodborne Illness Response Strategies. Edition 2012 Food Related Emergency Exercise Bundle (FREE)	Pages 99-103  V, VI, IX  Module 7  The established procedures are referenced and explained throughout several of the scenarios.  e notification of appropriate state and/or federal agencies when a complaint involves a product
NASDA Version 4.0 August 2011 NEHA Epi- Ready. Foodborne Illness Response Strategies. Edition 2012 Food Related Emergency Exercise Bundle (FREE) i. Program procedures provide guidance for the	Pages 99-103  V, VI, IX  Module 7  The established procedures are referenced and explained throughout several of the scenarios.  e notification of appropriate state and/or federal agencies when a complaint involves a product
NASDA Version 4.0 August 2011  NEHA Epi- Ready. Foodborne Illness Response Strategies. Edition 2012  Food Related Emergency Exercise Bundle (FREE)  i. Program procedures provide guidance for the that originated outside the agency's jurisdiction	Pages 99-103  V, VI, IX  Module 7  The established procedures are referenced and explained throughout several of the scenarios.  e notification of appropriate state and/or federal agencies when a complaint involves a product or has been shipped interstate.  Reference
NASDA Version 4.0 August 2011  NEHA Epi- Ready. Foodborne Illness Response Strategies. Edition 2012  Food Related Emergency Exercise Bundle (FREE)  i. Program procedures provide guidance for the that originated outside the agency's jurisdiction  Tool  RRT	Pages 99-103  V, VI, IX  Module 7  The established procedures are referenced and explained throughout several of the scenarios.  e notification of appropriate state and/or federal agencies when a complaint involves a product or has been shipped interstate.  Reference  Chapter 6, 10
NASDA Version 4.0 August 2011 NEHA Epi- Ready. Foodborne Illness Response Strategies. Edition 2012 Food Related Emergency Exercise Bundle (FREE) i. Program procedures provide guidance for the that originated outside the agency's jurisdiction	Pages 99-103  V, VI, IX  Module 7  The established procedures are referenced and explained throughout several of the scenarios.  e notification of appropriate state and/or federal agencies when a complaint involves a product or has been shipped interstate.  Reference

IAFP	Pages 6-7
NASDA Version 4.0 August 2011	IV, V, VI, IX, XII, XV
NEHA Epi-	Module 7
Ready. Foodborne Illness Response	
Strategies. Edition 2012	
CDC	Lesson 7
Foodborne Illness Outbreak Environmental	
Assessments	
NEHA (CFOI)	Detecting Outbreaks
IFSCOE	Colorado Integrated Food Safety Center of Excellence (CoE). The CoE's identify and
	develop model practices in foodborne disease surveillance and outbreak response.
Food Related Emergency Exercise Bundle	The established procedures are referenced and explained throughout several of the
(FREE)	scenarios.
2. Reporting Procedures	
	ated illness, food-related injury* or intentional food contamination are identified in each on-site
investigation report.	
Tool	Reference
RRT	Chapters 9, 10, 11
CIFOR	5.2
MFRPS	5.3
IAFP	Pages 34-41
NEHA Epi-	Modules 5, 8
Ready. Foodborne Illness Response	
Strategies. Edition 2012	
Strategies. Edition 2012 NEHA	Module 3 Environmental Assessment Exercise
Strategies. Edition 2012 NEHA I-FITT-RR	
Strategies. Edition 2012  NEHA I-FITT-RR  CDC	Module 3 Environmental Assessment Exercise  Lesson 2
Strategies. Edition 2012  NEHA I-FITT-RR  CDC Foodborne Illness Outbreak Environmental	
Strategies. Edition 2012  NEHA I-FITT-RR  CDC Foodborne Illness Outbreak Environmental Assessments	Lesson 2
Strategies. Edition 2012  NEHA I-FITT-RR  CDC Foodborne Illness Outbreak Environmental Assessments  NEHA (CFOI)	Lesson 2  Reviewing Investigation Findings
Strategies. Edition 2012  NEHA I-FITT-RR  CDC Foodborne Illness Outbreak Environmental Assessments	Lesson 2  Reviewing Investigation Findings  An example: Evaluation of Nebraska Foodborne Illness and Outbreak Response Using the
Strategies. Edition 2012  NEHA I-FITT-RR  CDC Foodborne Illness Outbreak Environmental Assessments  NEHA (CFOI)	Lesson 2  Reviewing Investigation Findings  An example: Evaluation of Nebraska Foodborne Illness and Outbreak Response Using the Council to Improve Foodborne Outbreak and Response (CIFOR) Proposed Performance
Strategies. Edition 2012  NEHA I-FITT-RR  CDC Foodborne Illness Outbreak Environmental Assessments  NEHA (CFOI)  IFSCOE	Lesson 2  Reviewing Investigation Findings  An example: Evaluation of Nebraska Foodborne Illness and Outbreak Response Using the Council to Improve Foodborne Outbreak and Response (CIFOR) Proposed Performance Measures 01/11/2017
Strategies. Edition 2012  NEHA I-FITT-RR  CDC Foodborne Illness Outbreak Environmental Assessments  NEHA (CFOI)	Lesson 2  Reviewing Investigation Findings  An example: Evaluation of Nebraska Foodborne Illness and Outbreak Response Using the Council to Improve Foodborne Outbreak and Response (CIFOR) Proposed Performance Measures 01/11/2017  Lessons 1-4. The training focuses on understanding how the foodborne illness could have
Strategies. Edition 2012  NEHA I-FITT-RR  CDC Foodborne Illness Outbreak Environmental Assessments  NEHA (CFOI)  IFSCOE  EATS	Lesson 2  Reviewing Investigation Findings  An example: Evaluation of Nebraska Foodborne Illness and Outbreak Response Using the Council to Improve Foodborne Outbreak and Response (CIFOR) Proposed Performance Measures 01/11/2017  Lessons 1-4. The training focuses on understanding how the foodborne illness could have occurred and identifying the contributing factors.
Strategies. Edition 2012  NEHA I-FITT-RR  CDC Foodborne Illness Outbreak Environmental Assessments  NEHA (CFOI)  IFSCOE  EATS  Food Related Emergency Exercise Bundle (FREE)	Lesson 2  Reviewing Investigation Findings  An example: Evaluation of Nebraska Foodborne Illness and Outbreak Response Using the Council to Improve Foodborne Outbreak and Response (CIFOR) Proposed Performance Measures 01/11/2017  Lessons 1-4. The training focuses on understanding how the foodborne illness could have

with CDC.			
Tool	Reference		
RRT	Chapters 3, 6, 13		
CIFOR	4.2, 4.3, 4.4, 7.5, 9.1		
MFRPS	5.5		
IAFP	Page 75		
NEHA Epi-	Module 8		
Ready. Foodborne Illness Response			
Strategies. Edition 2012			
NEHA	Module 7 Final Report & Recovery		
I-FITT-RR			
CDC	Lesson 8		
Foodborne Illness Outbreak Environmental			
Assessments			
IFSCOE	Yes		
EATS	Lessons 1-4. The training includes reporting on findings from the investigation		
Food Related Emergency Exercise Bundle	Sharing of final reports is outlined within the scenarios		
(FREE)			
3. Laboratory Support Documentation			
provide analytical support to the jurisdiction's for	written procedures, contract or MOU acknowledging, that a laboratory(s) is willing and able to bood program. The documentation describes the type of biological, chemical, radiological n be identified by the laboratory. The laboratory support available includes the ability to sample analysis, and clinical sample analysis.		
Tool	Reference		
CIFOR	4.2, 4.3, 4.4, 9.1,		
MFRPS	5.3.3.4		
IAFP			
NASDA Version 4.0 August 2011	VI		
NEHA Epi-	Modules 4 & 5		
Ready. Foodborne Illness Response			
Strategies. Edition 2012			
NEHA	Module 5 Collecting Samples and Laboratory Testing		
I-FITT-RR IFSCOE Yes Food Related Emergency Exercise Bundle (FREE) Lab documentation procedures are shared during the scenarios.			
		b. The program maintains a list of alternative la	aboratory contacts from which assistance could be sought in the event that a food-related

emergency exceeds the capability of the primary support lab(s) listed in paragraph 3.a. This list should also identify potential sources of laboratory support such as FDA, USDA, CDC, or environmental laboratories for specific analysis that cannot be performed by the jurisdiction's primary laboratory(s).

Tool	Reference
CIFOR	4.2, 4.3,
	4.4, 9.1
MFRPS	5.5
NASDA Version 4.0 August 2011	VI
NEHA (CFOI)	Collecting Samples
IFSCOE	Yes
Food Related Emergency Exercise Bundle	The scenarios presented in the modules address these issues.
(FREE)	

#### 4. Trace-back Procedures

a. Program management has an established procedure to address the trace-back of foods implicated in an illness, outbreak or intentional food contamination. The trace-back procedure provides for the coordinated involvement of all appropriate agencies and identifies a coordinator to guide the investigation. Trace-back reports are shared with all agencies involved and with CDC.

Tool	Reference		
RRT	Chapter 9		
CIFOR	5.2		
MFRPS	5.3.3.3		
IAFP	Forms J 1, 2 & 3 (pg. 154-154)		
NASDA Version 4.0 August 2011	VI, IX		
NEHA Epi-	Module 5		
Ready. Foodborne Illness Response			
Strategies. Edition 2012			
NEHA	Module 8 Food Recalls		
I-FITT-RR			
CDC	Lesson 7		
Foodborne Illness Outbreak Environmental			
Assessments			
NEHA (CFOI)	Conducting Product Tracing		
IFSCOE Yes			
Food Related Emergency Exercise Bundle	Lab documentation procedures are shared during the scenarios.		
(FREE)			
E Danalla			

#### 5. Recalls

a. Program management has an established procedure to address the recall of foods implicated in an illness, outbreak or intentional food contamination.

Tool	Reference	
RRT	Chapter 12	
CIFOR	5.2.4.1.1	
MFRPS	5.3.2.2	
NASDA Version 4.0 August 2011	VI, IX	
NEHA Epi-	Module 5	
Ready. Foodborne Illness Response		
Strategies. Edition 2012		
NEHA	Module 8 Food Recalls	
I-FITT-RR		
Food Related Emergency Exercise Bundle (FREE)	The scenarios presented in the modules address these issues.	
	o request or monitor a product recall, written procedures equivalent to 21 CFR, Part 7 are	
followed.		
Tool	Reference	
RRT	Chapter 12	
CIFOR	5.2	
NASDA Version 4.0 August 2011	VI, IX	
NEHA I-FITT-RR	Module 8 Food Recalls	
Food Related Emergency Exercise Bundle	The scenarios presented in the modules address these issues.	
(FREE)		
c. Written policies and procedures exist for veri	c. Written policies and procedures exist for verifying the effectiveness of recall actions by firms (effectiveness checks) when requested by	
another agency.		
Tool	Reference	
RRT	Chapter 12	
CIFOR	5.2	
IAFP		
NEHA	Module 8 Food Recalls	
I-FITT-RR		
NEHA (CFOI)	Conducting Product Testing	
Food Related Emergency Exercise Bundle The scenarios presented in the modules address these issues.  FREE)		
6. Media Management		

a. The program has a written policy or procedure that defines a protocol for providing information to the public regarding a foodborne illness outbreak or food safety emergency. The policy/procedure should address coordination and cooperation with other agencies involved in the investigation. A media person is designated in the protocol.

Tool	Reference
RRT	Chapters 3 & 6
CIFOR	3.6
MFRPS	5.3.4.2
IAFP	Page 73 and 105
NASDA Version 4.0 August 2011	VI, IX, XI
NEHA Epi-	Module 8
Ready. Foodborne Illness Response	
Strategies. Edition 2012	
NEHA	Module 6 Control Measures
I-FITT-RR	Module 8 Food Recalls
NEHA (CFOI)	Preparing for Investigation Reviewing Investigation Findings
IFSCOE	Yes
Food Related Emergency Exercise Bundle	The scenarios presented in the modules address these issues.
(FREE)	

#### 7. Data Review and Analysis

a. At least once per year, the program conducts a review of the data in the complaint log or database and the foodborne illness and food-related injury\* investigations to identify trends and possible contributing factors that are most likely to cause foodborne illness or food-related injury\*. These periodic reviews of foodborne illnesses may suggest a need for further investigations and may suggest steps for illness prevention.

Tool	Reference
RRT	Chapters 13 & 14
CIFOR	4.3, Chapter 8, 5.2.9
IAFP	2 & 3
NASDA Version 4.0 August 2011	XIV
NEHA Epi-	Module 2
Ready. Foodborne Illness Response	
Strategies. Edition 2012	
IFSCOE	Yes
Food Related Emergency Exercise Bundle	The scenarios presented in the modules address these issues.
(FREE)	

- b. The review is conducted with prevention in mind and focuses on, but is not limited to, the following:
- 1) Foodborne Disease Outbreaks\*, Suspect Foodborne Outbreaks\* and Confirmed Foodborne Disease Outbreaks\* in a single establishment;
- 2) Foodborne Disease Outbreaks\*, Suspect Foodborne Outbreaks\* and Confirmed Disease Outbreaks\* in the same establishment type;
- 3) Foodborne Disease Outbreaks\*, Suspect Foodborne Outbreaks\* and Confirmed Foodborne Disease Outbreaks\* implicating the same food;

- 4) Foodborne Disease outbreaks\*, Suspect Foodborne Outbreaks\* and Confirmed Foodborne Disease Outbreaks\* associated with similar food preparation processes;
- 5) Number of confirmed foodborne disease outbreaks\*;
- 6) Number of foodborne disease outbreaks\* and suspect foodborne disease outbreaks\*;
- 7) Contributing factors most often identified;
- 8) Number of complaints involving real and alleged threats of intentional food contamination; and
- 9) A number of complaints involving the same agent and any complaints involving unusual agents when agents are identified.

Tool	Reference	
RRT	Chapters 13 & 14	
CIFOR	4.3, Chapter 8	
IFSCOE	Campylobacter Outbreak at a Colorado Correctional Facility A Foodborne Outbreak Investigation Case Study [ Available at the COE in Colorado]	

c. In the event that there have been no food-related illness or food-related injury\* outbreak investigations conducted during the twelve months prior to the data review and analysis, program management will plan and conduct a mock foodborne illness investigation to test program readiness. The mock investigation should simulate a response to an actual confirmed foodborne disease outbreak\* and include onsite inspection, sample collection, and analysis. A mock investigation must be completed at least once per year when no foodborne disease outbreak\* investigations occur.

Tool	Reference	
RRT	Chapter 8	
IFSCOE	Mock scenarios are part of the investigative process	

## **FTE DATA CALCULATION**

Calculate productive hours per year for an employee doing 100% food inspections

Information For One Employee	Hours/Year	Hours/Day	Total Hours
Annual FTE Hours Per Year: Industry Standard			2080
Local Holiday Hours Per Year			0
Local Vacation Leave Hours Per Year			0
Local Sick Leave Hours Per Year			0
Local Family-Personal Leave Hours Per Year			0
Productivity Factoring Per Year			
Travel Time For Inspection			2080
Administrative Work (in-office work)			2080
Break time			2080
Others			2080
Personal Development Time Per Year			
Professional Development			2080
Others			2080
Productive Annual FTE Hours Per Year (FTE Conversion	Factor)		2080

ı	FOOD	SAFFTY	INSPECTION	HOLIRS	PFR VFΔR
ı	FUUD	SALLI	INSPECTION	HUUNS	PEN IEAN

Position Title	Percent of time spent on food inspections	Number of Employees	Total Hours
			0
			0
			0
			0
			0
			0
Total Food Safe	ety Inspection Hours		
Total Current F	TE		0.0

Actual working days	Actual working weeks
260	52



NUMBER OF FOOD SAFETY INSPECTIONS			
Type of Food Safety Inspection	# of Food Safety Inspections		
	_		
Total	0		

## STANDARD 8's REQUIRED FTE FOR YOUR JURISDICTION

	Low Risk Establishments	Frequency of Low Risk Est Inspections Per Year
Routine and Permitting		1.00
Follow Up Inspections/Reinspections		
Foodborne Illness Complaints		
Other		

## Total Number of Required Inspections

Median Hours Spent Per Inspection	0.75	
Total Inspection Time		

## Total Required FTE

## Standard 8.1 Staffing Level

#### Sources

-2017 Subcommittee # 2 - Survey 1 and 2

-2019 Pilot Study

Moderate Risk Establishments	Frequency of Moderate Risk Est Inspections Per Year	High Risk Establishments	Frequency of High Risk Est Inspections Per Year	Total
	2.00		3.00	0
				0
				0
				0
				0
1.25		2.00		
				0
				0.00
				Standard not met





#### **Draft CFP Training Manual Revision**

This mock-up includes proposed language in red to be added to the CFP Training Manual, pgs. 7-8, to better align Standard 2 with Standard 4:

#### **PERFORMANCE ELEMENTS**

The *CFP Training Plan and Log* contains a total of 23 "performance elements" within the six (6) inspection training areas.

- I. Pre-Inspection (2 Performance Elements)
  - Has the required equipment and forms to conduct the inspection.
  - Reviews establishment file for the <u>current risk category assigned</u>, previous inspection report, complaints on file, and if applicable, required HACCP Plans or documents supporting the issuance of a variance.
- II. Inspection Observations and Performance (7 Performance Elements)
  - Provides identification as a regulatory official to the person in charge, confirming agency authority for the inspection, and stating the purpose of the visit.
  - Has knowledge of the jurisdiction's laws, rules, and regulations required for conducting retail food/foodservice inspections.
  - Uses a risk-based inspection methodology to assess regulations related to employee practices and management procedures essential to the safe storage, preparation, and service of food and verify the establishment is assigned the correct risk category.
  - Obtains immediate corrective action for out of compliance employee practices and management procedures essential to the safe storage, preparation and service of food.
  - Correctly assesses the compliance status of other regulations (Good Retail Practices) that are included in the jurisdiction's prevailing statutes, regulations, and/or ordinances.
  - Verifies correction of out of compliance observations identified during the previous inspection. <u>Discusses options for the long-term control of risk factors.</u>
  - Correctly uses inspection equipment during the joint inspection.

#### IV. Written Communication – (3 Performance Elements)

- Completes inspection form per the jurisdiction's administrative procedures (e.g., observations, corrective actions, public health reasons, applicable code references, options for the long-term control of risk factors, compliance dates).
- Includes with the inspection report any compliance or regulatory documents identified or cross-referenced in written statements (e.g., exhibits, attachments, sample forms, embargo forms, destruction forms, suspension notices).
- Presents the inspection report, and when necessary cross-referenced documents, to the person in charge.

### Draft Attachment A - CFP Training Plan and Log Revision

This mock-up includes proposed language in red to be added to Attachment A – CFP Training Plan and Log, to better align Standard 2 with Standard 4:

**I. Pre-Inspection** 

2. Reviews establishment file for the <u>current risk category assigned</u> , previous inspection report, complaints on file, and if applicable, required HACCP Plans or documents supporting the issuance of a variance.	Training Method	Date Demonstrated By the Trainee	Trainee's Initials	Training Officer Initials
Reviewed previous inspection report noting documented out of compliance observations and comments.	JFT/OD			
Reviewed establishment file for complaint reports.	JFT/OD			
Reviewed establishment file for documentation indicating a need for a HACCP Plan.	JFT/OD			
Reviewed establishment file for documentation of food production or processes operating under a variance issued by the jurisdiction	JFT/OD			
Reviewed establishment file for documentation indicating the assigned risk category.				_

Addresses Standard 4 - Quality Assurance Program Element III

**II.** Inspection Observations and Performance (continued)

11. This pection Observations and I er	ioi illulic	e (continue)	<u>u.,</u>	
3. Uses a risk-based inspection methodology to correctly assess regulations related to employee practices and management procedures essential to the safe storage, preparation, and service of food and verify the establishment is assigned the correct risk category.	Training Method	Date Demonstrated By the Trainee	Trainee's Initials	Training Officer Initials
Verified Demonstration of Knowledge of the person in charge.	JFT			
Verified approved food sources (e.g., food from regulated food processing plants; shellfish documentation; game animal processing; parasite destruction for certain species of fish intended for raw consumption; receiving temperatures).	JFT			
Verified food safety practices for preventing cross-contamination of ready-to-eat food.	JFT			
Verified food contact surfaces are clean and sanitized, protected from contamination from soiled cutting boards, utensils, aprons, etc., or raw animal foods	JFT			
Verified the restriction or exclusion of ill employees. Verified no bare hand contact with ready-to-eat foods (or use of a preapproved, alternative procedure)	JFT			
Verified employee handwashing.	JFT			
Verified cold holding temperatures of foods requiring time/temperature control for safety (TCS food), or when necessary, verified that procedures are in place to use time alone to control bacterial growth and toxin production.	JFT			
Verified date marking of ready-to-eat foods TCS food held for more than 24 hours.	JFT			
Verified cooking temperatures to destroy bacteria and parasites.	JFT			
Verified hot holding temperatures of TCS food or when necessary, that procedures were in place to use time alone to prevent the outgrowth of spore-forming bacteria.	JFT			
Verified cooling temperatures of TCS food to prevent the outgrowth of spore-forming or toxin-forming bacteria.	JFT			
Verified reheating temperatures of TCS food for hot holding.	JFT			
Verified the availability of a consumer advisory for foods of animal origin served raw or undercooked.	JFT			
Identified food processes and/or procedures that require a HACCP				

Plan per the jurisdiction's regulations.	JFT		
Verified the establishment is assigned the correct risk category, and when necessary, informs the supervisor when the establishment is not in the proper risk category.	JFT		

Addresses Standard 4 - Quality Assurance Program Element III

**II. Inspection Observations and Performance (continued)** 

6. Verifies correction of out of compliance observations identified during previous inspection. <u>Discusses options for the long-term control of risk factors.</u>		Date Demonstrated By the Trainee	Trainee's Initials	Training Officer Initials
Verified correction of out of compliance observations identified during the previous inspection.	JFT			
Discussed options for the long-term control of risk factors with establishment managers when the same out-of-control risk factor occurs on consecutive inspections (e.g., risk control plans, standard operating procedures, equipment and/or facility modification, menu modification, buyer specifications, remedial training, or HACCP plans).				

Addresses Standard 4 - Quality Assurance Program Element IX

#### **IV. Written Communication**

1. Completes inspection form per the jurisdiction's administrative procedures (e.g., observations, corrective actions, public health reasons, applicable code references, options for the long-term control of risk factors, compliance dates).	Training Method	Date Demonstrated By the Trainee	Trainee's Initials	Training Officer Initials
Used correct inspection form.	JFT			
Completed a legible report.	JFT			
Accurately documented observations made during inspection.	JFT			
Completed inspection form in accordance with jurisdiction's administrative procedures.	JFT			
Cited correct code provisions/rules/regulations.	JFT			
Documented immediate corrective action for out-of-compliance foodborne illness contributing factors and Food Code Interventions (listed in Section II, Item 3).	JFT			
Documented time frames for correcting each out of compliance observation.	JFT			
Documented that options for the long-term control of risk factors were discussed with establishment managers when the same out-of-control risk factor occurs on consecutive inspections				

Addresses Standard 4 - Quality Assurance Program Element XVIII

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COMMITTEE NAME: Program Standards Committee - Subcommittee #1

DATE OF FINAL REPORT: 10/31/2019

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

REPORT SUBMITTED BY: Andre C. Pierce

#### **COMMITTEE CHARGE(S):**

#### Issue #2018 II-013

- 1. Examine whether there is an additional burden place on enrollees or FDA (in time, money, or added complexity of the Standards) associated with development of a system to ensure that jurisdictions are uniformly recognized for partial achievement of the Standards (charge originally assigned via Issue 2016 II-009)
- 2. Identify work on a cost/benefit analysis for recognizing partial achievement of the VNRFRPS following clarification from the FDA (charge originally assigned via 2016 II-009)
- 3. Identify inconsistencies in language between all Standards in the VNRFRPS

Issue #2018 II-014 - not originally assigned as a charge - Executive Board asked the PSC to continue work with partial recognition (#1) and plan review (#3)

- 1. 2018 II-014 #1 Recognize that enrolled agencies, especially local regulator, may not have control over their retail food regulations. Recognize efforts made to achieve this standard when the gap can be documented by the enrollee as part of their Standard 1 self-assessment.
- 2. 2018 II-014 #3 Work with PSC to include plan review in the VNRFRPS. The committee recognizes that facility design and construction support behaviors that reduce the occurrence of foodborne illness risk factors.

#### **COMMITTEE WORK PLAN AND TIMELINE:**

- 1. See the Program Standards Committee Work Plan document.
- 2. All subcommittee work was completed in October, 2019.

#### **COMMITTEE ACTIVITIES:**

- 1. Dates of committee meetings or conference calls: 2/19/2019, 3/21/2019, 5/30/2019, and 6/27/2019.
- 2. Overview of committee activities: Subcommittee #1 (Issue # 2018 II-013 & Issue # 2018 II-014) The PSC co-vice chair, Andre Pierce took the lead on scheduling subcommittee meetings. His work got the subcommittee on track to complete the assigned charges by the deadline. Members of the committee developed a survey related to partial achievement that was sent to VNRFRPS enrolled jurisdictions in North Carolina and Texas. There were 47 respondents- 91% were local jurisdictions. The results showed that most jurisdictions would like some way to track their partial achievement of standards for internal purposes only. Only three of the 47 respondents wanted a public facing website to report. Nearly half (49%) of the respondents had not heard about the tracking spreadsheet. The committee used the data to develop the position that the tracking spreadsheet is a useful tool for internal self-reporting and needs to be marketed, rather than having a public website for reporting. The issue will reflect these discussions and will close this charge. Additionally, the subcommittee discussed the value of plan review to support behaviors that reduce the occurrence of risk factors associated with foodborne illness. The subcommittee developed draft criteria and is recommending that those ideas be explored further in the next biennium with the submittal of PSC Issue #5 Continuation of Issue 2018 II—014 PSC2 Plan Review Incorporation in the Program Standards. The subcommittee also discussed potential inconsistencies in the VNRFRPS. No changes were identified at this time.

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

- a. 2018 II-013 #1 The subcommittee determined through a survey that Jurisdictions need tools to report progress on compliance with the Retail Program Standards to their boards, councils and other policy makers. The self-assessment tool is adequate for presenting data internally. The subcommittee developed an issue asking FDA to maintain and publish the SA Tool
- b. 2019 II-013 #2 The subcommittee determine there is minimal burden to maintain and post the SA Tool on the FDA website
- c. 2018 II-014 #1 The subcommittee determined through a survey that Jurisdictions need tools to report progress on compliance with the Retail Program Standards to their boards, councils and other policy makers. The self-assessment tool is adequate for presenting data internally. The subcommittee developed an issue asking FDA to maintain and publish the SA Tool

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

a. 2018 II-014#3 – The subcommittee recommends continuation of Issue 2018 II-014, charge 1, to have the FDA work with the Program Standards Committee (PSC) to incorporate plan review in the Voluntary National Retail Food Regulatory Program Standards (VNRFRPS).

#### 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:

- 1. PSC Issue #4 Maintenance and Posting of the Self-Assessment Tool (SA Tool)
  - a. List of content documents submitted with this Issue: None
  - b. List of supporting attachments:
    - (1) Subcommittee #1 Final Report (see attached PDF)
    - (2) Draft 2017 VNRFRPS Self-Assessment Audit Form (see attached PDF)
- 2. PSC Issue #5 Continuation of Issue 2018 II-014 PSC2
  - a. List of content documents submitted with this Issue:
  - b. List of supporting attachments: 

    No supporting attachments submitted
  - (1) Subcommittee #1 Final Report (see attached PDF)
  - (2) Preliminary Plan Review Proposal
  - (3) CFP Plan Review Guide (see http://www.foodprotect.org/media/guide/2016-plan-review-manual.pdf)

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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 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 2016-2918 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 Reevaluation 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)

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COMMITTEE NAME: Program Standards (PSC), Subcommittee 3

DATE OF REPORT: 
☐ Final subcommittee report

Date submitted: 10/31/2019 Date amended (if applicable): 12/3/2019 Date accepted by Executive Board: Click here to enter a date.

COMMITTEE ASSIGNMENT: 
Council II Council II Council III Executive Board

REPORT SUBMITTED BY: Christine Sylvis, Co-Chair and Kenesha Williamson, Co-Chair

#### COMMITTEE CHARGE(S): Issue # 2018-II-019

Collaborate with the FDA Office of Training Education and Development (OTED) and the Partnership for Food Protection Training and Certification Workgroup (PFP TCWG) to:

- 1. Continue review of all initiatives (existing, new or under development) involving the training, evaluation and/or certification of food safety inspection officers to ensure the sharing of information and eliminate unnecessary redundancy in the creation of work products or assignments of tasks/responsibilities.
- 2. Review the results of the PFP TCWG recommendations for the nationally recognized Retail Food Curriculum based on the Retail Food Competency and Curriculum Framework to determine if changes are needed in the Voluntary National Retail Food Regulatory Program Standards (VNRFRPS) Standard 2 curriculum; including, but not limited to:
  - a. Identifying any gaps and recommendations for change; and
  - **b.** Reviewing the time frame for completion of Standard 2, Steps 1 through 4, for new hires or staff newly assigned to regulatory retail food protection programs.
- Continue to assess if any changes will be needed in VNRFRPS Standard 2 Trained Regulatory Staff to provide better alignment with Standard 4 of the VNRFRPS.
- 4. Report back findings and recommendations to the 2020 Biennial Meeting of the Conference for Food Protection.

#### **COMMITTEE WORK PLAN AND TIMELINE:**

An introductory meeting in December 2018 followed by bi-weekly meetings January - February 2019 then monthly meetings through September 2019. Workgroup documents will be shared via FoodSHIELD and attached to calendar invitations. WebEx will be used for presenting workgroup material and reviewing documents, during monthly meetings. The committee's regulatory members will be assigned portions of the national framework courses to evaluate for discussion with the group. Polls will be forwarded via email, as needed, to voting members to finalize recommendations. Periodic reports will be prepared and submitted in February 2019, July 2019, and October 2019, in accordance with the CFP master calendar.

#### **COMMITTEE ACTIVITIES:**

#### 1. Overview of committee activities:

- a. Dates of committee conference calls: December 19, 2018, January 9, 2019, January 23, 2019, February 6, 2019, March 13, 2019, April 10, 2019, May 8, 2019, June 12, 2019, July 17, 2019, August 14, 2019, September 11, 2019, and October 2, 2019. Dates of electronic votes: February 16, 2019 and October 4, 2019.
- b. The conference call on December 19, 2018 was used to review the committee charges, determine the timeline for addressing the charges, and it was decided that FoodSHIELD will be used for document sharing. The conference call on January 9 addressed charge 1, and a list of training, evaluation and/or certification courses available to food safety inspection officers was developed. The conference call on January 23, 2019 addressed charge 3, and the committee started work on a document of the twenty Standard 4 Quality Assurance elements and associated trainings. The conference call on February 6, 2019 provided an overview of the Retail Food Competency and Curriculum Framework from International Food Protection Training Institute (IFPTI) and addressed the time frame for completion of Standard 2, steps 1 through 4. Conference calls March 13, 2019 through July 17, 2019 to review the IFPTI framework courses. Four teams were assembled with one industry and one regulatory member. Each team was assigned four courses to review (one per month) for its usefulness, whether there is any missing content, and if it should be implemented as "pre" or "post" coursework in the current VNRFRPS Standard 2 curriculum in Appendix B-1. The conference call on August 14, 2019 reviewed the list of charge 1 initiatives for training, certification, and evaluation of food inspection officers, charge 2a, and the recommendations received at that point, i.e. add, replace, or no action and indicating "pre" or "post" coursework. The conference call on September 11, 2019 continued discussion of group recommendations and discussed charge 3. Insufficient number of voting members on the call prohibited voting. On October 2, 2019, the final conference call was held. The group voted on majority of potential issues for charge 2a and charge 3. Voting continued electronically on October 4, 2019. The results of the vote were

emailed on October 14.

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

- a. Charge 1: The committee discussed initiatives (existing, new, or under development) involving the training, evaluation and/or certification available to Food Safety Inspection Officers (FSIO) in their respective jurisdictions (see attachment PSC subcommittee #3 Charge 1 Training Evaluation and Certification Initiatives).
- b. Charge 2a: The Committee reviewed 26 Integrated Food Safety System Basic Curriculum courses for Food Protection Professionals provided by the International Food Protection Training Institute (IFPTI) (see attachments PSC subcommittee #3 Charge 2 IFPTI Course Review and Integrated Food Safety System (IFSS) Food Protection Professionals Curriculum Framework). Courses B7 Emergency Response and B19 Pest Control were under development and not available for review. After the team's review, the committee discussed the training and voted on whether to (1.) replace existing Standard 2 curriculum in appendix B-1 with the IFPTI course, (2.) add the IFPTI course to existing Standard 2 curriculum in appendix B-1, or (3.) do not include the IFPTI course in existing Standard 2 curriculum in appendix B-1 ("no action"). The committee recommends the following changes to existing Standard 2 (Appendix B-1):
  - i. Reformat Appendix B-1 into a table with training topics in one column and courses which fulfill the curriculum topics in another column. The current formatting implies the course listed is the only course that will fulfill the training requirement. The proposed format better shows that other courses may be used if deemed equivalent by the regulatory jurisdiction. It is anticipated that there may be accessibility issues with ComplianceWire courses in the future and other comparable courses may be needed as substitutions. Attachment PSC subcommittee #3 Charge 2 Appendix B-1 Reformatted 1st Draft demonstrates suggested changes to Appendix B-1 using current Standard 2 curriculum; Attachment PSC subcommittee #3 Charge 2 Appendix B-1 Reformatted 2nd Draft demonstrates suggested changes to Appendix B-1 with all proposed issues below incorporated.
  - ii. IFPTI Course B2 (CC8029W): Replace FD252, Allergen Management in "post" curriculum. This course is a significant upgrade in course content providing more relevant and up to date information.
  - iii. IFPTI Course B8 Environmental Hazards (CC8024W): Add to "pre" curriculum. The committee agrees this is an important topic, not currently covered in Standard 2 curriculum, necessary for new (Food Safety Inspection Officer's) FSIO's baseline knowledge.
  - *iv.* IFPTI Course B12 Integrated Food Safety System (CC8018W): Add to "post" curriculum. The committee agrees this is an important topic, not currently covered in Standard 2 curriculum, necessary for new FSIO's baseline knowledge.
  - v. IFPTI Course B15 Jurisdiction (CC8037W): Add to "pre" curriculum. The committee agrees this is an important topic, not currently covered in Standard 2 curriculum, necessary for new FSIO's baseline knowledge.
  - vi. IFPTI Course B16 Labeling (CC8038W): Add to "post" curriculum. The committee agrees this is an important topic, not currently covered in Standard 2 curriculum, necessary for new FSIO's baseline knowledge.
  - vii. IFPTI Course B17 Laws, Regulations, Policies, & Procedures (CC8039W): Replace FDA35, Basic Food Law for State Regulators in "pre" courses. This course is a significant upgrade in course content providing more relevant and up to date information.
  - viii. IFPTI Course B19 Pest Control: Add to "pre" curriculum. The committee agrees this is an important topic, not currently covered in Standard 2 curriculum, necessary for new FSIO's baseline knowledge.
  - *ix.* IFPTI Course B20 Plumbing: Add to "pre" curriculum. The committee agrees this is an important topic, not currently covered in Standard 2 curriculum, necessary for new FSIO's baseline knowledge.
  - x. IFPTI Course B22 Professionalism (CC8025W): Add to "pre" curriculum. The committee agrees this is an important topic, not currently covered in Standard 2 curriculum, necessary for new FSIO's baseline knowledge.
  - xi. IFPTI Course B23 Public Health Principles (CC8026W): Replace FDA36, "Public Health Principles" in "pre" courses. The committee agrees this is an important topic, not currently covered in Standard 2 curriculum, necessary for new FSIO's baseline knowledge.
  - xii. IFPTI Course B24 Recalls (CC8041W): Add to "post" curriculum. The committee agrees this is an important topic, not currently covered in Standard 2 curriculum, necessary for new FSIO's baseline knowledge.
  - xiii. IFPTI Course B25 Sampling (CC8035W): Replace MIC13, Aseptic Sampling, in the pre-requisite curriculum. This course is a significant upgrade in course content providing more relevant and up to date information.
  - *xiv.* IFPTI Course B26 Sanitation Practices (CC8032W): Replace MIC15, Cleaning & Sanitizing, in "pre" courses. This course is a significant upgrade in course content providing more relevant and up to date information.
  - xv. IFPTI Course B27 Traceability (CC8042W): Add to "post" curriculum. The committee agrees this is an important topic, not currently covered in Standard 2 curriculum, necessary for new FSIO's baseline knowledge.
  - xvi. IFPTI Course B28 Transportation (CC8036W): Add to "post" curriculum. The committee agrees this is an important topic, not currently covered in Standard 2 curriculum, necessary for new FSIO's baseline knowledge.
- c. Charge 2b: The committee reviewed the time frame for completion of Standard 2, Steps 1 through 4, for new hires or staff newly assigned to regulatory retail food protection programs. The committee voted on February 16, 2019 to increase the timeframe from 18 to 24 months to align with Standard 2 of the Manufactured Food Regulatory Program Standards and to provide adequate time for standardization of staff.
- d. Charge 3: The committee reviewed the twenty quality assurance program elements in Standard 4 of the VNRFRPS. It was determined that all but three elements are contained in the CFP Field Training Manual, Training Plan and Log. To better align with

training in Standard 2 (attachment *PSC subcommittee #3 Charge 3 Quality Elements Cross-referenced*), the committee recommends adding the following three missing elements to the CFP Field Training Manual, Training Plan and Log:

- i. Standard 4 Performance Element III: "Verifies that the establishment is in the proper risk category and that the required inspection frequency is being met. Informs the supervisor when the establishment is not in the proper risk category or when the required frequency is not met." Add "Reviewed establishment file for documentation indicating the assigned risk category" to CFP Training Manual Section I Pre-inspection, #2. Reviews establishment file for previous inspection report, complaints on file, and if applicable, required HACCP Plans or documents supporting the issuance of a variance by the agency. Also add "Verified the establishment is assigned the correct risk category, and when necessary, informs the supervisor when the establishment is not in the proper risk category." to CFP Training Manual Section II Inspection Observations and Performance, #3 Uses a risk-based inspection methodology to correctly assess regulations related to employee practices and management procedures essential to the safe storage, preparation, and service of food.
- ii. Standard 4 Performance Element IX: "Discuss options for the long-term control of risk factors with establishment managers, when the same out-of-control risk factor occurs on consecutive inspections, in accordance with the jurisdiction's policies. Options may include, but are not limited to; risk control plans, standard operating procedures, equipment and/or facility modification, menu modification, buyer specifications, remedial training, or HACCP plans." Add "Discussed options for the long-term control of risk factors with establishment managers when the same out-of-control risk factor occurs on consecutive inspections (e.g., risk control plans, standard operating procedures, equipment and/or facility modification, menu modification, buyer specifications, remedial training, or HACCP plans)" to CFP Training Manual Section II Inspection Observations and Performance, #6 Verifies correction of out of compliance observations identified during previous inspection.
- iii. Standard 4 Performance Element XVIII: "Documents that options for the long-term control of risk factors were discussed with establishment managers when the same out-of-control risk factor occurs on consecutive inspections. Options may include, but are not limited to, risk control plans, standard operating procedures, equipment and/or facility modification, menu modification, buyer specifications, remedial training, or HACCP Plans." Add "Documented that options for the long-term control of risk factors were discussed with establishment managers when the same out-of-control risk factor occurs on consecutive inspections" to CFP Training Manual Section IV Written Communication, #1 Completes inspection form per jurisdiction's administrative procedures (e.g., observations; corrective actions; public health reason; applicable code reference; compliance dates).
- 3. Status of charges still <u>PENDING</u> and activities yet to be completed:

a. N/A

COMMITTEE REQUESTED ACTION FOR EXECUTIVE BOARD: 

No requested action at this time

#### **ATTACHMENTS:**

1. Content Documents: None

#### 2. Supporting Attachments (OPTIONAL): Not applicable

- a. See Issue titled: Report 2018-2020 Program Standards Committee; Attachment title: PSC subcommittee #3 Meeting #1 Minutes 12 19 2018
- See Issue titled: Report 2018-2020 Program Standards Committee; Attachment title: PSC subcommittee #3 Meeting #2 Minutes 1 09 2019
- c. See Issue titled: Report 2018-2020 Program Standards Committee; Attachment title: PSC subcommittee #3 Meeting #3 Minutes 1 23 2019
- d. See Issue titled: Report 2018-2020 Program Standards Committee; Attachment title: PSC subcommittee #3 Meeting #4 Minutes 2 06 2019
- e. See Issue titled: Report 2018-2020 Program Standards Committee; Attachment title: PSC subcommittee #3 Meeting #5 Minutes 3 13 2019
- f. See Issue titled: Report 2018-2020 Program Standards Committee; Attachment title: PSC subcommittee #3 Meeting #6 Minutes 4 10 2019
- g. See Issue titled: Report 2018-2020 Program Standards Committee; Attachment title: PSC subcommittee #3 Meeting #7 Minutes 5 8 2019
- h. See Issue titled: Report 2018-2020 Program Standards Committee; Attachment title: PSC subcommittee #3 Meeting #8 Minutes 6 122019
- See Issue titled: Report 2018-2020 Program Standards Committee; Attachment title: PSC subcommittee #3 Meeting #9
  Minutes 7 17 2019

- j. See Issue titled: Report 2018-2020 Program Standards Committee; Attachment title: PSC subcommittee #3 Meeting #10 Minutes 8 14 2019
- k. See Issue titled: Report 2018-2020 Program Standards Committee; Attachment title: PSC subcommittee #3 Meeting #11 Minutes 9 11 2019
- See Issue titled: Report 2018-2020 Program Standards Committee; Attachment title: PSC subcommittee #3 Meeting #12 Minutes 10 2 2019
- m. See Issue titled: Report 2018-2020 Program Standards Committee; Attachment title: PSC subcommittee #3 Charge 1 Training Evaluation and Certification Initiatives
- See Issue titled: Report 2018-2020 Program Standards Committee; Attachment title: PSC subcommittee #3 Charge 2 Appendix B-1 Reformatted 1st Draft
- See Issue titled: Report 2018-2020 Program Standards Committee; Attachment title: PSC subcommittee #3 Charge 2 Appendix B-1 Reformatted 2nd Draft
- p. See Issue titled: Report 2018-2020 Program Standards Committee; Attachment title: PSC subcommittee #3 Charge 2 IFPTI Course Review
- **q.** See Issue titled: Report 2018-2020 Program Standards Committee; Attachment title: PSC subcommittee #3 Charge 3 Quality Elements Cross-referenced
- r. See Issue titled: Report 2018-2020 Program Standards Committee; Attachment title: Integrated Food Safety System (IFSS) Food Protection Professionals Curriculum Framework
- s. See Issue titled: Report 2018-2020 Program Standards Committee; Attachment title: B2 Allergens IFPTI Course Profile
- t. See Issue titled: Report 2018-2020 Program Standards Committee; Attachment title: B17 Laws Regulations IFPTI Course Profile
- See Issue titled: Report 2018-2020 Program Standards Committee; Attachment title: B23 Public Health Principles IFPTI Course Profile
- See Issue titled: Report 2018-2020 Program Standards Committee; Attachment title: B25 Sampling IFPTI Course Profile
- w. See Issue titled: Report 2018-2020 Program Standards Committee; Attachment title: B26 Sanitation Practices IFPTI Course Profile
- x. See Issue titled: Report 2018-2020 Program Standards Committee; Attachment title: Standard 2 Appendix B-1 (see https://www.fda.gov/media/86752/download)
- y. See Issue titled: Report 2018-2020 Program Standards Committee; Attachment title: B8 Environmental Hazards IFPTI Course Profile
- z. See Issue titled: Report 2018-2020 Program Standards Committee; Attachment title: B12 Integrated Food Safety System IFPTI Course Profile
- aa. See Issue titled: Report 2018-2020 Program Standards Committee; Attachment title: B15 Jurisdiction IFPTI Course Profile
- bb. See Issue titled: Report 2018-2020 Program Standards Committee; Attachment title: B16 Labeling IFPTI Course Profile
- cc. See Issue titled: Report 2018-2020 Program Standards Committee; Attachment title: B19 Pest Control IFPTI Course Profile
- dd. See Issue titled: Report 2018-2020 Program Standards Committee; Attachment title: B20 Plumbing IFPTI Course Profile
- ee. See Issue titled: Report 2018-2020 Program Standards Committee; Attachment title: B22 Professionalism IFPTI Course Profile
- ff. See Issue titled: Report 2018-2020 Program Standards Committee; Attachment title: B24 Recalls IFPTI Course Profile
- gg. See Issue titled: Report 2018-2020 Program Standards Committee; Attachment title: B27 Traceability IFPTI Course Profile
- hh. See Issue titled: Report 2018-2020 Program Standards Committee; Attachment title: B28 Transportation IFPTI Course Profile
- ii. See Issue titled: Report 2018-2020 Program Standards Committee; Attachment title: VNRFRPS, Standard 2 (see https://www.fda.gov/food/voluntary-national-retail-food-regulatory-program-standards/voluntary-national-retail-food-regulatory-program-standards-december-2019)
- jj. See Issue titled: Report 2018-2020 Program Standards Committee; Attachment title: See Issue titled: Report 2018-2020 Program Standards Committee; Attachment title: VNRFRPS, Standard 3 (see https://www.fda.gov/food/voluntary-national-retail-food-regulatory-program-standards-december-2019)
- **kk.** See Issue titled: Report 2018-2020 Program Standards Committee; Attachment title: VNRFRPS, Standard 4 (see https://www.fda.gov/food/voluntary-national-retail-food-regulatory-program-standards/voluntary-national-retail-food-regulatory-program-standards-december-2019)
- II. See Issue titled: Report 2018-2020 Program Standards Committee; Attachment title: CFP Training Manual (see http://www.foodprotect.org/guides-documents/conference-for-food-protection-cfp-field-training-manual-for-regulatory-retail-food-safety-inspection-officers-5-31-13-cfp-update/)

- **mm.** See Issue titled: Report 2018-2020 Program Standards Committee; Attachment title: Manufactured Food Regulatory Program Standards (see https://www.fda.gov/MFRPS)
- nn. See Issue titled: Report 2018-2020 Program Standards Committee; Attachment title: Draft CFP Training Manual Revision
- **oo.** See Issue titled: Report 2018-2020 Program Standards Committee; Attachment title: Draft Attachment A CFP Training Plan and Log Revision (attached Word document)

#### Committee Final Reports are considered DRAFT until acknowledged by Council or accepted by the Executive Board

With the exception of material that is copyrighted and/or has registration marks, committee generated documents submitted to the Executive Board and via the Issue process (including Issues, reports, and content documents) become the property of the Conference.

COMMITTEE NAME: Program Standards Committee subcommittee #4

DATE OF FINAL REPORT: October 23, 2019 Date amended: 12/3/2019

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

REPORT SUBMITTED BY: James Mack, Chair

#### **COMMITTEE CHARGE(S):**

Issue # 2018 II-020 PSC 8

- 1. Maintaining the "Crosswalk Requirements for Foodborne Illness Training Programs" document as a resource for content baseline for foodborne illness training
- 2. Evaluating the following references for inclusion in the Crosswalk document
- 3. Reporting back any findings and recommendations to each biennial meeting of the Conference for Food Protection.

#### **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 #4 (Issue # 2018 II-020) held a conference call on December 6, 2018. A second call was scheduled for January 23, 2019 but was postponed due to the federal government shutdown. The subcommittee chair reached out to team members individually to discuss progress on their assigned tasks throughout 2019.
- 2. Overview of committee activities: The subcommittee had discussions regarding the use of the Crosswalk Requirements for Foodborne Illness Training Programs (Crosswalk) document for Standard #5. In addition, updating previous resources identified, such as CIFOR, occurred in 2019. EATS 102 was evaluated as a resource. EATS 101 is already a resource, so there was no need to review EATS 101. Subcommittee members continued to identify resources and report at the subcommittee meetings. Emphasis was on industry private sector courses. Four of the eight resources currently identified were reviewed for accuracy in order to maintain the Crosswalk document. Pending resources were reviewed against the Crosswalk document, to verify that the reference citations were still accurate. On February 11, 2019, the PSC committee chair reached out to FDA to request Pathlore access to non-regulatory subcommittee members for purposes of materials review related to the subcommittee charges. The subcommittee chair worked directly with the subcommittee members throughout the biennium as they worked on reviewing their assigned resources. The Crosswalk document was updated with the new resources that were reviewed.
- 3. Charges <u>COMPLETED</u> and the rationale for each specific recommendation:
  - a. Charge 1 The Crosswalk document was revised to include updated information.
  - b. Charge 2 Additional references were evaluated and included in the Crosswalk document.
  - c. Charge 3 This report and associated Issue submission complete 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:

- 1. PSC Committee Issue #3 Posting updated Crosswalk
  - 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: *Program Standards Committee* subcommittee #4 final report (see attached Word document)
    - (2)See Issue titled: Report 2018-2020 Program Standards Committee; Attachment title: Crosswalk-Requirements for Foodborne Illness Training Programs Based on Standard 5 2019 (see attached Word document)

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COMMITTEE NAME: Program Standards Committee subcommittee #5

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

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

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 guality 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. Charge 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)

- (1) Issue 2018 II-018 (see page 27 http://www.foodprotect.org/media/biennialmeeting/council-ii-final-issue-recommendations-1.pdf)
- (2) 2018 Program Standards Committee Final Report http://www.foodprotect.org/issues/packets/2018Packet/issues/II\_013.html. See the Reevaluation of VNRFRPS Standard 8 Subcommittee Report and supporting attachments for Standard 8.
- (3) Voluntary National Retail Food Regulatory Program Standards Standard 8 (see https://www.fda.gov/food/voluntary-national-retail-food-regulatory-program-standards-november-2019)
- (4) CFP Plan Review Guide (see http://www.foodprotect.org/media/guide/2016-plan-review-manual.pdf)
- (5) Standard 2 Appendix B-1 (see https://www.fda.gov/media/86752/download)
- (6) VNRFRPS, Standard 2 (see https://www.fda.gov/food/voluntary-national-retail-food-regulatory-program-standards/voluntary-national-retail-food-regulatory-program-standards-november-2019)
- (7) VNRFRPS, Standard 3 (see https://www.fda.gov/food/voluntary-national-retail-food-regulatory-program-standards/voluntary-national-retail-food-regulatory-program-standards-november-2019)
- (8) VNRFRPS, Standard 4 (see https://www.fda.gov/food/voluntary-national-retail-food-regulatory-program-standards/voluntary-national-retail-food-regulatory-program-standards-november-2019)
- (9) CFP Training Manual (see http://www.foodprotect.org/guides-documents/conference-for-food-protection-cfp-field-training-manual-for-regulatory-retail-food-safety-inspection-officers-5-31-13-cfp-update/)
- (10) Manufactured Food Regulatory Program Standards (see https://www.fda.gov/MFRPS)

#### **Standard 8 Staffing Level**

#### **Purpose of Standard 8 staffing level section:**

Standard 8 Section 1. Staffing Level requires a health department (HD) to demonstrate that they have the staff "necessary to support an inspection and surveillance system that is designed to reduce risk factors and other factors know to contribute to foodborne illness"

#### **Current criteria to pass Standard 8:**

A HD currently meets this standard if they demonstrate an inspection to FTE ratio range of 280-320 inspections per FTE. The Conference for Food Protection (CFP) developed an assessment tool and instruction guide that <u>can be used</u> by a HD if desired. If not the HD has to calculate their inspection to FTE ratio through their own method and see if it falls within the required range.

#### **Problem with inspection to FTE ratio range:**

It has been agreed by upon by subcommittee that this range is problematic as it's based on the idea that every inspection should take 4 hours. The subcommittee has also agreed that a range is problematic as it allows for an adequately staffed health department to fail the standard as they could fall below the range.

#### **Recommendations:**

We are recommending removing the range and allowing HDs to demonstrate to independent auditors that they are adequately staffed in a more appropriate way. The following are the 3 options we think are reasonable that a HD can use to demonstrate staffing levels.

- 1. A HD can use their own method they feel is appropriate for them to demonstrate adequate staffing levels
- 2. A HD can use the current assessment tool (with inspection to FTE section removed) developed by CFP to assess if they're adequately staffed
- 3. A health department can use the updated CFP assessment tool that calculates staffing levels by risk category
  - a. Using the updated vs. current assessment tool may make it easier for a HD to prove to their auditor that they are adequately staffed because:
    - i. It has a section that calculates how many FTEs a HD *should* have based on risk categories (current assessment does not do this)
    - ii. It then automatically compares how many FTEs a health department currently has with how many they should have (the current assessment only calculates current FTE, so it may be challenging to convince an auditor that a current calculated FTE # demonstrates a HD to be adequately staffed)

#### **Updated CFP Assessment Tool**

The following is <u>an example</u> of how to use the updated assessment tool to calculate if a health department is adequately staffed.

Discussion on Table 1. The risk category column is broken into three categories, the minimum required by Standard 8. The number of establishments will be unique to each health department. The rows in the remaining columns show values that are based off of survey data of 100 local and state health departments throughout the country (see footnotes for more details). A HD should feel free to use these values or input ones that more appropriately fit their organization.

Table 1.

Risk Category	Number of Establishments	Inspection Frequency <sup>1</sup>	Average Inspection Time (does not include travel) <sup>2</sup>	Reinspection frequency <sup>3</sup>	FBI Inspection Frequency <sup>4</sup>	Other Frequency <sup>5</sup>
Low	1,000	1	45 minutes	15%	1%	10%
Medium	2,000	2	75 minutes	15%	1%	10%
High	1,000	3	120 minutes	15%	1%	10%

Step 1. Calculate available annual inspection time per full time equivalent (FTE) using assessment tool. 1200 hours a year will be used for this example.

**Step 2. Calculate number of FTE currently available at health department.** This # is calculated in the current and updated assessment tools.

**Step 3. Calculate total number of hours required to inspect each risk category.** Formula for calculating # of inspection hours per risk type below (low risk type used for example):

 $(1000 \text{ establishments x 1 inspection a year} = 1000 \text{ inspections}) + (1000 \text{ establishments x 15 \% reinspections a year} = 150 \text{ inspections}) + (1000 \text{ establishments x 1\% FBI inspections a year} = 10 \text{ inspections}) + (1000 \text{ inspections x 10\% other inspections a year} = 100 \text{ inspections}) = 1260 \text{ inspections a year} \times 45 \text{ minutes an inspection} = 945 \text{ hours a year}$ 

Medium risk = 4520 inspections a year x 75 minutes = 5650 hours

High Risk = 3260 inspections a year x 120 minutes =6520 hours

Total inspection time = 945 + 5650 + 6520 = 13,115 inspection hours a year

#### Step 4. Calculate number of FTE's required

13,115 total inspection time hours /1200 inspection hours available per FTE = 10.93 FTEs

#### Step 5. Calculate if health department is adequately staffed

If FTEs currently available >= 10.93 FTEs that a HD should have then that HD is adequately staffed

<sup>&</sup>lt;sup>1</sup> Median inspection frequencies of 100 health departments from 2017 survey

<sup>&</sup>lt;sup>2</sup> Median inspection times of 100 health departments from 2017 survey

<sup>&</sup>lt;sup>3</sup> Median reinspection frequency %s of 60 health departments form 2017 survey2

<sup>&</sup>lt;sup>4</sup> Median food borne illness inspection frequency %s of 60 health departments from 2017 survey2

<sup>&</sup>lt;sup>5</sup> Final % value still being calculated, 10% being used for this demonstration

#### Appendix 8.2 Calculation for determining a required number of inspectors

This appendix is <u>an example</u> of how to calculate the number of field staff required to conduct inspections<sup>21</sup> of food plants. The data in the following table will vary significantly based on local or regional conditions. The State program may use the risk categories and inspection frequencies found in the statement of work for the food contract as a basis for determining the required number of inspectors.

Risk category	Number in inventory	Inspection frequency	Average inspection time (includes travel) <sup>22</sup>	Reinspection frequency
High	1,000	12 months	7.2 hours	10%
Medium	2,000	18 months	5.7 hours	10%
Low	1,000	24 months	4.2 hours	10%

1. Calculate available annual inspection time per full time equivalent (FTE).

For example, the State agency determines that after allowances for annual leave, sick leave, holidays, training, administrative time, and other activities each State program FTE has 1200 hours available for conducting inspections.

2. Calculate the number of hours required to inspect establishments in each risk category.

Formula for high risk establishment inspection time:

1000 firms x 100% coverage = 1000 inspections + 10% reinspection = 1100 total inspections per year x 7.2 hours = 7920 hours

Formula for medium risk establishment inspection time:

2000 firms x 66.6% coverage = 1333 inspections + 10% reinspection = 1466 total inspections per year x 5.7 hours = 8356 hours

Formula for low risk establishment inspection time:

1000 firms x 50% coverage = 500 inspections + 10% reinspection = 550 inspection total inspections x 4.2 hours = 2320 hours

3. Calculate the number of FTE's required.

#### Formula:

7920 hours for high risk + 8356 hours for medium risk + 2320 hours for low risk = 18596 inspection hours required / 1200 inspection hours available per FTE =  $\underline{15.5 \text{ FTEs}}$ 

<sup>&</sup>lt;sup>19</sup> Includes routine surveillance, reinspections, complaint or outbreak investigations, compliance follow-up investigations, risk assessment reviews, process reviews, and other direct establishment contact time such as on-site training.

Inspection times based on calculations presented in "DHHS Office of Inspector General's FDA Oversight of State Food Firm Inspections" dated June 2000.

# Standard 8

## **Current Standard 8 Model**

## Purpose regarding staffing levels:

- Assesses the adequacy of a health department's staffing levels, by calculating if it has an inspection to FTE ratio within the specified FDA range
  - The range is **280 320 inspections** per inspector

### •Problem 1:

• This range was created with the belief that every food inspection regardless of establishment type would take **4 hours**. This is problematic as health departments (HD) have establishments that vary by type and risk category making the required time to complete inspections also vary.

### •Problem 2:

• The very existence of a range creates the possibility that a HD can appear to be **overstaffed**. This creates the potential for that HD to have an *inspection to FTE ratio* that goes below the bottom value of the 280-320 range (thus making the HD fail to meet the standard). Standard 8 is evaluating if a HD has the "necessary" staff to perform the required number of inspections. If a HD has a unique need and the resources available to hire more staff than Standard 8 would require, it is not consistent with the intent of this standard to fail them.

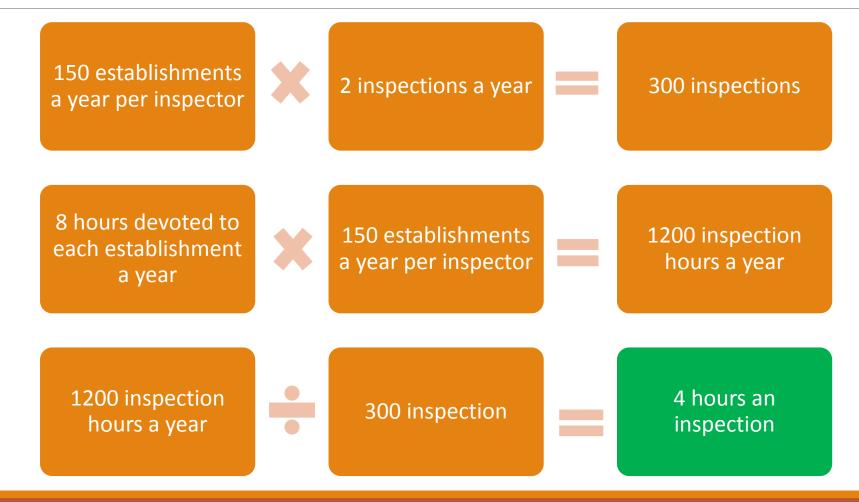
# The Logic Behind the 280-320 FTE Inspections Per Year Range

VNRFRPS Clearinghouse Work Group agreed that 1,120 – 1,280 inspection hours a year per one FTE
 "represents a reasonable range" of annual productive hours - VNRFRPS 2019 https://www.fda.gov/media/86864/download



• This then "allows for the same unit of measure to be applied to all jurisdictions regardless of their procedures and processes"-VNRFRPS 2019 https://www.fda.gov/media/86864/download

# The Logic Behind the 4 Hour Inspection



# Potential Problem with these Figures

- •150 establishments a year per inspector came from the 1961 International City Managers' Association the <u>Administration of Community Health Services https://babel.hathitrust.org/cgi/pt?</u>

  id=mdp.39015072177739&view=1up&seq=177 book sharing that "there is no widely accepted formula on which to base the number of staff persons" but that "some local agencies" use 150
- •2 inspections a year came from the <a href="mailto:1976-Food Service Sanitation Manual https://babel.hathitrust.org/cgi/pt?id=umn.31951002840720j&view=1up&seq=29">1976-Food Service Sanitation Manual https://babel.hathitrust.org/cgi/pt?id=umn.31951002840720j&view=1up&seq=29</a> that acknowledges the above 150 establishment number and adds without justification that "a minimum of two inspections of each establishment per year is required"
- •8 hours devoted to each establishment comes from the <a href="1997">1997</a> FDA Food Code <a href="https://www.fda.gov/Food/GuidanceRegulation/">https://www.fda.gov/Food/GuidanceRegulation/</a> RetailFoodProtection/FoodCode/ucm054458.htm which suggests "8 to 10 hours be allocated per establishment year" also without evidence or clear reasoning

**Conclusion:** There appears to be no strong justification for any of these values based on real data and research making it problematic that they are the criteria from which the 4 hour inspection time is based

## Our Solution

## •It is more accurate to assess a health department's staffing levels by:

- 1. categorizing establishments into 3 risk categories: low, moderate, high
- 2. use a **standardized frequency** each risk type should be inspected a year
- 3. use a **standardized inspection time** required for each risk type
- 4. calculate how many FTEs it "should" take to complete all of these inspections.
- 5. calculate how many FTEs the health department "currently" has
- 6. If the health department currently has an equal or greater number of FTEs than our new standard would require they would be considered sufficiently staffed

Note: The inspection to FTE ratio and the range which sets the standard would no longer be needed and would be removed from the Standard 8 Staffing Level assessment

# Why Categorize Establishments

- •Standard 8 states that a "process should exist for the regulated food establishments to be grouped into at least 3 categories based on food safety risk" VNRFRPS 2019 https://www.fda.gov/media/86864/download
- •The FDA recommends categorizing food establishments into risk categories because:
  - "By focusing inspections on the control of foodborne illness risk factors, inspectors can be assured that they are making a great impact on reducing foodborne illness" – FDA Food Code 2017 https:// www.fda.gov/food/fda-food-code/food-code-2017
  - "Studies have shown that the types of food served, the food preparation processes used, the volume of food, and the population served all have a bearing on the occurrence of foodborne illness risk factors in retail and foodservice establishments" – FDA Food Code 2017
  - "With limited resources, creating a variable inspection frequency for each category will allow inspection staff to effectively spend more time in high risk establishments that pose the greatest potential risk of causing foodborne illness." FDA Food Code 2017

# Follow Other FDA Recommended Inspection Standards

## •FDA's Manufactured Food Regulatory Program Standards 2016

Appendix 8.2: Calculation for determining a required number of inspectors https://www.fda.gov/media/100421/download

Risk category	Number in inventory	Inspection frequency	Average inspection time (includes travel)	Reinspection frequency
High		12 months	7.2 hours	10%
Medium		18 months	5.7 hours	10%
Low		24 months	4.2 hours	10%

- •Formula: (high risk inspection hours + medium risk + low risk = total inspection hours required/1200 inspection hours) = # FTEs required
- •Note: Average Inspection times came from <u>Department of Health and Human Services https://oig.hhs.gov/oei/reports/oei-01-98-00400.pdf</u> study of 37 states' inspection. 5.7 hours was the state average with a standard deviation of 1.5.

# How Our FTE Model Categorizes

- 1. Following FDA recommendations it would require that a health department (HD) group their establishments into 3 risk categories: low, moderate, and high risk
- 2. If a HD is unsure how to put their current risk category scale into a 3 category model, refer to Annex 5 Risk Categorization of Food Establishments Table https://www.fda.gov/media/110822/download. In this table there are 4 risk categories with descriptions. Risk category 1 would be low risk. Risk category 2-3 would be moderate risk. Risk category 4 would be high risk.
- 3. If a HD only has 2 risk categories put them in the most appropriate categories out of low, moderate, or high. E.g. low and high, moderate and high, etc

## **Annex 5 Descriptions of Risk Categories**

Risk 1: Examples include most convenience store operations, hot dog carts, and coffee shops. Establishments that serve or sell only prepackaged, non-time/temperature control for safety (TCS) foods. Establishments that prepare only non-TCS foods. Establishments that heat only commercially processed, TCS foods for hot holding. No cooling of TCS foods. Establishments that would otherwise be grouped in Category 2 but have shown through historical documentation to have achieved active otherwise be grouped in Category 3 but have shown through historical managerial control of foodborne illness risk factors.

Risk 2: Examples may include retail food store operations, schools not serving a highly susceptible population, and quick service operations. Limited menu. Most products are prepared/cooked and served immediately. May involve hot and cold holding of TCS foods after preparation or cooking. Complex preparation of TCS foods requiring cooking, cooling, and reheating for hot holding is limited to only a few TCS foods. Establishments that would documentation to have achieved active managerial control of foodborne illness risk factors. Newly permitted establishments that would otherwise be grouped in Category 1 until history of active managerial control of foodborne lillness risk factors is achieved and documented.

Risk 3: An example is a full service restaurant. Extensive menu and handling of raw ingredients. Complex preparation including cooking, cooling, and reheating for hot holding involves many TCS foods. Variety of processes require hot and cold holding of TCS food. Establishments that would otherwise be grouped in Category 4 but have shown through historical documentation to have achieved active managerial control of foodborne illness risk factors. Newly permitted establishments that would otherwise be grouped in Category 2 until history of active managerial control of foodborne illness risk factors is achieved and documented.

Risk 4: Examples include preschools, hospitals, nursing homes, and establishments conducting processing at retail. Includes establishments serving a highly susceptible population or that conduct specialized processes, e.g., smoking and curing; reduced oxygen packaging for extended shelf-life.

# Creating the Standard for Frequency and Inspection Time by Risk Category

## Methodology:

- •In 2017 HCPH surveyed 390 health departments (HD) across the country asking them for average inspection times and frequencies per the 3 risk categories. 100 complete responses were received.
- •To create a standard we categorized these HDs by the # of standards they achieved and evaluated if HDs with more standards met had inspection times and frequencies different from HDs with less standards met.
- •Statistical techniques demonstrated that their was no relationship between the # of standards a HD achieved and their times or frequencies
- •Thus there is no rational for emphasizing inspection times of HDs that passed more standards from the data we obtained
- •Therefore it made the most sense to use the average or median inspection times and frequencies per risk category of all the HDs that responded as a standard. Now these values would be based on real data from a diverse group of HDs.

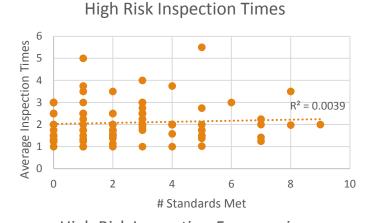
## Plots of # of Standards Met by Inspection Times and Frequencies Demonstrating no Relationship,

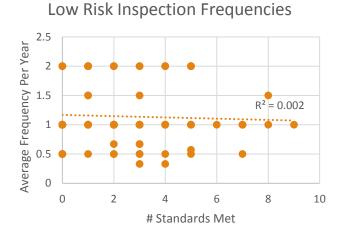
 $R^2 = 0.0131$ 

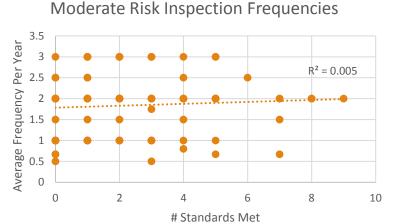


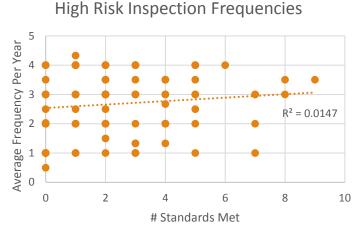
Average Inspection Times

**Moderate Risk Inspection Times** Average Inspection Times 10 # Standards Met # Standards Met









# Bivariate Linear Regression Results and Correlation Coefficients

Dependent Variable	P-Value	Pearson's Correlation Coefficient
Low Risk Freq.	0.67	-0.05
Low Risk Time	0.15	0.15
Mod Risk Freq.	0.49	0.07
Mod Risk Time	0.27	0.11
High Risk Freq.	0.24	0.12
High Risk Time	0.54	0.06
	Low Risk Freq.  Low Risk Time  Mod Risk Freq.  Mod Risk Time  High Risk Freq.	Low Risk Freq. 0.67  Low Risk Time 0.15  Mod Risk Freq. 0.49  Mod Risk Time 0.27  High Risk Freq. 0.24

Note:

Statistically Significant Relationship = P-Value < .05

Pearson's Correlation Coefficient: Perfect positive relationship = 1, Perfect negative relationship = -1

# Creating Standard Inspection Times by Risk Category

### **Median**

Low Risk: 45 minutes

Mod Risk: 75 minutes

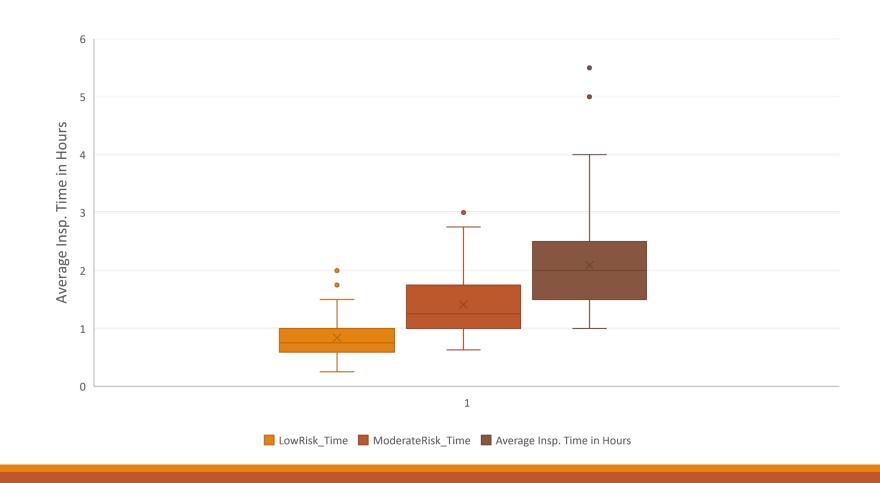
High Risk: 120 minutes

### **Average**

Low Risk: 50 minutes

Mod Risk: 85 minutes

High Risk: 125 minutes



# Creating Standard Inspection Frequencies by Risk Category

#### **Median**

Low Risk: 1 insp.

Mod Risk: 2 insp.

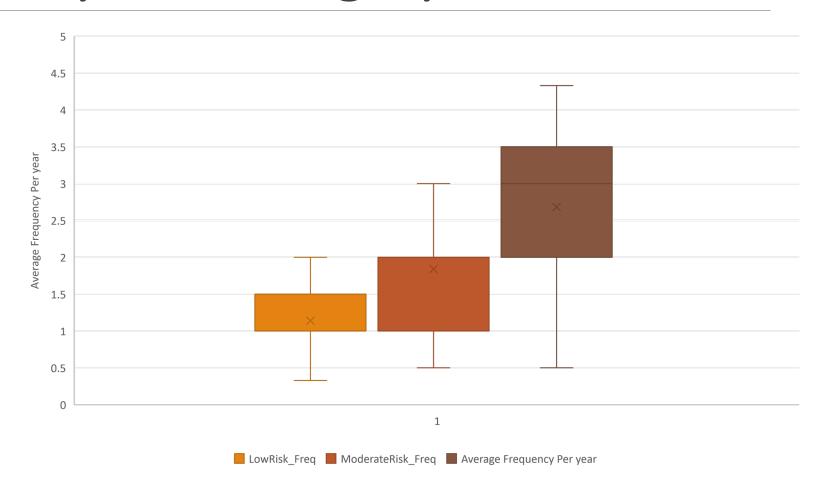
High Risk: 3 insp.

#### **Average**

Low Risk: 1.14 insp.

Mod Risk: 1.84 insp.

High Risk: 2.68 insp.



# Calculating How Many FTEs a Health Department "currently" has

- Note: This process uses the current Standard 8 model developed by the FDA with the sections devoted to the inspection to FTE ratio removed
- •The model now only needs to:
  - 1. calculate the annual productive hours of one FTE
  - 2. calculate the total food inspection hours the health department currently conducts
  - 3. divide the total food inspection hours by the annual productive hours of one FTE to calculate how many overall FTEs the health department "currently" has

Total food inspection hours / one FTE's annual productive hours = Total FTEs

## Calculating "current" FTEs

# FTE DATA CALCULATION Calculate productive hours per year for an employee doing 100% food inspections Information For One Employee Hours/Year Hours/Day Total Hours

Information For One Employee	Hours/Year	Hours/Day	<b>Total Hours</b>			
Annual FTE Hours Per Year: Industry Standard						
Local Holiday Hours Per Year	80		80			
Local Vacation Leave Hours Per Year	104		104			
Local Sick Leave Hours Per Year	78		78			
Local Family-Personal Leave Hours Per Year	0		0			
Productivity Factoring Per Year						
Travel Time For Inspection		1.5	1477			
Administrative Work (in-office work)	192		1285			
Training Time	20		1265			
Others	0		1265			
Personal Development Time Per Year						
Continuing Education Hours	12		1253			
Others	0		1253			

Oth	iers		U	_	1700
<b>Productive Annual</b>	l FTE Hours Per Year (I	FTE Conversion Fac	tor)		1253

Position Category	Food Safety Inspection Hours	Number of Employees	Total Hours
Food/NNA	1239	31	38397
Food/Pools	831	2	1663
Supervisors	42	3	126
Total Food Safety Ins	40186		
Total Local FTE	32.1		

Actual working days	Actual working weeks
227.25	45.45

# Calculating How Many FTEs a Health Department "should" have

- •Note: this process would be incorporated into the current Standard 8 model
- •The steps of the new process are below:
  - 1. A health department will input the number of establishments they have into each of the 3 risk categories of the table
  - 2. The table will automatically calculate how many inspections should be conducted for each risk category using the inspection frequency values from the survey
  - **3.** The table will then automatically calculate how many total hours are required to complete these inspections using the **inspection time values** from the survey
  - **4.** The table will lastly divide these total inspection hours by the annual productive hours of one FTE (this value is already calculated in the previous section) to calculate how many overall FTEs the health department "should" have

## Calculating "required" FTE

STANDARD 8's REQUIRED FTE FOR YOUR JURISDICTION							
	Low Risk Establishment	Frequency of Low Risk Est Inspections Per Year	Moderate Risk Establishment	Frequency of Moderate Risk Est Inspections Per Year	High Risk Establishment	Frequency of High Risk Est Inspections Per Year	Total Inspections
Routine and Permitting	2090	1.00	6374	2.00	104	3.00	1515
Follow Up Inspections/Re-inspections (15%)							255
Foodborne Illness Complaints (1%)							17
Other (10%)							170
	,						
Median Hours Spent Per Inspection	0.75		1.25		2.00		
Total Inspection Time	1568		15935		624		2475
Total Required FTE							19.7
Standard 8 Criteria Standard met							

#### Notes:

- Frequency of inspections 2017 HCPH Survey 1 (100 responses)
- Median Hours Spent Per Inspection -2017 HCPH Survey 1 (100 responses)
- Follow Up Inspections % (out of total # inspections) 2017 HCPH Survey 2 (60 responses)
- Foodborne Illness Complaints % (out of total # inspections)- 2017 HCPH Survey 2 (60 responses)
- Other % (out of total # inspections) E.g. from Standard 8 Staffing Level Assessment Workbook, pg. 10 complaints, outbreak investigations, risk assessment reviews, process reviews, variance process reviews, final construction inspections and "other direct establishment contact time"

## Meet or Not Meet Standard 8

•As demonstrated on previous slide, once the Standard 8 model is completed it will automatically calculate if a health department meets or does not meet the standard. E.g. below.

Jurisdiction X "should" have 5 FTE

Jurisdiction X "currently" has 4 FTE

should have > currently have



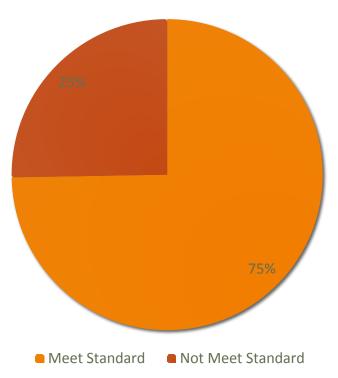
Jurisdiction Y "should" have 20 FTE
Jurisdiction Y "currently" has 23 FTE

should have =< currently have



## How Do Our Surveyed HDs Do?





## Recommendation #1

- A HD can use their own method
- A HD can use the current assessment tool
- A HD can use the new proposed assessment tool that calculates staffing levels by risk category

## Recommendation #2

- Use the new proposed model to determine staffing level
  - Option 1: use the standardized values from the survey
  - Option 2: use values that the HD determines to be appropriate for their program

## Recommendation #3

•Pilot the new proposed model among HDs for a period of time

## Conclusion

- The standard 4 hour inspection time needs to be updated
- Our survey demonstrates that inspection times and frequencies vary by risk category
- •An inspection to FTE ratio is not necessary to asses a HD's staffing levels, in fact it creates the potential for failing a health department that is sufficiently staffed

# Standard 8 Re-Evaluation of Staffing Level Model

### **Pilot Study Report**

Subcommittee #2

**Program Standards Committee** 

Conference for Food Protection

October 2019



#### TABLE OF CONTENTS

BACKGROUND	
ISSUE #2016 II-020	1
ISSUE #2018 II-018	2
PILOT STUDY	2
METHODOLOGY	3
VALIDATION OF PROPOSED MODEL	3
SAMPLING AND RECRUITMENT	4
DATA COLLECTION	5
SURVEY DETAILS	6
COMPARING MODELS	6
PILOT RESULTS	······ 7
JURISDICTION CHARACTERISTICS	7
CURRENT MODEL V PROPOSED MODEL	7
DISCUSSION	9
RECOMMENDATIONS	10
APPENDIX	11
ITEM A	11
ITEM B	14
ITEM C	21
ITEM D	24
ITEM E	28
ITEM F	29
ITEM G	30

#### **Background**

Regulatory food safety programs residing within health departments (State and Local) across the country are responsible for conducting food safety inspections for retail food establishments within their respective jurisdictions. These regulatory programs are required to abide by the regulations set forth, at a minimum, by the Food and Drug Administration (FDA) through the FDA Food Code. The FDA, in an effort to achieve uniformity, developed the Voluntary National Retail Food Regulatory Standards (VNRFRPS). The Retail Program Standards allow health departments to enroll and audit the effectiveness of their program. There are a total of 9 standards designed to assist regulatory food safety programs to improve and enhance the services they provide to protect the public.

#### Issue #2016 II-020

In 2016, an issue (#2016 II-020) was submitted to the Conference for Food Protection (CFP), regarding the ineffectiveness of a model used to determine compliance for Standard 8 (Fig. 1). Standard 8 assesses the regulatory food safety programs' level of *Program Support and Resources*. There are 12 items by which a health department conducts self and verification audits to see if they comply with Standard 8. According to a survey from the National Association of County Health Officials (NACCHO), there is a low percentage of health departments (<10%), that are able to complete Standard 8. Usually the reason for not meeting the standard is due to *Item 8.1: Staffing Level*. This item evaluates if a food safety program has sufficient full-time equivalent (FTE) staff to conduct food inspections. The model calculates if a health department is fully staffed using an inspection-to-FTE ratio. In order to meet Standard 8, the health department must fall into a specific range of 280-320 inspections -per inspector per year. The problems regarding the logic behind the ratio have been explained previously (see Appendix; Item A: Standard 8 Staffing Level).

The charges addressed in the first issue #2016 II-020 were evaluated by Conference for Food Protection, 2016-2018 Program Standards Committee, Standard 8 Subcommittee. The goal was to propose a new model, focused on risk-based inspections that would more accurately assess a health department's staffing levels. In 2017, the subcommittee surveyed 390 health departments across the country and collected data on average inspection times and frequencies by risk category. In total, 105 complete responses were received which were used to create a new data-driven model.

#### Issue #2018 II-018

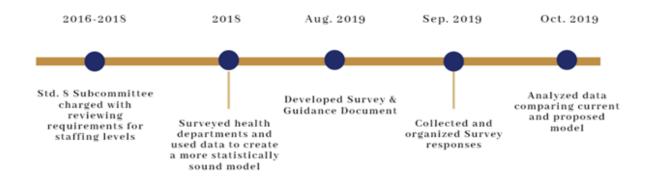
In 2018, following the work of the Standard 8 Subcommittee, more recommendations were submitted to CFP regarding the initial issue (#2016 II-020). The proposed solutions were accepted by CFP in 2018 and a new issue and subcommittee were created, Issue #2018 II-018 evaluated by Subcommittee #2. The new subcommittee was responsible for addressing the following charges:

- (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 VNRFRPS;
- (2) Use the supporting attachments listed in the 2016-2918 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 findings and recommendations to the 2020 Biennial Meeting.

#### **Pilot Study**

In August 2019, Subcommittee #2 met with the Program Standards Committee to discuss the work that had been completed on the new model development 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. A local health department led the study and the following report provides details on the Standard 8 Pilot Study.

Figure 1: Timeline



#### **Methodology**

#### Validation of the Proposed Model

In order to verify that the proposed model was statistically sound for the Pilot Study, Subcommittee #2 worked with Dr. Matthew Koslovsky, a Post-Doctoral Research Associate from Rice University focusing in Biostatistics. For his detailed C.V., see **Appendix**; **Item B: Dr. Koslovsky-CV**. 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 (Table 1). 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. Detailed data analysis including tests and p-values can be made available upon request.

Table 1: Median Inspection Times/Frequencies by Number of Standards Met

# Standards Met		0	1	2	3	4	5	6 or more
Number of Jurisdictions		n = 22	n = 17	n = 19	n = 17	n = 11	n = 11	n = 8
Modion	Low Risk	0.815	0.75	0.75	0.69	0.75	0.75	1
Median Inspection Time in Hours	Moderate Risk	1.105	1.5	1	1.375	1.5	1.25	1.585
III Hours	High Risk	1.875	2.5	1.75	2	2	1.75	2
Median	Low Risk	1	1	1	1	1	1	1
Inspection Frequency per	Moderate Risk	2	2	2	2	2	2	2
Year	High Risk	2	3	3	3	2.67	3	3

#### **Sampling & Recruitment**

In order to include health departments already involved in the Program Standards Committee, a mixture of non-random and random sampling was used. As shown in Figure 2, a total of 44 health departments were contacted to participate in the pilot. Of the 44 jurisdictions contacted, 13 were already involved with the Program Standards Committee and were aware of the purpose of the Pilot Study, the remaining 31 were chosen randomly from the list of original participants of the 2017 survey or were referred by an ineligible jurisdiction. Of the 40 eligible health departments, 22 consented to participate. Of the 22 consented health departments, 18 provided data, and 4 were not able to complete the survey. A total of 19 jurisdictions were included in the study once the local health department leading the study added their own data

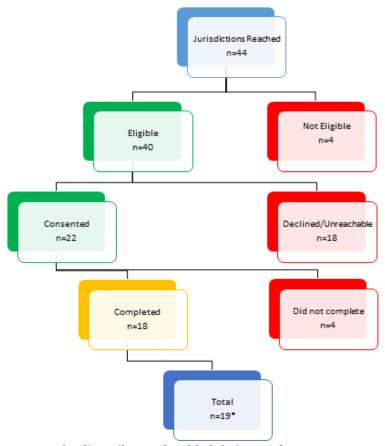


Figure 2: Participation Flow-Chart

\*Local health department leading Pilot Study added their own data

#### **Data Collection**

Participating health departments were given the option of providing the requested staffing level data either via a 1) weblink to a SurveyMonkey questionnaire (see **Appendix; Item C: Survey**) or 2) phone call as a guided interview with one of the Pilot Study team members. SurveyMonkey was chosen as the platform for collecting data in order to have an organized database of participant's responses. Participants were also provided a guidance document (see Appendix; Item D: Guidance Document) with useful definitions and descriptions to help interpret the questions and provide the appropriate data in the correct format. Upon recruitment, participating departments had one month (from August 30th until September 30th) to either complete the questionnaire on SurveyMonkey or schedule and complete through a phone call.

#### **Survey Details**

The survey aimed to collect data necessary to determine the total productive hours per FTE, total inspection hours each health department currently conducts, the total inspection hours each health department should be conducting, the total current FTE and the total required FTE. To determine the total productive hours for each jurisdiction, the survey included questions about the time spent traveling to inspections, conducting administrative work, and professional development as well as time spent on breaks, holiday, and vacation. To have a better understanding of total productive hours, the survey asked each jurisdiction to list all types of Environmental Health Specialist (EHS) employees (such as managers, supervisors, and regular EHS staff) and include the average percent of time that each employee spends on food inspections. A second objective of the survey was to obtain data which would allow us to observe each jurisdiction's method of categorizing inspections, as well as the average time spent on food-borne illness, routine, and other types of inspections.

#### **Comparing Models**

Participant data was taken from the SurveyMonkey database and moved to an Excel workbook where it was organized to review staffing levels for each health department. First, the data was run through the current Standard 8 model (see Appendix, Item E: Standard 8 - Assessment Workbook). By doing this, we obtained the current FTE and inspection-to-FTE ratio for each health department. If a health department falls above or below the ratio, then the health department does not meet Standard 8. We then determined which departments "passed" or "failed" to meet the staffing level requirements using the current Standard 8 model.

The data was then analyzed using the proposed Standard 8 model (see Appendix, Item F: Standard 8 - Proposed Model Workbook). 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 has is greater than or equal to the number of FTES the HD 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. Finally, we checked which health departments "passed" or "failed" to meet the staffing level requirements using the proposed Standard 8 model.

#### **Pilot Results**

#### **Jurisdiction Characteristics**

A total of 16 States were represented in the Pilot Study. Of the 19 health departments, 16 jurisdictions were Local Health Departments, and the remaining 3 were State Health Departments or Agencies. After organizing the data, we observed each health department's characteristics such as total EHS employees, total inspections in a year, and total establishments in their jurisdictions (Table 2). Sizes of participating departments varied substantially, with the lowest number of EHS employees being 2 and the highest 99.

Table 2: Employees, total inspections, and total establishments per jurisdiction

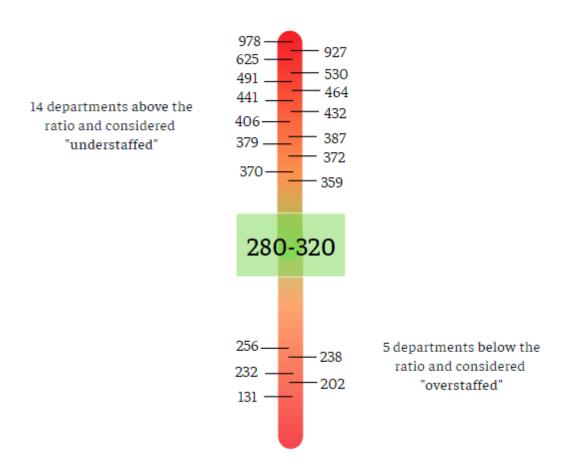
<b>Total Employees</b>	<b>Total Inspections</b>	Total Establishments
2	512	128
2	144	109
4.6	764	585
6	464	303
6	488	262
7	1889	1889
7	1065	606
9	1676	961
9	1627	1384
9	1321	648
10	5475	3618
16	4518	6629
21.1	9211	6363
22	4655	2599
25	9490	4508
29.75	8015	3753
36	17463	8568
56	12623	8830
99	47216	25300

#### **Current Model v Proposed Model**

When analyzing the data using the current model, all (100%) of the participating health departments failed Item 8.1: Staffing Level. Of the 19 health departments, 5 fell below the established ratio of 280-320 inspections per FTE (Fig. 3). Falling below the ratio indicates that the health department is "overstaffed"; that is, each EHS is assigned too few

inspections per year. The remaining 14 health departments fell above the ratio and were considered "understaffed"; in other words, each EHS is assigned too many inspections per year. A major problem with the current ratio is that health departments who are "overstaffed" should actually be considered sufficiently staffed, with each EHS assigned an attainable number of inspections to complete per year. If the 5 health departments who were "overstaffed" were not restricted by the ratio, they would have "passed" Standard 8, indicating a compliance rate of about 26%. The ratio seems to penalize health departments who have too many EHS.

Figure 3: "Understaffed" and "Overstaffed" departments based on current model



When analyzing the data using the proposed model, 10 (52.6%) health departments "passed" Item 8.1: Staffing Level. The model was able to confirm that those 10 health departments currently had an equal or greater number of EHS employees required to complete the inspections in their jurisdictions. The remaining 9 (47.4%) health departments "failed" to meet item 8.1. The model was able to confirm that those 9 health departments currently had a lower number of EHS employees required to complete the inspections in their jurisdictions.

When looking at the data more closely, there were a few interesting results that were observed between the jurisdictions that "failed" (n=9) and those who "passed" (n=10) the proposed model (Table 3). On average, jurisdictions who "passed" had less FTEs (8.6 vs 15.3), fewer employee position categories (3.2 vs. 4.2), and less food establishments categorized as high risk (24% vs 38%). Jurisdictions who "passed" also had, on average, more total productive hours (1337 vs. 1043) and more employees who dedicated a higher percent of their time to food inspections. Alternatively, jurisdictions that "failed" spent more time, on average, on travel (61 vs. 23 min/day) and administrative work (93 vs. 71 min/day). Another interesting observation was that of the 10 jurisdictions that "passed" in the proposed model, half (5) originally fell above the 280-320 ratio (overstaffed) and half fell below (understaffed).

Table 3: Differences of Jurisdictions who "Passed" or "Failed" the Proposed Model

				Average	Average	
		Total Productive	e Average travel	administrative	inspection/FTE	Average "high-risk"
	<b>Total FTE</b>	Hours	time	time	ratio	establishments
Passing	8.6	1337	23 min/day	71 min/day	334	24%
Failing	15.3	1043	61 min/day	93 min/day	543	38%

#### **Discussion**

When using the proposed model, the number of jurisdictions who met *Item 8.1: Staffing* Level, increased by half (0% to 52%). If the jurisdictions who were "overstaffed" (5) based on the current model were not limited by the inspection-to-FTE-ratio, the number of jurisdictions meeting *Item 8.1: Staffing Level* in the proposed model would have only increased from 26% to 52%. This shows that using the ratio to evaluate staffing levels severely limits the ability to meet Standard 8. Further, the increase in passing rate between the current and proposed models would not have been as high if the ratio was not used.

This provides additional evidence that the current inspection-to-FTE ratio is an inadequate method to assess staffing levels. According to a survey by NACCHO, health departments reported completing Standard 1 (55%), Standard 3 (51%), Standard 6 (46%), and Standard 7 (49%). Similarly, the completion rate based on the proposed model (52%) can be considered comparable to the rates for other Program Standards. The characteristics observed among the participating health departments demonstrate the variability between health departments. We acknowledge that the proposed model cannot take into consideration all of the different factors that can impact staffing level. However, we believe the proposed model is a more reasonable and logical method to calculate staffing level.

For detailed contact information on the Pilot Study team refer to **Appendix**, **Item G**: Pilot Study Team Roster. Refer any questions/comments on the Pilot Study to any of the team members. Data can be made available upon request.

#### Recommendations

On October 21, 2019, the voting members from Subcommittee #2 voted to recommend a modification for Standard 8 to include adding the new proposed model assessment tool as an alternative method to determine compliance. Each jurisdiction that is completing a self-audit will have the option of either using the current or proposed model assessment tools. The intent of the recommendation is not to weaken the Standard, but to provide a secondary assessment tool that can measure practical performance of the enrollee against the Standard. This recommendation has been submitted as an issue for consideration in the Conference for Food Protection 2020 Biennial Meeting.

#### **Appendix**

#### Purpose of Standard 8 staffing level section:

Standard 8 Section 1. Staffing Level requires a health department (HD) to demonstrate that they have the staff "necessary to support an inspection and surveillance system that is designed to reduce risk factors and other factors know to contribute to foodborne illness"

#### **Current criteria to pass Standard 8:**

A HD currently meets this standard if they demonstrate an inspection to FTE ratio inspection-to-FTE ratio range of 280-320 inspections per FTE. The Conference for Food Protection (CFP) developed an assessment tool and instruction guide that <u>can be used</u> by a HD if desired. If not the HD has to calculate their inspection to FTE ratio through their own method and see if it falls within the required range.

#### **Problem with inspection to FTE ratio range:**

It has been agreed by upon by subcommittee that this range is problematic as it is based on the idea that every inspection should take 4 hours. There are two major problems we have identified with the inspection-to-FTE ratio:

#### Problem 1:

• This range was created with the belief that every food inspection regardless of establishment type would take **4-hours**. This is problematic as health departments have establishments that vary by type and risk category making the required time to complete inspections also vary.

#### Problem 2:

• The very existence of a range creates the possibility that a HD can appear to be **overstaffed**. This creates the potential for that HD to have a ratio that goes below the bottom value of the 280-320 range (thus making the HD fail to meet the standard).

#### The logic behind the 4-hour inspection



#### **Problems with these numbers**

- **150 establishments a year per inspector** came from the 1961 International City Managers' Association the Administration of Community Health Services https:// babel.hathitrust.org/cgi/pt?id=mdp.39015072177739&view=1up&seq=177 book sharing that "there is no widely accepted formula on which to base the number of staff persons" but that "some local agencies" use 150
- 2 inspections a year came from the 1976 Food Service Sanitation Manual https:// babel.hathitrust.org/cgi/pt?id=umn.31951002840720j&view=1up&seq=29 that acknowledges the above 150 establishment number and adds without justification that "a minimum of two inspections of each establishment per year is required"
- 8 hours devoted to each establishment comes from the 1997 FDA Food Code https:// wayback.archive-it.org/7993/20170113023657/http:/www.fda.gov/Food/ GuidanceRegulation/RetailFoodProtection/FoodCode/ucmo54458.htm which suggests "8 to 10 hours be allocated per establishment year" also without evidence or clear reasoning

**Conclusion:** There appears to be no strong justification for any of these values based on real data and research making it problematic that they are the criteria from which the 4-hour inspection time is based.

#### **Proposed Model Assessment Tool**

The following is <u>an example</u> of how to use the updated assessment tool to calculate if a health department is adequately staffed.

Discussion on Table 1. The risk category column is broken into three categories, the minimum required by Standard 8. The number of establishments will be unique to each health department (HD). The rows in the remaining columns show values that are based off of survey data of 100 local and state health departments throughout the country (see footnotes for more details). A HD should feel free to use these values or input ones that more appropriately fit their organization.

#### Table 1.

Risk Category	Number of Establishments	Inspection Frequency <sup>1</sup>	Average Inspection Time (does not include travel) <sup>2</sup>	Reinspection frequency <sup>3</sup>	FBI Inspection Frequency <sup>4</sup>	Other Frequency <sup>5</sup>
Low	1,000	1	45 minutes	15%	1%	10%
Medium	2,000	2	75 minutes	15%	1%	10%
High	1,000	3	120 minutes	15%	1%	10%

Step 1. Calculate available annual inspection time per full time equivalent (FTE) using assessment tool. 1200 hours a year will be used for this example.

Step 2. Calculate number of FTE currently available at health department. This # is calculated in the current and updated assessment tools.

Step 3. Calculate total number of hours required to inspect each risk category. Formula for calculating # of inspection hours per risk type below (low risk type used for example):

(1000 establishments x 1 inspection a year = 1000 inspections) + (1000 establishments x 15 % reinspections a year = 150 inspections) + (1000 establishments x 1% FBI inspections a year = 10 inspections) + (1000 inspections x 10% other inspections a year = 100 inspections) = 1260 inspections a year x 45 minutes an inspection = 945 hours a year

Medium risk = 4520 inspections a year x 75 minutes = 5650 hours

High Risk = 3260 inspections a year x 120 minutes =6520 hours

Total inspection time = 945 + 5650 + 6520 = 13,115 inspection hours a year

#### Step 4. Calculate number of FTE's required

13,115 total inspection time hours /1200 inspection hours available per FTE = 10.93 FTEs

#### Step 5. Calculate if health department is adequately staffed

If FTEs currently available >= 10.93 FTEs that a HD should have then that HD is adequately staffed

<sup>&</sup>lt;sup>1</sup> Median inspection frequencies of 105 health departments from 2017 survey

<sup>&</sup>lt;sup>2</sup> Median inspection times of 105 health departments from 2017 survey

<sup>&</sup>lt;sup>3</sup> Median reinspection frequency %s of 60 health departments form 2017 survey2

<sup>&</sup>lt;sup>4</sup> Median food borne illness inspection frequency %s of 60 health departments from 2017 survey2

<sup>&</sup>lt;sup>5</sup> Final % value still being calculated, 10% being used for this demonstration

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#### **RESEARCH INTERESTS**

Theory and Methods: Bayesian modeling, variable selection, graphical models, nonparametric Bayes, statistical computing, multistate Markov models, R package development, varying-coefficient models, hidden Markov models, variational inference

Application: cancer prevention, smoking behaviors, mental health, addiction, physical activity, nutrition, microbiome, mHealth, ecological momentary assessment, intensive longitudinal data, environmental health, human health and performance in space

#### **EDUCATION**

#### The University of Texas Health Science Center, Houston, TX

Doctor of Philosophy, Biostatistics, GPA: 4.0/4.0

Dec 2016

- · Minor: Health Promotions and Behavioral Sciences
- · Title: Deterministic Bayesian variable selection developments for binary outcomes · Advisor: Michael D. Swartz, PhD

#### The University of Texas, Austin, TX

Bachelor of Science, Mathematics

Aug 2011

· Concentration: Scientific Computation

#### **EXPERIENCE**

#### *Rice University*, Houston, TX

Post-Doctoral Research Associate

March 2018 - Current

- · NSF/RTG Post-Doctoral Fellowship in Data Science
- · Advisor: Marina Vannucci, PhD

#### KBRwyle, Houston, TX

Biostatistician

July 2016 - March 2018

- · Human Health and Performance Contract
- · Johnson Space Center

The University of Texas Health Science Center, Houston, TX

Pre-Doctoral Fellow

Jan 2015 - Dec 2016

- · National Cancer Institute Pre-Doctoral Fellowship
- · Cancer Education and Career Development Program

Pre-Doctoral Trainee

Aug 2013 - Jan 2015

· National Institutes of Health Pre-Doctoral Traineeship

#### Science Systems and Applications, Inc., Hampton, VA

Summer Intern

May 2014 - Aug 2014

- · DEVELOP National Program
- · Langley Research Center

#### National Space Biomedical Research Institute, Houston, TX

Summer Apprentice

May 2013 - Aug 2013

· Biostatistics

Laboratory · Johnson

Space Center

#### Cancer Prevention and Research Institute of Texas, Austin, TX

Summer Intern

May 2010 - Oct 2010

- · University of Texas School of Public Health
- · Biostatistics Department

#### **TEACHING EXPERIENCE**

University of Texas Health Science Center, Department of Biostatistics and

Data Science

Lecturer (Ad Hoc), Foundations of Biostatistics (PH1690) Fall 2019

Lecturer (Ad Hoc), Foundations of Biostatistics (PH1690) Summer 2019

· Student evaluation of overall effectiveness - 4.86/5.0

Teaching Assistant, Theory of Biostatistics II (PH1911) Spring 2016

Teaching Assistant, Linear Models (PH1915) Fall 2015

Teaching Assistant, Intermediate Biostatistics (PH1700) Fall 2015 Teaching

Assistant, Applied Statistical Analysis I (PH1820) Summer 2015 Teaching

Assistant, Applied Statistical Analysis II (PH1821) Spring 2013

#### **PUBLICATIONS**

#### Submitted/In Progress

- 1. Koslovsky, M.D. & Vannucci, M. DTMbvs: Dirichlet-tree multinomial regression models with Bayesian variable selection for microbiome Data - an R package. BMC Bioinformatics. (Revised)
- 2. Koslovsky, M.D., Hoffman, K., Daniel-MacDougall, C., & Vannucci, M., A joint model for predicting phenotypic responses with human microbiome data. (Submitted)
- 3. Koslovsky, M.D., H'ebert, E.T., Businelle, M.S., & Vannucci, M. An efficient Bayesian varying-coefficient modeling approach for behavioral mHealth data. (Submitted)
- 4. Rosenberg, M.J., Koslovsky, M.D., Noyes, M., Reschke, M.F., & Clement, G. Tandem Walk in Simulated Martian Gravity and Visual Environment. (Submitted)
- 5. **Koslovsky, M.D.**, Liang, M.<sup>†</sup>, & Vannucci, M. A Bayesian hidden Markov model for accommodating social desirability bias in mHealth data. (In Progress)

- 6. Shaddox, E.<sup>†</sup>, **Koslovsky, M.D.**, & Vannucci, M. A Spiked Dirichlet Process Prior for Joint Network Inference. (In Progress)
- 7. H'ebert, E.T., Koslovsky, M.D., & Businelle, M.S. Time-varying relations for smoking behaviors captured in a novel, smartphone-based just-in-time adaptive intervention. (In Progress)
- 8. Denti, F.<sup>‡</sup>, **Koslovsky, M.D.**<sup>‡</sup>, Guindani, M., Vannucci, M., & Whiteson, K.L. Bayesian models for understanding the modulating factors of microbiome data. In S. Datta & S. Guha (Eds.), Statistical Analysis of Microbiome Data. Springer Verlag. (In Progress)
  - $^\dagger$  indicates PhD student in Dr. Vannucci's research group at Rice University  $^\ddagger$  indicates equal contribution

#### Statistical Methodology

- 9. Koslovsky, M.D., Swartz, M.D., Chan, W., Leon-Novelo, L., Wilkinson, A.V., Kendzor, D.E., & Businelle, M.S. (2018). Bayesian variable selection for multistate Markov models with interval-censored data in an ecological momentary assessment study of smoking cessation. Biometrics, 74(2), 636-644.
- 10. Koslovsky, M.D., Swartz, M.D., Leon-Novelo, L., Chan, W., & Wilkinson, A.V. (2018). Using the EM algorithm for Bayesian variable selection in logistic regression models with related covariates. Journal of Statistical Computation and Simulation, 88(3), 575-596.

#### **Applications**

- 11. Zwart, S.R., Rice, B.L., Dlouhy, H., Shackelford, L.C., Heer, M., Koslovsky, M.D., & Smith, S.M. (2018). Dietary acid load and bone turnover during longduration spaceflight and bed rest. The American Journal of Clinical Nutrition, 107(5), 834-844.
- 12. Conkin, J., Sanders, R.W., Koslovsky, M.D., Wear, M.L., Kozminski, A.G., & Abercromby, A.F. (2018). A systematic review and meta-analysis of decompression sickness in altitude physiological training. Aerospace Medicine and Human Performance, 89(11), 941-951.
- 13. Koslovsky, M.D., H'ebert, E.T., Swartz, M.D., Chan, W., Leon-Novelo, L., Wilkinson, A.V., Kendzor, D.E. & Businelle, M.S. (2017). The time-varying relations between risk factors and smoking before and after a quit attempt. Nicotine and Tobacco Research, 20(10), 1231-1236.
- 14. Conkin, J., Wessel, J.H., Norcross, J.R., Bekdash, O.S., Abercromby, A.F., Koslovsky, M.D., & Gernhardt, M.L. (2017). Hemoglobin oxygen saturation with mild hypoxia and microgravity. Aerospace Medicine and Human Performance, 88(6), 527-534.

#### **Proceedings**

15. Meyers, J., Garcia, Y., Arellano, J., Boley, L., Goodenow D., Kerstman, E., Koslovsky, M.D., Reyes, D., Saile, L., Taiym, W., & Young, M. (2018, September 16-21). Validation of the NASA Integrated Medical Model: A Space Flight Medical Risk Prediction Tool. Paper presented at Probabilistic Safety Assessment and Management 14, Los Angeles, CA.

- **PRESENTATIONS** Koslovsky, M.D.\*, Hoffman, K., Daniel-MacDougall, C., & Vannucci, M. "A Bayesian Model of Microbiome Data for Simultaneous Identification of Covariate Associations and Prediction of Phenotypic Outcomes." Joint Statitsics Meetings, Denver, CO. Aug 2019. (contributed poster presentation)
  - Koslovsky, M.D.\*, Hoffman, K., Daniel-MacDougall, C., & Vannucci, M. "A Bayesian Model of Microbiome Data for Simultaneous Identification of Covariate Associations and Prediction of Phenotypic Outcomes." BigDIA, Houston, TX. Dec 2018. (contributed poster presentation)
  - Yu, D., Sedory, A.C., Mohammadi, K., Koslovsky, M.D., & Swartz, M.D.\*. "Trio RVEMVS: A fast Bayesian variable selection method for trios that identifies individual rare variants," International Genetic Epidemiology Society Meetings, San Diego, CA, Oct 2018. (platform presentation)
  - Koslovsky, M.D.\*, Arellano, J., Schaefer, C., Feiveson, A., & Young, M. "CommClust: A network-based algorithm for clustering multivariate repeated measures data." NASA HuMan Research Program Investigators' Workshop, Galveston, TX. Jan 2018. (contributed poster presentation)

#### **AWARDS**

- Dr. M. Stewart West Memorial Scholarship, 2015
- UTHealth Division of Biostatistics Travel Award, 2015
- Richard D. Remington Memorial Student Scholarship, 2014
- Robert, H Bigelow Endowed Scholarship, 2013

#### **MENTORING**

- Yefei Zhang, UTHealth, PhD Biostatistics candidate, Dissertation Committee, 01/2017-Current
- Scott Liang, Rice University, PhD Statistics student, Co-mentor, 03/2019Current
- James Warner, Rice University, Rice Undergraduate Data Science Summer Program, 2018
- Karan Adams, Rice University, Rice Undergraduate Data Science Summer Program, 2018
- Stoyan Komitov, Rice University, Rice Undergraduate Data Science Summer Program, 2018
- Alex Aguilar, Rice University, PhD Statistics candidate, NASA Summer Intern, 2018
- Austin Vo, University of Central Florida, NASA Summer Intern, 2017
- UTHealth New Student Mentor, Fall 2013

#### COMPUTER **SKILLS**

Languages & Software: R, C++, Rcpp, Shiny, LATEX, STATA, SAS, WinBUGS

#### **PROFESSIONAL**

**AFFILIATION** 

Member

• American Statistical Association, 2015 – Current

#### **PROFESSIONAL**

Reviewer

**SERVICE** 

• Biometrical Journal, Biometrics, Biostatistics, Nature Communications

#### Board Member

Johnson Space Center IRB

#### **Board Member**

Conference for Food Protection: Program Standards Committee, KBRwyle, NASA

#### **CONTINUING SERVICE**

- HACASA Short Course "Randomized Clinical Trials replacing Traditional Analyses with Better Alternatives," Houston, TX, May 2018
- Joint Statistical Meetings Short Course "Network Meta-Analysis," Baltimore, MD, Aug 2017
- NASA Human Research Program Investigator's Workshop "A New Dawn: Enabling Human Space Exploration," Galveston, TX, Jan 2017
- Technology Collaboration Center "Omics Workshop," Houston, TX, Spring 2017
- Tableau Conference 2016 Tableau Classroom Training- "Tableau Desktop II," Austin, TX, Fall 2016

- ENAR Short Course "An Introduction to Statistical Machine Learning," Austin, TX, Spring 2016
- ENAR Tutorial Session "Data Visualizations in R with shiny and ggplot2," Austin, TX, Spring 2016
- ENAR Tutorial Session "High Performance Computing with R," Austin, TX, Spring 2016
- ASA Biopharmaceutical Section FDA Industry Statistics Workshop "Equivalence and Similarity Testing," Washington, DC, Fall 2015
- ASA Biopharmaceutical Section FDA Industry Statistics Workshop "Designing Observational Comparative Studies Using Propensity Score Methodology in Regulatory Settings," Washington, DC, Fall 2015
- Joint Statistical Meetings "Adaptive Methods for Modern Clinical Trials," Seattle, WA, Summer 2015
- UT Summer Statistics Institute "Introduction to Mixed Models with Applications," Austin, TX, Summer 2015
- UT Summer Statistics Institute "Big Data Analytics," Austin, TX, Summer 2015

#### Item B: Dr. Koslovsky - CV

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#### **Standard 8 Pilot Survey**

Subcommittee #2 established by the Program Standards Committee is conducting a survey to pilot a model evaluating the staffing requirements as outlined by Standard 8 of the Voluntary National Retail Food Regulatory Program (FDA). The purpose of this survey is to collect the necessary data to conduct a staffing level audit for your Health Department.

You will need to use the guidance documented provided to assist you in filling out the information on the survey.

1. Please provide your name and jurisdiction
2. On average, how many hours per year do EHS (Environmental Health Specialist) employees spend on the following: (If not applicable, please answer "N/A")
Holiday
Vacation
Sick leave
Family/Personal leave
3. On average, how many hours per year do your EHS employees spend on the following:  (If not applicable, please answer "N/A")
Traveling to/from inspections
Administrative work
Break time
Professional development (training, continuing education)

4. Please list <u>all employees</u> who conduct food safety inspections using the following format:

department  Example: Environmental Health Specialist-Training, 60%, 12	r of this type of employee in your health
(If less than 6 positions, please answer "N/A" for empty boxes)	
Position 1	
Position 2	
Position 3	
Position 4	
Position 5	
Position 6	
5. Please provide the total number of inspections for your department's entire jurisdiction in one y	
6. How many of each of the following establishme	ents does your department conduc
inspections on? (If not applicable, please answer "N/A")	
Low-risk	
Moderate-risk	
High-risk	
7. How many routine inspections were conducted	l in 2018?

#### **Item C: Pilot Study Survey**

8. How many permitting inspections were conducted in 2018?
*9. What is the average time spent conducting each of the following inspections in
your department?
(If not applicable, please answer "N/A")
*Note: Please specify when using hours or minutes.
Follow-ups/reinspections
Food-borne illness complaints
Complaint investigations
domplaint investigations
Outbreak investigations
Compliance follow-up inspections
Risk assessment reviews
Process reviews
Variance process reviews
Final construction inspections
Other

### INSTRUCTIONS FOR PROVIDING DATA REQUESTED FOR PILOT

#### **Guidance Notes:**

These notes are intended to guide the survey process by providing you with definitions, examples, and instructions on how to answer the survey questions. We also suggest where you might find the information needed if you do not have it readily available. Use the checklist provided on Page 3 ensure you have all the information to fill this survey.

#### **Question 1:**

"Holiday, Vacation, Sick Leave, Family Personal Leave" - These hours may vary by seniority of staff or other factors, please provide the best average for a 100% full-time EHS staff. Your Human Resources department may be a good resource to obtain some of this information.

#### **Question 2:**

"Traveling to/from inspections" - Districts vary in size and therefore this number will be different across health departments. Please use a best estimate or average time for a full-time equivalent EHS staff.

"Administrative work" - This includes any office time and administrative work an EHS employee does outside of food inspection. This does **NOT** include completing the inspection report.

"Professional development" - This includes things like training and continuing education.

#### **Question 3:**

"Employees who conduct food safety inspections" - For this question, we ask that you take time to consider all of the employees that conduct food safety inspections. Most health departments have inspectors whose time is dedicated solely to food safety, but have others that may dedicate only a small percentage of their time to food. For example, supervisors may conduct inspections, but only dedicate about 10% of their time to this. Use as many rows as needed to list all types of employees who conduct food inspections, even if their job titles are similar. For example:

- 1. EHS I, 80%, 15
- 2. EHS II, 60%, 5
- 3. EHS Supervisor, 40%, 2
- 4. EHS Manager, 5%, 1

#### **Question 4:**

"Total number of inspections" - Inspections are defined as routine inspections, re-inspections, complaint investigations, outbreak investigations, compliance follow-up inspections, risk assessment reviews, process reviews, variance process reviews, foodborne illness complaint response, final construction inspections and other direct establishment contact time

### **Item D: Survey Guidance Document**

such as on-site training that is performed by the field inspection staff. (Standard 8 Staffing Level Assessment Workbook: Instruction Guide, page 10).

#### **Question 5:**

"Low - Moderate - High Risk" - Do your best to categorize all of your establishments into low, moderate, and high risk categories.

- If you have more than three categories, attempt to distribute your establishments into the categories provided.
- If you currently use fewer than three categories (Example: Low and High), then only provide the number of establishments for those categories and leave the unused one blank.
- If you do not already have a process in place to categorize food establishments in your jurisdiction, the FDA Food Code has a recommended guide to assist with categorizing, refer to Annex 5, Table 1 (Page 4 of this document). You can also review a recommendation of how to categorize your establishments below:
  - 1. **Low risk establishments** = Examples include most convenience store operations, or establishments that sell pre-packaged or non-TCS (temperature control for safety) food.
  - 2. **Moderate risk establishments** = Examples may include retail food store operations. They may have a limited menu. Most products are prepared/cooked and served immediately.
  - 3. **High risk establishments** = Examples include full service restaurants. Extensive menu and handling of raw ingredients. Complex preparation including cooking, cooling, and reheating for hot holding involves many TCS foods.

#### **Question 6 & 7:**

"Routine Inspections" - A full review and evaluation of a food establishment's operations and facilities to assess its compliance with food safety law, at a planned frequency determined by the regulatory authority. This does not include reinspections and other follow-up or special investigations.

"Permitting Inspections" - A review of a food establishment's operations and facilities to determine if a permit will be issued for the establishment to operate.

#### **Question 8:**

"Average time" - For each category determine the time spent on the activity from beginning to end, plus any writing and delivering reports if applicable. For example, for follow-up/re-inspections: average time = (inspection start to finish) + writing and delivering report. Leave blank if category is not applicable to your jurisdiction.

### **CHECKLIST**

Before starting the survey please gather all information mentioned on the below checklist. It is vital to the success of this pilot study that you try and obtain as accurate of information as possible.

Note: Annual Non-Inspection Hours and Annual Productive Hours are for an EHS employee dedicated to 100% food inspections. While there may be some variation in these hours per employee please provide the best possible average.

	<b>Annual Non-Inspection Hours</b>	<u> </u>	Annual Productive Non-Food Inspection <u>Hours</u>
0000	Holiday Vacation Sick Leave Family/Personal Leave		Travel time to and from inspections Administrative work (not including inspection reports) Break time (lunch, break, etc.) Professional development (training, continuing education)
	EHS or Related Positions		Other Inspection Data
	A list of all types of EHS personnel or related positions (ANYONE who conducts a food establishment inspection)	0 0	Total number of food safety inspections conducted in 2018 List of all food establishments in your jurisdiction How many routine/permitting inspections

Annex 5, Table 1. Risk Categorization of Food Establishments

RISK CATEGORY	DESCRIPTION	FREQUENCY #/YR
1	Examples include most convenience store operations, hot dog carts, and coffee shops. Establishments that serve or sell only pre-packaged, non- time/temperature control for safety (TCS) foods. Establishments that prepare only non-TCS foods. Establishments that heat only commercially processed, TCS foods for hot holding. No cooling of TCS foods. Establishments that would otherwise be grouped in Category 2 but have shown through historical documentation to have achieved active managerial control of foodborne illness risk factors.	1
2	Examples may include retail food store operations, schools not serving a highly susceptible population, and quick service operations. Limited menu. Most products are prepared/cooked and served immediately. May involve hot and cold holding of TCS foods after preparation or cooking. Complex preparation of TCS foods requiring cooking, cooling, and reheating for hot holding is limited to only a few TCS foods. Establishments that would otherwise be grouped in Category 3 but have shown through historical documentation to have achieved active managerial control of foodborne illness risk factors. Newly permitted establishments that would otherwise be grouped in Category 1 until history of active managerial control of foodborne illness risk factors is achieved and documented.	2
3	An example is a full service restaurant. Extensive menu and handling of raw ingredients. Complex preparation including cooking, cooling, and reheating for hot holding involves many TCS foods. Variety of processes require hot and cold holding of TCS food. Establishments that would otherwise be grouped in Category 4 but have shown through historical documentation to have achieved active managerial control of foodborne illness risk factors. Newly permitted establishments that would otherwise be grouped in Category 2 until history of active managerial control of foodborne illness risk factors is achieved and documented.	3
4	Examples include preschools, hospitals, nursing homes, and establishments conducting processing at retail. Includes establishments serving a highly susceptible population or that conduct specialized processes, e.g., smoking and curing; reduced oxygen packaging for extended shelf-life.	4

AGENCY Standard 8: Staffing Levels FTE (Full-Time Employee) Data DATE

FTE DATA C	FTE DATA CALCULATIONS								
Program Descri	iption and Supporting	Information:							
r rogram Beser	paon ana sapporan	5 mormacion.							
FOOD SAFE	TY PROGRAM FT	E HOURS P	ER YEAR	•					
	urs Per Year: Industr			2080					
	Local Holiday Hours Per Year  Local Vacation Leave Hours Per Year								
	Local Sick Leave Hou	ırs Per Year							
	Local Family-Person		Per Year						
Annual FTE Ho	urs Per Year: Local In	•		2080					
	Productivity Factoria								
	Personal Developme								
Productive Ann	nual FTE Hours Per Y	ear (FTE Conve	ersion Factor): Local Inspector	2080					
FOOD SAFE	TY INSPECTION I	HOURS PER	YEAR						
Position	Food Safety	Number of	Total Food Safety						
Category	Inspection Hours	Employees	Inspection Hours						
			0						
			0	_					
	0								
Total Food Safe	ety Inspection Hours			0					
Other Local Ins	pector EH Inspection	Hours		0					
Actual Food Sa	fety Inspection Hour	s		0					
Total Local FTE			C	<mark>).0</mark>					

**AGENCY** Standard 8: Staffing Levels Inspection-to-FTE Ratio

DATE

INSPECTION-TO-FTE RATIO					
In accordance with Standard 8 Self-Assessment Guidance provided in the January 2011 version of the					
Program Standards, the Inspection-to-FTE Ratio must fall between 280 and 320.					
Local program number of Food Safety Inspections	0				
Local program number of FTEs	0.0				
Inspection-to-FTE RATIO	#DIV/0!				

Calculate pro	ductive hours per year for an employee	doing 100% fo	od inspections	;
	, , , , ,	0		
In	formation For One Employee	Hours/Year	Hours/Day	Total Hours
Annual FTE Hour	s Per Year: Industry Standard			208
	Local Holiday Hours Per Year			
	Local Vacation Leave Hours Per Year			
	Local Sick Leave Hours Per Year			
	Local Family-Personal Leave Hours Per Year			
Productivity Fa	ctoring Per Year			
	Travel Time For Inspection			208
	Administrative Work (in-office work)			208
	Break time			208
	Others			208
Personal Devel	opment Time Per Year			
	Professional Development			208
	Others			208
Productive A	nnual FTE Hours Per Year (FTE Conversion	n Factor)		208
<b>FOOD SAF</b>	ETY INSPECTION HOURS PER YE	AR		
Position Title	Percent of time spent on food inspections	Number of Employees	Total Hours	
			0	
			0	
			0	
			0	
			0	
			0	
Total Food Sa	fety Inspection Hours		0	
Total Took 3a	icty inspection from			

STANDARD 8's REQUIRED FTE FOR YOUR JURISDICTION								
	Low Risk Establishments	Frequency of Low Risk Est Inspections Per Year	Moderate Risk Establishments	Frequency of Moderate Risk Est Inspections Per Year	High Risk Establishments	Frequency of High Risk Est Inspections Per Year	Total	
Routine and Permitting		1.00		2.00		3.00	C	
Follow Up Inspections/Reinspections							C	
Foodborne Illness Complaints							C	
Other							c	
Total Number of Required Inspections							(	
Median Hours Spent Per Inspection	0.75		1.25		2.00			
Total Inspection Time							C	
Total Required FTE							0.00	
Standard 8.1 Staffing Level							Standard not met	
Sources								
-2017 Subcommittee # 2 - Survey 1 and 2								
-2019 Pilot Study								

#### PILOT STUDY TEAM

#### Michael Schaffer, MBA, CPO

Subcommittee #2 Co-Chair Director Environmental Public Health Division Harris County Public Health Michael.Schaffer@phs.hctx.net

#### Riddhi Patel, MBBS, MPH, PhD(s)\*

PhD Student - Epidemiology The University of Texas School of Public Health at Houston Graduate Research Assistant Sarcoma Medical Oncology The University of Texas MD Anderson Cancer Center Riddhi.R.Patel@uth.tmc.edu

#### Jo Ann Monroy, MPH

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#### Jessica Ortiz, MA

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#### **ACKNOWLEDGEMENTS**

The Pilot Study Team would like to thank all members from Subcommittee #2 and the Program Standards Committee for their feedback and suggestions. Their input and expertise was invaluable throughout the process to develop a recommended solution to the Standard. Special thanks to the 18 jurisdictions who took the time and effort to provide the data necessary to drive this Pilot Study.

<sup>\*</sup>Riddhi Patel conducted the 2017 survey and originally developed the proposed model from which all this work was based on.

### Standard #4 Clearinghouse Questions

Submitted by Carrie Pohjola, WI DATCP

Carrie.Pohjola@Wisconsin.gov, 715-579-9487

An issue was submitted during the 2018 Biennial Conference for Food Protection with regard to individuals conducting field exercises. Background information regarding this issue submission is as follows:

When conducting a Standard 4 audit for jurisdictions; the auditor must ensure that the jurisdiction meets the applicable requirements. At this time, there is no consideration for performing an audit on larger jurisdictions. Jurisdiction sizes are only taken into consideration in calculating the program effectiveness. There are jurisdictions in the country that have over 100 inspectors not within their first 18 months of training as part of their food program. This means that an auditor will have to verify that at least 300 field reviews and the applicable file reviews are conducted and that they meet the requirements listed. This creates an undue hardship on the auditor and should be re-examined. In Standard 1, 2, and 6, there is a statistical model utilized to pull a random sampling of the content to be reviewed, with which the auditor can then use to determine whether the jurisdiction meets the requirements. It is recommended that for jurisdictions with over 20 inspectors performing foodservice or retail food inspection work, a similar statistical measure be provided or allowed to determine whether the jurisdiction meets the Standard.

Currently, there is no specification requiring an auditor to verify that the individual(s) performing the field reviews have been conducted by someone that has completed Steps 1-3 in Standard 2, and is recognized by the program manager as having the field experience and communication skills necessary to train new employees.

Should the auditor then verify the training records, affidavits, certificates, etc... for those individual(s) that are performing the field reviews? If so, it is recommended that a field evaluator course, track, and/or certificate be established to demonstrate Steps 1-3 of Standard 2 have been completed. This will be especially beneficial when auditing large jurisdictions with many individual(s) performing the field reviews. Although the Retail Program Standards are voluntary, and auditors volunteer, performing an audit is highly time consuming and any means to make this process more efficient would be beneficial.

#### **Questions:**

- 1. When conducting the field exercises and applicable file review for Standard #4, does the evaluator need to be trained in Standard #2, Trained Staff?
- 2. Does an auditor need to review all field exercise files for all staff when conducting a verification of Standard #4?

#### **AUDITOR VERIFYING STANDARD 2 TRAINING**

Key Words: STD-02, STD-04, Field Exercises, Verification Audit, File Review

#### **Issue Description**

### Background

Currently there are no specifications that require an auditor to verify that the individual(s) performing the field reviews of other staff members has completed Steps 1-3 in Standard 2. Would this require the auditor to verify via training records, affidavits, and the like, that the individual(s) performing the field reviews has completed these steps? If so, is it recommended that a field evaluator course, track, and/or certificate be established to demonstrate Steps 1-3 of Standard 2 have been completed. This will be especially beneficial when auditing large jurisdictions with many individual(s) performing the field reviews.

#### Rationale

#### **Question/Problem**

When conducting the field exercises and applicable file review for Standard #4, does the staff member conducting the review need to be trained in Standard #2, Trained Staff? Does an auditor need to verify that this training has occurred?

#### **Response from Clearinghouse**

The Standard 4 Self-Assessment Instructions and Worksheet states that field reviews must be conducted by someone who has:

- A) Completed Steps 1-3 in Standard 2; and
- B) Recognized by the program manager as having the field experience and communication skills necessary to train new employees.

Currently there are no requirements that an auditor verify that staff members conducting field reviews with other employees have completed steps 1-3 in Standard 2. An auditor is not required to verify additional paperwork related to any Standard 2 criteria when conducting the Standard 4 verification audit.

#### **Update: EXPLANATION OF THE STATISTICAL MODEL for STANDARD 4**

The criteria used for evaluating the inspectional performance of jurisdictions have changed resulting in the need to update the statistical model. Previously in large jurisdictions (jurisdictions with 10 or more inspectors) the evaluation is based on direct oversight of two inspections per inspector, with respect to 10 items of performance. There will now be 20 items on performance instead of 10.

Using the previous statistical model and assumptions, a team achieving 88 percent at each inspection would pass the evaluation 75 percent of the time. Therefore, this 88 percent level of performance was used as a simple representation of a team that is good enough that we want them to have a good chance of passing, but not so good that they would not find it advantageous to improve. But now with 20 items instead of 10 a jurisdiction with 88 percent level of performance would pass only 59% of the time. This would fail too many high performing jurisdictions.

Large jurisdictions (jurisdictions with 10 or more inspectors) the evaluation is based on direct oversight of three inspections per inspector, with respect to 20 items of performance. With the additional inspections evaluated the 88 percent performing jurisdiction will pass 75% of the time.

#### Evaluation of performance of small jurisdictions

A statistical issue was to determine a reasonable standard for those jurisdictions with less than 10 inspectors. When the sample gets this small, the relative error in the estimated fractions gets so large that the "each of 20 items rule" will fail good programs too frequently. Therefore, the 88 percent level of performance at each inspection was the feature of the standard that was kept constant in designing the sample sizes for the smaller jurisdictions

In jurisdictions with less than 10 inspectors, the statistical solution is to group all of the individual ratings, disregarding the individual items. For 5 inspectors we would review  $5 \times 3 = 15$  inspections, with respect to all 20 items combined. This gives 300 observations. It is not possible to make a total observation test mimic exactly a 10 item test, but the minimum passing rates will be about as stringent as the 75 percent for each of 10 aspects test:

For 4 to 9 inspectors, conduct three co-inspections for each inspector. Chart 4-1 shows the lowest total passing score out of the complete set of combined items that would give at least a 75 percent chance of passing for a team with an 88 percent chance of getting any particular observation correct. For a team of three or less, it is recommended that extra oversight inspections be performed to produce a total of 12 inspections. This is an intuitive judgment call that any set smaller than 12 could randomly turn out to be odd enough to produce an unfair rating.

### Standard 4: Uniform Inspection Program Self-Assessment Worksheet

Chart 4-1: Method of Calculation for Jurisdictions with Less Than Ten Inspectors

# of inspectors	# inspections needed	# of items needed to be marked IN compliance in order to meet Standard 4 criteria
<4	12 minimum	200 (out of 240 possible Items)
4-9	3 per inspector	4 inspectors = 200 (out of 240 possible Items) 5 inspectors = 252 (out of 300 possible Items) 6 inspectors = 303 (out of 360 possible Items) 7 inspectors = 355 (out of 420 possible Items) 8 inspectors = 407 (out of 480 possible Items) 9 inspectors = 459 (out of 540 possible Items)

#### NOTE:

1. These minimum inspection program assessment criteria are comparable to the 75% IN Compliance rate for each of the ten inspection program areas for jurisdictions with 10 or more inspectors.

#### Example:

For 6 inspectors, there will be 3 field visits per inspector = 18 visits 18 visits X 20 Items per visit = 360 Total Possible Items

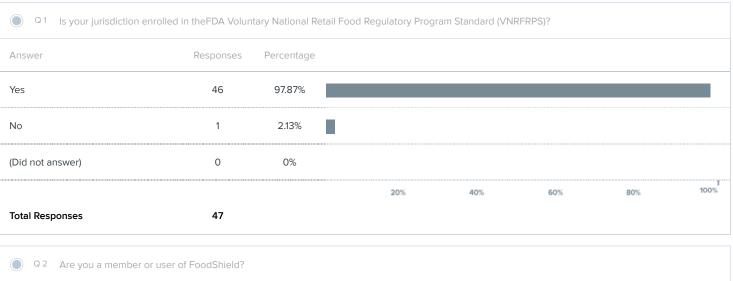
4/15/2019

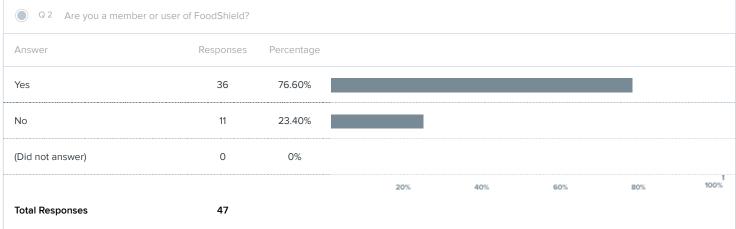
Bar Graph

## **Survey Metrics**

Date Metrics		Deployment Metrics	
Start Date End Date	14-Mar-19 4-Mar-29	Sent Delivered Bounced	0 0 0
Response Metrics			
Completed Unique Access Rate Incomplete Incomplete Incl. in Report	47 0.00% 0 0		

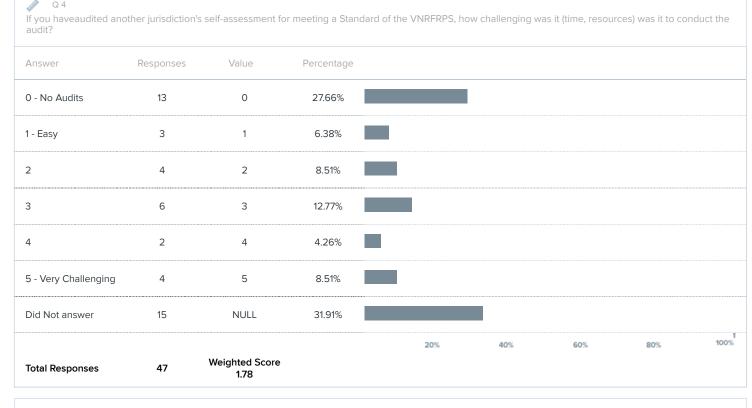
### Bar Graph Report

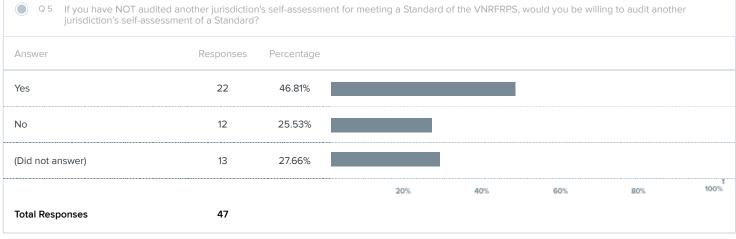




Q3 Have you ever audited another jurisdiction's self-assessment for meeting a Standard of the VNRFRPS?

Answer Partial Achievement Survey	Responses	Percentage		
Yes	19	40.43%		
No	28	59.57%		
(Did not answer)	0	0%		
			20% 40% 60% 80% 100	
Total Responses	47			





Q 6 Would you be willing to audit a partial achievement (individual elements) of a Standard?						
Answer	Responses	Percentage				
Yes	33	70.21%				

•	. 6/20 . 6			24. 0.45
	No Partial Achievement Survey	14	29.79%	
	(Did not answer)	0	0%	
				20% 40% 60% 80% 100%
	Total Responses	47		

My jurisdiction wants the option to have recognition for meeting part of a Standard in the VNRFRPS								
Answer	Responses	Percentage						
Yes	32	68.09%						
No	15	31.91%						
(Did not answer)	0	0%						
			20%		40%	60%	80%	100%
Total Responses	47							

Q 8 What benefits would partia	rrecognition prov	vide your organ	IIZdlIOII:					
Answer	Responses	Percentage						
Approval from governing agency/local authority	8	17.02%						
National recognition	3	6.38%						
Gratification of achievement within your agency	17	36.17%						
None	8	17.02%						
My organization is not interested in partial recognition	3	6.38%						
Money	3	6.38%						
Other (Please specify)	4	8.51%						
(Did not answer)	1	2.13%						
				20%	40%	60%	80%	100

Q 9 Are you familiar with the	e VNRFRPS progress	tracking spreadsheet draft (PS2017_SA_Audit_Form_Draft.xlsx) ?
Answer	Responses	Percentage
Yes	24	51.06%
No	23	48.94%
(Did not answer)	0	0%

0/2010			Dai Giapii				
Partial Achievement Surv	еу		20%	40%	60%	80%	100%
Total Responses	47						
Q 10 Is your organization a sta	nte or local jurisdicti	ion?					
Answer	Responses	Percentage					
Local	43	91.49%					
Federal	1	2.13%					
Tribal	0	0%					
State/Territory (Please specify)	3	6.38%					
(Did not answer)	0	0%					
			20%	40%	60%	80%	100%
Total Responses	47						

#### PRELIMINARY PLAN REVIEW PROPOSAL

# Reasons for including plan review in Voluntary National Retail Food Regulatory Program Standards

Programs standards exist to evaluate if the regulatory program is effectively controlling and/or reducing foodborne illness risk factors through periodic assessment of existing programs to identify if improvement is needed.

Plan review identifies if the proposed or remodeled establishment will have adequate facilities, systems, and equipment to safely store, prepare and serve food.

Lack of plan review or incomplete plan review may result in conditions that contribute to foodborne illness, such as a lack of proper equipment to properly store or hold food at safe temperatures, unsanitary conditions that promote pest infestation, contamination from employees, raw animal foods, unclean food contact surfaces, etc.

#### **Requirement Summary:**

Food establishment plan review is recognized as an important food program component that allows:

- Regulatory agencies to ensure that food establishments are built or renovated according to current regulations or rules.
- Industry to establish an organized and efficient flow of food.
- Regulatory agencies to eliminate code violations prior to construction.

#### **Description of Requirement:**

Competency of personnel conducting the plan review

- Training
- Continuing Education

For all new and substantially remodeled establishments [defined in program regulations]

#### **Outcome:**

Regulatory agency reviews all plans for food establishments to determine compliance with applicable sections of the Food Code, or local regulations. If the regulatory program does not have resources to conduct plan review or if the agency does not have jurisdiction over plan review, indicate if there another agency within the jurisdiction that provides this service (such as when the inspecting agency does not issue the food safety license).

#### **Documentation:**

Plan review process and required documentation requested from applicants

Subjects/areas reviewed for each plan, including but not limited to:

#### PRELIMINARY PLAN REVIEW PROPOSAL

- Appropriate facilities to prepare food safely
- Systems to prevent foodborne illness and injury
- Adequate space and equipment for all CCPs in the flow of food
- Plumbing systems safe water and waste water disposal; appropriate backflow prevention; adequate supply of hot water; size and location of dish washing sinks and machines; drain boards; removal of grease – trap or interceptor; sewage disposal; produce washing/food preparation sink; utility sink
- Prevention of cross-contamination (areas and/or time for preparation of raw and readyto-eat foods)
- Adequate numbers and capacity of food storage and production equipment
- Proper hygiene hand washing sinks are provided in all necessary areas and are easilyaccessible
- Menu review to identify HACCP process flows
- Cleaning and maintenance of facilities, premises and equipment; equipment on legs or sealed to the floor
- Chemical storage locations
- Waste storage and removal
- Electrical system capacity; adequate lighting and shielded
- HVAC ventilation to remove grease, odors and moisture kitchen and restrooms
- Prevention of conditions that contribute to pest infestation
- Approved food service equipment NSF or similarly-approved
- Adequate storage for clean utensils, food, linens, single-service articles and equipment
- Adequate storage for employee personal belongings, locker rooms, restrooms

Documentation of all plan reviews (approval, conditional, denial) within specified time frame in standardized format.

Reviewer – checks x % for compliance.

Here are the minutes from the kickoff call (12/19/2018):

- Greeting and antitrust statement.
  - > Attendance was taken at the start of the call.
- Proposed calendar for calls is 1/9, 1/23, 2/6 then second Wednesdays of the subsequent months (3/13, 4/10, 5/8, 6/12, 7/10, 8/14) which concludes on September 11<sup>th</sup>. We'd also like to ask for flexibility, as we may need to include additional calls in the coming months. If we are all in agreement with the proposed schedule of calls, calendar invitations will be sent out by the end of this week.
  - > 1/09 Review Charge 1
  - > 1/23 Review Charge 3
  - > 2/06 Review Charge 2. David Read will review the IFPTI group work for Charge 2.
- Discuss procedures/Food Shield access and use. Meeting minutes will be posted on our Food Shield workgroup page within 48 hours of our calls.
  - > Angie Cyr sent out the Food Shield usernames and passwords from that website on November 5th. Confirmed successful access to the workgroup documents.
- Goals/Review the charges assigned to this subcommittee. Subcommittee reports will be prepared and submitted according to the CFP master calendar. The first of which is due by 2/09/2018.
  - > The charges under the issue 2018 II-019 were reviewed with the group and explained briefly.
  - > David Read gave an update on his work specifically reviewing the regulatory training program. He shared the website to reference his group work, <a href="https://ifpti.org/retail-food-framework/">https://ifpti.org/retail-food-framework/</a>
  - > To prepare for the upcoming call, the group was asked to review the documents uploaded to Food Shield. Pages 2,3, 19-25 of the 2017 Program Standards Committee Report are pertinent to us, as we continue reviewing the issue.

#### Call Participants (8)

DeBrena Hilton
Adam Kramer
Amanda Douglas
Christine Sylvis
Matthew Walker
Kenesha Williamson
David Read
Katey Kennedy

Here are the minutes from the call (1/09/2019):

#### What are some current initiatives used for training food safety inspection officers?

Mark – Standard 2 training curriculum, review of codes specific to Iowa, and all staff attend FD 218 risk based inspection methods, FD 312 special processes, and FD 215 managing retail food safety. Matt – Compliance Wire for special processes training.

#### What is the difference between Compliance Wire and Pathlore?

David – FDA moved away from Compliance Wire and started using Pathlore going forward. They migrated their learning management system.

DeBrena – Tulsa uses their state agency partners to present the same FDA courses. Sometimes the FDA specialist will present and the State will present a portion of the course.

#### Which of the FDA courses has the course in a box instructor material available?

Christine - Several districts are burdened with the cost of hosting the instructor, paying the course fees, etc.

Some customized internal trainings are given on report writing and fine points of the inspection process. Modeled after the old FD 170 course.

FDA website does offer several additional online courses (food defense, allergens, basics of auditing, etc.) and Pathlore has some new courses which have just been added.

#### What subjects do we feel the courses do not address?

In-house trainings have been developed to train FSIOs on report writing, applying HACCP, etc. because it is difficult to receive the feedback on understanding from the online courses.

DeBrena – Tulsa has been doing some in-house consistency / standardization training activities to ensure the district is monitoring for uniformity of assessment and marking. They use the web-based Kahoot polling software for staff tabletop exercises.

Christine - In Southern Nevada, they also give their team more intense plumbing system training and review of HACCP principles.

Districts are also bringing in Meat and Poultry inspection bureau partners to cover cross-jurisdictional matters.

Food Safety Centers of Excellence offers foodborne illness training and EATS 101 and portions of 102. DeBrena – Tulsa is currently working with Epi to develop some new training for foodborne illness exercises. They have developed a PowerPoint to present various scenarios the inspectors will encounter.

Adam – They gave the new staff approximately a dozen different mock scenarios and practice entering the report and role playing with retail operators.

Christine – Southern Nevada uses a similar method as part of the report writing training.

### What is meant by non-traditional food outlets on the retail food curriculum framework?

It is the current verbiage used in place of "ethnic foods".

DeBrena – To address non-traditional food outlets, they use the ethnic foods presentation from FDA. AFDO has some resources on ethnic foods, shared kitchens, cottage foods, catering, etc.

# How does everyone address temporary food events whether large scale or small scale? Are there formal training courses or materials offered?

DeBrena – Tulsa has a temporary events coordinator to help with planning and permitting. Oklahoma has a full classroom setting training course and an on-site training.

Northern Arizona University has a public education course for food safety basics. Applications include camping and emergency situations.

#### What are the current initiatives for certification of FSIOs?

Melissa – Uses both the managers and inspector HACCP certification programs available through the International HACCP Alliance. Environmental assessments team is sent to root cause analysis training from ASQ (American Society for Quality).

Christine – Southern Nevada uses the 40hr Haswoper trainings.

Melissa – Recommends inspectors take an ANSI approved food safety manager training to obtain CFPM certification. She would like to see consistency in the requirements for FSIOs maintaining CEUs. (NCBRT) - National Center for Biomedical Research and Training Academy - Counterterrorist Course is available, as well as EHTER training for environmental health & emergency preparedness strike teams.

• What are some current initiatives for the evaluation of food safety inspection officers?

Districts are referencing the individual training logs, the CFP training manual, and using the assessment forms from Standard 4. There are several documents in Food Shield which have been developed by districts for general evaluations.

Call Participants (9)

DeBrena Hilton
Adam Kramer
Amanda Douglas
Christine Sylvis
Matthew Walker
Kenesha Williamson
David Read
Melissa Vaccaro
Mark Speltz

Here are the minutes from the call (1/23/2019):

# The group discussed gaps and alignment between Standard 2 and Standard 4, using our workgroup's Standard 4 QA Elements and Training Courses table:

Mark – Reviewed the CFP training plan to double check for elements which are not line items in the training log. Proposed updating the CFP training manual with our findings. We need the CFP manual to mirror those elements.

Christine – She asked four new staff members go through the elements to identify which areas were not part of the required training. Considers most jurisdictions to have an internal review of the basics of inspection.

Mark – Trying to address individualistic policies in a national curriculum will be difficult. Ultimately, how do we address individual procedural trainings?

Dave – Some of this looks like a best practices list. Much of these elements will be addressed during standardization.

Christine – FDA considers standardization to be a qualitative assessment of an inspector's training and not a training program itself.

#### Do the districts approach new inspector training with standardization in view?

Melissa – Yes. We make sure they will be able to pass standardization.

# Element 3 - How do the districts train staff to understand why risk type is assigned, how to recognize changes in the operation which affect risk type assignment, or identification of an incorrectly permitted facility?

Mark – In alignment with Standard 3, lowa uses customized training to address basics of inspection.

Melissa – Districts have custom training to support methods of risk-based inspection course.

DeBrena - Digital health department lists the facilities and their corresponding risk types.

Mark – We will need to proceed with caution on proposing that instructor led FD courses be included in the Standard 2 requirement. Some of the courses are not offered very frequently and some may be discontinued.

Dave – Recommends we refrain from listing names of courses or listing "equivalent courses". He recommends we focus on the competency areas. He recalls changes to the standard 2 curriculum were discouraged during the last two conferences.

Mark – Maybe all we need to propose for standard 4 is that we create an addendum which lists optional courses.

Dave - Changes to the curriculum may not be worthwhile right now, given that the curriculum framework project is still underway.

# What if an inspector felt those trainings were not adequate? What other resources are used to support?

Some of the digital health department systems call out repeat violations to the inspector. This element requires long term coaching and communication training as a support. Additional support is provided in having the inspector demonstrate competencies.

**Group assignment** – We reviewed the table of twenty quality elements with trainings identified in the right column. The regulatory members of the group were asked to provide the table to recently hired staff and obtain feedback for discussion on or before our next discussion of charge #3. Review the standard 2 curriculum.

# Resources – IFPTI page and Google FDA ORAU and Pathlore will provide access to the current curriculum.

#### Christine – David, how does the retail food framework fit into the food industry framework?

David – It is still being built with the intention of making the introductory courses an adequate starting point for any individual working in food protection.

Christine will set up a WebEx and allow David to present the information during our discussion of charge #2.

#### Call Participants (9)

DeBrena Hilton
Christine Sylvis
Matthew Walker
Kenesha Williamson
Amanda Douglas
Mark Speltz
Melissa Vaccaro
Adam Kramer

**David Read** 

Here are the minutes from the call (2/06/2019):

#### • WebEx presentation on the national curriculum framework from IFPTI:

Dave provided the group some background information on how the integrated food safety system content was developed and updated us on current progress. There has been recurrent feedback from the food industry regarding the consistency and standardization of inspectors. The FDA website has some additional resources available to learn more about the Partnership for Food Protection. A set of competencies was created to ensure all food protection professionals have a robust foundation of knowledge to equip them to fulfill their job roles. The framework itself provides a way of organizing the collection of competencies across all learning experiences for the field of food protection. The base level of the framework contains the entry level or general competencies pertinent to all food protection professionals. The framework is also divided into food protection program areas such as retail food or manufactured food. The next level of the framework contains more specialized content areas or advanced knowledge. When using the framework (<a href="http://incs.ifpti.org/">http://incs.ifpti.org/</a>), more information on each competency can be accessed by clicking the icon directly below the title of the individual content area. There are assessments within the framework content areas which are currently do not have an established pass or fail rating.

# Can anyone set up an account on IFPTI's website? If regulators access the assessment from the Pathlore website, is there a certificate which can be generated from the activity?

Yes, anyone within the regulatory field can access the assessments without cost through Pathlore. The framework is designed to allow a user to take the assessments without having taken the courses. The user may choose to retest.

#### • The group discussed Charge #2:

Does the group consider the Standard 2 (steps 1-4) completion time frame of 18 months adequate? Matt - Yes. The time frame does seem generous. Perhaps we could recommend that the 90% could be scaled for jurisdictions of different staff sizes. Consider jurisdictions with less than 10 inspectors. DeBrena – Turnover does interfere with the standardization time frame. Steps 1 through 3 have been met within the eighteen months consistently within Tulsa.

Katey – We need to consider the rationale for any recommendation that parameters be scaled for jurisdictions who serve smaller populations.

# What is the background or history as to whether the 18-month time frame was introduced to synchronize with the standard for manufactured food?

For manufactured food standard, the time frame is 24 months.

DeBrena- The six-month differential between the manufactured food standard and the retail food standard may be an allowance for the small jurisdiction size.

Christine – The time frame issue could be separate from the staff size and may be attributed to the availability of the standardization official.

It seems we all agree to recommend increasing the completion time frame for steps 1-4 to 24 months. The motion will be forwarded to the voting members of this subcommittee via email.

Are there gaps or recommendations for change(s) to the Standard 2 curriculum?

Dave – FDA has been funding the development of the IFSS framework. There is a potential transition to supplementing or replacing the ORAU courses with the framework in the future. If we are considering changes to the curriculum, we may want to identify specific content areas and not courses themselves.

# The group is encouraged to explore the framework and complete some of the assessments, in preparation for our March meeting.

Dave - If you want to use the INCS assessment process please click the link below, then click in one of the brown boxes to the right of the entry box on the lower part of the curriculum framework which brings up the detailed framework content areas. Then on the full framework page click on one of the basic brown color content areas to go to the course description and competencies, next click the blue Take Assessment button that takes you to the login page. Click on create account and fill in the requested information.

http://incs.ifpti.org/Frameworks/Home

Call Participants (7)
DeBrena Hilton
Amanda Douglas
Christine Sylvis
Matthew Walker
Kenesha Williamson
David Read

Katey Kennedy

#### Here are the minutes from the call (3/13/2019):

We discussed the content areas below. To prepare for our future meetings, we asked that regulatory members access the assigned coursework through Pathlore, review the framework competencies, and complete (7) assessments each for the basic curriculum content areas. Industry members were asked to explore the competencies as well on the IFPTI website. Industry members now have a regulatory partner with whom they will share the assignments for the applicable content areas. As we're all reviewing the material, let's consider its usefulness, whether there is any missing content, and how it would be implemented as "pre" or "post" coursework to replace ORA U. Appendix B of Standard 2 was attached to the March meeting invitation. Partner discussions prior to meetings are encouraged. For our March 13<sup>th</sup> meeting, the top row assignments were reviewed.

	Christine Sylvis w/ Kenesha Williamson	DeBrena Hilton w/ Melissa Vaccaro	Mark Speltz w/ Amanda Douglas	<u>Matt Walker</u>
3/13	B1 Regulatory Program Foundations	B8 Environmental Hazards	B15 Jurisdiction	B22 Professionalism
4/10	B2 Allergens	B9 Food / Feed Defense Awareness	B16 Labeling	B23 Public Health Principles
5/8	B3 Biological Hazards	B10 HACCP	B17 Laws, Regulations, Policies, & Procedures	B24 Recalls
6/12	B4 Biosecurity	B11 Imports	B18 Personal Safety	B25 Sampling
7/10	B5 Communication Skills	B12 Integrated Food Safety System	B19 Pest Control	B26 Sanitation Practices
8/14	B6 Data & Information Systems	B13 Inspections, Compliance, & Enforcement	B20 Plumbing	B27 Traceability
9/11	B7 Emergency Response	B14 Investigation Principles	B21 Preventive Controls	B28 Transportation

#### Having reviewed the initial courses assigned, what feedback do you have?

Amanda and Mark – B15 Jurisdiction. We thought the course gave a good overview of the subject and was well designed to provide the information in a logical order. The course does not have slide numbers, so as with regards to feedback we have provided the slide header:

- Unit 1 Foundations State & Local Jurisdiction Authority. Suggest a change to a word in the paragraph that states food 'consumed', suggest changing to food 'sold or distributed'. It would be inaccurate to describe food purchased at a retailer and then consumed at a home just across the state line as intrastate commerce.
- · Unit 3 Activities under the State Retail Food Program. It states FDA develops the Retail Food Program, we felt that the CFP process develops with input/oversight from FDA.
- The Exam at the end of the course only provides a score, it does not let you know which questions you got incorrect. This could help determine what part of the course you may need to retake etc.

Mark – On AFDO's website, the courses are cross-referenced. There was not much interactive content within the course. The lack of interactive features seems like a step back considering the way that online coursework is developed today. The terminology is bridged from the manufacturing content. Violative is commonly used in manufacturing regulation. We scheduled an hour. However, we had to move through the content more quickly toward the end.

Christine and Kenesha – B1 Regulatory Foundations. Upon logging into Pathlore, it was a little confusing trying to determine which course was correct. So, having a cross-reference would be helpful. Slide numbers would have been helpful. The very first course was long. Providing a projected time frame would be helpful. The content includes a lengthy history on how the law and enforcement actions were developed. It was nice to see a great list of tips for training new inspectors on when to involve a supervisor and how to think critically during the inspection. Program standards were mentioned. There was some terminology which was concerning for new inspectors to be translating this knowledge to the retail food industry. For example: the word violative seems to have been used interchangeably with "hazardous" or "priority". The coursework frames were not very interactive. Perhaps the relevant terminology could have been hyperlinked throughout the course instead of being featured at the beginning. The knowledge checks and final exam does not give a detailed performance summary. It just gives a score.

DeBrena – B8 Environmental Hazards. For someone just starting out, the course content is pretty basic. I agree with the comments that have been shared. I will contact Melissa to continue reviewing B8.

Matt – B22 Professionalism. The material was divided into six units. It was a lot of reading with a few pictures. They did provide a few good examples. It seems this would be a good fit for the "pre" courses. But, it would not be a replacement for the existing standard content. There was some overlapping content. Overall, the content was refreshing. It took around 45 mins to complete.

#### How long did it take to complete the courses?

Christine – The regulatory foundations course seemed to require approximately 1.5hrs be scheduled to complete it.

Katey – Within Appendix B of Standard 2, there are time estimates for completion of coursework.

#### Do we recommend adding this content to the Standard 2 curriculum as a replacement or supplement?

Mark – It is difficult to say. Is the new curriculum framework intended to replace the Standard 2 curriculum? If so, what is the intended time frame?

Katey – I will get those answers and update the group.

#### Call Participants (9)

DeBrena Hilton
Adam Kramer
Katey Kennedy
Christine Sylvis
Matthew Walker
Kenesha Williamson
Robert Sudler
Mark Speltz
Amanda Douglas

#### Here are the minutes from the call (4/10/2019):

We discussed the content areas below. As we all continue reviewing the material, let's consider its usefulness, whether there is any missing content, and how it would be implemented as "pre" or "post" coursework to replace FDA ORA U.

	Christine Sylvis w/ Kenesha Williamson	DeBrena Hilton w/ Melissa Vaccaro	Mark Speltz w/ Amanda Douglas	Matt Walker
3/13	B1 Regulatory Program Foundations	B8 Environmental Hazards	B15 Jurisdiction	B22 Professionalism
<mark>4/10</mark>	B2 Allergens	B9 Food / Feed Defense Awareness	B16 Labeling	B23 Public Health Principles
5/8	B3 Biological Hazards	B10 HACCP	B17 Laws, Regulations, Policies, & Procedures	B24 Recalls
6/12	B4 Biosecurity	B11 Imports	B18 Personal Safety	B25 Sampling
7/10	B5 Communication Skills	B12 Integrated Food Safety System	B19 Pest Control	B26 Sanitation Practices
8/14	B6 Data & Information Systems	B13 Inspections, Compliance, & Enforcement	B20 Plumbing	B27 Traceability
9/11	B7 Emergency Response	B14 Investigation Principles	B21 Preventive Controls	B28 Transportation

The group continued discussion on course reviews. Feedback is focused on making key comparisons between the IFPTI curriculum framework and standard 2 curriculum. Ultimately, we will need to make recommendations for replacement or supplement.

Christine and Kenesha – B2 Allergens. The course seemed much shorter than the initial course, B1. The U.S. recognized allergens and allergens recognized overseas were explained well. The link for the full list of tree nuts did not lead us to the correct FDA page. We had to google search the FALCPA list to access the correct FDA page. There is currently no allergens course in the standard 2 curriculum.

Dave – The courses are now under review to make improvements where needed. It has been determined that the courses will be made to be more interactive. We should also keep in mind that the courses are created to be introductory for regulators.

DeBrena – B8 Environmental Hazards. It was a good foundation for new regulatory staff. Again, it would be helpful to have slide numbers and a recap on the overall performance. It would be better for the module to provide a quick reference to the correct answer instead of just displaying the word "correct" when the right selection was chosen. The content seemed to be more geared toward manufacturing. In unit 2, it would be better to explain that Norovirus is the number one cause of viral foodborne illness cases. In unit 4, the photos do not match the content being discussed. The subject was food safety instead of workplace safety. The photos should support that.

DeBrena - B10 HACCP. The term validity. Videos in unit 4. FSMA. Recall information could have been more in depth versus the existing standard 2 HACCP content. The majority of standard 2 HACCP bullet points were covered. The course took roughly 1 hr. The two video clips were a nice inclusion. However, the videos did not adequately explain the concepts.

- Unit 1 Foundations is course content geared towards Retail Food or Manufacturing? Many of
  the examples and pictures emphasize manufacturing. We also suggest adding radiological hazard
  language in the opening slides. Also, be consistent with use of Radiological throughout if it is going
  to be used and mirror FSMA rules.
- Unit 2 Virus slide. Suggest rewording or structuring slide so that it is clear that Norovirus in the #1 cause. Currently worded that viruses in general are the number one cause of illness in US.
- Unit 3 Suggest adding more retail food pictures to balance out all the manufacturing pictures. Assessment Knowledge Check 1 sampling question not covered very well in module.
- Unit 4 Food Safety Plans: personnel safety pictures used instead of food safety symbolic pictures.
   Control Factors: expound more on why source is important as a control factor. GRAS definition clarification needed that explains that GRAS is a chemical or substance added to food.
- Course Assessment Question 9: is the question asking about pre or post packaging. Needs to be reworded so that its clear.
- Note: B9 Food/Feed Defense Awareness. The course could not be found in Pathlore. On the IFPTI course list menu, no course number is listed. Dave checked into it and found that the course does exist. But, the course was not provided on Pathlore.

#### Amanda and Mark – B16 Labeling.

#### Course Overall:

- No slide numbers or time to complete course/sections.
- inconsistency on knowledge base confirmation on whether a question was answered correctly.
- There were a few videos (a little basic), but not sure if they were positioned correctly i.e. they seemed to introduce a new topic, would prefer an intro slide prior to the video.
- Some of the label images were too small to read, even on a large screen.
- The course did seem very long.

#### Course Design:

- The course design may benefit from being aligned under regulated areas i.e. Human Food FDA / FSIS, Dietary Supplements, and Animal feed and then having the specific topics under each area i.e. regulations, label requirements, etc. this could help with repetition, flow and refresher training. It is a lot of information for a new employee, especially if they are not responsible for a certain regulated area i.e. animal feed, the information becomes irrelevant.
- The competency flow did not align with the course, so by having it aligned under regulated areas could help better align it.

#### Specific Course Feedback:

- Unit 1 Label Vs Labeling Slide. Include supplement labeling on a website
- Unit 2 Labeling components required allergy information is referencing 'Produced in a facility that processes peanuts' which is not required
- Unit 2 Labeling components trail mix labeling confusing
- Unit 3 Labeling laws referencing outdated FDA 2013 Food code

Dave – One of the reasons that the course covers both food and animal feed is because of the regulatory oversight for those areas. The course is more general education for anyone entering the food regulation field. The course is being revised as well.

Matt - B23 Public Health Principles. The course did a great job covering the content. I recommend it as a replacement for FDA36. It is lengthy at seven units in total. However, the content is relevant and interesting. The course gave a lot of good examples to explain the principles. While there is not much interactivity, it does not necessarily need it. Both courses have the same name and align well. Reviewed FDA36 and B23 side by side to gather feedback.

To prepare for the next call, the group was asked to revisit the standard 2 online courses to better support analysis of content alignment.

Call Participants (9)

DeBrena Hilton

Katey Kennedy

Christine Sylvis

Matthew Walker

Kenesha Williamson

Robert Sudler

**Amanda Douglas** 

**David Read** 

Adam Kramer

#### Here are the minutes from the call (5/08/2019):

Call Participants (7)
Christine Sylvis
Matthew Walker
Ed Robinson (visitor)
Kenesha Williamson
Robert Sudler
David Read
Adam Kramer

We discussed the content areas below. As we all continue reviewing the material, let's consider its usefulness, whether there is any missing content, and how it would be implemented as "pre" or "post" coursework to replace FDA ORA U.

	Christine Sylvis w/ Kenesha Williamson	DeBrena Hilton w/ Melissa Vaccaro	Mark Speltz w/ Amanda Douglas	<u>Matt Walker</u>
3/13	B1 Regulatory Program Foundations	B8 Environmental Hazards	B15 Jurisdiction	B22 Professionalism
4/10	B2 Allergens	B9 Food / Feed Defense Awareness	B16 Labeling	B23 Public Health Principles
<mark>5/8</mark>	B3 Biological Hazards	В10 НАССР	B17 Laws, Regulations, Policies, & Procedures	B24 Recalls
6/12	B4 Biosecurity	B11 Imports	B18 Personal Safety	B25 Sampling
7/10	B5 Communication Skills	B12 Integrated Food Safety System	B19 Pest Control	B26 Sanitation Practices
8/14	B6 Data & Information Systems	B13 Inspections, Compliance, & Enforcement	B20 Plumbing	B27 Traceability
9/11	B7 Emergency Response	B14 Investigation Principles	B21 Preventive Controls	B28 Transportation

The group continued discussion on course reviews. Feedback is focused on making key comparisons between the IFPTI curriculum framework and standard 2 curriculum. Ultimately, we will need to make recommendations for replacement or supplement.

Christine and Kenesha – B3 Biological Hazards. There was very little about thermal processing as a control for biological hazards. Standard 2 gave more detail on microbiology. We recommend splitting the course due to its length.

Unit 1 - Pathogens vs Spoilage Organisms slide mentions that off-flavors are a characteristic of food compromised by the outgrowth of pathogens. This should be included under the spoilage organism column.

Sampling slides mention the term "for-cause" sampling. Where does this wording come from? The message could be rephrased to better represent circumstances such as traceback investigations for foodborne illness or precautionary circumstances. Also, the regulatory sampling slide gives the impression that the regulator will be completing the sampling in manufacturing environments.

Unit 2 – Aflatoxins slide mentions some effects of carcinogens. But, the slide does not explain that aflatoxins are carcinogens. Perhaps the previous slides could have included a brief explanation that many aflatoxins are considered carcinogenic.

Other Mycotoxins slide mentions that fumonisin consumption can be fatal. But, it is unclear as to whether that fatality is found in humans or just horses and swine. Also, are humans becoming affected through consumption of swine or the rice and corn directly?

Toxin-Mediated Infection slide does not explain that the terms toxicoinfection and toxin-mediated infection are interchangeable.

Examples of Incubation Periods slide uses a bullet point format to provide the information. This may have been better as a data table.

Biofilm slide could have included a nice tie-in to the messages about sampling, as L. monocytogenes is difficult to remove from a facility due to biofilms.

Unit 3 – Food Packaging slide provides an explanation of MAP below the bullet points for both MAP and general ROP without connecting the explanation directly to MAP.

Vectors: Humans slide contains a photo of a food handler correctly wearing gloves and using a utensil to handle food. It would be better to show bare hand contact.

Unit 4 – Listeria slide shows a photo of a drain cover in a pool. This should be a floor drain photo within a food establishment.

Food Contact Surfaces slide uses the terms direct and indirect food-contact surfaces. This is not in alignment with the terms food-contact surface and nonfood contact surface used in retail food.

Unit 5 – Several slides continued to mention only MAP as a type of packaging which can aid in the control of pathogenic growth.

Controlling campylobacter slide has the bacteria name misspelled in two of the sentences.

Estimated time to complete the course: approx. 2 hrs.

Dave – The photos and graphics were done by persons who do not have a food safety background. The photos are still being reviewed. The special processes topic is explored further in the retail food section.

DeBrena – B10 HACCP. Unit 2: Record Review for Accuracy – consider changing "validity" wording. Too much like verification vs validation and makes you think you are talking about validations whereas the slide is discussing verification. Overall comment: Verification vs Validations needs better disused and language on slides needs to stay true their meaning.

Unit 4: Videos? Seem out of place, not necessary, too short if they are going to be used. Would be better if video clips provided snippet of each of the 7 steps of HACCP instead of just 2.

Unit 5: Laws Regulations and Guidance: suggest creating stand-alone paragraph to explain implementation of FSMA. Need better clarification of State Agriculture programs, USDA, FDA, State and local oversight and co-regulation. Also, better explanation of FSMA (food safety plans) vs HACCP.

Assessment question—there was a question for recall procedure. We felt this was not adequately covered in module for use as a question. Recall information could have been more in depth versus the existing standard 2 HACCP content. The majority of the standard 2 HACCP bullet points were covered. The course took roughly 1 hr. The two video clips were a nice inclusion. However, the videos did not adequately explain the concepts.

Dave – Most of the questions/issues have been addressed for the HACCP course. As for FDA 16, 17, and 18, some of the HACCP coursework was existing. So, the IFPTI course is intended to blend all three and replace them.

Amanda and Mark – B17 Laws, Regulations, Policies, & Procedures. We do not have any significant feedback. We thought the course was well aligned with the competencies and covered all the topics. As stated on previous calls the content is a little dry, and we believe in future the courses will have more interaction.

Matt - B24 Recalls. Basics of it were useful. The course included videos. Nice change. The use of subtitles was also great from an accessibility aspect. If we were to add it to the curriculum, it should be included in the post courses. It would be good for a new EHS to get this intro to recalls, though not all jurisdictions are involved in issuing recalls.

Dave – Some new EHS can be involved in recall verification checks via phone call or site visits.

To prepare for the next call, the group was asked to revisit the standard 2 online courses to better support analysis of content alignment.

#### Here are the minutes from the call (6/12/2019):

We discussed the content areas below. As we all continue reviewing the material, let's consider its usefulness, whether there is any missing content, and how it would be implemented as "pre" or "post" coursework to replace FDA ORA U.

	Christine Sylvis w/ Kenesha Williamson	DeBrena Hilton w/ Melissa Vaccaro	Mark Speltz w/ Amanda Douglas	<u>Matt Walker</u>
3/13	B1 Regulatory Program Foundations	B8 Environmental Hazards	B15 Jurisdiction	B22 Professionalism
4/10	B2 Allergens	B9 Food / Feed Defense Awareness	B16 Labeling	B23 Public Health Principles
5/8	B3 Biological Hazards	B10 HACCP	B17 Laws, Regulations, Policies, & Procedures	B24 Recalls
<mark>6/12</mark>	B4 Biosecurity	B11 Imports	B18 Personal Safety	B25 Sampling
7/10	B5 Communication Skills	B12 Integrated Food Safety System	B19 Pest Control	B26 Sanitation Practices
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Christine and Kenesha - B4 Biosecurity. Currently, there is no biosecurity in the currently curriculum. So, this content would be an addition. It's more in depth than we consider to be necessary. Overall, it seemed to have been designed for manufacturing instead of food service. Several case studies were included. That is beneficial for the learner.

#### Unit 1

At the beginning of the Unit 1, the definition of biosecurity is very broad. It seems to reference what we understand to be the basics of food protection within retail/restaurant environments. Is it the best definition? Is this term more widely used in manufacturing?

Three parts of a facility's biosecurity plan: exclusion, management, and containment. All of which should be SOPs for the facility.

#### Unit 2

The definition for fomite includes living and non-living matter. I understood fomites to be inanimate objects or materials which can become contaminated and transfer pathogens.

Explanations for food processing were nicely worded. Nice use of plain language to differentiate between harvest/slaughter and processing.

#### Unit 3

Biosecurity zone slide defines a controlled access point as the third point. However, it would be better suited as the first definition because personnel would have to enter controlled or restricted zones through this point of access.

The slides which describe the types of PPE need some additional wording to relate the subject to its significance in the prevention of contamination within a facility or operation.

Is the term enhanced inspection interchangeable with the term investigation as an inspection type? This was included on the slide which described how inspectors should protect themselves.

#### Unit 4

The slide which discusses the importance of planning for the regulatory visit includes a non-working link to the FDA Investigations Operations Manual. The distinction between disinfection and sanitizing needs to be better explained. The material did not include an explanation of communicating breaches within the sanitation chain as part of the recall protocol.

#### Unit 5

The FDA Investigation Operations Manual link at the beginning on unit 5 did navigate to the correct webpage. The knowledge check question 2 seems to assess whether the learner has read the material at the provided links to both the FDA and USDA documents. The slide with those links could be improved by including a brief explanation of the main focuses of those two

- documents. FDA being routine operations and USDA being emergency preparedness and response to adverse events.
- DeBrena B11 Terminology. The slide which explains the term custom(s) broker includes the abbreviation CBP. The phrase CBP custody is used but is not explained until later slides. At which point, CBP is defined as Customs and Border Protection. The text under the example figure for Harmonized Tariff Schedule Code has very low resolution and is difficult to read. Unit 5 includes a "Real World Applications" video on investigations which took a very long time to load. Upon completing the final unit, there was no button available on screen to navigate to the actual course assessment. FD251 references imports. So, the material presented in the module is covered there. We do not recommend the material replace FD251. Course completion time was 47 mins.
- Mark B18 Personal Safety. It sounds like there is some redundant material in other courses regarding PPE. We noticed that the course provided specific instructions on how an inspector should execute personal safety rather than describing the types of PPE. It mentioned that an inspector should reach out to a facility in advance to determine what types of hazards to personal safety may be there. The buddy system for entering coolers and freezers was also mentioned for personal safety reasons. However, there may not always be more than one inspector conducting the inspection. Ladder safety was also included. We considered the content to be focused on more OSHA recommendations than necessary for the food protection field. Examples of hazard signage and PPE requirement signage was very useful. The content should be more of an overview and could be confusing. Basics of inspection course, FDA 38, includes a brief inclusion of personal safety by informing the inspector of appropriate clothing, shoes, head cover.
- Christine Our jurisdiction does not allow our inspectors to operate or disassemble the facility's equipment such as a dish machine. So, we address it through internal training as well.
- Mark An overall awareness is helpful. In Iowa, we follow a similar approach. Our team are not OSHA specialists. So, recognizing signage is good.
- Adam If the module used the term MSDS was used, the information should be updated to SDS.
- Amanda One of the assessment questions was related to chemical safety. I believe it used the term SDS.
- Matt B25 Sampling. Aseptic sampling and chain of custody was explained. The FDA operations manual was referenced. Unit 3 includes a three-minute video with subtitles to demonstrate how to collect aseptic samples. The video is step by step and well done. The overall quality of the module is good. I recommend it being added to Standard 2 in the post coursework. I would not recommend it as a replacement because it is more comprehensive. FIO4, Foodborne Illness Investigations 4: Conducting a Food Hazard Review, covers the sampling content as post coursework. FIO4 does a better job of describing how prepare for sampling visit in advance. However, that component is not necessary for the IFPTI content. Approximately 60 mins to complete it.

On the next meeting, we will review our workgroup's charges, progress, and timeline. Please review the tracking sheet and provide recommendations for the courses assigned.

Call Participants (7)

Mark Speltz Adam Kramer Amanda Douglas Matt Walker DeBrena Hilton Christine Sylvis Kenesha Williamson Hello Group,

## Here are the minutes from the call (7/17/2019):

We discussed the content areas below. As we all continue reviewing the material, let's consider its usefulness, whether there is any missing content, and how it would be implemented as "pre" or "post" coursework to replace FDA ORA U.

	Christine Sylvis w/ Kenesha Williamson	DeBrena Hilton w/ Melissa Vaccaro	Mark Speltz w/ Amanda Douglas	<u>Matt Walker</u>
3/13	B1 Regulatory Program Foundations	B8 Environmental Hazards	B15 Jurisdiction	B22 Professionalism
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8/14	B6 Data & Information Systems	B13 Inspections, Compliance, & Enforcement	B20 Plumbing	B27 Traceability
9/11	B7 Emergency Response	B14 Investigation Principles	B21 Preventive Controls	B28 Transportation

#### We started the call with review of our charges, progress, and timeline:

Christine - We have a good start on charge 1. The updated list of charge 1 initiatives is being reviewed today on WebEx. What started as just a table has been changed to a list similar to Appendix B-1.

# FD 170, is the course available? While checking some of the course links listed on Appendix B-1, we found several non-working links.

Robert – FDA is aware that several links on Appendix B-1 are no longer functional. Course numbers have also changed for a few of the listings. FD 170 is available. It just has a different path. The updated Appendix B-1 is not yet published.

## Epi-Ready, is this an online or instructor led course?

Dave and Matt – Centers of Excellence administered the course in our jurisdictions. It was between 2 and 2.5 days of training.

## I-FIIT-RR, is this for regulators?

Kenesha – The course is a free NEHA workshop online. Companies can host a self-funded workshop for their teams. It is a one-day training.

# Reviewed charge 2. In review of this charge, we discussed the course review worksheet relative to charge 2a.

We will send out copies of the course review worksheet to everyone. The worksheet will be included in the final report. Each group of reviewers will need to make sure the recommendations column is accurate and complete. Forward the updates to Kenesha.

Charge 2b is complete. The timeline for completing Standard 2, Steps 1 through 4, was recommended to increase from 18 months to 24 months.

#### With only two meetings left, we want to complete charges 2a and 3.

To complete our charges within the remaining two meetings: (1) we will have brief recaps of course notes; (2) groups will send notes directly to Kenesha; (3) the August meeting will cover charge 2a; and (4) the September meeting will cover charge 3.

Amanda and Mark – B19 Pest Control. The course was not available for review. It is still under development.

Melissa – B12 Integrated Food Safety System. Our group did not have a chance to complete the course yet. We will have the notes before the next meeting.

Christine and Kenesha – B5 Communication. We did not have time to review the current Standard 2 course for comparison. We will cross reference it before the next meeting.

Dave – There is a new B20 Plumbing course that is currently being reviewed. The B20 course from the PFP workgroup is currently not available on the IFPTI website.

Dave will give the reviewers access to the new plumbing course. This will be Mark, Amanda, and Matt.

Please continue reviewing the course review worksheet and provide recommendations for the courses assigned.

Call Participants (8)

Robert Sudler Christine Sylvis Kenesha Williamson Dave Read Amanda Douglas Melissa Vaccaro Adam Kramer Matt Walker Hello Group,

Here are the minutes from the call (8/14/2019):

We started the call with a review of the recommendations we have so far, i.e. add, replace, or no action and indicating "pre" or "post". The course review worksheet was displayed via WebEx.

	Christine Sylvis w/ Kenesha Williamson	DeBrena Hilton w/ Melissa Vaccaro	Mark Speltz w/ Amanda Douglas	<u>Matt Walker</u>
3/13	B1 Regulatory Program Foundations	B8 Environmental Hazards	B15 Jurisdiction	B22 Professionalism
4/10	B2 Allergens	B9 Food / Feed Defense Awareness	B16 Labeling	B23 Public Health Principles
5/8	B3 Biological Hazards	B10 HACCP	B17 Laws, Regulations, Policies, & Procedures	B24 Recalls
6/12	B4 Biosecurity	B11 Imports	B18 Personal Safety	B25 Sampling
7/17	B5 Communication Skills	B12 Integrated Food Safety System	B19 Pest Control	B26 Sanitation Practices
8/14	B6 Data & Information Systems	B13 Inspections, Compliance, & Enforcement	B20 Plumbing	B27 Traceability
9/11	B7 Emergency Response	B14 Investigation Principles	B21 Preventive Controls	B28 Transportation

Kenesha – Everyone's updates were received and loaded into the master worksheet that we are reviewing today.

Christine – B1 Regulatory Program Foundations. We still need to go back and review the existing Standard 2 content for cross-reference. B2 Allergens does have an existing course in the post curriculum. FD 252. We will review it before adding our recommendations on these two courses. B4 Biosecurity is currently not in the curriculum. We recommend no action because it is very geared to manufacturing.

DeBrena – B8 Environmental Hazards. We added comments indicating adjustments we would like to see before recommending addition of the course. We will go back to take another look to see what the specific modifications would be. We will do so for B8 through B13.

Mark and Amanda – B16 Labeling. We recommended no action in its current condition. We like the topic of labeling to be included in curriculum. We'd consider recommending addition, if course is revamped. B20 Plumbing we found to be the same as the old course. We contacted Dave Read on this.

Matt – B20 Plumbing. Dave provided a link to some of the new frames which worked for me.

Mark – Since pest control and plumbing content are not currently in Standard 2, we recommend adding them.

Katey – Those content areas may have been excluded because there were no formal courses available. So, if they are available now, that will be helpful.

Matt – B24 Recalls. I recommended no action here because the content may not be very useful. Most jurisdictions do not handle recalls. B26 Sanitation Practices is a good replacement for MIC 15. It would be good to have inspectors seeing this before taking the plan review course.

Mark and DeBrena recommend including B24 Recalls as good information for exposure. Katey reminded that Standard 5 does include handling recalls.

During the next meeting, we will complete our discussions of charge 2a and charge 3 and we will finalize our committee's recommendations by voting.

Updated workgroup docs will be sent out before the next meeting: Workgroup Doc 3 – Updated IFPTI course review worksheet; Workgroup Doc 6 – Table of Standard 4 quality elements updated with CFP Training Manual references; Workgroup Doc 7 – CFP Training Manual with notes added on pages 7 and 8 identifying Standard 4 quality elements.

## Call Participants (7)

Christine Sylvis Kenesha Williamson Mark Speltz Amanda Douglas Matt Walker DeBrena Hilton Katey Kennedy Hello Group,

Here are the minutes from the call (9/11/2019):

# We continued discussing Charge 2a (identifying any gaps and recommendations for changes to Standard 2 curriculum)

Christine – We were unable to access the FD252 allergens course and make our recommendation. The link on the FDA website is not valid. When word searching for allergens course, the search results only provide the Pathlore course. The link for the current Communication Skills for Regulators course in Appendix B is also no longer valid. We also could not find the emergency response course listed on AFDO's GenEds list.

Mark – In the 2015 Appendix B, there is different link. The link is class.ucanr.edu instead of class.ucanr.org. On the FDA site, there is a separate link for the Communication Skills course.

Dave – Given that many of the existing Compliance Wire courses are 10+ years old, it's not likely that FDA will continue those courses. The course review sheet includes several recommendations not to replace the existing curriculum. So, we will need to consider this. Also, it is uncertain whether FDA will continue with using Pathlore as its learning management system.

Christine – Perhaps we need to connect with FDA on the implications of our recommendations based on their ultimate plans for the courses.

Mark – Discussed the accessibility of the coursework. Many of the course names and numbers had to be cross-referenced back to the IFPTI site. The course names are often not consistent.

Dave – The update and release of the courses are being completed at a rate of one per month. The process involves a workgroup of subject matter experts who develop the courses for FDA. That work has been completed. Now the look and feel of the courses is being updated. Once that is complete, the courses are given to FDA. Be mindful to cite content areas instead of specific course numbers to be removed. Ultimately, the general education for all food inspectors will come into alignment with integrated food safety under FSMA. Exposure to the additional knowledge is good for all.

#### Discussed Charge #3 and the updated Workgroup Doc 6 - Standard 4 Elements Table.

Christine – The Basics of Inspection course really touches on majority of the quality elements. Many of the quality elements are drafted from the CFP training manual. Quality Element 3 is not.

Mark – Since risk type and inspection frequency are varied by jurisdiction, it seems appropriate to have this addressed by the inspector's training plan under additional jurisdictional competencies.

Christine – Element 7 would not be met by jurisdictions which do not use the IN/OUT/N/O/N/A format for their inspections, if we are just considering report writing.

All – Element 7 is really covered through the training plan parts 2 and 3 of Inspection Observations and Performance. We will update Workgroup Doc 6 to include our feedback from today's call for the quality elements table. The correlation between Standard 2 and 4 is in the CFP training manual. It has not been updated since 2008.

Due to low participation on last week's call, we are setting up another call for the first week in October. Hopefully, everyone can attend. Our group needs to vote on the committee's suggested changes to Standard 2 and discuss issue submissions.

Call Participants (4)
Christine Sylvis
Kenesha Williamson
Mark Speltz
Dave Read

#### **Final Meeting**

## Here are the minutes from the call (10/02/2019):

During the meeting, the group discussed all pending items. We connected with Angie Cyr for some clarifications prior to the meeting. Dave Read cautioned the group to consider that courses which are not recommended become unavailable. CFP meets once every two years. Also, many of the new courses are designed with the intention to increase the learner's competency and not mimic the course design of the past. Christine reviewed the language of our charge as it relates to the standard 2 curriculum.

The 5 (out of 7) voting members on the call voted on the committee's suggested changes to Standard 2. Pending items for today's vote:

- Each topic/class added to Standard 2, Appendix B1 will require an individual issue submission with reasoning why it should be included (Charge 2A)
- Change in format of Standard 2, Appendix B1 will require an issue submission (Charge 2A)
- Change of date for Standard 2 post training will require and issue submission with reasoning why (Charge 2B)
- Changes to CFP Training Manual to align Standard 4 with Standard 2 each addition will require an individual issue submission with reasoning why (**Charge 3**)

#### Voted Actions for IFPTI courses

B8 Environmental Hazards (CC8024W) – Add to the pre-coursework

**Pending** B10 HACCP (CC8033W) – Additional feedback needed from reviewers; Vote via Survey Monkey B12 Integrated Food Safety System (CC8018W) – Add to post-coursework

**Pending** B13 Inspections, Compliance, & Enforcement (CC8019W) - Additional feedback needed from reviewers; Vote via Survey Monkey

**Pending** B14 Investigation Principles (CC8020W) - Additional feedback needed from reviewers; Vote via Survey Monkey

B15 Jurisdiction (CC8037W) – Replace FDA 35 in the pre-coursework

Pending B16 Labeling (CC8038W) - Additional feedback needed from reviewers; Vote via Survey Monkey

B17 Laws, Regulations, Policies, & Procedures (CC8039W) – Add to pre-coursework

B19 Pest Control (under development) – Add to pre-coursework

B20 Plumbing CC8001W (under development) – Add to pre-coursework

B22 Professionalism (CC8025W) - Add to the pre-coursework

B23 Public Health Principles (CC8026W) - Replace FDA 36 in pre-coursework

B24 Recalls (CC8041W) – Add to post-coursework

B25 Sampling (CC8035W) – Replace MIC13 in the pre-coursework

B26 Sanitation Practices (CC8032W) – Replace MIC15 in the pre-coursework

B27 Traceability (CC8042W) – Add to post-coursework

B28 Transportation (CC8036W) – Add to post-coursework

Updates to the CFP Training Manual were reviewed. The group agreed to recommend that Traceability, Recalls, and Transportation be included with Integrated Food Safety System under a header of the same name in "post" coursework.

Christine Sylvis will be an issue submitter. We need volunteers to be co-issue submitters. Issue submitters will need to attend the biennial meeting to discuss the issue and answer any questions from Council. Also, we can have up to (2) issue submitters per issue. As of today, we will have approximately 20 issues.

Next, we will complete our final report, vote on remaining items, and coordinate volunteers for issue submission through Survey Monkey.

## **Pending Vote**

- 1. B10 HACCP (CC8033W) course recommendation
- 2. B13 Inspections, Compliance, & Enforcement (CC8019W) course recommendation
- **3.** B14 Investigation Principles (CC8020W) course recommendation
- 4. B16 Labeling (CC8038W) course recommendation
- **5.** Add to CFP Training Manual Section 1 Pre-inspection, #2 Reviews establishment file for previous inspection report, complaints on file... (review current risk category) and Section II Inspection observations and performance #3 Uses a risk-based inspection methodology to correctly assess regulations... (verifies risk category is correct based on inspection observations)
- **6.** Add to CFP Training Manual Section II Inspection Observations and Performance, #6 addresses violations on previous inspection being corrected
- **7.** Add to CFP Training Manual Section IV. Written Communication, #1. Completes inspection form per jurisdiction's administrative procedures addresses violations on previous inspection being corrected

## Call Participants (8)

Kenesha Williamson<sup>v</sup> Christine Sylvis<sup>v</sup>

Adam Kramer

Mark Speltz<sup>v</sup>

Dave Read

Amanda Douglas<sup>v</sup>

Matt Walker<sup>v</sup>

Katey Kennedy

Charge 1: Initiatives (existing, new, or under development) involving the training, evaluation and/or certification available to Food Safety Inspection Officers (FSIO):

#### Training - Existing

## ORAU Pre

- Public Health Principles FDA 36
- Overview of Microbiology MIC01
- Food Microbiological Control 2A: Gram-Negative Rods MIC02
- Food Microbiological Control 2A: Gram-Positive Rods and Cocci MIC03
- Food Microbiological Control 2A: Foodborne Viruses MIC04
- Food Microbiological Control 4: Foodborne Parasites MIC05
- Food Microbiological Control: Mid-Series Exam MIC16
- Food Microbiological Control 5: Controlling Growth Factors MIC06
- Food Microbiological Control 6: Control by Refrigeration and Freezing MIC07
- Food Microbiological Control 7A: Control by Thermal Processing MIC08
- Food Microbiological Control 7B: Control by Pasteurization MIC09
- Food Microbiological Control 10: Aseptic Sampling MIC13
- Food Microbiological Control 10: Cleaning and Sanitizing MIC15
- Basic Food Law for State Regulators FDA35
- Basics of Inspections: Beginning an Inspection FDA38
- Basics of Inspections: Issues and Observations FDA39
- An Introduction to Food Security Awareness FD251 (https://www.fda.gov/training-and-continuing-education/office-training-education-and-development-oted/introduction-food-security-awareness) NOTE: Required Exam is available via (www.compliancewire.com)
- Communication Skills for Regulators

#### **ORAU Post**

- An Introduction to Food Security Awareness MIC10
- Food Microbiological Control 8: Technology-based Food Processes MIC11
- Food Microbiological Control 9: Natural Toxins MIC12
- Basics of HACCP: Overview of HACCP FDA16
- Basics of HACCP: Prerequisite Programs and Preliminary Steps FDA17
- Basics of HACCP: Prerequisite Programs and Preliminary Steps FDA18
- Foodborne Illness Investigations 1: Collecting Surveillance Data FI01
- Foodborne Illness Investigations 2: Beginning an Investigation FI02
- Foodborne Illness Investigations 3: Expanding the Investigation FI03
- Foodborne Illness Investigations 4: Conducting a Food Hazard Review FI04
- Foodborne Illness Investigations 5: Epidemiological Statistics FI05
- Foodborne Illness Investigations 6: Final Report FI06
- Food Allergens FD252 (Course must be accessed through http://class.ucanr.edu/)

## FEMA courses can be accessed at: http://training.fema.gov/IS/NIMS.asp

- Introduction to Incident Command System IS-100.C
- ICS for Single Resources and Initial Action Incidents IS-200.C
- NIMS an Introduction IS-700.B

#### FDA ComplianceWire

- Food Code Chapter 7: Poisonous and Toxic Materials FD112 Food Code (FDAFC01)
- Food Code Chapter 1: Purpose and Definitions FD112 Food Code (FDAFC02)
- Food Code Chapter 3: Part I FD112 Food Code (FDAFC03)
- Food Code Chapter 5: Water, Plumbing, and Waste FD112 Food Code (FDAFC04)
- Food Code Chapter 3: Part II FD112 Food Code (FDAFC05)
- Food Code Chapter 3: Part III FD112 Food Code (FDAFC06)
- Food Code Chapter 2: Supervision FD112 Food Code (FDAFC07)
- Food Code Chapter 4: Part I FD112 Food Code (FDAFC08)
- Food Code Chapter 6 FD112 Food Code (FDAFC09)
- Food Code Chapter 4: Part II FD112 Food Code (FDAFC10)
- Food Code Chapter 8: Enforcement and Annex 1 FD112 Food Code (FDAFC11)
- HACCP (CC8033W)
- Employee Hygiene: Food Service (FOOD1)
- HACCP (FOOD5)
- Preventing Microbial Cross-Contamination (FOOD3)

## IFPTI Courses on ComplianceWire

- Regulatory Program Foundations (CC8021W)
- Allergens (CC8029W)
- Biological Hazards (CC8028W)
- Biosecurity (CC8023W)
- Communication Skills (CC8011W) Course must be accessed through FDA Pathlore at: (https://orauportal.fda.gov/stc/ORA/psciis.dll?linkid=675280&mainmenu=ORA&top\_frame=1)
- Data & Information Systems (CC8017W)
- Environmental Hazards (CC8027W)
- HACCP (CC8033W)
- Imports (CC8034W)
- Integrated Food Safety System (CC8018W)
- Inspections, Compliance, & Enforcement (CC8019W)
- Investigation Principles (CC8020W)
- Jurisdiction (CC8037W)
- Labeling (CC8038W)
- Laws, Regulations, Policies, & Procedures (CC8039W)
- Personal Safety (CC8031W)

## PSC subcommittee #3 Charge 1 Training Evaluation and Certification Initiatives

- Preventive Controls (CC8040W)
- Professionalism (CC8025W)
- Public Health Principles (CC8026W)
- Recalls (CC8041W)
- Sampling (CC8035W)
- Sanitation Practices (CC8032W)
- Traceability (CC8042W)
- Transportation (CC8036)

#### **FDA Pathlore**

- Fermentation at Retail (FD8009W)
- Curing, Smoking, Drying of Meat, Poultry and Fish and the Processing of Fermented Sausages (FD8005W)
- Reduced Oxygen Packaging at Retail (FD8004W)
- Juicing at Retail (FD8008W)
- Shellfish Tanks at Retail (FD8007W)
- Custom Processing of Meats at Retail (FD8006W)
- HACCP (CC8033W)
- Plumbing Controls for Commercial Food Establishments (CC8001W)
- Pest Control in Food Establishments (FD180W100)

#### **Instructor Led Courses**

- FD112 Food Code
- FD218 Risk-Based Inspection Methods in Retail
- FD204 Temporary Food Establishments
- FD207 Plan Review for Food Establishments
- FD312 Special Processes at Retail
- FD215 Managing Retail Food Safety
- ER310 Food Safety Issues in the Event of Disasters
- EPI-Ready in person training through (NEHA/Centers of Excellence)
- AFDO Environmental Sampling in Retail Food Facilities

#### Training – New

- CDC EATS 101
- CDC EATS 102

## Training - Under Development

- FD170 Application of Inspection and Investigation Techniques
- IFPTI Pest Control
- IFPTI Plumbing
- IFPTI Emergency Response

In-house training provided by State/Local Health Departments:

- Report writing
- State-specific
- Software
- Compliance and enforcement
- Risk-based inspection methods
- HACCP (application)
- Plumbing/backflow
- Consistency training (marking under same number)
- Meat/poultry inspection
- Scenario/mock inspection/role playing
- Ethnic Food Book
- Temporary Food Establishment training
- Mobile Vending training
- NAU Back Country Excursions
- Food Service During Disasters

## **Training Resources**

- AFDO Ethnic Food CD/App
- AFDO Salvage Food
- AFDO Dented Cans
- AFDO Incubator (Community/Shared) Kitchens
- AFDO Cottage Food
- Centers of Excellence (COE) food safety tools

## **Evaluation**

- CFP Training manual forms for new hires
- Standard 4 20 Quality Elements
- Standardization

## Certification

- NEHA Registered Environmental Health Specialist/Registered Sanitarian (REHS/RS)
- NEHA Certified Professional Food Safety (CPFS)
- NEHA Certified Foodborne Outbreak Investigator (CFOI)
- HACCP Alliance Certified HACCP Manager
- NSF Certified HACCP Manager
- ASQ (American Society for Quality) Root Cause Analysis Training
- 40 Hour HAZWOPER
- ANSI Food Safety Manager

## Program Standard #2

APPENDIX B-1: Curriculum for Retail Food Safety Inspection Officers
For state, local & tribal regulators to register on-line for free access to web courses, go to:
<a href="http://www.fda.gov/Training/ForStateLocalTribalRegulators/ucm121831.htm">http://www.fda.gov/Training/ForStateLocalTribalRegulators/ucm121831.htm</a>

## Pre-requisite ("Pre") curriculum courses

(to be completed during the 25 joint inspection period AND prior to conducting any independent inspections)

CURRICULUM TOPICS	COURSES WHICH FULFILL CURRICULUM TOPICS
PUBLIC HEALTH PRINCIPLES	
1. Public Health Principles	FDA36 (90)
MICROBIOLOGY	
1. Overview of Microbiology	MIC01 (60)
2. Gram-Negative Rods	MIC02 (60)
3. Gram-Positive Rods & Cocci	MIC03 (90)
4. Foodborne Viruses	MIC04 (60)
5. Foodborne Parasites	MIC05 (90)
6. Mid-Series Exam	MIC16 (30)
7. Controlling Growth Factors	MIC06 (90)
8. Control by Refrigeration & Freezing	MIC07 (60)
9. Control by Thermal Processing	MIC08 (90)
10. Control by Pasteurization	MIC09 (90)
11. Aseptic Sampling	MIC13 (90)
12. Cleaning & Sanitizing	MIC15 (90)
PREVAILING STATUTES, REGULATIONS, ORDIN	NANCES
1. Basic Food Law for State Regulators	FDA35 (60)
2. Basics of Inspection: Beginning an	FDA38 (90)
Inspection	
3. Basics of Inspection: Issues &	FDA39 (90)
Observations	
4. An Introduction to Food Security	FD251 (60) (https://www.fda.gov/training-and-
Awareness	continuing-education/office-training-education-and-
	development-oted/introduction-food-security-
	<u>awareness</u> ) Note: Required exam is available via
	www.compliancewire.com.
5. FDA Food Code	NOTE: Specific state/local laws & regulations to be
	addressed by each jurisdiction
COMMUNICATION SKILLS	
1. Communication Skills for Regulators	CC 8011W (60) Note: Course can be accessed through
	FDA Pathlore at: (https://
	orauportal.fda.gov/stc/ORA/psciis.dll?linkid=675280&
	mainmenu=ORA⊤_frame=1)

## Curriculum ("Post") courses

(to be completed any time prior to Food Code Standardization AND within 18 months of hire or assignment to the regulatory retail food program)

CURRICULUM TOPICS	COURSES WHICH FULFILL CURRICULUM TOPICS	
MICROBIOLOGY		
1. Control by Retorting	MIC10 (90)	
2. Technology-Based Food Processes	MIC11 (120)	
3. Natural Toxins	MIC12 (90)	
HACCP		
1. Overview of HACCP	FDA16 (60)	
2. Prerequisite Programs & Preliminary Steps	FDA17 (60)	
3. The Principles	FDA18 (60)	
ALLERGEN MANAGEMENT		
1. Food Allergens	FD252 (60)	
EPIDEMIOLOGY		
1. Collecting Surveillance Data	FI01 (90)	
2. Beginning the Investigation	FI02 (90)	
3. Expanding the Investigation	FI03 (90)	
4. Conducting a Food Hazard Review	FI04 (90)	
5. Epidemiological Statistics	FI05 (90)	
6. Final Report	FI06 (30)	
EMERGENCY MANAGEMENT		
FEMA – Incident Command System and National Incident Management System: Course available from		
FEMA web link <a href="http://training.fema.gov/IS/NIMS.asp">http://training.fema.gov/IS/NIMS.asp</a>		
Introduction to Incident Command System	IS-100.C, Introduction to Incident Command	
	System, (180) ICS-100 or IS-100 for FDA	
2. ICS for Single Resources and Initial Action	ICS-200.C, IS-200.C, ICS for Single Resources	
Incidents	and Initial Action Incidents, (180) ICS-200	
3. NIMS an Introduction	ICS 700.B, NIMS an Introduction, (180) ICS-700	

( ) Average time in minutes required to take the course, 60 minutes equals .1 CEU, 90-120 minutes equals .2 CEUs

Estimated total hours for "Pre" courses are 42 hours.

Estimated total hours for "Post" courses are 26 hours.

Estimated total hours for completion of all Program Standard #2 coursework are 68 hours

## Program Standard #2

## APPENDIX B-1: Curriculum for Retail Food Safety Inspection Officer

# Pre-requisite ("Pre") curriculum courses

(to be completed during the 25 joint inspection period AND prior to conducting any independent inspections)

CURRICULUM TOPICS	COURSES WHICH FULFILL CURRICULUM TOPICS
ENVIRONMENTAL HEALTH FOUNDATION	
Public Health Principles	CC8026W <sup>P</sup>
2. Environmental Hazards	CC8024W <sup>P</sup>
3. Jurisdiction	CC8037W <sup>P</sup>
4. Pest Control	[IFPTI Course under development]
5. Plumbing	CC8001W [IFPTI Course under development]
MICROBIOLOGY	CC8001W [IFFIT Course under development]
1. Overview of Microbiology	MIC01 <sup>c</sup> (60)
2. Gram-Negative Rods	MICO2 <sup>c</sup> (60)
3. Gram-Positive Rods & Cocci	MIC03 <sup>c</sup> (90)
4. Foodborne Viruses	MICO4 <sup>c</sup> (60)
5. Foodborne Parasites	MIC05 <sup>c</sup> (90)
6. Mid-Series Exam	MIC16 <sup>c</sup> (30)
	` '
7. Controlling Growth Factors	MICO6 <sup>c</sup> (90)
8. Control by Refrigeration & Freezing	MICO7 <sup>c</sup> (60)
9. Control by Thermal Processing	MIC08 <sup>c</sup> (90)
10. Control by Pasteurization	MIC09 (90) <sup>c</sup>
11. Sampling	CC8035W <sup>P</sup>
12. Sanitation Practices	CC8032W <sup>P</sup>
PREVAILING STATUTES, REGULATIONS, C	
1. Laws, Regulations, Policies, &	CC8039W <sup>P</sup>
Procedures	
2. Basics of Inspection: Beginning an	FDA38 <sup>c</sup> (90)
Inspection	
3. Basics of Inspection: Issues &	FDA39 <sup>c</sup> (90)
Observations	
4. An Introduction to Food Security	FD251 (60) (https://www.fda.gov/training-and-continuing-
Awareness	education/officetraining-education-and-development-
	oted/introduction-food-security-awareness ) NOTE:
	Required Exam is available via ( <u>www.compliancewire.com</u> )
5. FDA Food Code	
(NOTE: Specific state/local laws &	
regulations to be addressed by each	
jurisdiction)	
6. Jurisdiction	CC8037W <sup>P</sup>
COMMUNICATION SKILLS	
1. Communication Skills for Regulators	CC8011W (60) NOTE: Course must be accessed through
	FDA Pathlore at: (https://

# PSC subcommittee #3 Charge 2 Appendix B-1 Reformatted 2nd Draft

	orauportal.fda.gov/stc/ORA/psciis.dll?linkid=675280&main menu=ORA⊤_frame=1)
PROFESSIONALISM	
1. Professionalism	CC8025W <sup>P</sup>

# Curriculum ("Post") courses

(to be completed any time prior to Food Code Standardization AND within 18 months of hire or assignment to the regulatory retail food program)

CURRICULUM TOPICS	COURSES WHICH FULFILL CURRICULUM TOPICS	
MICROBIOLOGY	COURSES WHICH FOLFILE CORRICOLOW TOPICS	
1. Control by Retorting	MIC10 <sup>c</sup> (90)	
Technology-Based Food Processes	MIC11 <sup>c</sup> (120)	
3. Natural Toxins	MIC12 <sup>c</sup> (90)	
HACCP	WIC12 (90)	
1. Overview of HACCP	FDA16 <sup>c</sup> (60)	
2. Prerequisite Programs & Preliminary Steps	FDA17 <sup>c</sup> (60)	
3. The Principles	FDA18 <sup>c</sup> (60)	
ALLERGEN MANAGEMENT		
1. Food Allergens	CC8029W <sup>P</sup>	
EPIDEMIOLOGY		
1. Collecting Surveillance Data	FI01 <sup>c</sup> (90)	
2. Beginning the Investigation	FI02 <sup>c</sup> (90)	
3. Expanding the Investigation	FI03 <sup>c</sup> (90)	
4. Conducting a Food Hazard Review	FI04 <sup>c</sup> (90)	
5. Epidemiological Statistics	FI05 <sup>c</sup> (90)	
6. Final Report	FI06 <sup>c</sup> (30)	
INTEGRATED FOOD SAFETY SYSTEM		
1. Integrated Food Safety System	CC8018W <sup>P</sup>	
2. Imports	CC8034W <sup>P</sup>	
3. Recalls	CC8041W <sup>P</sup>	
4. Traceability	CC8042W <sup>P</sup>	
5. Transportation	CC8036W <sup>P</sup>	
EMERGENCY MANAGEMENT		
FEMA – Incident Command System and National Incident Management System: Course available from		
FEMA web link <a href="http://training.fema.gov/IS/NIMS.asp">http://training.fema.gov/IS/NIMS.asp</a>		
1. Introduction to Incident Command System	IS 100.C, ICS-100 or IS-100 for FDA (180)	
2. ICS for Single Resources and Initial Action	IS-200C, ICS-200 (180)	
Incidents		
3. NIMS an Introduction	IS-700.B, ICS 700 (180)	

# PSC subcommittee #3 Charge 2 Appendix B-1 Reformatted 2nd Draft

( ) Average time in minutes required to take the course, 60 minutes equals .1 CEU, 90-120 minutes equals .2 CEUs

<sup>P</sup>Course available on Pathlore

<sup>c</sup>Course available on ComplianceWire

Estimated total hours for "Pre" courses are XX hours.

Estimated total hours for "Post" courses are XX hours.

Estimated total hours for completion of all Program Standard #2 coursework are XX hours

## **B1 Regulatory Program Foundations (CC8021W)**

<u>FDA Pathlore Course Description:</u> Introductory knowledge, skills, and abilities related to the elements of feed and food regulatory programs.

- a) Goal: The student will be able to exhibit introductory knowledge, skills, and abilities related to the elements of feed and food regulatory programs.
- b) Scope: Topics covered in this course include foundations, laws and regulations, feed/food protection agencies, program standard areas, IFSS, mutual reliance (recognition and reciprocity).

Committee Review: Slide numbers would have been helpful. The very first course was long. Providing a projected time frame would be helpful. The content includes a lengthy history on how the law and enforcement actions were developed. It was nice to see a great list of tips for training new inspectors on when to involve a supervisor and how to think critically during the inspection. Program standards were mentioned. There was some terminology which was concerning for new inspectors to be translating this knowledge to the retail food industry. For example: the word violative seems to have been used interchangeably with "hazardous" or "priority". The coursework frames were not very interactive. Perhaps the relevant terminology could have been hyperlinked throughout the course instead of being featured at the beginning. The knowledge checks and final exam does not give a detailed performance summary; it just gives a score.

Committee Recommendation: No action

### B2 Allergens (CC8029W)

<u>FDA Pathlore Course Description:</u> Introductory knowledge, skills, and abilities related to food allergens, controls and regulatory requirements.

- (a) Goal: Discuss the control of allergens in relation to food safety.
- (b) Scope: This course will cover introductory knowledge, skills, and abilities related to food allergens, controls, and regulatory requirements. Topics include foundations of allergens, labeling requirements, FSMA, control measures, and educational resources.

<u>Committee Review:</u> This course is currently under revision by IFPTI. The U.S. recognized allergens and allergens recognized overseas were explained well. The link for the full list of tree nuts did not lead us to the correct FDA page. We had to google search the FALCPA list to access the correct FDA page.

<u>Committee Recommendation:</u> We recommend replacing FD252, Allergen Management in "post" courses with this course.

#### B3 Biological Hazards (CC8028W)

<u>FDA Pathlore Course Description:</u> Introductory knowledge, skills, and abilities related to biological hazards, focusing on sources of contamination, growth factors, and control methods.

#### Committee Review:

#### Unit 1

 Pathogens vs Spoilage Organisms slide mentions that off-flavors are a characteristic of food compromised by the outgrowth of pathogens. This should be included under the spoilage organism column. Sampling slides mention the term "for-cause" sampling. Where does this wording come
from? The message could be rephrased to better represent circumstances such as
traceback investigations for foodborne illness or precautionary circumstances. Also, the
regulatory sampling slide gives the impression that the regulator will be completing the
sampling in manufacturing environments.

#### Unit 2

- Aflatoxins slide mentions some effects of carcinogens. But, the slide does not explain
  that aflatoxins are carcinogens. Perhaps the previous slides could have included a brief
  explanation that many aflatoxins are considered carcinogenic.
- Other Mycotoxins slide mentions that fumonisin consumption can be fatal. But, it is unclear as to whether that fatality is found in humans or just horses and swine. Also, are humans becoming affected through consumption of swine or the rice and corn directly?
- Toxin-Mediated Infection slide does not explain that the terms toxicoinfection and toxin-mediated infection are interchangeable.
- Examples of Incubation Periods slide uses a bullet point format to provide the information. This may have been better as a data table.
- Biofilm slide could have included a nice tie-in to the messages about sampling, as L. monocytogenes is difficult to remove from a facility due to biofilms.

#### Unit 3

- Food Packaging slide provides an explanation of MAP below the bullet points for both MAP and general ROP without connecting the explanation directly to MAP.
- Vectors: Humans slide contains a photo of a food handler correctly wearing gloves and using a utensil to handle food. It would be better to show bare hand contact.

#### Unit 4

- Listeria slide shows a photo of a drain cover in a pool. This should be a floor drain photo within a food establishment.
- Food Contact Surfaces slide uses the terms direct and indirect food-contact surfaces. This is not in alignment with the term food-contact surface and nonfood contact surface used in retail food.

#### Unit 5

- Several slides continued to mention only MAP as a type of packaging which can aid in the control of pathogenic growth.
- Controlling campylobacter slide has the bacteria name misspelled in two of the sentences. Estimated time: approx. 2 hrs.

<u>Committee Recommendation:</u> Standard 2 curriculum microbiology section covers these topics, no need to replace.

## **B4 Biosecurity (CC8023W)**

## FDA Pathlore Course Description:

Introductory knowledge, skills, and abilities related to controlling disease transmission between people, animals, and plants. There are six modules in this course.

#### Committee Review:

which should be SOPs for the facility.

#### Unit 1

At the beginning of the Unit 1, the definition of biosecurity is very broad. It seems to reference what we understand to be the basics of food protection within retail/restaurant environments. Is it the best definition? Is this term more widely used in manufacturing? Three parts of a facility's biosecurity plan: exclusion, management, and containment. All of

#### Unit 2

The definition for fomite includes living and non-living matter. I understood fomites to be inanimate objects or materials which can become contaminated and transfer pathogens. Explanations for food processing were nicely worded. Nice use of plain language to differentiate between harvest/slaughter and processing.

#### Unit 3

Biosecurity zone slide defines a controlled access point as the third point. However, it would be better suited as the first definition because personnel would have to enter controlled or restricted zones through this point of access.

The slides which describe the types of PPE need some additional wording to relate the subject to its significance in the prevention of contamination within a facility or operation. Is the term enhanced inspection interchangeable with the term investigation as an inspection type? This was included on the slide which described how inspectors should protect themselves.

## Unit 4

The slide which discusses the importance of planning for the regulatory visit includes a non-working link to the FDA Investigations Operations Manual. The distinction between disinfection and sanitizing needs to be better explained. The material did not include an explanation of communicating breaches within the sanitation chain as part of the recall protocol.

#### Unit 5

The FDA Investigation Operations Manual link at the beginning on unit 5 did navigate to the correct webpage. The knowledge check question 2 seems to assess whether the learner has read the material at the provided links to both the FDA and USDA documents. The slide with those links could be improved by including a brief explanation of the main focuses of those two documents. FDA being routine operations and USDA being emergency preparedness and response to adverse events.

<u>Committee Recommendation:</u> Currently, there is no biosecurity in the curriculum. It's more in depth than we consider to be necessary. Overall, it seemed to have been designed for manufacturing instead of food service. Several case studies were included. That is beneficial for the learner. We do not recommend addition.

#### **B5 Communication Skills (CC8030W)**

FDA Pathlore Course Description:

Introductory knowledge, skills, and abilities related to effective communication in the regulatory field.

- (a) Goal: Discuss the skills required for an effective communicator in the regulatory field.
- (b) Scope: Inspectors can expect to be introduced to the basic knowledge, skills, and abilities related to effective communication in the regulatory field. Topics discussed include foundations, specific communication skills (oral, written, effective listening, feedback, etc.), situational awareness, agency policies on communication, and educational resources.

#### Committee Review:

#### Unit 1

A slide mentions that an inspector may need to use the services of a translator. Should this say interpreter rather than a translator?

#### Unit 2

The slides which describe assertive communication as the preferred style for regulators contradict themselves. While assertiveness was described as a tool to achieve mutual respect and understanding, one of the slides gave a recommendation to use "I" statements. For example, "I would like begin the tour so that we can finish by 5 pm".

#### Unit 3

Several of the situational awareness photos need to be replaced with photos which better suit the content.

Some of the course exam questions were poorly worded. For example, the question asks if one should contact a supervisor if the facility operators is perceived to be lying is poorly worded.

#### Committee Recommendation:

Covers many of the same topics as "Communication Skills for Regulators" currently required in "pre" courses which seems more applicable for retail food establishments. Recommend no action.

## **B6 Data & Information Systems (CC8017W)**

#### FDA Pathlore Course Description:

Introductory knowledge, skills, and abilities related to systems used by regulatory agencies to store, process, and manage data and information.

<u>Committee Review:</u> Mostly a basic computer course hardware, software, data, database, mainframe, etc. The Unit 1 foundational information seemed largely irrelevant except for the distinction between data and information and the databases used by health departments and FDA.

Section 4, FDA 20.88 agreements provided useful information new inspectors may not be aware of. Section 2 also provided useful information on social media, but most jurisdictions have internal policies covering this for employees.

The "FOOD Tool" slide in Unit 1 is described as the CDC's database for foodborne illness outbreak data. Food Outbreak Online Database (FOOD) Tool. Is this still used? Shouldn't this be NORS (National Outbreak Reporting System)?

The Unit 3 and Unit 4 content does well in supporting the regulator's training on basics of inspection. These units provided good information on the knowledge a regulator must manage and the access and control of information: Freedom of Information Act, securing and updating passwords, etc. The bulk of the content seems to be common knowledge for new inspectors. Perhaps individuals who are unfamiliar with the internet and web-based applications would find the information beneficial.

<u>Committee Recommendation:</u> Overall, information not recommended to add to Standard 2. Most of this information is general knowledge of computers currently taught in school. Social media, malware, specific databases are usually often covered by jurisdictional internal policies. No action.

## **B7 Emergency Response**

FDA Pathlore Course Description: The course is still under development

Committee Review: N/A

Committee Recommendation: No action

### **B8 Environmental Hazards (CC8024W)**

<u>FDA Pathlore Course Description:</u> Introductory knowledge, skills, and abilities related to environmental hazards as sources of contamination, and associated control methods.

#### **Foundations**

- 1. Define relevant terminology
- 2. Give examples of food and feed products that may be affected by environmental hazards.
- 3. Describe where to find resources.
- 4. Describe the consequences of contamination by environmental hazards.
- 5. Discuss how sampling is used to detect environmental hazards.
- 6. Give examples of how a milestone event impacted public policy.
- Give examples of illness caused by environmental hazards.

## **Environmental Hazards of Concern**

- 1. Identify the categories of environmental hazards.
- 2. Give examples of each category of environmental hazard.
- 3. Associate environmental hazards with products or processes.

#### Sources and Pathways

- 1. Discuss how environmental hazards contaminate products and processes.
- 2. Describe vectors of contamination.
- 3. Give examples of food contamination sources.
- 4. Give examples of feed contamination sources.
- 5. Differentiate between intentional and unintentional contamination.

## **Control Factors**

- 1. Explain the concept of acceptable levels of exposure.
- 2. Describe best management practices that are used to prevent spread of environmental hazards.
- 3. Give examples of preventive controls.
- 4. Describe control point monitoring.

- 5. Explain why source is important as a control factor.
- 6. Discuss response options for contamination

#### Duration

Unit 1: Foundations - 23 minutes

Unit 2: Environmental Hazards of Concern – 21 minutes

Unit 3: Sources and Pathways – 38 minutes

Unit 4: Factors - 11 minutes

Estimated time = 1 hour and 33 minutes

#### Committee Review:

#### Unit 1

Foundations – is course content geared towards Retail Food or Manufacturing? Many of the examples and pictures emphasize manufacturing. We also suggest adding radiological hazard language in the opening slides. Also, be consistent with use of Radiological throughout if it is going to be used and mirror FSMA rules.

#### Unit 2

Virus slide. Suggest rewording or structuring slide so that Norovirus is clearly the #1 cause. Currently worded that viruses in general are the number one cause of illness in US.

#### Unit 3

Suggest adding more retail food pictures to balance out all the manufacturing pictures. Assessment Knowledge Check 1 – sampling question not covered very well in module.

#### Unit 4

Control Factors Slide – Food Safety Plans: personnel safety pictures used instead of food safety symbolic pictures.

Control Factors: expound more on why source is important as a control factor. GRAS definition clarification needed that explains that GRAS is a chemical or substance added to food.

Course Assessment – Question 9: is the question asking about pre or post packaging. Needs to be reworded so that its clear.

Overall, we thought courses were good foundation for new regulatory staff. We also thought that it would be helpful for the modules to have slide number to be able to reference slides later. We concur with others that the exams at the end of the courses should provide feedback on questions that were missed so that the "student" learns the correct information. The assessments taken during each unit would also be better if the answer was reiterated why it was correct or why the answer chosen was incorrect. We like that a description pops up when hovering over photos.

Committee Recommendation: Good introduction to hazards, add to "pre" courses.

#### B9 Food / Feed Defense Awareness

FDA Pathlore Course Description: N/A

<u>Committee Review:</u> Unable to review this module because the course was not submitted by the course developer, is not on Pathlore or in the course catalog. Dave Read checked into it and found that the course does exist, but the course was not provided on Pathlore. Committee Recommendation: No action

## **B10 HACCP (CC8033W)**

<u>FDA Pathlore Course Description:</u> Introductory knowledge, skills, and abilities related to the hazard analysis and critical control points (HACCP) system There are five modules in this course.

#### Committee Review:

#### Unit 2

Record Review for Accuracy – consider changing "validity" wording. Too much like verification vs validation and makes you think you are talking about validations whereas the slide is discussing verification. Overall comment: Verification vs Validations needs better disused and language on slides needs to stay true their meaning.

#### Unit 4

Videos. Seem out of place, not necessary, too short if they are going to be used. Would be better if video clips provided snippet of each of the 7 steps of HACCP instead of just 2.

#### Unit 5

Laws Regulations and Guidance: suggest creating stand-alone paragraph to explain implementation of FSMA. Need better clarification of State Agriculture programs, USDA, FDA, State and local oversight and co-regulation. Also, better explanation of FSMA (food safety plans) vs HACCP.

Assessment question—there was a question for recall procedure. We felt this was not adequately covered in module for use as a question.

<u>Committee Recommendation:</u> Comparable to current "post" HACCP series (FDA16-18). If possible, merge with current courses. Recommend no action.

#### B11 Imports (CC8034W)

<u>FDA Pathlore Course Description:</u> Introductory knowledge, skills, and abilities related to the regulation of feed and food products grown, produced or manufactured outside of or returned to the US.

- a) Goal: The student will be able to apply knowledge of import requirements.
- b) Scope: The topics in this course include foundations, acts and regulations, entry process, inspection, investigation, compliance and enforcement actions, import fraud.

<u>Committee Review:</u> The slide which explains the term custom(s) broker includes the abbreviation CBP. The phrase CBP custody is used but is not explained until later slides. At which point, CBP is defined as Customs and Border Protection. The text under the example figure for Harmonized Tariff Schedule Code has very low resolution and is difficult to read. Unit 5 includes a "Real World Applications" video on investigations which took a very long time to load. Upon completing the final unit, there was no button available on screen to navigate to the actual course assessment. FD251 references imports, so the material presented in the module is covered there. Course completion time was 47 mins.

<u>Committee Recommendation:</u> We do not recommend the material replace FD251, An Introduction to Food Security Awareness, but differing information is important; add to "post" courses to supplement FD251.

## **B12 Integrated Food Safety System (CC8018W)**

<u>FDA Pathlore Course Description:</u> Introductory knowledge, skills, and abilities related to the concept of a national collaborative and cooperative network of federal, state, local, tribal, and territorial feed and food protection agencies working in concert to protect the U.S. human and animal food supply.

- (a) Goal: Describe how collaborative interrelationships of regulatory agencies promote and protect public health in a global environment.
- (b) Scope: This course will cover introductory knowledge, skills, and abilities related to the concept of a national collaborative and cooperative network of federal, state, local, tribal, and territorial feed and food protection agencies working in concert to protect the U.S. human and animal food supply. Topics include foundations of IFSS, stakeholders, mutual reliance, and program standards.

#### Committee Review:

Reading – reading description of images not helpful stating same thing as image that is presented.

"Example" images - throughout presentation - placeholders?

Module covered the basic foundations of an IFSS and identified the stakeholders. Also covered mutual reliance between stakeholders and covered the different program standards. 35 minutes to complete.

Committee Recommendation: Add to "post" course work.

## B13 Inspections, Compliance, & Enforcement (CC8019W)

<u>FDA Pathlore Course Description:</u> Introductory knowledge, skills, and abilities related to ensuring regulatory compliance through inspection and enforcement activities.

- a) Goal: The student will be able to explain compliance activities as they relate to the safety of feed and food programs.
- b) Scope: Topics in this course will include Foundations, Jurisdiction, inspection classifications, Inspection tools, Inspection techniques, Pre-inspection, Inspection process, post inspection, enforcement measures

<u>Committee Review:</u> Would be nice to be able to modify and brand to individual jurisdictional procedures.

Introductory knowledge, skills, and abilities related to ensuring regulatory compliance through inspection and enforcement activities. We have covered foundations, jurisdiction, inspection classification, inspection tools, inspection techniques, pre-inspection, inspection process, post-inspection, and enforcement measures.

<u>Committee Recommendation:</u> Only replace if the FDA 38, 39 & Communication can be merged with this course. No action.

## **B14 Investigation Principles (CC8020W)**

<u>FDA Pathlore Course Description:</u> Introductory knowledge, skills, and abilities related to conducting an investigation of a food safety-related event.

- a) Goal: The student will be able to describe an investigation.
- b) Scope: Topics covered in this course include foundations, communication, agency collaboration, investigation skills pre-investigation, investigation, post-investigation.

Committee Review: Example of Collaborating on Releasing Information, Released Early-

"EXAMPLE image" used – also on the following:

Unit 3- Examples of Potentially Involved Agencies

Unit 5 -Commodity Research Example One, two

Unit 6 -Observational Evidence Example

## **Exam - Question 5**, not clarified in reading material:

The Incident Command System (ICS) is:

a) A flexible system that allows agencies the ability to innovate as necessary.

 $\odot$ 

b) A rigid system.

After successful completion of exam, suggest providing a reference slide or information to inform learner of correct choices for the incorrect selections that were made.

<u>Committee Recommendation:</u> Some material covered in FDA38 – Basics of Inspection course; no action.

## **B15 Jurisdiction (CC8037W)**

<u>FDA Pathlore Course Description:</u> Introductory knowledge, skills, and abilities related to various regulatory agencies and their authority over feed and food.

- a) Goal: The student will be able to describe which agencies have authority to conduct specific regulatory activities.
- b) Scope: The topics covered in this course include foundations, law, crossing boundaries, interagency agreements.

<u>Committee Review:</u> We thought the course gave a good overview of the subject and was well designed to provide the information in a logical order. The course does not have slide numbers, so as with regards to feedback we have provided the slide header:

#### Unit 1

Foundations State & Local Jurisdiction Authority. Suggest a change to a word in the paragraph that states food 'consumed', suggest changing to food 'sold or distributed'. It would be inaccurate to describe food purchased at a retailer and then consumed at a home just across the state line as intrastate commerce.

#### Unit 3

Activities under the State Retail Food Program. It states FDA develops the Retail Food Program, we felt that the CFP process develops with input/oversight from FDA.

The Exam at the end of the course only provides a score, it does not let you know which questions you got incorrect. This could help determine what part of the course you may need to retake etc.

On AFDO's website, the courses are cross-referenced. There was not much interactive content within the course. The lack of interactive features seems like a step back considering the way that online coursework is developed today. The terminology is bridged from the manufacturing content. Violative is commonly used in manufacturing regulation. We scheduled an hour. However, we had to move through the content more quickly toward the end.

Committee Recommendation: Add to "pre" courses.

## B16 Labeling (CC8038W)

#### FDA Pathlore Course Description:

Introductory knowledge, skills, and abilities related to labeling requirements, and the components of feed and food product labels.

- a) Goal: The student will be able to explain label requirements.
- b) Scope: The topics covered in this course include foundations, labeling laws and regulations, labeling components, feed, food.

#### Committee Review:

#### Course Overall:

- No slide numbers or time to complete course/sections.
- inconsistency on knowledge base confirmation on whether a question was answered correctly or not.
- There were a few videos (a little basic), but not sure if they were positioned correctly i.e. they seemed to introduce a new topic, would prefer an intro slide prior to the video.
- Some of the label images were too small to read, even on a large screen.
- The course did seem very long.

## Course Design:

- The course design may benefit from being aligned under regulated areas i.e. Human Food FDA / FSIS, Dietary Supplements, and Animal feed and then having the specific topics under each area i.e. regulations, label requirements, etc. this could help with repetition, flow and refresher training. It is a lot of information for a new employee, especially if they are not responsible for a certain regulated area i.e. animal feed, the information becomes irrelevant.
- The competency flow did not align with the course, so by having it aligned under regulated areas could help better align it.

#### Unit 1

Label Vs Labeling Slide. Include supplement labeling on a website

#### Unit 2

Labeling components required allergy information is referencing 'Produced in a facility that processes peanuts' which is not required

- Labeling components trail mix labeling confusing

#### Unit 3

Labeling laws referencing outdated FDA 2013 Food code

Committee Recommendation: No action in current condition. Like the topic of labeling to be included in curriculum; consider addition if course is revamped.

## B17 Laws, Regulations, Policies, & Procedures (CC8039W)

<u>FDA Pathlore Course Description:</u> Introductory knowledge, skills, and abilities related to the system of federal, state, and local laws that provide the authority to regulate feed and food, and associated policies and procedures.

- a) Goal: The student will be able to employ legal authorities when conducting regulatory activities.
- b) Scope: The topics covered in this course include foundations, constitution, law, regulation, policy, procedures, guidance.

<u>Committee Review:</u> We do not have any significant feedback. We thought the course was well aligned with the competencies and covered all the topics. As stated on previous calls the content is a little dry, and we believe in future the courses will have more interaction.

<u>Committee Recommendation:</u> Replace FDA35, Basic Food Law for State Regulators in "pre" courses.

#### B18 Personal Safety (CC8031W)

#### FDA Pathlore Course Description:

Introductory knowledge, skills, and abilities related to hazards encountered by regulators, and appropriate protective actions to mitigate hazards.

- (a) Goal: Choose safe practices based on assessment of risk.
- (b) Scope: This course will provide introductory knowledge, skills and abilities related to hazards encountered by regulators as well as appropriate protective actions to mitigate hazards. Specific topics include foundations of personal safety, chemical hazards, equipment hazards, physical/environmental hazards, miscellaneous hazards, safety equipment, and educational resources.

Committee Review: It sounds like there is some redundant material in other courses regarding PPE. We noticed that the course provided specific instructions on how an inspector should execute personal safety rather than describing the types of PPE. It mentioned that an inspector should reach out to a facility in advance to determine what types of hazards to personal safety may be there. The buddy system for entering coolers and freezers was also mentioned for personal safety reasons. However, there may not always be more than one inspector conducting the inspection. Ladder safety was also included. We considered the content to be focused on more OSHA recommendations than necessary for the food protection field. Examples of hazard signage and PPE requirement signage was very useful. The content should be more of an overview and could be confusing. Basics of inspection course, FDA 38, includes a brief inclusion of personal safety by informing the inspector of appropriate clothing, shoes, head cover.

<u>Committee Recommendation:</u> Given that the material is not covered, it would not replace the current curriculum; no action.

## **B19 Pest Control (under development)**

<u>IFPTI Course Description:</u> Explain how pest activity can impact food safety. Discuss pests of significance to human and animal health. Discuss the importance of facility design for pest control. Describe sanitation practices for pest control. Discuss detection of pests. Discuss how pest management is used to control pests.

<u>Committee Review:</u> This course is currently under development and unable to review. However, this topic is important for new inspectors.

Committee Recommendation: Recommend adding to "pre" courses.

## B20 Plumbing (CC8001W - under development)

<u>FDA Pathlore Course Description:</u> This one-hour online course provides information on plumbing controls used in commercial food establishments to protect the potable water supply from contamination. The course consists of 4 lessons: Course Introduction, Cross-Connection Fundamentals, Physical and Mechanical Backflow Prevention, Protection for Drains, Wells, and Septic Systems.

This online course is a prerequisite for several OTED face-to-face courses designed to increase knowledge in identifying plumbing issues in food manufacturing facilities when conducting food GMP inspections. The commodity specific face-to-face course will increase skills and ability to interpret industry situations related to conducting food GMP inspections by FDA investigators/State inspectors.

<u>Committee Review:</u> B20 Plumbing is still in development but appears to be largely complete; I was provided with PDFs of the storyboards and narration for this review. This course includes significant improvements over the other courses I reviewed, having expanded accessibility features, narration, and knowledge checks that include 4+ answers. Some knowledge checks had "choose all that apply" options or asked the participant to choose the correct diagram to match the concept described. The photos and diagrams are matched for backflow prevention devices and other fixtures, which is helpful. I would consider this course a big upgrade from CC8001W.

The course has 5 units: Foundations, Water Source, Wastewater Systems, Backflow Prevention and Jurisdictional Authority. It provides a rationale for proper plumbing, citing an example from the EPA Cross-Connection Control Manual. (Kool-Aid that got mixed with a now-banned pesticide; it would have been prevented with a backflow prevention device.) The material identifies the differences between public and private water supplies, informing the regulator as to which questions to ask. B20 also covers preventing cross-connections, air gaps, maintenance, transport, and so on.

<u>Committee Recommendation:</u> Add to the Standard 2 pre-requisite curriculum. As an aside, it could also replace CC8001W as the pre-requisite for FD207 Plan Review.

## **B21 Preventive Controls (CC8040W)**

#### FDA Pathlore Course Description:

Introductory knowledge, skills, and abilities related to measures implemented by feed and food manufacturing facilities to ensure feed and food safety.

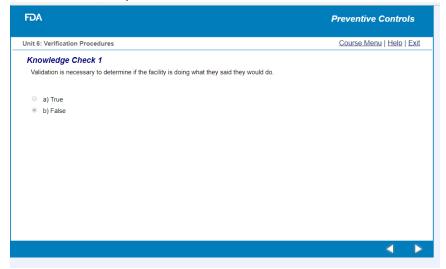
- a) Goal: The student will be able to describe the principles of preventive controls.
- b) Scope: Topics covered in this course include foundations, food safety plans, hazard

analysis, monitoring preventive control programs, corrective action plans, verification procedures, recordkeeping.

<u>Committee Review:</u> The course is geared towards manufacturing and could confuse if used for retail.

- -Course flows well.
- -Knowledge checks were good.

Unit 6 - Validation question incorrect. "Verification" should be the wording. Screenshot below:



- -Final Exam Q9 wording is confusing.
- -Final exam does not state which question was answered incorrectly

<u>Committee Recommendation:</u> Not applicable to retail food; no action.

## **B22 Professionalism (CC8025W)**

## FDA Pathlore Course Description

Introductory knowledge, skills, and abilities related to ethics, integrity, and personal conduct during job-related activities.

- (a) Goal: The student will be able to exhibit the use of integrity and positive interpersonal conduct in the performance of professional and personal activities.
- (b) Scope: Topics covered in this course include foundations, ethics, conduct, personal management, communication, and interpersonal skills.

<u>Committee Review:</u> The coursework is divided into 6 units: Foundations, Ethics, Conduct, Personal Management, Communications and Interpersonal Skills. It defines professionalism, explains its value and the rationale for regulators to act with integrity and the accountability to the public.

The course includes straightforward and relevant scenarios for situations where a regulator could fail to conduct themselves appropriately and how to avoid even the perception of improper conduct. This content is largely text but includes illustrations and photos on most slides.

Each unit has a pair of questions at the end; they are not difficult, only requiring the participant to choose between 2 options. That said, they do underscore important concepts and prevent the participant from just clicking through the course on auto-pilot. The 10-question assessment at the conclusion is similar and provides a final percentage upon completion.

The course required about 45 minutes to complete.

Committee Recommendation: Add to the "pre" curriculum courses.

## **B23 Public Health Principles (CC8026W)**

<u>FDA Pathlore Course Description:</u> Introductory knowledge, skills, and abilities related to how regulatory agencies promote health and prevent and control feed- and food-related illness.

- a) Goal: The student will be able to discuss basic public health concepts.
- b) Scope: Topics in this course include foundations, assessment, policy development, education and outreach, disease mitigation, emerging health issues, feed/food safety professional's role in public health.

<u>Committee Review:</u> The course covers 7 units: Foundations, Assessment, Policy Development, Education and Outreach, Disease Mitigation, Emerging Health Issues and the Regulator's Role in Public Health. I reviewed FDA36 and B23 side-by-side to compare the content between the courses. I recommend B23 as a replacement for FDA36; it covers the much of the same material but is designed to be more relevant to a regulator working in food safety.

The course provides good examples to explain each of the principles. Rather than recount the history of John Snow versus cholera (FDA36), B23 cites more contemporary examples, including "mad cow disease" in Great Britain and E. coli O157:H7 at Jack in the Box in 1993. These examples are used to describe subsequent changes in public policy.

The course required about 75 minutes to complete. It follows the same format as B22, with text, illustrations and photos on most slides. The 10-question assessment at the end includes questions binary questions similar to those found in B22.

Committee Recommendation: Replace FDA36, "Public Health Principles" in "pre" courses.

## B24 Recalls (CC8041W)

## FDA Pathlore Course Description:

Introductory knowledge, skills, and abilities related to the process of removing a product from commerce.

- a) Goal: The student will be able to describe the recall process in regulatory programs.
- b) Scope: Topics covered in this course include foundations, risk assessment, documentation, communications, recall process, product disposition.

<u>Committee Review:</u> The course has 6 units: Foundations, Risk Assessment, Documentation, Communications, Recall Process and Product disposition. Units 1 and 2 each include a subtitled video, which is a nice addition and a nod to accessibility. Useful distinctions, like the difference between recalls and market withdrawals, and adulteration versus misbranding, are explained throughout the course. The information is relevant for state regulatory agencies that monitor recalls and notify local jurisdictions, and for those agencies that assist in verifying that a product is being removed. However, local jurisdictions are not always involved in recalls (and the course helpfully points out that local health departments don't typically have the authority to initiate a

recall). As a newer state regulator, I felt the content was useful in many instances, and was my first exposure to some of the information.

I am tentatively recommending that B24 be added, unless we are finding that too many courses are being added and not enough are being removed or replaced. I am concerned about adding an unnecessary burden to inspectors by including this in the Standard 2 curriculum if it does not pertain to their normal duties. It required about 70 minutes to complete.

<u>Committee Recommendation:</u> Add to the "post" curriculum courses.

## B25 Sampling (CC8035W)

## FDA Pathlore Course Description:

Introductory knowledge, skills, and abilities related to feed and food sample collection, and the role of the laboratory.

- a) Goal: The student will be able to employ sampling protocols when collecting samples.
- b) Scope: Topics covered in this course include foundations, sampling methodology, procedures, laboratory.

<u>Committee Review:</u> B25 has just 4 units: Foundations, Sampling Methodology, Procedures and Laboratory. It defines integrity and validity in regard to sampling, describing the rationale in collecting and documenting samples that are legally and scientifically defensible. Aseptic sampling and chain of custody is explained. The course references the FDA Inspections Operations Manual as a resource for determining how much of a sample is required to be representative. (Maybe include a link that to that manual?)

Unit 3 includes a three-minute video with subtitles to demonstrate how to collect aseptic samples. The shots throughout the video are framed well and allow the viewer to clearly see each step as it is demonstrated. FI04, Foodborne Illness Investigations 4: Conducting a Food Hazard Review, covers the some of this sampling content but is more focused on preparing (logistics and interviewing) for the site visit. B25 is more analogous to MIC13. It took approximately 60 minutes to complete.

Committee Recommendation: Replace MIC13, Aseptic Sampling, in the pre-requisite curriculum.

## **B26 Sanitation Practices (CC8032W)**

#### FDA Pathlore Course Description:

Introductory knowledge, skills, and abilities related to cleaning, sanitizing, and disinfecting, and the importance of facility and equipment sanitary design.

- (a) Goal: Describe the importance of sanitary design and practices.
- (b) Scope: This course will consist of introductory knowledge, skills and abilities related to cleaning, sanitizing and disinfecting as well as the importance of facility and equipment sanitary design. Topics include foundations of sanitation, cleaning, sanitizing, disinfecting, sanitary engineering, and educational resources.

<u>Committee Review:</u> The course consists of 6 units: Foundations, Cleaning, Sanitizing, Disinfecting, Sanitary Engineering and Sources/Routes of Contamination. It addresses construction materials, contact and non-contact surfaces, the distinction between cleaning and sanitizing, proper layout and so on. The material addresses the limitations and thresholds for different methods of sanitization (chemical, thermal, radiation). It also identifies barriers to

effective cleaning and sanitization. The course took about 75 minutes to complete, but it might be more like 90 minutes for someone new to the material.

<u>Committee Recommendation:</u> Replacing MIC15, Cleaning & Sanitizing, in the Standard 2 Prerequisite curriculum; it's a significant upgrade across the board. Also, this course covers a lot of the fundamentals for FD207 Plan Review and may be a suitable pre-requisite for that course.

## **B27 Traceability (CC8042W)**

## FDA Pathlore Course Description:

Introductory knowledge, skills, and abilities related to tracking feed and food throughout the supply chain.

- a) Goal: The student will be able to describe the role of traceability in feed and food programs.
- b) Scope: Topics covered in this course include foundations, preliminary review, supply chain, documentation, communications, technology.

<u>Committee Review:</u> This course has 6 units: Foundations, Preliminary Review, Supply Chain, Documentation, Communication and Technology. It serves as a primer for tracking human and animal foods through the supply chain. The traceback processes and necessary documentation are clearly defined, and the rationale is provided for when and why a traceback is conducted. (Or a traceforward...) It has some overlap with the Foodborne Illness Investigations series. But, it is distinct and focused enough that it would not replace any of them. It seems most relevant to epidemiologists; most of the local jurisdictions I work with have epidemiological staff and perhaps one inspector that is crossed-trained on epi.

#### Unit 3:

Supply Chain has a 2-minute video, subtitled, that describes a traceability study, followed by a traceback diagram. The diagram might be better served as a larger image (expandable or clicking to enlarge), as it is difficult to see at the current resolution. Some images have the option of clicking a line of text to read a description of the image.

Like B24 (Recalls), this course has useful information for all regulators, but I am unsure as to how necessary it would be for regulators that work on teams with trained epidemiologists. It took about 75 minutes to complete.

<u>Committee Recommendation:</u> Add to "post" curriculum.

## **B28 Transportation (CC8036W)**

## FDA Pathlore Course Description:

Introductory knowledge, skills, and abilities related to preventing contamination of feed and food during transport.

- a) Goal: The student will be able to describe how transportation affects feed and food safety.
- b) Scope: Topics in this course include foundations, transportation methods, inspections, security, product safety.

<u>Committee Review:</u> The course contains 5 units: Foundations, Transportation Methods, Inspections, Security and Product safety. It required about 90 minutes to complete.

The first section includes a 4-minute video (subtitled) on the importance of transportation. Unit 2 includes a 2-minute video on a *Salmonella enteritidis* outbreak that sounds like it is referencing the Schwan's incident investigated in Minnesota. The video and header indicate the outbreak happened in 1984, but the well-known outbreak occurred in 1994. A minor detail; is this an error? Also found a typo in Unit: Product Safety on the Air Distribution Exchange slide in the heading.

The Security unit has useful information on chain of custody. The content is well-written and includes examples from relevant outbreaks. It appears to be more pertinent to manufactured foods and agriculture, rather than retail foods. Much of the content (pest control, HACCP, temperature control) that would be applicable to retail food inspections is covered in other courses.

<u>Committee Recommendation:</u> Add to "post" curriculum.

# VNRFRPS Table-Standard 4

#	Performance Element	CFP Training Manual
1.	Has required equipment and forms to conduct the inspection.	Pre-inspection
2.	Reviews the contents of the establishment file, including the previous inspection report, reported complaints on file, and, if applicable, required HACCP Plans or documents supporting the issuance of a variance.	Pre-inspection
3.	Verifies that the establishment is in the proper risk category and that the required inspection frequency is being met. Informs the supervisor when the establishment is not in the proper risk category or when the required frequency is not met.	Needs to be added under Pre-inspection #2 (review current risk category) and Inspection observations and performance #3 (verifies risk category is correct based on inspection observations)
4.	Provides identification as a regulatory official to the person in charge and states the purpose of the visit.	Inspection observations and performance
5.	Interprets and applies the jurisdiction's laws, rules, policies, procedures, and regulations required for conducting retail food establishment inspections.	Inspection observations and performance
6.	Uses a risk-based inspection methodology to conduct the inspection.	Inspection observations and performance
7.	Accurately determines the compliance status of each risk factor and Food Code intervention (i.e., IN compliance, OUT of compliance, Not Observed, or Not Applicable).	Joint inspections during training process/ Section II Inspection Observations and Performance & Section III Inspection Observations and Performance
8.	Obtains corrective action for out-of-compliance risk factors and Food Code interventions in accordance with the jurisdiction's policies.	Inspection observations and performance
9.	Discuss options for the long-term control of risk factors with establishment mangers, when the same out-of-control risk factor occurs on consecutive inspections, in accordance with the jurisdiction's policies. Options may include, but are not limited to; risk control plans, standard operating procedures, equipment and/or facility modification, menu modification, buyer specifications, remedial training, or HACCP plans.	Section II Inspection Observations and Performance, #6 addresses violations on previous inspection being corrected, what if they were not

# VNRFRPS Table-Standard 4

		corrected and long-term control is needed? Needs to be added to Inspection
		Observations and Performance, #6
10.	Verifies correction of out-of-compliance observations identified during the previous inspection.	Inspection observations and performance
	In addition, follows through with compliance and enforcement in accordance with the jurisdiction's policies.	
11.	Conducts an exit interview that explains the out-of-compliance observations, corrective actions, and timeframes for correction, in accordance with the jurisdiction's policies.	Oral communication
12.	Provides the inspection report and, when necessary, cross-referenced documents, to the person in charge or permit holder, in accordance with the jurisdiction's policies.	Written communication
13.	Demonstrates proper sanitary practices as expected from a food service employee.	Professionalism
14.	Completes the inspection form per the jurisdiction's policies (i.e. observations, public health reasons, applicable code reference, compliance dates).	Written communication
15.	Documents the compliance status of each risk factor and intervention (IN, OUT, NA, NO).	Implied in written communication?
16.	Cites the proper code provisions for risk factors and Food code interventions, in accordance with the jurisdiction's policies.	Written communication
17.	Documents corrective action for out-of-compliance risk factors and Food code interventions in accordance with the jurisdiction's policies.	Written communication
18.	Documents that options for the long-term control of risk factors were discussed with establishment managers when the same out-of-control risk factor occurs on consecutive inspections. Options may include, but are not limited to, risk control plans, standard operating procedures, equipment and/or facility modification, menu modification, buyer specifications, remedial training, or HACCP Plans.	Section IV. Written Communication, 1. Completes inspection form per jurisdiction's administrative procedures Needs to be added
19.	Compliance or regulatory documents (i.e. exhibits, attachments, sample forms) are accurately completed, appropriately cross-referenced within the inspection report, and included with the inspection report, in accordance with the jurisdiction's policies.	Written communication
20.	Files reports and other documentation in a timely manner, in accordance with the jurisdiction's policies.	





# **IFSS Framework Food Protection Professionals Curriculum Framework**

	Basic	Basic [Program Specific]		Advanced		Advanced [Program Specific]		Technical Specialist [Expert]		Technical Specialist [Program Specific]		Leadership	
	Biological	Dairy - on farm Program 842		Communication Skills	60	Dairy - on Egg [shell] Program Program Program  A34 A35  Unproces		Audit Comm	Unproce	Dairy - on farm Program		Advocacy	
	T Biosecurity	Egg		ion Emergency Response	Good Agricultural Practices [GAPs]	Egg Fish & Produce [shell] Seafood Program Program Program A35 A37 Unprocessed Concentration		Communication Cri	Unprocessed Concentration	Egg [shell] Program		Communication Management	
	Communication n Skills	hell] F am F aprocessed F			al Practices	Produce Growing Program Areas Program Program Areas Program Ass Centration		Critical Em Thinking Re	tration	Fish & Seafood Program			
	Data & Information Systems	[shell] Produce ogram Program  s43 s44 Unprocessed Foundations 829		Enforcement <sub>A3</sub>	[GAPs]	fish as Patrol Program ram  Shellfish as Patrol Program as A33 Unprocessed Electives A28		Emergency V Response A	Unproce	Produce Program		Communication Skills	
	Response  Environmental Hazards	Shellfish Growing Areas Program		Evidence	A19	gram USDA APHIS		Food Defense Vulnerability Assessment	Unprocessed Electives	Shellfish Growing Areas Program		kills Compliance	
- Charles N	Food / Feed Defense	Growing rogram s		Food/ Feed Defense				IFSS	es				
Del ic a food ca	HACCP	USDA APHIS		Imports	A20	Import Concentration [FDA]		lership kills	1722	USDA APHIS		Emergency Response	
for professional	IFSS	Import Foundations [Federal Agencies]		IFSS		Animal Food Program		Legal Proceedings Preparation		Animal Food Program		Human Resource Management	
Re training standar	Imports  Inspections, Compliance, &	8		Inspections				Management Skills	Ma			IFSS	
gulatory Prog	Enforcement  Investigation Principles	Animal Food Program  848  Communication Skills 832	Level 1 Profess		Manufactur	Dairy Processing Program [U	Level 2 Professional	nt Policy Development	anufactured C	Dairy Processing Program	Level 3 Professional	Laws & Regulations	Level 4 Profess
Regulatory Program Foundations at	Jurisdiction	Dairy Processing Program  847  Emergency Response	evel 1 Professional Certificate	Instructor Skills [Elective]	Manufactured Concentration	Meat & Poultry [USDA FSIS]	sional Certificate		Manufactured Concentration		Certific		Level 4 Professional Certificate
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mank (5) 54FD	Policies, & Procedures	Meat & Poultry [USDA FSIS]  849  Food Processes  Bass		Lat		Shellfish ed Plant am Program		Program Evaluation		Manufactured Program		Legislative Affairs	
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mission of the	Public Health Principles	Shellfish Plant Program  851  Pest Control 833		Product Disposition	A25	nal Vessel ne Sanitation ies Program ce [CDC]		Risk Analysis		<sub>R</sub>		Program Resources	
Partnership for	Recalls  Sampling	Reta		Risk Analysis				supe	125	Retail Food Program			ADM
Food Protection	Sanitation Practices	Retail Food Program    BE2		Sampling	A26	Retail Food Program		Research Design [Elective]		ogram		Risk Management	- N
's Integrate	Traceability	gram Sampling		Transportation		rogram		Statistical Analysis [Elective]				Strategic Planning	

# **B2 Allergens**

**Definition:** An overview of food allergens, including labeling requirements, preventive controls, and societal impact.

**Topic Area TLO:** Discuss the control of allergens in relation to food safety.

# **Topic Area ELOs:**

- Explain the risks of allergen exposure.
- Identify major food allergens.
- Describe potential routes of allergen cross-contact.
- Use agency resources to evaluate allergen controls.
- Explain allergen labeling requirements.

# **Unit 1: Foundations**

**Definition:** Food allergens related to food programs.

**TLO:** Discuss foundational information related to major food allergens.

#### ELOs:

- Define relevant terminology.
- Differentiate food allergy from food intolerance.
- Discuss the prevalence of food allergy in the United States.
- Identify major food allergens as recognized by FDA and USDA.
- Give examples of foods deemed major allergens in non-U.S. countries.
- Discuss the public health significance of food allergens.
- Describe the symptoms of an allergic reaction.
- Describe the treatment of an allergic reaction.

- The regulator has a knowledge or awareness of the existence of allergens.
- The regulator can define what an allergen is.
- The regulator has a knowledge or awareness of regulations tied to allergens.
- The regulator has a knowledge or awareness that allergens have the potential to cause a health hazard.
- The regulator can give examples of some of the major allergens:
  - a. List the major food allergens
  - b. 8 common allergens
- The regulator has a knowledge or awareness of regulations related to allergens:
  - a. Name the regulation
  - b. Undeclared allergens
    - Recalls
  - c. Animal feed is exempt
  - d. Labeling requirements
- The regulator can discuss the importance of regulating allergens.
- The regulator has a knowledge or awareness of routes of exposure for allergens:
  - a. Hygiene hypothesis

•	Discuss allergens in
	relation to recalls.

# Unit 2: Labeling Requirements

**Definition:** Food labeling requirements pertaining to major food allergens.

**TLO:** Discuss allergen labeling requirements.

# ELOs:

- Discuss the purpose of the Food Allergen Labeling and Consumer Protection Act (FALCPA).
- Give examples of allergen labeling options under FALCPA.
- Give examples of scientific terms vs. plain language.
- Give examples of allergen labeling for tree nuts, fish, and crustacean shellfish.
- Discuss the placement of allergen provisions on food labels.
- Discuss the use of allergen advisory ("may contain") statements.

# **TLO Behavioral Anchors - not all-inclusive**

- The regulator has knowledge or awareness that allergens must be declared on the label.
- The regulator has a knowledge or awareness of which allergens must be declared on the label:
  - a. Big 8 (USA)
- The regulator has a knowledge or awareness of different allergen labeling options.

#### Unit 3: FSMA

**Definition:** The provisions of FSMA specifically related to major allergens.

**TLO:** Discuss the allergen provisions of the Food Safety Modernization Act (FSMA).

# ELOs:

# TLO Behavioral Anchors - not all-inclusive

The regulator has a knowledge or awareness that because of FSMA, allergens are considered health hazards.

- Discuss "adulterant" in relation to allergens under FSMA.
- Discuss "hazard" in relation to allergens under FSMA.
- Define "food allergen cross-contact".

# **Unit 4: Control Measures**

**Definition:** Measures by industry to prevent allergen cross-contamination.

**TLO:** Discuss control measures to prevent allergen crosscontact.

# ELOs:

- Define "allergen threshold".
- Define "dedicated" in relation to allergen crosscontact.
- Discuss cleaning methods to remove allergen residues.
- Discuss the role of product changeover in relation to allergen crosscontact.
- Discuss the scheduling of processing runs in relation to allergen cross-contact.

- The regulator has a knowledge or awareness of various control measures.
- The regulator has a knowledge or awareness of control measures utilized to prevent cross-contact.
- The regulator can name several control measures:
  - a. Cleaning
  - b. Sanitizing
  - c. Physical separation
  - d. Dedicated equipment
  - e. Labeling
  - f. Colored coding
  - g. Dedicated facility
  - h. Gloves
  - i. Air flow controls
  - j. Training
- The regulator can explain how control measures prevent cross-contact.
- The regulator can recognize when control measures are not properly implemented.

# B17 Laws, Regulations, Policies, & Procedures

**Definition:** Introductory knowledge, skills, and abilities related to the system of federal, state, and local laws that provide the authority to regulate feed and food, and associated policies and procedures.

Topic Area TLO: Employ legal authorities when conducting regulatory activities.

# **Topic Area ELOs:**

- Discuss legal authorities.
- Differentiate among law, regulations, and ordinances.
- Explain legal authorities to conduct activities.
- Describe administrative protocols.
- Apply authorities to determine compliance.

#### **Unit 1: Foundations**

**Definition:** Base knowledge of laws, regulations, policies and procedures related to feed and food programs.

**TLO:** Differentiate between laws, regulations, policies, and procedures applicable to regulatory activities.

# ELOs:

- Define relevant terminology.
- Explain the significance of key laws.
- Describe the relationship between laws and regulations.
- Describe how administrative protocols support laws and regulations.
- Describe how model codes can be adopted.

#### TLO Behavioral Anchors - not all-inclusive

- The regulator can define key terms:
  - a. Laws (acts, statutes, and ordinances), regulations, policies, procedures and authority
- The regulator can provide an example of each key term.
- The regulator can identify laws, regulations, policies, and procedures applicable to your agency.
- The regulator can list the laws, regulations, policies, and procedures pertinent to your position.
- The regulator can describe how each is developed:
  - Authority versus agency requirements (example: Congress gives FDA authority in FD&C Act, FDA promulgates regulations to carry out the law)
  - b. Have awareness of the difference between a law and regulation
- The regulator can describe the relationship of policies and procedures to laws and regulations.
  - Support of regulatory activities (example: relationship of sampling to the law, regulation, policy and procedure)
  - b. Describe when to refer to each one
  - c. Identify regulatory actions your agency may take for non-compliant firms

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**TLO Behavioral Anchors - not all-inclusive** 

**Definition:** The system of

fundamental principles according to which Federal, State and local agencies are governed.

**TLO:** Describe how constitutional law grants and limits authorities.

# ELOs:

- Describe how the federal constitution grants and limits agency powers.
- Describe how state constitutions grant and limit agency powers.
- Explain the difference between State and Federal rights and limits.
- Explain due process.
- Explain individual rights guaranteed by the constitution.
- Describe the separation of powers between the executive, legislative, and judicial branches of government.

- The regulator has a basic knowledge or awareness of the constitution:
  - a. Define Constitutional law
  - b. Constitution establishes fundamental principles of all laws
  - c. 3 branches of the federal government
  - d. Commerce clause (interstate commerce)
    - Grants authority and accountability
- The regulator has a knowledge or awareness of rights of the individual protected under the Constitution:
  - a. Interpretation of rights example: FD&C Act requires payment for some samples because of the Constitution, other agencies may not
  - b. Food Law and regulations may require owner giving up rights
  - c. Seizures, embargoes, stop sales, inspections
- The regulator has a knowledge or awareness of the Federal constitution versus state constitution.
- The regulator has a knowledge or awareness of the delegation of authority.

# Unit 3: Law

**Definition:** The foundational knowledge of the process by which laws are created and how authority is delegated.

**TLO:** Discuss how laws determine regulatory authority.

# ELOs:

- Describe legislative processes.
- Explain how local

- The regulator can define regulatory authority.
- The regulator can define a law, act/statute:
  - a. Include enforcement authority
  - b. Authority to write regulations
- The regulator has a knowledge or awareness of Laws establish and limit regulatory authority:
  - a. Agencies are not able to exceed regulatory authority
- The regulator has a knowledge or awareness of which laws provide the authority to do the regulator's job.
- The regulator can find where in the law your authority is

ordinances differ from state and federal statutes.

- Explain delegation of authority.
- Differentiate between statutory and case law.
- Explain how law authorizes enforcement actions.

# derived from:

a. Delegation of authority

# **Unit 4: Regulation**

**Definition:** An administrative act or rule, based on law, prescribed by agency authority.

**TLO:** Explain how regulations assist agencies to implement laws.

#### ELOs:

- Identify pertinent regulations that are applicable to regulatory programs.
- Explain the general process by which regulations are developed.
- Describe the FDA cooperative program model regulations.
- Describe how regulations are published.

# **TLO Behavioral Anchors - not all-inclusive**

- The regulator can explain the relationship between a law and regulation:
  - a. What is the difference between a regulation and a law
  - b. Regulations provide information about the implementation of laws
  - c. Laws prevail over regulations
  - d. Regulations are based on the law
- The regulator has a knowledge or awareness that your agency implements regulations.
- The regulator can list regulations your agency implements.
- The regulator can clarify enforcement authority:
  - a. Discretion
- The regulator can list the information that regulations may provide about implementation of the law:
  - a. Standards
  - b. Who/what is regulated
  - c. Required procedures
  - d. Point of reference
  - e. Minimum requirements
  - f. Clarity
  - g. Required process

# **Unit 5: Policy**

**Definition:** Set of principles formulated or adopted by an agency to influence and determine actions.

**TLO:** Describe the purpose of

- The regulator can define a policy.
- The regulator can give examples of policies.
- The regulator can provide the basis for consistent implementation or application of the law.
- The regulator can outline legal requirements in plain

# agency policies.

# **ELOs:**

- Describe how policies are developed.
- Differentiate between regulatory and administrative policies.
- Give examples of when a regulatory policy is applicable.
- Give examples of when an administrative policy is applicable.
- Discuss the relationship between policy and procedures.

# language.

- The regulator can link policies to specific laws and regulations.
- The regulator can give examples of what agency policies accomplish:
  - a. Provide agency positions/strategy
  - b. Correct an issue
  - c. Address a need
  - d. Emerging technology
  - e. To provide a scientific basis
- Provide additional information about laws and regulations

# **Unit 6: Procedures**

**Definition:** Providing a standard method for conducting activities.

**TLO:** Explain the purpose of procedures used in federal, state, and local regulatory programs.

#### ELOs:

- Describe the process of procedure development.
- Describe the process of procedure implementation.
- Explain the importance of following procedures.
- Explain how procedures are used to obtain compliance.

- The regulator can define a procedure:
  - a. Series of steps to be followed
  - b. Provides the instruction and/or paperwork to carry out an activity
  - c. Describe how policies will be put into action
  - d. Determines who will do what
  - e. Step by step instructions/guidance
  - f. More detailed than policy
  - g. Identify specific forms or documents
- The regulator can give examples of procedures used in their agency.
- The regulator can describe how procedures benefit the agency:
  - a. Improve time efficiency
  - b. Improves sharing of information
  - c. Efficient use of resources

Give examples of when to use applicable procedures. Unit 7: Guidance **TLO Behavioral Anchors - not all-inclusive** The regulator can define what is a guidance document a. Interpretation of regulation b. Recommendations, not law or legally binding c. Recommendations or instructions on how to meet agency expectations d. Guidelines to assist in carrying out regulatory requirements e. Regulatory authorities current thinking on a subject or method f. Not mandatory g. Can be used by industry and regulators The regulator can give an example of guidance documents. The regulator can recognize how their agency uses guidance documents. The regulator can describe the relationship of a guidance document to a regulation. The regulator can describe what guidance documents accomplish: a. Support a consistent application of laws, regulations, policies and procedures b. Provide additional clarity for vague or gray areas within the regulations c. Provides historical and scientific background to regulation and policy d. Standardize response to a defined situation e. Explain a complex subject or procedure f. Clarify laws, regulations, policy and procedures, g. Guidance documents often point to additional resources h. Help implement best practices i. Additional information to support and/or complete an activity Provide information that can be used to attain and remain in compliance





**Definition:** Introductory knowledge, skills, and abilities related to how regulatory agencies promote health and prevent and control feed- and food-related illness.

**Topic Area TLO** (Terminal Learning Objective): Discuss basic public health concepts.

# **Topic Area ELOs** (Enabling Learning Objective):

- Explain public health principles.
- Discuss how public health principles are applied to the food system to protect consumers.
- Explain the relationships among agent, host, and environment with respect to hazards in food.
- Explain the agency's role to protect consumers.
- Apply public health principles while conducting regulatory activities.

# **Unit 1: Foundations**

**Definition:** Base knowledge of public health principles and successes related to feed and food programs.

**TLO:** Discuss public health principles and successes.

# ELOs:

- Define relevant terminology.
- Locate resources.
- State the goal of public health.
- Describe the three components of public health.
- Explain what actions public health professionals take to promote public health.
- Provide examples of public health programs.
- Provide examples of public health

- The regulator can describe the goal of public health:
  - a. Promote population health
- The regulator can give an example of public health programs.
- The regulator can list the three components of public health:
  - a. Assessment
  - b. Policy development
  - c. Assurance
- The regulator can describe a public health success.





successes.

# Unit 2: Assessment

**Definition:** The evaluation of data to determine the impact from exposure to disease and the effects on public health.

**TLO:** Describe the best practices for public health assessments.

# ELOs:

- Explain the importance of assessment.
- Explain the role of epidemiology.
- Explain the role of risk factors.
- Discuss the purpose of data collection and analysis.
- Explain the public health implications of a disease.
- Differentiate active and passive surveillance.

# **TLO Behavioral Anchors - not all-inclusive**

- The regulator can discuss the role of epidemiology.
- The regulator can explain the importance of data collection.
- The regulator can discuss the importance of assessment.
- The regulator can describe active surveillance.
- The regulator can describe passive surveillance.

# **Unit 3: Policy Development**

**Definition:** A basic knowledge of policy development.

**TLO:** Describe policy development and implementation.

# ELOs:

- The regulator can describe how incidents influence public health policy.
- The regulator can discuss how political forces affect public health policy.
- The regulator can give an example of public health policy implementation.





- Explain how incidents drive policy.
- Explain how research influences policy.
- Explain how stakeholders influence policy.
- Explain how the political process influences policy.
- Explain how policy is implemented.
- Give an example of the implementation of a public health policy.

# Unit 4: Education and Outreach

**Definition:** A description of how the public health professional can be proactive to educate and protect the community.

**TLO:** Describe the use of education and outreach in public health.

#### ELOs:

- Explain the importance of education and outreach.
- Give examples of health communication methods.
- Identify relevant public health issues for outreach.
- Describe populations that would benefit from education and outreach.
- Explain outreach methods for intended

- The regulator can describe the importance of education and outreach in public health.
- The regulator can give an example of a public health communication method.





audience.	
Unit 5: Disease Mitigation	TLO Behavioral Anchors - not all-inclusive
Definition: Basic knowledge of disease mitigation.  TLO: Describe approaches to prevent, reduce, or control disease.	<ul> <li>The regulator can discuss methods to prevent or control disease.</li> <li>The regulator can describe a disease control strategy.</li> <li>The regulator can list two means of disease transmission.</li> </ul>
Discuss the importance of disease mitigation.     Discuss disease prevention strategies.     Explain modes of disease transmission.     List risk factors that increase susceptibility to disease in populations.	
Unit 6: Emerging Health Issues	TLO Behavioral Anchors - not all-inclusive
<b>Definition:</b> How emerging health issues can influence public health.	<ul> <li>The regulator can give an example of an emerging health issue.</li> <li>The regulator can describe how an emerging health issues impacts regulation.</li> </ul>
TLO: Identify how emerging health issues affect public health.	
ELOs:	
<ul> <li>Describe the concept of emerging health issues.</li> <li>Provide an example of how an emerging</li> </ul>	





health issue has impacted public health policy and regulation.

 Provide examples of currently emerging health issues.

# Unit 7: Feed/Food Safety Professional's Role in Public Health

**Definition:** Basic knowledge of how food regulatory agencies promote public health.

**TLO:** Describe the role of the food safety professional in public health.

# ELOs:

- Describe the contribution of feed/food safety activities to public health.
- Discuss how feed/food safety is influenced by public health.
- Describe the role of feed/food safety professionals in mitigation of public health threats.
- Describe the role of feed/food safety professionals in promoting public health.
- Give an example of how a feed/food safety professional promotes public health.

- The regulator can describe the regulator's role in promoting public health.
- The regulator can provide an example of how a food safety regulator promotes public health.





# IFSS Framework – Basic Level Gen Eds **B25 Sampling**

**Definition:** Introductory knowledge, skills, and abilities related to feed and food sample collection, and the role of the laboratory.

**Topic Area TLO** (Terminal Learning Objective): Employ sampling protocols when collecting samples.

**Topic Area ELOs** (Enabling Learning Objectives):

- Discuss sampling techniques.
- Explain sampling protocols.
- Determine if sample collection is necessary.
- Employ authority to collect samples.
- · Apply sampling procedures.

Unit 1: Foundations	TLO Behavioral Anchors - not all-inclusive				
Definition: Basic knowledge of sampling related to feed and food programs.  TLO: Collect a sample with documentation.	<ul> <li>The regulator can describe the agency's policies for sample collection: <ul> <li>a. Chain of custody</li> <li>b. Documentation</li> <li>c. Sampling techniques</li> </ul> </li> <li>The regulator can describe the importance of correct documentation.</li> <li>The regulator can independently demonstrate correct</li> </ul>				
<ul> <li>ELOs:</li> <li>Define sampling terminology.</li> <li>Discuss sample collection methods.</li> <li>Explain why samples are collected.</li> <li>Record required information pertaining to a sample.</li> <li>Describe the different types of samples.</li> </ul>	sample documentation.  The regulator can explain the importance of correct documentation:  a. Identification b. Chain of custody c. Proper documentation of seal d. Sample technique documentation e. Shipping documentation f. Time g. Temperature h. Volume				
Unit 2: Sampling Methodology	TLO Behavioral Anchors - not all-inclusive				
<b>Definition:</b> Knowledge needed to collect a sample.	<ul> <li>The regulator can describe considerations for sampling:         <ul> <li>a. Expiration</li> <li>b. Time restraints</li> <li>c. Staffing/team</li> </ul> </li> </ul>				





# **B25 Sampling**

**TLO:** Discuss the factors to consider when collecting a sample.

#### ELOs:

- Determine equipment to use when collecting samples.
- Explain time related factors when collecting a sample.
- Give examples of key factors used to determine what makes a sample.
- Explain the difference between random and selective sampling.

- d. Method of sampling
  - Representation of the lot
- e. Equipment
- f. Sample type
  - Finished product
  - Environmental samples
  - Ingredients
  - Surveillance vs for cause
- g. Safety
- h. Enclosed areas
- i. Aware of your sampling environment
- The regulator can explain the ramifications if sampling factors are not considered:
  - a. Product contamination
  - b. cross contamination
  - c. cross contact
  - d. Enforcement action fails

# **Unit 3: Procedures**

**Definition:** A series of steps used to collect a sample.

**TLO:** Explain the procedures utilized when collecting a sample.

# ELOs:

- Apply official procedures when collecting samples.
- Record information on proper forms.
- Describe chain of custody.
- Give examples of procedures to follow when collecting a sample.

- The regulator can provide information to aid in decision making:
  - a. To determine the scope of the recall
  - b. To support the risk assessment
- The regulator can conduct recall audit checks:
  - a. Verify unsafe products are off the market.
- The regulator can discuss the role of documentation in validation, tracking, and organization:
  - a. Defensibility
  - b. Evidence to support a recall
- The regulator can discuss procedures when collecting a sample.
- The regulator can describe agency sampling policy.
- The regulator can discuss personal safety in sampling.
- The regulator can demonstrate sampling procedures.
- The regulator can describe methods related to specific sample types.
- The regulator can demonstrate safe sampling techniques.





# **B25 Sampling**

- Recognize the importance of expiration dates.
- Discuss issues associated with transport of samples.
- Describe the difference between an aseptic sample and a nonaseptic sample.

# **Unit 4: Laboratory**

**Definition:** Basic knowledge of laboratory functions pertaining to samples.

**TLO:** Discuss the role of the laboratory in feed/food safety.

# ELOs:

- Explain the importance of the laboratory.
- Describe lab receiving processes for samples collected.
- Explain the lab results to the stakeholders.
- Recognize the analytical capabilities of laboratories.

- The regulator can identify the laboratory's function in feed/food safety:
  - a. Receive
  - b. Analyze
  - c. Report results
  - d. Interpret results
- The regulator can describe how laboratories use quality control to produce defensible results.
- The regulator can discuss agency policy related to communication with the laboratory.





# IFSS Framework – Basic Level Gen Eds **B26 Sanitation Practices**

**Definition:** Introductory knowledge, skills, and abilities related to cleaning, sanitizing, and disinfecting, and the importance of facility and equipment sanitary design.

**Topic Area TLO** (Terminal Learning Objective): Describe the importance of sanitary design and practices.

# **Topic Area ELOs** (Enabling Learning Objective):

- Discuss the principles of sanitary design and practices.
- Identify the appropriate use of cleaners, sanitizers, and disinfectants.
- Describe the use of cleaners and sanitizers in specific situations.
- Explain regulatory agency policies in regard to sanitation, design, and employee practices.
- Explain the use of cleaning and sanitizing to control adulterants.

# **Unit 1: Foundations**

# **Definition:** Sanitation practices and sanitary design of facilities and equipment.

**TLO:** Discuss sanitation practices and sanitary design of facilities and equipment.

# ELOs:

- Discuss sanitary design of facilities and equipment.
- Discuss the importance of GMPs, GRPs, and GAPs.
- Describe principles of sanitation.
- Describe the purpose of SSOPs.
- Describe the importance of employee sanitation training.
- Give examples of monitoring records.
- Discuss water chemistry.

- The regulator can identify three facility sanitary design principles:
  - a. Exterior and upstream considerations
  - b. Piping
  - c. Facility plan review
  - d. Airflow
  - e. Clean ability
  - f. No niches/harborages areas
  - g. Facility design meets the needs of the food sector
  - h. Traffic patterns
  - i. Process flow considerations
  - j. Food contact surfaces made of food compatible materials (Food Code 4-101.11)
  - k. Vermin control
  - I. Water source and quality
- The regulator can identify an equipment sanitary design principle:
  - a. UL
  - b. Cleanable to a microbiological level
  - c. NSF International
  - d. Facility plan review
  - e. Cleanability
  - f. No niches/harborage areas
  - g. 3-A Sanitation Standards, Inc.
  - h. Self-draining
  - i. Accessible for inspection and maintenance
- The regulator can discuss a biological hazard related to sanitary design:
  - a. Minimize bacterial growth





# **B26 Sanitation Practices**

- b. Transportation as a hazard
- c. Biohazards
- d. Sanitation provides a five (5) log reduction
- e. Validation of cleaning and sanitizing protocols
- f. Environmental hazards
- The regulator can identify cleaning and sanitizing protocols:
  - a. Allergen control
  - b. Food safety plan
  - c. Sanitation Standards of Operation (SSOPs)
  - d. Employee training
  - e. Sanitary operational performance
  - f. Cleaning vs sanitizing
  - g. SOPs describe how sanitation is conducted
  - h. Management oversight
  - i. Current Good Manufacturing Practices (cGMP), current Good Retail Practices (cGRP), current Good Agriculture Practices (cGAP)
  - j. Cross-contamination prevention
  - k. Monitoring records
  - I. Biofilms
  - m. Types of sanitizers
  - n. Labels
  - o. Hot water
  - p. Follow label instructions
  - q. Heat
- The regulator can explain how clean ability impacts sanitization.
- The regulator can describe how sanitary design, adequate cleaning and sanitizing lead to hazard reduction.

# **Unit 2: Cleaning**

# **Definition:** The process of removing visible material such as soil, dirt, and organic matter from facilities and equipment.

- a. The regulator can describe two different types of cleaning:
  - a. Cleaning vs sanitizing
  - b. High pressure washing
  - c. Dustless cleaning methods





# **B26 Sanitation Practices**

**TLO:** Discuss the process of removing visible material such as soil, dirt, and organic matter from facilities and equipment.

# ELOs:

- Describe the factors that affect the efficacy of cleaning agents.
- Explain how water chemistry can affect cleaning agents.
- Discuss types of cleaning agents and their function on soil.
- Describe cleaning methods.
- Explain the importance of following the manufacturer's directions for use.
- Explain the importance of breaking down equipment for cleaning.

- d. Dry clean
- e. Flushing (dry feed)
- f. Rinsing (wet)
- g. Wet clean
- h. Clean-in-Place (CIP)
- i. Clean-out-of-Place (COP)
- j. Equipment teardown
- The regulator can discuss two concerns with cleaning supply usage:
  - Types of detergents/soaps
  - Contact time
  - Concentration strengths
  - Appropriate cleaning supplies
  - Matching cleaners with intended use
  - Follow label instructions
  - Cleaning solution labeling
  - Material Safety Data Sheets (MSD)
  - Cleaning frequencies
  - Proper storage of chemicals
- The regulator can provide two examples of appropriate cleaning methods.
- The regulator can discuss four concerns with cleaning supply usage.

# **Unit 3: Sanitizing**

**Definition:** Reducing the presence of microorganisms.

**TLO:** Discuss the process of reducing the presence of microorganisms.

# ELOs:

- Explain the importance of using approved food-grade sanitizers.
- Describe the factors that affect the efficacy of sanitizers.
- Describe the types of

- The regulator can list two considerations for microorganism control:
  - a. Prescribed treatment matches threat
  - b. Environmental hazards
  - c. Importance of cleaning before sanitizing
  - d. Pathogens of concern
  - e. Cross contamination (sanitizer residue, overspray, etc.)
- The regulator can describe the concept of how sanitizers work for microorganism control:
  - a. Types of sanitizers
  - b. Label instructions
  - c. Parts per million (PPM)
  - d. Sanitizer concentrations
  - e. Methods, chemical, and hot water
  - f. Contact time
  - g. Test strips
  - h. Temperature effects on efficacy
  - i. Drying





# **B26 Sanitation Practices**

- sanitizing agents.
- Discuss the purpose of sanitizers.
- Discuss sanitizers' requirements for use.
- Describe sanitizing strategies.
- Identify sanitizer test methods.
- The regulator can describe three considerations for microorganism control.
- The regulator can describe proper use of two sanitizers for microorganism control.

# **Unit 4: Disinfecting**

**Definition:** The use of specialized techniques to destroy or irreversibly inactivate pathogenic microorganisms but not necessarily their spores.

**TLO:** Discuss the use of specialized techniques to destroy or irreversibly inactivate pathogenic microorganisms but not necessarily their spores.

# ELOs:

- Explain the importance of using approved food-grade disinfectants.
- Describe the factors that affect the efficacy of disinfectants.
- Discuss the purpose of disinfectants.
- Discuss disinfectants' requirements for use.
- Describe disinfecting strategies.
- Identify disinfectant test methods.

- The regulator can identify a specialized technique for disinfection:
  - a. Oxidation
  - b. Ozone
  - c. Ultra violet (UV)
  - d. Time/temperature/concentration
  - e. Potential of hydrogen (pH) control
  - f. Irradiation
  - g. Membrane technologies
  - h. Onsite disinfection generation
- The regulator can distinguish between sanitizing and disinfecting.
- The regulator can discuss a specialized technique for disinfection.





B26 Sanitation Practices			
Unit 5: Sanitary Engineering	TLO Behavioral Anchors - not all-inclusive		
Definition: The design and construction of facilities and equipment to reduce of prevent Contamination and facilitate cleaning and sanitizing.  TLO: Discuss how facility and equipment design impacts sanitation.	<ul> <li>The regulator can discuss three equipment design considerations:         <ul> <li>a. Appropriate materials</li> <li>b. Smooth, non-absorbent, easily cleanable construction</li> <li>c. UL or NSF International certified</li> <li>d. Non-corrosive and durable</li> <li>e. Self-draining</li> <li>f. Biofilms</li> </ul> </li> </ul>		
ELOs:  • Discuss the concept	<ul> <li>g. Non-toxic materials</li> <li>h. No niches</li> <li>i. Accessibility</li> <li>The regulator can describe three sanitary design principles:</li> <li>a. Appropriate wastewater disposal</li> </ul>		
of building envelope.  • Discuss the importance of proper equipment layout.	<ul> <li>b. Biohazard areas</li> <li>c. Allergen control</li> <li>d. Employee movement</li> <li>e. Refuse storage/removal</li> <li>f. Loading dock design and maintenance</li> <li>g. Clean rooms</li> <li>h. Water source</li> <li>i. Water quality</li> <li>j. Upstream considerations</li> </ul>		
	<ul> <li>k. Emerging pathogens of concern on building design</li> <li>l. Hygienic compatibility</li> <li>m. Facility flow, incoming to finished product</li> <li>n. Exterior considerations</li> <li>o. Airflow systems</li> <li>p. Condensation</li> <li>q. Negative airflow vs positive</li> <li>r. Pest control</li> <li>s. Hygienic design of maintenance enclosures</li> </ul>		
Unit 6: Sources and Routes of	<ul> <li>t. Plumbing design and installation</li> <li>The regulator can discuss six equipment design considerations.</li> <li>The regulator can describe six sanitary design principles.</li> <li>TLO Behavioral Anchors - not all-inclusive</li> </ul>		
Contamination			
<b>Definition:</b> Hazards, practices, and facility/equipment design that may lead to contamination.	The regulator can list two improper activities that may lead to contamination:  a. Splash may transfer pathogens (droplet or airborne)		





# **B26 Sanitation Practices**

**TLO:** Discuss hazards, practices, and facility/equipment design that may lead to contamination.

# **ELOs:**

- Discuss potential hazards.
- Explain routes of contamination.
- Describe how people can be a source of contamination.
- Describe how cleaning practices can contribute to contamination.
- Explain the importance of vector control.
- Discuss the water source.

- b. Cross contamination
- c. Allergen cross contact
- d. Improper cleaning, sanitizing, and disinfecting
- e. Employee hygiene
- The regulator can list facility/equipment design attributes that may lead to contamination:
  - a. Improper design of facilities and equipment
  - b. Improper maintenance of facilities and equipment
  - c. Hidden niches
  - d. Airborne contaminants
  - e. Vector control
  - f. Water management (standing water, drains)
- The regulator can identify three types of hazards:
  - a. Chemical, Physical, Microbial hazards
- The regulator can explain how improper activities lead to contamination.
- The regulator can explain how improper design of facility/equipment and maintenance may lead to contamination.





## **B8 Environmental Hazards**

**Definition:** Introductory knowledge, skills, and abilities related to environmental hazards focusing on sources of contamination and associated control methods.

**Topic Area TLO:** Explain the properties of environmental hazards.

# **Topic Area ELOs:**

- Discuss the characteristics of environmental hazards.
- Identify categories and examples of environmental hazards.
- Recognize impacts of environmental hazards on animal feed and human food.
- Differentiate among environmental hazards.
- Describe methods to control environmental hazards.

#### **Unit 1: Foundations**

**Definition:** Basic knowledge of environmental hazards related to feed and food products and processes.

**TLO:** Describe the effect of environmental hazards in feed and food products and processes.

# ELOs:

- Define relevant terminology.
- Describe where to find resources.
- Give examples of feed and food products that may be affected by environmental hazards.
- Give examples of how a milestone event impacted public policy.
- Describe the consequences of contamination by environmental hazards.
- Give examples of illness caused by

- The regulator can define environmental hazards.
- The regulator has a knowledge or awareness of the effect of environmental hazards:
  - a. Environmental hazards can cause injury, illness, or death in people and animals.
- The regulator has a knowledge or awareness of the effects of environmental hazards in food and feed:
  - a. Short term and long term
  - b. Name types of injury or illness caused by environmental hazards
- The regulator can explain the difference between environmental and biological hazards.





environmental hazards.

 Discuss how sampling is used to detect environmental hazards.

# **TLO Behavioral Anchors - not all-inclusive**

# **Unit 2: Environmental Hazards of Concerns**

**Definition:** Basic knowledge of environmental hazards that can be a risk or threat.

**TLO:** Explain which environmental hazards can adulterate the feed and food supply.

# ELOs:

- Identify the categories of environmental hazards.
- Give examples of each category of environmental hazard.
- Associate environmental hazards with products or processes.

- The regulator can name the three categories of environmental hazards that can adulterate feed and food:
  - a. Physical
  - b. Chemical/toxin
    - Radiological
  - c. Biological
- The regulator can define adulteration.
- The regulator can give examples for each of the three categories of environmental hazards that can adulterate feed and food:
  - a. Physical glass
  - b. Chemical/toxin rat poison
  - c. Biological salmonella, listeria
- The regulator has a knowledge or awareness that there may be allowable limits of various physical, chemical, and biological elements such as:
  - a. Physical insect parts
  - b. Chemical/toxin- pesticides, aflatoxins
  - c. Biological coliforms

# Unit 3: Sources and Pathways

**Definition:** Basic knowledge of the sources and pathways that environmental hazards can take in contaminating products and processes.

**TLO:** Explain how products and processes can become contaminated by environmental hazards.

#### ELOs:

 Discuss how environmental

- The regulator can name the three categories of environmental hazards that can adulterate feed and food:
  - a. Physical
  - b. Chemical/toxin
    - Radiological
  - c. Biological
- The regulator can define adulteration.
- The regulator can give examples of each of the three categories of environmental hazards that can adulterate feed and food:
  - a. Physical glass
  - b. Chemical/toxin rat poison
  - c. Biological salmonella, listeria





- hazards contaminate products and processes.
- Differentiate between intentional and unintentional contamination.
- Describe vectors of contamination.
- Give examples of food contamination sources.
- Give examples of feed contamination sources.

- The regulator has a knowledge or awareness that there may be allowable limits of various physical, chemical, and biological elements such as:
  - a. Physical insect parts
  - b. Chemical/toxin pesticides, aflatoxins
  - c. Biological coliforms

# **Unit 4: Control Factors**

**Definition:** Basic knowledge of methods to control environmental hazards.

**TLO:** Discuss methods used to control environmental hazards.

# ELOs:

- Explain the concept of acceptable levels of exposure.
- Describe best management practices that are used to prevent spread of environmental hazards.
- Give examples of preventive controls.
- Describe control point monitoring.
- Explain why source is important as a control factor.
- Discuss response options for contamination.

- The regulator has a knowledge or awareness that methods exist to control environmental hazards.
- The regulator can define the terms eliminate, prevent, and control for environmental hazards.
- The regulator can identify methods that reduce, control, monitor, or eliminate environmental hazards:
  - a. Proper cleaning and sanitation
  - b. Environmental monitoring programs
  - c. Sequencing or flushing
  - d. Time and temperature controls
  - e. Corrective actions
  - f. Process flow
  - g. Chemical control program





# **B12 Integrated Food Safety System (IFSS)**

**Definition:** Introductory knowledge, skills, and abilities related to the concept of a national collaborative and cooperative network of federal, state, local, tribal, and territorial feed and food protection agencies working in concert to protect the U.S. feed and food supply.

**Topic Area TLO:** Describe how collaborative interrelationships of regulatory agencies promote and protect public health in a global environment.

# **Topic Area ELOs:**

- Discuss the IFSS elements.
- Explain the IFSS.
- Distinguish regulatory roles in a global environment.
- Explain responsibilities and roles that contribute to the IFSS.
- Describe the global food supply system.

# **Unit 1: Foundations**

**Definition:** Basic knowledge of the IFSS concept, development, and sustainment.

**TLO:** Discuss the origins, mandates, and drivers of the IFSS.

# ELOs:

- Define relevant terminology.
- Discuss the concept of IFSS.
- Discuss the development of the IFSS.
- Explain IFSS sustainability.
- Discuss the relationship between the IFSS and FSMA.
- Describe the IFSS role throughout the global food/feed supply.

- The regulator has a knowledge or awareness of the origin of the IFSS:
  - a. 50 state meetings
    - Food and Feed Associations
      - FSLTT
  - b. PFP
- The regulator has a knowledge or awareness of the IFSS mandate:
  - a. What is FSMA?
    - Briefly describe FSMA
- The regulator has a knowledge or awareness of the IFSS drivers:
  - a. Collaboration to protect public health
  - b. Uniformity
- The regulator can describe the timeline of IFSS development.
- The regulator can give examples of FSMA rules.
- The regulator has knowledge or awareness of the need to increase efficiency by leveraging resources across overlapping jurisdictions:
  - a. Stakeholders
  - b. Examples of collaboration
    - Cooperative agreements / grant, contracts, MOUs
      - Joint work planning
      - o Rapid Response Team
- The regulator knows how the IFSS impacts public health.





# Unit 2: Stakeholders

**Definition:** Government, nongovernment organizations, and industry with vested interest in the IFSS.

**TLO:** Describe the stakeholders within the IFSS.

#### ELOs:

- Identify the types of stakeholders.
- Describe how stakeholders influence public policy.
- Discuss roles for each type of stakeholder.
- Describe the relationship between the Partnership for Food Protection (PFP) and the IFSS.
- Identify the associations that comprise the Council of Association Presidents (CAP).
- Match feed/food trade associations within their primary target audience.
- Describe the role of feed/food safety alliances.

- The regulator has a knowledge or awareness IFSS stakeholders:
  - a. Industry
    - Retail
    - Manufacturing
    - Unprocessed
    - Importers
  - b. Government
    - FSLTT
    - Military
  - c. Laboratories
  - d. Representative groups
    - Alliances
    - Organizations
    - Associations
- The regulator has a knowledge or awareness of additional IFSS stakeholders:
  - a. Consumers
    - Human Food
    - Animal Food
- The regulator can discuss examples and roles of Industry Associations:
  - a. NRA
  - b. GMA
  - c. AFIA
- The regulator can discuss examples and roles of regulatory associations:
  - a. AAFCO
  - b. AFDO
  - c. NEHA
- The regulator can discuss examples and roles of laboratory associations:
  - a. APHL
  - b. Private vs government labs
- The regulator can give examples of collaborative partnerships:
  - a. NCIMS
  - b. ISSC
  - c. FSPCA
  - d. PSA
- The regulator can give examples of international and domestic partnerships.
- The regulator can discuss examples and roles of laboratory and academia:
  - a. Consulting
  - b. Process authorities





	c. Cooperative Extension Services
	d. Develop emerging technology
	e. Research
	The regulator can describe your role as a stakeholder in
	the IFSS.
	The regulator can describe how you interact with other
	stakeholders in the IFSS.
Unit 3: Mutual Reliance	TLO Behavioral Anchors - not all-inclusive
Definitions Courses	
<b>Definition:</b> Government	The regulator can define mutual reliance:
agency agreements that	a. Sharing of resources
support mutual reliance.	b. Improved communication
<b>TLO:</b> Discuss how agreements	c. Utilizing partner strengths
support mutual reliance.	The regulator can define agreements:
Sapport mataan ronanso.	a. Contracts
ELOs:	b. Compliance agreements
Discuss the use of	c. Cooperative agreements
funding vehicles to	d. MOUs
support mutual	The regulator can explain why mutual reliance is
reliance programs.	important:
<ul> <li>Discuss the</li> </ul>	a. Efficiency
relationship	<ul> <li>Increased impact</li> </ul>
between formal	■ Increase work output
agreements and the	b. Improved trust
IFSS.	c. Share inspectional and lab results
Discuss the	■ Equivalent data
importance of third-	d. Interagency cooperation
party audit	e. Leveraging resources
programs.  • Describe mutual	<ul><li>Joint work planning</li></ul>
Describe mutual reliance conducted	<ul> <li>Joint inspections</li> </ul>
under cooperative	The regulator can describe how mutual reliance leads to
programs.	comparability:
p. ogramo.	a. Training
	b. Joint exercises
	c. Uniform enforcement of consumer laws
	d. Quality regulatory Systems
	e. Program standards
	The regulator can give examples of different types of
	agreements:
	a. Inter-agency
	b. Industry and agency
	The regulator can discuss how mutual reliance
	agreements support the IFSS.
Unit 4: Program Standards	TLO Behavioral Anchors - not all-inclusive
	The regulator has a knowledge or awareness of how
	program standards affect efficiency and uniformity.





- The regulator has a knowledge or awareness of the importance of building a quality management system.
- The regulator has a knowledge or awareness of how the standards may help protect public health.
- The regulator has a knowledge or awareness of the focus on prevention.
- The regulator has a knowledge or awareness of whether your program is enrolled in program standards.
- The regulator can explain increased efficiency and uniformity:
  - a. Building infrastructure
  - b. Mutual reliance
  - c. Consistency between agencies
  - d. Collaboration
- The regulator can explain the importance of a quality management system:
  - a. Continuous improvement
  - b. Known standards
  - c. Focus on prevention
  - d. Legally defensible regulatory system
- The regulator can discuss the impact of standards on the protection of public health:
  - a. Faster incident response time
  - b. Risk based inspections
  - c. Consumer and industry confidence
- The regulator can explain the focus on prevention:
  - a. Benefits of risk-based inspections
  - b. Importance of sampling
  - c. Benefits of uniform program standards (UPS)
  - d. Reduction in foodborne illness



# FDA U.S. FOOD & DRUG

# IFSS Framework - Basic Level Gen Eds

# **B15 Jurisdiction**

**Definition:** Introductory knowledge, skills, and abilities related to various regulatory agencies and their authority over feed and food.

**Topic Area TLO:** Discuss which agencies have authority to conduct specific regulatory activities.

# **Topic Area ELOs:**

- Discuss authority for regulatory activities.
- Describe the importance of collaboration with other agencies.
- Determine which agency has authority to conduct specific regulatory activities.
- Identify agency responsibilities related to program area.
- Explain the statutory authority for jurisdiction.

# **Unit 1: Foundations**

**Definition:** Base knowledge of jurisdiction authority related to feed and food programs.

**TLO:** Describe jurisdictional authority related to feed and food programs.

#### ELOs:

- Define relevant terminology.
- Describe statutory authority for feed/food regulation.
- Identify jurisdictional responsibilities for feed and food regulated products.
- Discuss differences in federal, state, local, tribal, and territorial jurisdiction.
- Discuss dualagency jurisdictions.
- Describe the relationships between agencies.

- The regulator has a knowledge or awareness of their agency's statutory authority:
  - a. Know what you regulate
  - b. Know what law your authority comes from
- The regulator has a knowledge or awareness of state, local, and federal laws and rules associated with the regulator's feed and food program.
- The regulator can recognize the difference between a statute and a regulation
- The regulator can discuss the regulatory implications of overlapping authority.
- The regulator can differentiate between delegated and statutory authority.
- The regulator has a knowledge or awareness of when you don't have authority:
  - a. Know where to refer what you don't regulate
    - Local
    - State
    - Federal
      - o Interstate commerce
- The regulator can list state, local, and federal laws and rules associated with the regulator's feed and food program:
  - a. FD&C Act
  - b. State laws and regulations
  - c. FSMA
  - d. Local ordinances
- The regulator can cite where the regulator's authority comes from.





# Unit 2: Law

**Definition:** Base knowledge of the statutes, regulations and ordinances related to feed and food products.

**TLO:** Discuss the creation of laws related to feed and food products.

# ELOs:

- Describe how laws are created.
- Differentiate between statutes, regulations, and ordinances.
- Describe the difference between interstate, intrastate and international commerce laws.
- Describe statutory authority within each regulatory agency.
- Describe the concept of due process.
- Give examples of statutory limits of regulations.

# **TLO Behavioral Anchors - not all-inclusive**

- The regulator has a knowledge or awareness of the origin of laws:
  - a. History of FDA creation in 1906
  - b. Reaction to emerging public health issues
  - c. Special interest
- The regulator has a knowledge or awareness of the development of legislation:
  - a. Different levels of government
  - b. Branches of government
  - c. Legislative process
- The regulator can discuss how science informs laws.
- The regulator can give examples of an emerging health issue that resulted in a regulation change.
- The regulator can discuss "adoption by reference":
  - a. Food Code
  - b. PMO
  - c. CFRs

# **Unit 3: Crossing Boundaries**

**Definition:** Base knowledge of interagency collaboration required for cross jurisdictional issues related to feed and food products.

**TLO:** Describe collaborative authority between agencies regulating feed and food products.

# ELOs:

- The regulator has a knowledge or awareness of shared authority:
  - a. More than one agency may have jurisdiction
- The regulator has a knowledge or awareness that one agency will be the lead.
- The regulator can explain the concept of the delegation of authority.
- The regulator can discuss a situation where another agency may also have jurisdiction over a firm that you regulate.
- The regulator can explain that agreements may define





- Discuss the IFSS concept.
- Give examples of dual-agency jurisdictions.
- Describe state cooperative programs.
- Give examples of agency collaboration.

shared authority between agencies.

• The regulator can give an example of delegated authority.

# Unit 4: Inter-agency Agreements

**Definition:** Base knowledge of collaboration required for interagency issues related to feed and food products.

**TLO:** Describe formal agreements between agencies regulating feed and food products.

# ELOs:

- Describe the purpose of a MOU.
- Discuss the purpose of delegated authority.
- Describe the purpose of cooperative agreements.
- Give examples of interagency agreements.

- The regulator has a knowledge or awareness of the existence of formal agreements between agencies.
- The regulator has knowledge or awareness that agreements may mandate additional performance requirements:
  - a. Training
  - b. Reporting
  - c. Certifications
- The regulator can give examples of formal agreements:
  - a. MOUs
    - International
    - Associations
    - OGAs
  - b. FDA District policy
  - c. State contract
  - d. Cooperative agreements
  - e. State audits





# **B16 Labeling**

**Definition:** Introductory knowledge, skills, and abilities related to labeling requirements, and the components of feed and food product labels.

**Topic Area TLO:** Explain label requirements.

# **Topic Area ELOs:**

- Describe the types of labels.
- Review product labels for regulatory compliance.
- Recognize product-specific label requirements.
- Describe product label requirements.
- Identify product label components.

# **Unit 1: Foundations**

**Definition:** Basic knowledge of labeling.

**TLO:** Discuss labeling fundamentals.

#### ELOs:

- Define relevant terminology.
- Discuss regulatory requirements for labeling.
- Discuss the purpose of supplemental labeling.
- Locate available resources.
- Explain how labels provide consumer information.
- Explain the purpose for product labeling.

- The regulator can discuss two purposes of labeling:
  - a. Consumer knows what they are purchasing
  - b. Comparison between similar products
  - c. Deter purchase of undesirable ingredients (allergens)
  - d. Advertising restrictions
  - e. Public health rationale of labeling
  - f. Triggers for recall
  - g. Economically motivated adulteration
  - h. Traceforward and traceback
  - i. Highly susceptible population
  - j. Misbranding
- The regulator can identify three regulatory labeling requirements:
  - a. Jurisdiction specific requirements
  - b. Additives
  - c. Bulk labeling vs retail labeling requirements
  - d. 21 Code of Federal Register (CFR) 101
  - e. Specific instructions
  - f. Specifics of graphics
  - g. Labels should be legible
  - h. All packaged foods should be labeled
  - i. Making false health claims
  - j. Standards of identity (common names)
  - k. English
  - I. Restrictions on product use (between animal species)
  - m. Purpose of product (feed and pet food)
  - n. Guaranteed analysis (feed and pet food)
- The regulator can discuss two requirements for a specific label:
  - a. Principle display panel





	<ul> <li>b. Net weight in metric for imports</li> <li>c. Manufacturer/distributer</li> <li>d. Country of origin labeling (COOL)</li> <li>e. Supplemental labeling</li> <li>f. Affordable Care Act (ACA) Labeling</li> <li>g. Safe handling instructions</li> <li>h. Cooking/handling instructions</li> <li>i. Allergens</li> <li>j. Ingredients</li> <li>k. Information display panel</li> <li>l. Nutritional Labeling and Education Act (NLEA)</li> <li>m. Infant formula</li> <li>The regulator can discuss four purposes of labeling.</li> <li>The regulator can identify six regulatory requirements for a specific label.</li> </ul>
Unit 2: Labeling Laws and	TLO Behavioral Anchors - not all-inclusive
Pefinition: Basic knowledge of labeling laws and regulations.  TLO: Describe the authority for labeling.  ELOS:  Identify the agency that regulates a commodity. Identify the labeling requirements for specific commodities.  Describe the process for verifying label compliance. Identify commodities exempt from labeling requirements.  Identify commodities exempt from labeling requirements.  Distinguish between agency labeling requirements.  Explain the recall rationale for improperly labeled products.	<ul> <li>The regulator can list two labeling authorities: <ul> <li>a. Federal trade commission</li> <li>b. Food and Drug Administration (FDA)</li> <li>c. U. S. Department of Agriculture (USDA)</li> <li>d. State</li> <li>e. Local</li> <li>f. Tribal</li> <li>g. Territorial</li> <li>h. Centers for Disease Control and Prevention (CDC)</li> <li>i. National Shellfish Sanitation Program (NSSP)</li> </ul> </li> <li>The regulator can list two federal acts: <ul> <li>a. Food, Drug and Cosmetic Act (FD &amp; C)</li> <li>b. Federal Meat Inspection Act (FMIA)</li> <li>c. Patient Protection and Affordable Care Act (PPACA)</li> <li>d. Poultry Products Inspection Act</li> <li>e. Egg Products Inspection Act</li> <li>f. Agricultural Marketing Act</li> <li>g. Fair Packaging and Labeling Act (FPLA)</li> <li>h. Nutrition Label Education Act (NLEA)</li> </ul> </li> <li>The regulator can list five labeling authorities.</li> <li>The regulator can list four federal acts.</li> </ul>
Unit 3: Labeling Components	TLO Behavioral Anchors - not all-inclusive
<b>Definition:</b> Basic knowledge of	The regulator can identify the two required panels:





label requirements.

**TLO:** Describe the components of a label.

#### **ELOs:**

- Describe required components of a label.
- Discuss label claims.
- Determine if ingredients are approved for use.
- Describe accompanying labeling.
- Explain labeling format requirements.
- Explain the net weight / net quantity of contents requirements.

- a. Principle display panel
- b. Information panel
- c. Accompanying information
- d. The regulator can list three requirements found on the principle display panel.
- e. Name of food
- f. Net quantity of contents
- g. Pictures
- h. Size of letters (font)
- i. English language
- The regulator can list three requirements found on the information panel:
  - a. Manufactured for/distributed by
  - b. Ingredients in plain language
  - c. Colors (Yellow #5, etc.)
  - d. Ingredients listed in order by weight
  - e. Nutrition fact panel
  - f. Serving size
  - g. Allergen declaration
  - h. English language
- The regulator can list three examples of accompanying information:
  - a. Country of Origin (COOL)
  - b. Sulfites
  - c. Organics
  - d. Safe food handling
  - e. Genetically modified organism (GMO) -may be required labeling in some states
  - f. Claims
  - g. Disclosure (dietary supplements and medical foods)
  - h. Pamphlets (retail)
  - i. Date marking (retail, egg, milk)
  - j. Lot number
  - k. Best if used by
  - I. Keep refrigerated
  - m. Refrigerate after opening
  - n. Unpasteurized juice warning statement (retail)
- The regulator can explain the importance of three items found on the principle display panel.
- The regulator can explain the importance of three of the items found on the information panel.

#### Unit 4: Food

**Definition:** Basic knowledge of food labeling requirements.

- The regulator can describe an alternate principle display panel.
- The regulator can identify safe handling label on





**TLO:** Describe the labeling requirements for food.

#### ELOs:

- Identify the principle display panel of a food label.
- Identify the alternate principle display panel.
- Discuss when a handling/holding statement is required.
- Identify food label requirements for susceptible populations.
- Explain the labeling requirements for allergens.
- Identify the labeling requirements for dietary supplements.

packaged raw meat and poultry, and shell eggs.

- The regulator can identify the dietary supplement label:
  - a. No unsubstantiated health claims
  - b. Disclosure
  - c. Supplemental facts
- The regulator can identify the allergen labeling requirements:
  - a. Common name
  - b. Contains statement
- The regulator can identify a labeling requirement for highly susceptible populations:
  - a. Consumer advisory
  - b. Label of unpasteurized juices
  - c. Infant formula
- The regulator can list a component of the dietary supplement label.
- The regulator can list the eight allergens that require allergen labeling.
- The regulator can identify the three foods listed on a consumer advisory.

#### Unit 5: Feed

- The regulator can recognize the seven required components of a standard feed label:
  - a. Product name
  - b. Product purpose statement
  - c. Guaranteed analysis
  - d. Ingredient statement
  - e. Manufacture name & address
  - f. Net weight
  - g. Feeding directions
- The regulator can recognize the required components of a pet food label:
  - a. Seven listed above PLUS:
    - American Association of Feed Control Officials (AAFCO) Nutritional Adequacy Statement, or the AAFCO Nutrient Profile Statement
    - Calorie count
- The regulator can recognize the required components of a pet treat label:
  - Same as standard label no American
     Association of Feed Control Officials (AAFCO)
     Nutrient Profile required
- The regulator can recognize required components of a medicated feed labels:
  - a. Active drug ingredient (name and amount)
  - b. Medical purpose





c. Caution statement
d. Warning statement
The regulator has knowledge or awareness of the
format (ordering) of the required components of a standard feed label.
The regulator can give examples of optional claims/components on a pet food label e.g., claims,
advertising).



## DA U.S. FOOD & DRUG

#### IFSS Framework - Basic Level Gen Eds

#### **B19 Pest Control**

**Definition:** The management of pests that can be perceived to be detrimental to the production of safe human food and food for animals.

**Topic Area TLO:** Explain how pest activity can impact food safety.

#### **Topic Area ELOs:**

- Describe integrated pest management.
- Describe a pest infestation.
- Recognize when to take regulatory action.
- Discuss agency options for dealing with pest issues.
- Describe pest control measures.

#### **Unit 1: Foundations**

**Definition:** Knowledge, skills, and abilities to recognize pests and their significance to human and animal health.

**TLO:** Discuss pests of significance to human and animal health.

#### ELOs:

- Give examples of types of pests.
- Differentiate between types of pests.
- Discuss the public health significance of pests.

- The regulator can give examples of pests:
  - a. Birds
  - b. Rodents
  - c. Insects
  - d. Animals
- The regulator can discuss pest infestation in a facility:
  - a. Insects
  - b. Rodents
- The regulator can discuss the origins of significant pests:
  - a. Geography
- The regulator can discuss the public health significance of pests:
  - a. Zoonotic diseases
  - b. Pests as a vector
- The regulator can identify pests of public health significance:
  - a. Insects
  - b. Rodents
- The regulator can explain the public health significance of pests.
- The regulator can give an example of a zoonotic disease:
  - a. Bird flu
  - b. Rabies
  - c. Hanta virus





#### **Unit 2: Facility Design**

**Definition:** Knowledge related to facility design to control pests.

**TLO:** Discuss the importance of facility design for pest control.

#### ELOs:

- Give examples of pest exclusion in facility design.
- Discuss how plant and grounds maintenance will reduce harborage areas.
- Discuss the importance of pesticide storage areas.
- Discuss how pest control station layout would be used in a facility to control pests.

#### **TLO Behavioral Anchors - not all-inclusive**

- The regulator can identify methods of pest exclusion:
  - a. Screens
  - b. Tight doors
  - c. Air curtains
  - d. Engineering controls
  - e. Strip curtains
- The regulator can discuss the importance of plants and grounds maintenance:
  - a. Harborage areas
  - b. Weeds
  - c. Standing water
  - d. Dumpster
  - e. Trash disposal
- The regulator can discuss why bait station layout is important.
- The regulator can discuss the importance of proper pesticide storage:
  - a. Labeling
  - b. Dedicated areas
  - c. Locked storage
- The regulator can recognize ineffective methods of pest exclusion:
  - a. Torn screen
  - b. Short curtains
  - c. Improper door fit
- The regulator can recognize the improper placement/location of bait stations.
- The regulator can explain how proper pesticide storage prevents adulteration.

#### **Unit 3: Sanitation Program**

**Definition:** Knowledge, skills, and abilities related to sanitation programs for pest control.

**TLO:** Describe sanitation practices for pest control.

#### ELOs:

 Recognize regulations associated with pest management (GMPs, GAPs,

- The regulator can identify guidance documents, laws, and regulations to develop a sanitation program for pest management:
  - a. GMPs
  - b. GRPs
  - c. GAPs
  - d. Defect action levels (allowable limits: wings, leas)
  - e. 8 points of sanitation (HACCP)
- The regulator can describe proper labeling and storage of chemicals used for pest control.
- The regulator can describe sanitation methods to control pests.



## FDA U.S. FOOD & DRUG

#### IFSS Framework - Basic Level Gen Eds

#### GRPs).

- Discuss sanitation measures to prevent adulteration from pests.
- Describe measures to eliminate sources that attract pests.
- Identify approved chemicals for pest control.
- Discuss importance of pesticide chemical labeling.
- Discuss importance of pesticide chemical storage.
- Recognize defect action level list.

- The regulator can use guidance documents, laws, and regulations to develop a sanitation program for pest management:
  - a. GMPs
  - b. GRPPs
  - c. GAPs
  - d. Defect action levels
- The regulator can assess proper labeling and storage of chemicals used for pest control.
- The regulator can give examples of sanitation methods for pest control:
  - a. Cleaning schedule
  - b. Monitoring
  - c. Training (SSOP/prerequisite programs)
  - d. Maintenance of grounds
- The regulator can recommend ways to prevent adulteration in a given scenario:
  - a. Cross contamination
  - b. Removing food sources
  - c. Closed containers
  - d. Waste removal

#### **Unit 4: Detection**

**Definition:** Knowledge, skills, and abilities to detect pests while conducting regulatory activities.

**TLO:** Discuss detection of pests.

#### ELOs:

- Recognize evidence of presence of pests.
- Determine what equipment is needed for detection of pests.
- Discuss agency procedures for pest infestation.

- The regulator can list equipment needed to detect pests:
  - a. Black light
  - b. Flashlight
  - c. Tracking powder
- The regulator can list agency procedures for addressing pest infestation:
  - a. Seizure
  - b. Place product on hold
  - c. Destruction of product
- The regulator can list evidence of pest activity.
- The regulator can use equipment needed to detect pests.
- The regulator can implement agency procedures for addressing pest infestation:
  - a. Seizure
  - b. Place product on hold
  - c. Destruction of product
- The regulator can identify evidence of pest activity:
  - a. Urine stains
  - b. Rodent droppings
  - c. Gnawing
  - d. Nesting materials
  - e. Odors





## Unit 5: Integrated Pest Management

- The regulator can define integrated pest management.
- The regulator can give examples of effective pest control measures:
  - a. Prevention/exclusion
  - b. Pesticide application
  - c. Bait stations
  - d. Fly strips
  - e. Traps
  - f. Bug zappers
- The regulator can describe why pest control is necessary.
- The regulator can discuss how a pest control plan is used:
  - a. Training
  - b. Monitoring
  - c. Scheduled treatment
- The regulator can identify some approved pesticides and application methods:
  - a. Certified or trained pest control operator
- The regulator can explain how integrated pest management is used to control pests.
- The regulator can recognize when an appropriate control measure is needed.
- The regulator can explain benefits of a pest control plan:
  - a. Prevent adulteration of human and animal food
  - b. Reduction or prevention of economic loss
  - c. Enhanced regulatory compliance
  - d. Identify problem area





## IFSS Framework – Basic Level Gen Eds **B20 Plumbing**

**Definition:** Knowledge, skills, and abilities related to the delivery, distribution or storage of potable and non-potable water in a manufacturing food facility and retail food establishment.

**Topic Area TLO** (Terminal Learning Objective): **Discuss how plumbing affects public health.** 

Topic Area ELOs (Enabling Learning Objective):

- Explain the significance of plumbing.
- Explain the regulatory significance of water systems.
- Consider water source
- Discuss agency authority related to plumbing.
- Identify plumbing issues.

#### **Unit 1: Foundations**

**Definition:** An introduction to plumbing systems to keep water and food safe.

**TLO:** Discuss key concepts in plumbing.

#### **ELOs:**

- Explain the public health significance of plumbing design.
- Identify water source.
- Describe the water system.
- Describe the concept of backflow.
- Differentiate between an indirect and direct connection.

- The regulator can give examples of public health concerns related to poor or improper plumbing designs:
  - a. Hazard
  - b. Connection between safe and unsafe supplies
  - c. Contaminating water source
  - d. Contaminating food
- The regulator can distinguish between a public and a private water supply.
- The regulator can distinguish between potable and nonpotable water.
- The regulator can list some components of a water system:
  - a. Pipes
  - b. Pumps
  - c. Tanks
  - d. Fixtures
  - e. Source
- The regulator can describe the concept of backflow:
  - a. Back siphonage
  - b. Back pressure
  - c. Prevention
- The regulator can recognize examples of public health concerns related to poor or improper plumbing design.
- The regulator can discuss the significance of a public and private water supply.
- The regulator can discuss the significance of potable and non-potable water.
- The regulator can elaborate on the concerns of individual water system components.
- The regulator can give an example of indirect and direct connections:
  - a. Air gap





#### **B20 Plumbing**

- b. Air break
- c. Tight connections/Fixed connection

#### **Unit 2: Water Source**

**Definition:** Knowledge related to water sources.

**TLO:** Recognize the public health significance of protecting a water source.

#### ELOs:

- Differentiate between public and private water supply systems.
- List well construction considerations.
- Identify types of treatment systems.

#### TLO Behavioral Anchors - not all-inclusive

- The regulator can give examples of the public health significance of unprotected water sources:
  - a. Hazard
  - b. Connection between safe and unsafe supplies
  - c. Contaminating water source
  - d. Contaminating food
- The regulator can differentiate between public and private water supply systems:
  - a. Municipal or Public
  - b. Well or Private
  - c. Other Spring
- The regulator can list well construction considerations:
  - a. Pitless adapter
  - b. Diversion ditches
  - c. Fencing
  - d. Drainage
  - e. Covers or housing
  - f. Vent screen
  - g. Dug
  - h. Drilled
- The regulator can list different types of water treatment systems:
  - a. UV systems
  - b. Chlorinator
  - c. Reverse Osmosis
- The regulator can recognize examples of public health concerns related to unprotected water sources.
- The regulator can match terms with images of water supply systems.
- The regulator can match terms with images of well construction considerations.

#### **Unit 3: Wastewater System**

**Definition:** Knowledge related to wastewater systems.

**TLO:** Discuss wastewater systems.

#### ELOs:

- Identify wastewater systems.
- Differentiate between public and private wastewater systems.

- The regulator can identify wastewater systems:
  - a. Public/municipal
  - b. Private (septic)
- The regulator can give examples of private wastewater systems:
  - a. Septic
  - b. Private wastewater treatment plants
  - c. Holding tanks





IF35	Framework – Basic Level Gen Eds				
B20 Plumbing					
Unit 4: Backflow Prevention	TLO Behavioral Anchors - not all-inclusive				
<b>Definition:</b> Knowledge of backflow prevention methods.	The regulator can define cross connection:     a. Water				
<b>TLO:</b> Discuss methods for preventing contamination.	<ul> <li>b. Waste</li> <li>The regulator can list methods for preventing cross connections:</li> </ul>				
<ul> <li>ELOs:</li> <li>Define cross connection.</li> <li>Discuss methods for</li> </ul>	<ul> <li>a. Air gap</li> <li>b. Air break</li> <li>c. Backflow prevention devices</li> <li>The regulator can give examples of backflow</li> </ul>				
preventing cross connections.  Identify types of backflow prevention	prevention devices:  a. Hose bib vacuum break  b. Dual check valve with an atmospheric vent  c. Reduced pressure zone backflow preventer  (RPZ)				
devices.  • Discuss considerations for selecting a backflow prevention device.	<ul> <li>d. Check valves</li> <li>e. Pressure vacuum breakers</li> <li>The regulator can list considerations for selecting backflow prevention devices:</li> </ul>				
provention device.	<ul> <li>a. Backflow</li> <li>Back pressure</li> <li>Back siphonage</li> <li>b. Continuous or non-continuous pressure</li> <li>c. Low or high hazard</li> </ul>				
	The regulator can recognize methods for preventing cross connections.				
	The regulator can differentiate between an air gap and an air break.  The regulator can recognize types of beautiful.				
	<ul> <li>The regulator can recognize types of backflow prevention devices.</li> </ul>				
Unit 5: Jurisdictional Authority	TLO Behavioral Anchors - not all-inclusive				
<b>Definition:</b> Knowledge related to agency authority over water, waste water, and plumbing systems.	The regulator can identify which agencies may have authority pertaining to water systems:  a. Local  b. State  c. Federal				
<b>TLO:</b> Describe agency authority.	The regulator can identify which agencies may have authority pertaining to wastewater systems:				
ELOs:  • Identify agency's	a. Local b. State c. Federal				
authority pertaining	The regulator can identify which agencies may have authority pertaining to plumbing systems:				

- to water systems.
- Identify agency's authority pertaining to wastewater systems.
- authority pertaining to plumbing systems: a. Local
  - b. State
  - c. Federal
- The regulator can list which regulations are used by the





## IFSS Framework – Basic Level Gen Eds **B20 Plumbing**

 Identify agency's authority pertaining to plumbing systems. regulator's jurisdiction.

The regulator can list which regulations are used by the regulator's jurisdiction.





#### **B22 Professionalism**

**Definition:** Introductory knowledge, skills, and abilities related to ethics, integrity, and personal conduct during job-related activities.

**Topic Area TLO:** Exhibit the use of integrity and positive interpersonal conduct in the performance of professional and personal activities.

#### **Topic Area ELOs:**

- Explain standards for professional conduct.
- Demonstrate professional conduct.
- Distinguish between professional and unprofessional conduct.
- Observe the agency's ethics and personal conduct policies.
- Apply professionalism to specific situations.

#### **Unit 1: Foundations**

**Definition:** Base knowledge of professionalism related to feed and food programs.

**TLO:** Explain professionalism.

#### ELOs:

- Define relevant terminology.
- Give examples of professional and unprofessional behavior.
- Explain the legal principles of professionalism.
- Explain moral principles of professionalism.
- Discuss the concept of the "perception of impropriety".

#### **TLO Behavioral Anchors - not all-inclusive**

- The regulator has a knowledge or awareness of their agency's policies regarding conduct.
- The regulator can describe professional appearance:
  - a. Dress to conditions
  - b. Personal hygiene
- The regulator can describe what professional communication is:
  - a. Language usage
  - b. Direct communicators
  - c. Appropriate vocabulary
  - d. Active listening
  - e. Unbiased
- The regulator can list attributes associated with professionalism:
  - a. Respectfulness
  - b. Civility
  - c. Character
  - d. Dedication to human and animal health
- The regulator can recognize professionalism in others.
- The regulator can calibrate professional behavior to working conditions and environment.

#### **Unit 2: Ethics**

**Definition:** Core knowledge of professional conduct that elicits trust and demonstrates integrity.

- The regulator can discuss ethics:
  - a. Treat people fairly and equally
  - b. Transparency in motivations
  - c. Make and sound and rational choices





**TLO:** Discuss the principles of business and personal integrity within the work environment.

#### ELOs:

- Explain the importance of an agency code of conduct.
- Discuss the components of a code of conduct.
- Explain confidentiality.
- Give examples of conflict of interest.
- Discuss purpose of ethical behavior in a work environment.
- Give examples of ethical and unethical behavior.
- Explain the organization's values.

- d. Be unbiased
- e. Stay faithful in your personal value and ethics
- f. Follow the law
- The regulator can describe professional behavior:
  - a. Shouldn't obstruct the work environment
  - b. Don't be selfish in your business relationships
  - c. Be a team player
  - d. Deliver on time
  - e. Represent yourself in a positive way
- The regulator can describe professional credibility:
  - a. Authenticity
  - b. Honest trustworthy truthful
- The regulator sets a positive example for others.
- The regulator can recognize integrity in ambiguous situations.
- The regulator can demonstrate ethical consistency in actions.

#### **Unit 3: Conduct**

**Definition:** Expectations of personal behaviors.

**TLO:** Discuss the profession's expectations of behavior.

#### ELOs:

- Differentiate between acceptable and unacceptable behaviors.
- Give examples of acceptable and unacceptable behaviors.
- Differentiate between objective and subjective behavior.
- Give examples of objective and subjective behavior.
- Differentiate between bias and unbiased behaviors.

- The regulator can discuss agency's expectation of behavior:
  - a. Shouldn't obstruct the work environment
  - b. Don't be selfish in your business relationships
  - c. Be a team player
  - d. Deliver on time
  - e. Represent yourself in a positive way
  - f Etc.
- The regulator can distinguish between acceptable and unacceptable behavior.
- The regulator has a knowledge or awareness of the regulator's agency's policies.
- The regulator can demonstrate consistency in professional behavior.
- The regulator can set a positive example for others.





•	Identify societal
	customary behavior
	appropriate for the
	workplace.

 Explain the importance of recognizing differences in workplace customs.

#### TLO Behavioral Anchors - not all-inclusive

#### Unit 4: Personal Management

**Definition:** The individual's responsibility for their actions and behaviors.

**TLO:** Discuss the impact of subjective personal behaviors in the workplace.

#### **ELOs:**

- Explain subjective personal behavior.
- Give examples of subjective personal behaviors.
- Recognize the need to modify subjective personal behaviors.
- Identify resources to address negative subjective personal behaviors.
- Explain the importance of being accountable for actions.
- Identify the components to manage time in the workplace.

- The regulator can provide examples of subjective behavior that would impact the workplace:
  - a. Playing inappropriate music
  - b. Offensive clothing
  - c. Offensive jokes
  - d. Offensive language
  - e. Off color remarks
  - f. Poor personal hygiene
  - g. Offensive Tattoo
  - h. Inappropriate media usage
  - i. Bullying
  - j. Body language
- The regulator can provide examples of how those behaviors impact the workplace:
  - a. Loss production
  - b. Communication degradation
  - c. Credibility
  - d. Contributes to a hostile environment
- The regulator can give examples of appropriate reactions to negative behaviors:
  - a. Agency
  - b. Personal
- The regulator can give examples of appropriate action to negative behaviors:
  - a. Agency
  - b. Personal

#### **Unit 5: Communications**

**Definition:** Disseminating, receiving, or exchanging information with other individuals in a clear, concise, factual, and courteous manner.

#### **TLO:** Employ professional

- The regulator can give examples of unprofessional communication:
  - a. Bullying
  - b. Sexual harassment
  - c. Inappropriate nonverbal (body language)
  - d. Etc.





communication skills while conducting work-related activities.

#### ELOs:

- Explain professional communication skills.
- Explain the importance of communicating in a clear, concise, factual, and courteous manner.
- Give examples of communicating in a clear, concise, factual, and courteous manner in the workplace.
- Give examples of unprofessional communications.
- Determine the appropriate communication method for target audience.

- The regulator can explain professional communication skills.
- The regulator can give examples of professional communication:
  - a. Active listening
  - b. Report writing
  - c. Etc.
- The regulator can discern what constitutes professional communications in varying conditions:
  - a. Effective and clear communication
    - Emails
    - Reports
    - Phone
    - Etc.
- The regulator can identify different levels of vernacular appropriate for different audiences:
  - a. Co-worker
  - b. Management
  - c. Regulated population
  - d. Etc.

#### **Unit 6: Interpersonal Skills**

- The regulator can identify interpersonal skills in the workplace:
  - a. Team player
  - b. Collaborative
  - c. Appropriate language
  - d. Etiquette
- The regulator can list elements associated with emotional intelligence:
  - a. Social awareness
  - b. Use appropriate behavior
  - c. Cognizant of team morale
  - d. Culture awareness
  - e. Respect
  - f. Play nice in the sand box
  - g. Considerate of other
- The regulator can demonstrate interpersonal skills in the workplace:
  - a. Problem solving
  - b. Decision making
  - c. Assertiveness
  - d. Negotiation
- The regulator can discuss the importance of emotional intelligence:
  - a. Relation to the development of interpersonal





skills
b. For improving interpersonal skills





## IFSS Framework – Basic Level Gen Eds **B24 Recalls**

**Definition:** Introductory knowledge, skills, and abilities related to the process of removing a product from commerce.

**Topic Area TLO** (Terminal Learning Objective): Describe the recall process in regulatory programs.

#### Topic Area ELOs (Enabling Learning Objective):

- Explain the recall process.
- Explain why recalls are initiated.
- Determine when to recommend that a recall may be necessary.
- Explain agency roles in recalls.
- Identify components in the recall process.

#### **Unit 1: Foundations**

**Definition:** Basic knowledge of recalls related to regulatory programs.

**TLO:** Describe the importance of recalls.

#### ELOs:

- Define key terminology.
- Give examples of what could initiate a recall.
- Explain the differences between recall classifications.
- Describe the importance of interagency and industry collaboration.
- Explain the need for communication with stakeholders.
- Explain agency's plan for removing product from the distributions system.
- Explain firm's plan for removing product from the distribution system.
- Explain the purpose of

- The regulator can discuss how recalls contribute to maintaining human and animal health.
- The regulator can describe the regulator's agency's policies for recalls.
- The regulator can explain the reasons to initiate a recall:
  - a. Enforcement action to keep human and animal food safe
  - b. Remove economic adulteration
- The regulator can explain the impact if the product isn't removed.
- The regulator can explain the reasons for a voluntary recall:
  - a. Process for allowing the producer to take responsibility for not complying with the requirements





## IFSS Framework – Basic Level Gen Eds **B24 Recalls**

a market withdrawal.
Trace a product
through the supply
chain.

#### **Unit 2: Risk Assessment**

# **Definition:** Process to evaluate information for potential health impact of the product if it remains on the market.

**TLO:** Discuss the importance of risk assessment in product safety assurance.

#### **ELOs:**

- Explain the importance of risk assessment to determine if a recall is needed.
- Give examples of triggers that could initiate a recall.
- Explain how the potential severity of the hazard affects risk.
- Explain how probability of exposure affects risk.
- Describe how recall classes I, II, III would affect a recall decision.

#### **TLO Behavioral Anchors - not all-inclusive**

- The regulator can name conditions that would initiate a recall
- The regulator can name conditions that would impact the scope of a recall.

#### **Unit 3: Documentation**

**Definition:** Records needed when conducting a recall.

**TLO:** Explain the importance of documents needed when conducting a recall.

- The regulator can provide information to aid in decision making:
  - a. To determine the scope of the recall
  - b. To support the risk assessment
- The regulator can conduct recall audit checks:
  - a. Verify unsafe products are off the market.
- The regulator can discuss the role of documentation in validation, tracking, and organization:





#### **B24 Recalls**

#### ELOs:

- Identify documents used to track product movement.
- Give examples of documents that should be reviewed.
- Identify the documents that need to be collected.
- Review documents used to determine the scope of the recall.

#### a. Defensibility

b. Evidence to support a recall

#### **Unit 4: Communications**

**Definition:** Information sharing and messaging strategies between agencies and stakeholders.

**TLO:** Discuss the role of communication during a recall.

#### ELOs:

- Describe the importance of interagency and industry communication.
- Explain how communication is coordinated during a recall.
- Identify requirements related to information sharing.
- Describe the roles of regulatory agencies in issuing public communications.
- Explain the importance of sharing lessons learned from recalls.
- Describe media types used to inform stakeholders of a recall.
- Describe the criteria of

- The regulator can describe the communication process with stakeholders while conducting a recall:
  - a. Articulate the chain of command
  - b. Describe agency's jurisdiction
  - c. Describe agency's communication policy
- The regulator can inform stakeholders that there is a recall:
  - a. Recall alerts
  - b. Inform the regulated population of the necessity
  - c. Adapt communication to the stakeholders
  - d. List the steps to take a recall
- The regulator can gather information for a recall:
  - a. Ask the right questions and document
  - b. Active listening
  - c. To maintain a better understanding of the situation
- The regulator can give examples of agency communication policies.
- The regulator can discuss the process of assembling a recall team.
- The regulator can explain regulations to substantiate a recall.





## IFSS Framework – Basic Level Gen Eds **B24 Recalls**

- the messaging types that are used during a recall.
- Explain the criteria for issuing a public health message during a recall.
- Explain how sensitive communication should be shared with affected stakeholders.
- Explain when sensitive communication would be shared with affected stakeholders.
- Describe the agency internal communication process during a recall.
- Explain how public health recall messaging would affect international distribution.

#### TLO Behavioral Anchors - not all-inclusive

# **Definition:** The process of removing unsafe products from all points of production, distribution, manufacturing, processing, storage, retail, and consumer ownership.

Unit 5: Recall Process

**TLO:** Explain how the recall process is used to remove unsafe products.

#### **ELOs:**

- Describe how the decision is made to initiate a recall.
- Describe the process of implementing a recall.
- Discuss the importance of notifying the public.
- Describe the process of recall validation.

- The regulator can name the conditions that trigger a
- The regulator can list steps necessary to remove unsafe product from the marketplace.
- The regulator can identify recall information to share with stakeholders.
- The regulator can explain how the scope of the recall impacts complexity.
- The regulator can identify the actions associated with each recall classification.





## IFSS Framework – Basic Level Gen Eds **B24 Recalls**

- Describe the process of determining if a recall should be initiated.
- Describe the process of how a recall would be conducted.
- Explain the process of how relevant stakeholders are notified of a recall.
- Describe how to verify that a recall has been properly conducted by a firm.

#### **Unit 6: Product Disposition**

**Definition:** Ensuring that unsafe products do not reenter the marketplace.

**TLO:** Explain the role of product disposition during a recall.

#### **ELOs:**

- Explain the importance of product disposition.
- Give examples of reconditioning products.
- Explain when a product needs to be destroyed.
- Describe coordination that may be needed between agencies for product disposition.
- Describe the verification needed to ensure proper product disposition.

- The regulator can define what disposition means.
- The regulator can discuss the methods for holding a product.
- The regulator can define methods of disposition.
- The regulator can discuss the importance of documentation.
- The regulator can explain recall effectiveness checks:
  - a. Trace back trace forward
  - b. Collect evidence for disposition validation
- The regulator can explain how to avoid the reintroduction of unsafe product back into the food chain:
  - a. Identify the product and document storage of the product
  - b. Witness and document destruction of product
  - c. Describe the appropriate security measures





## IFSS Framework – Basic Level Gen Eds **B27 Traceability**

**Definition:** Introductory knowledge, skills, and abilities related to tracking feed and food throughout the supply chain.

**Topic Area TLO** (Terminal Learning Objective): Describe the role of traceability in feed and food programs.

#### **Topic Area ELOs** (Enabling Learning Objective):

- Explain product traceforward/traceback concepts.
- Trace the source of a food.
- Explain a product traceback diagram.
- Explain agency roles in traceforward/traceback.
- Identify components of product traceforward/traceback.

#### **Unit 1: Foundations**

**Definition:** Basic knowledge of traceability related to feed and food programs.

**TLO:** Describe the importance of product tracing.

#### ELOs:

- Define key terminology.
- Explain factors that would initiate a traceforward/traceback.
- Explain the difference between traceforward and traceback.
- Describe the importance of interagency and industry collaboration.
- Describe when traceforward/traceback is utilized.
- Describe the primary functions of CORE.
- Describe the primary function of ICS.

- The regulator can define what product tracing is:
  - a. Difference between tracing (documentation) and tracking (following product)
  - b. Define product (ingredient to finished product)
  - c. Define trackback and traceforward
- The regulator has knowledge or awareness of the purpose of product tracing:
  - a. Find product source, e.g. grower, manufacturer, importer
  - b. To ensure safe product
  - c. Locate product to remove from commerce
  - d. Identifies responsible or accountable party
- The regulator has knowledge or awareness of why product tracing is important:
  - a. Provides product manufacturing information
  - b. Identify source of product to determine how adulteration occurred
  - c. To gather information during outbreaks (jurisdiction, interstate violation responsibility)
  - d. Provides information needed for tracking outbreak vehicles
  - e. Establishes scope and depth of a situation
  - f. Identifies potential impact zone or region
  - g. Decreases response time in a recall
- The regulator can give examples of product traceback and traceforward.
- The regulator has knowledge or awareness of the importance of communication in product tracing situations:





#### **B27 Traceability**

Unit 2: Preliminary Review	TLO Behavioral Anchors - not all-inclusive
	<ul><li>c. Dissemination of information</li></ul>
	b. Information sharing
	the supply chain
	a. Allow for ease of communication throughout

**Definition:** Analysis of surveillance data to determine if a traceforward/traceback investigation is warranted.

**TLO:** Identify the critical information from the surveillance reports needed for a traceforward/traceback.

#### **ELOs:**

- Describe routine surveillance activities that might trigger a traceforward/traceback.
- Describe the importance of time frames when reviewing surveillance reports.
- Identify the potential health risk indicated by surveillance data.
- Describe the subject matter expertise needed to assess surveillance data.
- Explain how the RFR contributes to conducting traceforward/traceback investigations.

- The regulator has knowledge or awareness of the product tracing process.
- The regulator has an awareness of how products are identified:
  - a. Production records: date, run time:
  - b. Labeling info (brand name, ingredients, net weight, etc.)
  - c. Lot numbers or other identification
  - d. Product distribution list
  - e. Firm information (address, key personnel)
  - f. Manufacturer or grower information
  - g. Distributor information
  - h. Shipper info, i.e. trucking company and date shipped
- The regulator has knowledge or awareness of the importance of firm history information:
  - a. Inspection history
- The regulator has knowledge or awareness of the factors to consider for tracing:
  - a. Pending imminent health hazards
  - b. Epi findings or ties to foodborne outbreaks
  - c. Product/environmental samples
  - d. Vector and/or vehicle
  - e. Analysis report
  - f. Outbreak demographics
  - g. Target customers
  - h. Date and location of initial finding (a place to start)
  - i. Hazard associated with the product
  - j. Aware of the risk associated with the hazard
  - k. Foodborne illness reporting
  - Implicated product(s) and associated products
  - m. Degree of certainty with product
  - n. Consumer complaints
- The regulator can list factors to consider during product tracing:
  - a. Process or treatment performed on product
  - b. Packaging type or material
  - c. Components of the product
  - d. Intended use of the product

Unit 3: Supply Chain TLO Behavioral Anchors - not all-inclusive





## IFSS Framework – Basic Level Gen Eds **B27 Traceability**

**Definition:** The system of moving raw or manufactured products and ingredients from growing/raising, harvesting, processing, and manufacturing and all distribution points to consumption.

**TLO:** Discuss the complexity of traceability throughout the supply chain.

#### ELOs:

- Explain the farm to table concept.
- Describe major transportation systems.
- Describe industry best practices for product traceability.
- Describe how foreign suppliers may affect traceability.
- Explain how to use a traceback diagram to identify potential points of contamination in the supply chain.
- Explain requirements for industry to disclose customer purchases to regulatory agencies.

- The regulator has knowledge or awareness of product flow through the food production chain:
  - a. Define supply chain and give an example
  - b. Give examples of food chains
  - c. List stakeholders to the supply chain
  - d. Growing, harvesting, packing/processing, shipping, distributing, manufacturing, point of sale
- The regulator has knowledge or awareness of the importance of records:
  - a. Accurate
  - b. Legible
  - c. Accessible
  - d. Incomplete or missing records (batch, production, shipping)
  - e. One step forward, one step back
- The regulator has knowledge or awareness of the challenges of traceability:
  - a. Incomplete or missing product identification
  - b. An ingredient can be used in multiple products with multiple companies
  - c. Distribution can be worldwide
  - d. Language barriers
  - e. The sheer volume of a production run
  - f. Shelf life can vary between perishable and shelf stable
- The regulator has knowledge or awareness and knowledge of the challenges of traceability:
  - a. Supply chain relations (including regulator)
  - b. Diversity of operations (examples consolidators, repackers, warehouses, importers, shippers)
  - c. Distribution can flow through multiple wholesale and retail chains
  - d. Changing consumer trends
    - Increase in farm to table
    - Increase consumption of raw product
    - Cottage foods
  - e. Identifying parties responsible for the product (broker, distributor, firm)
  - f. Proprietary information
  - g. Firm's definition of the term "lot" (e.g. produce industry)
  - h. Global product identification
- The regulator has knowledge or awareness of the jurisdictional issues.





#### **B27 Traceability**

B27 Traceability							
	a. Jurisdictional boundaries						
	b. Awareness of changing authorities through the						
Unit 4: Documentation	supply chain  TLO Behavioral Anchors - not all-inclusive						
Unit 4: Documentation	TLO Benavioral Anchors - not all-inclusive						
<b>Definition:</b> The records							
needed when doing a							
traceforward/traceback.	The regulator can give three examples of types of						
	records for determining traceforward and traceback:						
	a. Sanitary transport records						
TLO: Explain key documents	b. Signatures						
needed for tracing product	c. Invoices/bills of lading						
movement.	d. Production log						
	e. Receipts						
	f. Shipping documents						
ELOs:	g. Certificates of analysis						
	h. Hazard analysis						
<ul> <li>Identify documents</li> </ul>	i. Food safety plan						
used to track product	j. Lot number k. Shelf life						
movement.	k. Shell life I. Product label						
Describe document							
retention requirements	<ul> <li>The regulator can explain the importance of regulatory documentation:</li> </ul>						
for the industry.	a. Regulatory notes						
Give examples of documents that should	b. Interview notes						
be collected.	c. Photographs						
Give examples of key	d. Product/Process flow diagram						
information needed for	e. Sample receipts						
product tracing.	The regulator can locate relevant agency policies:						
Describe the	a. Recall effectiveness checks						
importance of collecting	b. Embargo						
documents for the	The regulator can give six examples of records for						
timeframes of interest.	determining traceforward and traceback.						
	The regulator can demonstrate the effective collection						
	of regulatory documentation.						
	The regulator can describe relevant agency policies.						
Unit 5: Communications	TLO Behavioral Anchors - not all-inclusive						
<b>Definition:</b> Information sharing							
and messaging strategies							
between agencies and	The regulator can give examples of status						
stakeholders during a	communication:						
traceforward/traceback.	a. Keep supervisor apprised						
	b. Email/phone clarifications of assigned tasks						
	c. Keeping firm apprised of progress						
<b>TLO:</b> Discuss requirements for	The regulator has knowledge or awareness of the						
communication during a	existence of agency policy:						
traceforward/traceback.	a. Proprietary information						
a according to according	b. Communication restrictions						





#### **B27 Traceability**

#### ELOs:

- Describe the importance of interagency/industry communication.
- Explain how communication is coordinated during a traceback.
- Identify requirements related to information sharing.
- Explain how the ICS system is used to facilitate communications.

- c. Affidavits
- d. Lab reports
- The regulator can identify three effective ways of communicating during traceforward and traceback:
  - a. Interview techniques
  - b. Memos
  - c. Can ask clarifying/relevant questions
  - d. Effective notetaking
  - e. Speaking to the most responsible person
  - f. Clear and concise
  - g. Can follow instructions
  - h. Logic model (timeline of steps)
- The regulator can identify one record that must be maintained for accuracy:
  - a. Transport records
  - b. Supplier list
  - c. Lot numbers
  - d. Facility location
  - e. Accurate contact list
  - f. Regulatory notes
- The regulator can explain the importance of status communication.
- The regulator can identify a traceforward and traceback communication policy.
- The regulator can role play an effective way of communicating during traceforward and traceback.
- The regulator can identify three records that must be maintained for accuracy.

#### **Unit 6: Technology**

**Definition:** The systems or devices used to enhance traceability.

**TLO:** Explain how technology is used to improve traceability.

#### ELOs:

- Give examples of technology used to track products.
- Describe how data systems can help identify patterns.
- Discuss advantages

- The regulator can list two means of technology used in traceability:
  - a. Wi-Fi access to real-time answers
  - b. Global Positioning System (GPS)
  - c. Electronic records
  - d. Camera technology
  - e. Cell phone apps
- The regulator has knowledge or awareness of relevant traceability databases:
  - a. Reportable food registry
  - b. Radio-frequency identification (RFID) technology
  - c. Shopper identification cards
- The regulator can give an example of how technology improves traceability:
  - a. Ease of exchange





#### **B27 Traceability**

of using technology
to enhance
traceability.

- b. Faster verification
- c. Economically motivated adulteration
- d. Finding documentation
- e. Genome sequencing
- The regulator recognizes the impact of communication outlets on traceability:
  - a. Radio/television reporting for consumer safety
  - b. Social media
- The regulator can give an example of how to use technology in traceability.
- The regulator can give an example of a relevant database.
- The regulator can give three examples of how technology improves traceability.
- The regulator can identify communication outlets.





## IFSS Framework – Basic Level Gen Eds **B28 Transportation**

**Definition:** Introductory knowledge, skills, and abilities related to preventing contamination of feed and food during transport.

**Topic Area TLO** (Terminal Learning Objective): Describe how transportation affects feed and food safety.

#### Topic Area ELOs (Enabling Learning Objectives):

- Articulate the requirements for protection of product.
- Explain how transportation practices can lead to adulterated product.
- Evaluate whether mishandling of products has occurred.
- Describe jurisdictional authority over transported products.
- Evaluate whether mishandling has resulted in adulterated product.

Unit 1: Foundations	TLO Behavioral Anchors - not all-inclusive
Definition: Basic knowledge of transportation related to feed and food safety.  TLO: Describe basic information regarding the role of transportation.	<ul> <li>The regulator can describe the role of safe transportation within the food chain.</li> <li>The regulator can describe transportation equipment impact on food safety.</li> <li>The regulator can discuss the sanitary transportation rule.</li> <li>The regulator can discuss key requirements of the sanitary transportation rule: <ul> <li>a. Discuss waivers and exemptions</li> </ul> </li> </ul>
ELOs:	a. Discuss warvers and exemptions
<ul> <li>Define relevant terminology.</li> <li>Locate resources.</li> <li>Describe the importance of transportation.</li> <li>Give examples of stakeholders.</li> <li>Demonstrate knowledge of transportation regulations.</li> <li>Identify agency jurisdiction for transportation.</li> </ul>	
Unit 2: Transportation Methods	TLO Behavioral Anchors - not all-inclusive
<b>Definition:</b> Description of transportation methods.	The regulator can identify the transportation modes used in food and feed.





#### **B28 Transportation**

**TLO:** Discuss transportation options used for feed and food.

• The regulator can discuss considerations in the selection of a transportation mode.

#### ELOs:

- Identify transportation modes used in feed/food systems.
- Recognize the mode of transportation suited for specific products.
- Recognize hazards unique to specific modes of transportation.
- Explain the importance of dedicated transportation equipment.
- Discuss required identification of equipment.

#### **Unit 3: Inspections**

**Definition:** Basic knowledge necessary to conduct inspections of various conveyances.

**TLO:** Discuss the complexity of traceability throughout the supply chain.

#### **ELOs:**

- Discuss required documentation.
- Describe inspection role in transportation incidents.

- The regulator can discuss the elements of the inspection process:
  - a. Design
  - b. Sanitary conditions
  - c. Controlled environment
  - d. Etc.
- The regulator can explain how the inspection process ensures food transportation safety:
  - a. Proper design
  - b. Sanitary conditions
  - c. controlled environment
  - d. Properly maintained
  - e. Properly equipped
  - f. Stored
  - g. Design
  - h. Training
  - i. Documentation





## IFSS Framework – Basic Level Gen Eds **B28 Transportation**

## Describe the disposition of damaged products. Give examples of disposition of salvaged

- products.
   Describe procedures for the inspection of specific transportation conveyances.
- Discuss receiving procedures.
- Discuss the importance of maintaining shipping documentation.

#### **TLO Behavioral Anchors - not all-inclusive**

#### **Unit 4: Security**

**Definition:** Basic knowledge of how security measures maintain safe transportation.

**TLO:** Describe security measures designed to ensure safe transportation.

- The regulator can demonstrate knowledge of securing product during transportation:
  - a. Seals/padlocks
  - b. Etc.

#### ELOs:

- Discuss the importance of transportation security.
- Identify areas of vulnerability.
- Identify the importance of seals.
- Give examples of security breaches.
- Describe the importance of documentation.

#### **Unit 5: Product Safety**

**Definition:** Basic knowledge of how to maintain and protect product safety during transportation.

- The regulator can demonstrate knowledge of securing product during transportation:
  - a. Seals/padlocks





#### **B28 Transportation**

**TLO:** Discuss the importance of protecting products during transportation.

#### b. Etc.

 The regulator can discuss the risks associated with loading, transportation and storage.

#### ELOs:

- Discuss the importance of sanitation practices in transportation.
- Give examples of safe handling methods in feed transportation.
- Discuss the importance of pest control.
- Discuss the importance of environmental control.
- Explain the importance of preventing cross contamination.

## Retail Program Standards Ver 3.0 [Draft]

	Self-Assessme	nt / Audit ver	incation Sumn	nary & Gap Ai	<b>1aiysis</b>
Jurisdiction Name:					
Report completed by:					
<b>Full Self-Assessment Date:</b>					
<b>Program Standards Version:</b>	2017				
<b>Self-Assessment Period</b>					

Table 1 - Summary Table of Progress Towards Meeting the Retail Program Standards

MET	NO.	STANDARD TITLE	PROGRESS	STA	NDA	RD	ELE	MEN	TS*										
NO	1	REGULATORY FOUNDATION	No elements met	<u>1a</u>	<u>1b</u>	<u>1c</u>	<u>2a</u>	<u>2b</u>	<u>3a</u>	<u>4a</u>									
NO	2	TRAINED REGULATORY STAFF	No elements met	<u>1a</u>	<u>1b</u>	<u>2a</u>	<u>2b</u>	<u>3a</u>	<u>3b</u>	<u>4a</u>	<u>4b</u>	<u>5a</u>							
NO	3	INSPECTION PROGRAM BASED ON HACCP PRINCIPLES	No elements met	<u>1a</u>	<u>1b</u>	<u>1c</u>	<u>2a</u>	<u>3a</u>	<u>4a</u>	<u>4b</u>	<u>4c</u>	<u>5a</u>	<u>6a</u>						
NO	4	UNIFORM INSPECTION PROGRAM	No elements met	<u>1a</u>	<u>1b</u>	<u>1c</u>	<u>2</u>	<u>2i</u>	<u>2ii</u>	<u> 2iii</u>	<u>2iv</u>	<u>2v</u>	2vi	<u>2vii</u>	2viii	<u>2ix</u>	<u>2x</u> <u>2</u>	<u>xi 2</u>	<u>xii</u>
				2xiii	2xiv	<u>2xv</u>	<u>2xvi</u>	<u>2xvii</u>	2xviii	2xix	<u>2xx</u>	<u>3a</u>	<u>3b</u>						
NO	5	FOODBORNE ILLNESS AND FOOD DEFENSE	No elements met	<u>1a</u>	<u>1b</u>	<u>1c</u>	<u>1d</u>	<u>1e</u>	<u>1f</u>	<u>1g</u>	<u>1h</u>	<u>1i</u>	<u>2a</u>	<u>2b</u>	<u>3a</u>	<u>3b</u>	<u>4a</u> 5	<u>5a</u>	<u>5b</u>
		PREPAREDNESS AND RESPONSE		<u>5c</u>	<u>6a</u>	<u>7a</u>	<u>7b1</u>	<u>7b2</u>	<u>7b3</u>	<u>7b4</u>	<u>7b5</u>	<u>7b6</u>	<u>7b7</u>	<u>7b8</u>	<u>7b9</u>	<u>7c</u>			
NO	6	COMPLIANCE AND ENFORCEMENT	No elements met	<u>1a</u>	<u>1b</u>	<u>2a</u>	<u>2b</u>												
NO	7	INDUSTRY AND COMMUNITY RELATIONS	No elements met	<u>1a</u>	<u>1b</u>														
NO	8	PROGRAM SUPPORT AND RESOURCES	No elements met	<u>1a</u>	<u>2a</u>	<u>2b</u>	<u>3a</u>	<u>3b</u>	<u>4a</u>	<u>4b</u>	<u>4c</u>	<u>4d</u>	<u>4e</u>	<u>4f</u>	<u>4g</u>	<u>4h</u>			
NO	9	PROGRAM ASSESSMENT	No elements met	<u>1a</u>	<u>1b</u>	<u>1c</u>	<u>2a</u>	<u>2b</u>	<u>3a</u>	<u>3b</u>									

<sup>\*</sup> Elements that are met are identified by strikethrough text.

Click the below hyperlink link for additional Program Standards guidance, instructions and PDF files located the FDA Retail Food website <a href="http://www.fda.gov/Food/GuidanceRegulation/RetailFoodProtection/ProgramStandards/ucm245409.htm">http://www.fda.gov/Food/GuidanceRegulation/RetailFoodProtection/ProgramStandards/ucm245409.htm</a>

#### **Standard 1: Regulatory Foundation**

## **Program Self-Assessment and Verification Audit Form** (January 2017)

Click the below hyperlink link to open the online PDF verison of Standard 1

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Click the below hyperlink link to open the online PDF verison with Instuctions

Missing Link, Still in Draft Status

#### PROGRAM SELF-ASSESSMENT (SA) SUMMARY

Printed Name of the Person who conducted the SA:	
Self-Assessor's Title:	
Jurisdiction Name:	Enter this field data on the 'Jurisdiction Name' field on the 'Self-Assessment Summary' worksheet page.
Jurisdiction Address:	
Phone / Fax / E-mail:	
Date the Standard 1 Self-Assessment was Completed:	
SA indicatesthe Jurisdiction MEETS the Standard 1 criteria:	NO
Phone / Fax / E-mail: Date the Standard 1 Self-Assessment was Completed:	

I affirm that the information represented in the Self-Assessment of Standard 1 is true and correct

Signature of the Self-Assessor:

#### **VERIFICATION AUDIT (VA) SUMMARY**

Printed Name of the Person who conducted the VA:	
Verification Auditor's Title:	
Auditor's Jurisdiction Name:	
Auditor's Jurisdiction Address:	
Phone / Fax / E-mail:	
Date the Verification Audit of Standard 1 was Completed:	
VA indicates the Jurisdiction MEETS the Standard 1 criteria:	

I affirm that the information represented in the Verification Audit of Standard 1 is true and correct

Signature of the Verification Auditor:

Table 2 - Program Self-Assessment and Verification Audit Table for Standard 1

Standard Sub-Elements Criteria	Self-Assessor's Comments	VA MET	If NO, why criterion not met
1. Assessment of the Program's Regulatory			
a. The jurisdiction has documentation that it has performed a side-			
by-side comparison of its prevailing statutes, regulations, rules and			
other pertinent requirements against the current published edition			
of the FDA Food Code or one of the two most recent previous			
editions of the FDA Food Code.			
b. The jurisdiction's side-by-side comparison includes an			
assessment of major Food Code Interventions and Risk Factors,			
Good Retail Practices, and Compliance/Enforcement			
Administrative requirements.			
c. The regulatory foundation assessment clearly identifies the			
jurisdictions corresponding requirement to the applicable Code			
Section. The assessment provides a determination as to whether a			
specific provision in the jurisdiction's regulation meets the intent			
of the corresponding FDA Food Code Section.			
2. Food Code Interventions and Risk Factors			
a. The jurisdiction's initial Food Code assessment indicates that			
the agency's regulatory requirements contain at least 9 of the 11			
FDA Food Code intervention and risk factor controls. By the third			
verification audit the jurisdiction's assessment indicated that the			
agency's regulatory requirement contain all 11 of the Food Code			
invention and risk factor controls. Documentation from: Part I –			
Self Assessment Worksheet and Part I – Verification Audit			
Worksheet			
b. The jurisdiction's Food Code assessment indicates that the			
agency has a corresponding requirement for ALL FDA Food Code			
provisions related to the interventions and risk factor controls.			
NOTE: Auditor's random selection of Food Code Intervention and			
Risk Factor Control Sections confirms the jurisdiction's			
assessment that a corresponding requirement is contained in the			
agency's rules, regulations, ordinances, code, or statutes.			
3. Good Retail Practices			

a. The jurisdiction's initial Food Code assessment indicates that	
regulatory requirements contain at least 95 percent of the FDA	
Food Code Good Retail Practices Sections. NOTE: Auditor's	
random selection of Good Retail Practices Code Sections confirms	
the jurisdiction's assessment that a corresponding requirement is	
contained in the agency's code or statutes. Documentation from:	
Part II – Self-Assessment Worksheet and Part II – Verification	
Audit Worksheet	
4. Compliance and Enforcement	
a. The jurisdiction's initial Food Code assessment indicates that	
a. The jurisdiction's initial 1 ood Code assessment indicates that	
regulatory requirements contain ALL the FDA Food Code	
ž	
regulatory requirements contain ALL the FDA Food Code	
regulatory requirements contain ALL the FDA Food Code Compliance and Enforcement Sections identified in the Standard.	
regulatory requirements contain ALL the FDA Food Code Compliance and Enforcement Sections identified in the Standard. NOTE: Auditor's random selection of Compliance and	
regulatory requirements contain ALL the FDA Food Code Compliance and Enforcement Sections identified in the Standard. NOTE: Auditor's random selection of Compliance and Enforcement Code Sections confirms the jurisdiction's assessment	
regulatory requirements contain ALL the FDA Food Code Compliance and Enforcement Sections identified in the Standard. NOTE: Auditor's random selection of Compliance and Enforcement Code Sections confirms the jurisdiction's assessment that a corresponding requirement is contained in the agency's code	

General notes Pertaining to the Program Self-Assessment or the Verification Audit		

## **Standard 2: Trained Regulatory Staff**

# **Program Self-Assessment and Verification Audit Form** (January 2017)

Click the below hyperlink link to open the online PDF verison of Standard 2

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### PROGRAM SELF-ASSESSMENT (SA) SUMMARY

Printed Name of the Person who conducted the SA:	
Self-Assessor's Title:	
Jurisdiction Name:	Enter this field data on the 'Jurisdiction Name' field on the 'Self-Assessment Summary' worksheet page.
Jurisdiction Address:	
Phone / Fax / E-mail:	
Date the Standard 2 Self-Assessment was Completed:	
SA indicatesthe Jurisdiction MEETS the Standard 2 criteria:	NO

I affirm that the information represented in the Self-Assessment of Standard 2 is true and correct

Signature of the Self-Assessor:

## **VERIFICATION AUDIT (VA) SUMMARY**

Printed Name of the Person who conducted the VA:	
Verification Auditor's Title:	
Auditor's Jurisdiction Name:	
Auditor's Jurisdiction Address:	
Phone / Fax / E-mail:	
Date the Verification Audit of Standard 2 was Completed:	
VA indicates the Jurisdiction MEETS the Standard 2 criteria:	

I affirm that the information represented in the Verification Audit of Standard 2 is true and correct

Table 3 - Program Self-Assessment and Verification Audit Table for Standard 2

Standard Sub-Elements Criteria	SA MET	<b>Self-Assessor's Comments</b>	VA MET	If NO, why criterion not met
1. Employee Training Records		<u>'</u>		
a. The jurisdiction maintains a written training record for each			T	
employee that includes the date of hire or assignment to the				
agency's retail food protection program.				
b. The jurisdiction written training record provides documentation				
that each employee has completed the Standard #2 pre-requisite				
("Pre") training curriculum PRIOR to conducting independent				
retail food or foodservice inspections.				
2. Initial Field Training			Į.	
a. The jurisdiction maintains a written training record that provides				
confirmation that each employee completed a minimum of 25 joint				
field training inspections of retail food and/or foodservice				
establishments (if less than 25 joint field training inspections are				
performed, written documentation on file that FSIO has				
successfully demonstrated all required inspection competencies)				
PRIOR to conducting independent retail food or foodservice				
inspections				
b. The jurisdiction maintains a written training record that provides				
confirmation that each employee successfully completed a field				
training process similar to that contain in the CFP Field Training				
Manual provided in Appendix B-2, Standard 2, PRIOR to				
conducting independent inspections of retail food and/or				
foodservice establishments.				
3. Independent Inspections / Completion of ALL	ı		1	1
a. The jurisdiction maintains a written training record that provides				
confirmation that each employee completed a minimum of 25				
independent retail food and/or foodservice inspections PRIOR to				
field standardization.				
b. The jurisdiction written training record provides documentation				
that each employee has completed ALL aspects of the Standard #2				
training curriculum ("Pre") and ("Post") courses PRIOR to field				
standardization.				
4. Field Standardization				

a. The jurisdiction maintains a written training record that provides documentation that each employee successfully completed a Standardization process similar to the 'FDA Procedures for Standardization' within 18 months of hire or assignment to the retail food protection program.		
b. The jurisdiction maintains a written training record that provides documentation that each standardized employee has maintained their standardization by performing a minimum of 4 joint inspections with a "training standard" every 3 years.		
5. Continuing Education and Training		
a. The jurisdiction maintains a written training record that provides documentation that each employee conducting retail food and/or foodservice inspections has accumulated 20 hours of continuing education every 36 months after the initial training (18) months is completed.		

General notes Pertaining to the Program Self-Assessment or the Verification Audit		

## **Standard 3: Inspection Program Based On HACCP Principles**

## **Program Self-Assessment and Verification Audit Form** (January 2017)

Click the below hyperlink link to open the online PDF verison of Standard 3

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## PROGRAM SELF-ASSESSMENT (SA) SUMMARY

page.

I affirm that the information represented in the Self-Assessment of Standard 3 is true and correct

Signature of the Self-Assessor:

## **VERIFICATION AUDIT (VA) SUMMARY**

Printed Name of the Person who conducted the VA:	
Verification Auditor's Title:	
Auditor's Jurisdiction Name:	
Auditor's Jurisdiction Address:	
Phone / Fax / E-mail:	
Date the Verification Audit of Standard 3 was Completed:	
VA indicates the Jurisdiction MEETS the Standard 3 criteria:	

I affirm that the information represented in the Verification Audit of Standard 3 is true and correct

Table 4 - Program Self-Assessment and Verification Audit Table for Standard 3

Standard Sub-Elements Criteria	SA MET	Self-Assessor's Comments	VA MET	If NO, why criterion not met
	SAME	Sen-Assessor's Comments	VANILI	If NO, why effection not met
1. Inspection Form Design  a. The jurisdiction's inspection form identifies foodborne illness	T			
a. The jurisdiction's inspection form identifies foodborne liness risk factors and Food Code interventions.				
b. The jurisdiction's inspection form documents actual				
observations using the convention IN, OUT, NA, and NO.				
c. The jurisdiction's inspection form documents compliance and enforcement activities.				
2. Risk Assessment Categories				
a. A risk assessment is used to group food establishments into at				
least 3 categories based on their potential and inherent food safety				
risks.				
3. Inspection Frequency				
a. The jurisdiction's inspection frequency is based on the assigned				
risk categories.				
4. Written and Implement Corrective Action Policy				
a. The jurisdiction has a written and implemented policy that				
requires on-site corrective action for foodborne illness risk factors				
observed to be out of compliance.				
b. The jurisdiction has a written and implemented policy that				
requires discussion for long-term control of foodborne illness risk				
factors.				
c. The jurisdiction has a written and implemented policy that				
requires follow-up activities on foodborne illness risk factor				
violations.				
5. Variance Requests				
a. The jurisdiction has a written and implemented policy on				
variance requests related to foodborne illness risk factors and Food				
Code interventions.				
6. Verification and Validation of HACCP Plans				
a. The jurisdiction has a written and implemented policy for the				
verification and validation of HACCP plans when a plan is				
required by Code.				

General notes Pertaining to the Program Self-Assessment or the Verification Audit		

## **Standard 4: Uniform Inspection Program**

# **Program Self-Assessment and Verification Audit Form** (January 2017)

Click the below hyperlink link to open the online PDF verison of Standard 4 Missing Link, Still in Draft Status Click the below hyperlink link to open the online PDF verison with Instuctions

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### PROGRAM SELF-ASSESSMENT (SA) SUMMARY

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Printed Name of the Person who conducted the SA:	
Self-Assessor's Title:	
Jurisdiction Name:	Enter this field data on the 'Jurisdiction Name' field on the 'Self-Assessment Summary' worksheet page.
Jurisdiction Address:	
Phone / Fax / E-mail:	
Date the Standard 4 Self-Assessment was Completed:	
SA indicatesthe Jurisdiction MEETS the Standard 4 criteria:	NO
7 00 1 1 1 0 0 0	

I affirm that the information represented in the Self-Assessment of Standard 4 is true and correct

Signature of the Self-Assessor:

## **VERIFICATION AUDIT (VA) SUMMARY**

Printed Name of the Person who conducted the VA:	
Verification Auditor's Title:	
Auditor's Jurisdiction Name:	
Auditor's Jurisdiction Address:	
Phone / Fax / E-mail:	
Date the Verification Audit of Standard 4 was Completed:	
VA indicates the Jurisdiction MEETS the Standard 4 criteria:	

I affirm that the information represented in the Verification Audit of Standard 4 is true and correct

Table 5 - Program Self-Assessment and Verification Audit Table for Standard 4

Standard Sub-Elements Criteria		<b>Self-Assessor's Comments</b>	VA MET	If NO, why criterion not met
1. Written Quality Assurance Program Document	_			
a. The jurisdiction has a written quality assurance program that				
covers all regulatory staff that conducts retail food and/or				
foodservice inspections.				
b. The jurisdiction periodically conducts an analysis of the results				
of the quality assurance program to identify quality or consistency				
problems among the staff in the twenty quality elements.				
c. The jurisdiction's written quality assurance program describes				
corrective actions to address an individual retail food program				
inspector's performance quality or consistency issues when they				
are identified.				
2. Twenty Quality Assurance Program Elements				
The jurisdictions quality assurance program provides a method to				
review or monitor, either individually or programmatically, the				
concepts in the twenty quality elements. The twenty elements				
follow in I. through XX.				
I. The jurisdiction's quality assurance program assures that each				
inspector has the required equipment and forms to conduct the				
inspection.				
II. The jurisdiction's quality assurance program assures that each				
inspector reviews the contents of the establishment file, including				
the previous inspection report, reported complaints on file, and, if				
applicable, required HACCP Plans or documents supporting the				
issuance of a variance.				
III. The jurisdiction's quality assurance program assures that each				
inspector verifies that the establishment is in the proper risk				
category and that the required inspection frequency is being met,				
Informs the supervisor when the establishment is not in the proper				
risk category or when frequency is not met.				
IV. The jurisdiction's quality assurance program assures that each				
inspector provides identification as a regulatory official to the				
person in charge and states the purpose of the visit.				
V. The jurisdiction's quality assurance program assures that each				
inspector interprets and applies the jurisdiction's laws, rules,				
policies, procedures, and regulations required for conducting retail				
food inspections.				

VI. The jurisdiction's quality assurance program assures that each	
inspector uses a risk-based inspection methodology to conduct the	
inspection.	
VII. The jurisdiction's quality assurance program assures that each	
inspector accurately determines the compliance status of each risk	
factor and Food Code intervention (i.e., IN compliance, OUT of	
compliance, Not Observed, or Not Applicable).	
VIII. The jurisdiction's quality assurance program assures that	
each inspector obtains corrective action for out-of-compliance risk	
factors and Food Code interventions in accordance with the	
jurisdictions policies.	
IX. The jurisdiction's quality assurance program assures that each	
inspector discusses options for the long-term control of risk factors	3
with establishment managers when the same out-of-control risk	
factor occurs on consecutive inspections, in accordance with the	
jurisdiction's policies. Options may include, but are not limited to,	
risk control plans, standard operating procedures, equipment	
and/or facility modification, menu modification, buyer	
specifications, remedial training, or HACCP Plans.	
X. The jurisdiction's quality assurance program assures that each	
inspector verifies correction of out-of-compliance observations	
identified during the previous inspection. In addition, follows	
through with compliance and enforcement in accordance with	
jurisdiction's policies.	
XI. The jurisdiction's quality assurance program assures that each	
inspector conducts an exit interview that explains the out-of-	
compliance observations, corrective actions, and timeframes for	
correction, in accordance with the jurisdiction's policies.	
XII. The jurisdiction's quality assurance program assures that each	
inspector provides the inspection report and, when necessary, cross	
referenced documents, to the person in charge or permit holder, in	
accordance with the jurisdiction's policies.	
XIII. The jurisdiction's quality assurance program assures that	
each inspector demonstrates proper sanitary practices as expected	
from a food service employee.	

TYTE COLUMN 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1				
XIV. The jurisdiction's quality assurance program assures that				
each inspector completed the inspection form per the jurisdiction's				
policies (i.e., observations, public health reasons, applicable code				
reference, compliance dates).				
XV. The jurisdiction's quality assurance program assures that each				
inspector document the status of each risk factor and intervention				
(IN, OUT, NA, NO).				
XVI. The jurisdiction's quality assurance program assures that				
each inspector cites the proper code provisions for risk factors and				
Food Code interventions, in accordance with the jurisdiction's				
policies.				
XVII. The jurisdiction's quality assurance program assures that				
each inspector documents corrective action for out-of-compliance				
risk factors and Food Code interventions in accordance with the				
jurisdiction's policies.				
XVIII. The jurisdiction's quality assurance program assures that				
each inspector documents that options for the long-term control of				
risk factors were discussed with establishment managers when the				
same out-of-control risk factor occurs on consecutive inspections.				
Options may include, but are not limited to, risk control plans,				
standard operating procedures, equipment and/or facility				
modification, menu modification, buyer specifications, remedial				
training, or HACCP Plans.				
XIX. The jurisdiction's quality assurance program assures that				
each inspector accurately completes compliance or regulatory				
documents (i.e., exhibits, attachments, sample forms),				
appropriately cross-references them within the inspection report,				
and includes them with the inspection report, in accordance with				
the jurisdiction's policies.				
XX. The jurisdiction's quality assurance program assures that each				
inspector files reports and other documentation in a timely manner,				
in accordance with the jurisdiction's policies.				
3. Demonstration of Program Effectiveness Using the S	Statistical M	lethod in Standard 4: Self-Asses	ssment Wor	ksheet
a. The program effectiveness measure documents that 2 self-				
assessment field reviews were conducted for each employee				
performing retail food and or foodservice inspection work during				
the five-year self-assessment period. [New staff who have not				
completed Steps 1 through 3 of Standard 2 are exempt from this				
field measurement.]				
4				

b. Based on the self-assessment field reviews using the statistical		
method described in Standard 4: Self-Assessment Worksheet, the		
jurisdiction's regulatory staff achieves a rate of 75% on each		
quality element for jurisdictions with 10 or more inspectors. For		
jurisdictions with less than 10 inspectors, the achievement rate		
meets or exceeds the Table 4-1 calculation.		

General notes Pertaining to the Program Self-Assessment or the Verification Audit			

## Standard 5: Foodborne Illness and Food Defense Preparedness and Response

## **Program Self-Assessment and Verification Audit Form** (January 2017)

Click the below hyperlink link to open the online PDF verison of Standard 5

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### PROGRAM SELF-ASSESSMENT (SA) SUMMARY

Printed Name of the Person who conducted the SA:	
Self-Assessor's Title:	
Jurisdiction Name:	Enter this field data on the 'Jurisdiction Name' field on the 'Self-Assessment Summary' worksheet page.
Jurisdiction Address:	
Phone / Fax / E-mail:	
Date the Standard 5 Self-Assessment was Completed:	
SA indicatesthe Jurisdiction MEETS the Standard 5 criteria:	NO
Jurisdiction Name:  Jurisdiction Address:  Phone / Fax / E-mail:  Date the Standard 5 Self-Assessment was Completed:	Enter this field data on the 'Jurisdiction Name' field on the 'Self-Assessment Summary' worksheet policy of the self-Assessment Summary worksheet policy of the

I affirm that the information represented in the Self-Assessment of Standard 5 is true and correct

Signature of the Self-Assessor:

#### **VERIFICATION AUDIT (VA) SUMMARY**

( ) = 0 ( ) =	
Printed Name of the Person who conducted the VA:	
Verification Auditor's Title:	
Auditor's Jurisdiction Name:	
Auditor's Jurisdiction Address:	
Phone / Fax / E-mail:	
Date the Verification Audit of Standard 5 was Completed:	
VA indicates the Jurisdiction MEETS the Standard 5 criteria:	

I affirm that the information represented in the Verification Audit of Standard 5 is true and correct

Table 6 - Program Self-Assessment and Verification Audit Table for Standard 5

Standard Sub-Elements Criteria	SA MET	Self-Assessor's Comments	VA MET	If NO, why criterion not met
1. Investigation Procedures				
a. The program has written operating procedures for responding to and/or conducting investigations of foodborne illness and food-related injury that clearly identify the roles, duties, and responsibilities of program staff and how the program interacts with other relevant departments and agencies. (The procedures may be contained in a single source document or in multiple documents.)				
b. The program maintains contact lists for individuals, departments, and agencies that may be involved in the investigation of foodborne illnesses, food-related injuries or contamination of food.				
c. The program maintains a written operating procedure or a Memorandum of Understanding (MOU) with the appropriate epidemiological investigation program/department to conduct foodborne illness investigations and to report findings. The operating procedure or MOU clearly identifies the roles, duties, and responsibilities of each party.				
d. The program maintains logs or databases for all complaint or referral reports from other sources alleging food-related illness, food-related injury or intentional food contamination. The final disposition for each complaint is recorded in the log or database and is filed in, or linked to, the establishment record for retrieval purposes.				
<ul> <li>e. Program procedures describe the disposition, action, or follow-up, and reporting required for each type of complaint or referral report.</li> <li>f. Program procedures require disposition, action or follow-up on</li> </ul>				
each complaint or referral report alleging food-related illness or injury within 24 hours.  g. The program has established procedures and guidance for collecting information on the suspect foods' preparation, storage or handling during on-site illness, food-injury, or outbreak investigations.				

h. Program procedures provide guidance for immediate		
notification of appropriate law enforcement agencies if at any time		
intentional food contamination is suspected.		
i. Program procedures provide guidance for the notification of		
appropriate state and/or federal agencies when a complaint		
involves a product that originated outside the agency's jurisdiction		
or has been shipped interstate.		
2. Reporting Procedures		
a. Possible contributing factors to the illness, food-related injury,		
or intentional food contamination are identified in each on-site		
investigation report.		
b. The program shares final reports of investigations with the state		
epidemiologist and reports of confirmed disease outbreaks with		
CDC.		
3. Laboratory Support Documentation	 	
a. The program has a letter of understanding, written procedures,		
contract or MOU acknowledging that a laboratory(s) is willing and		
able to provide analytical support to the jurisdiction's food		
program. The documentation describes the type of biological,		
chemical, radiological contaminants or other food adulterants that		
can be identified by the laboratory. The laboratory support		
available includes the ability to conduct environmental, food,		
and/or clinical sample analyses.		
b. The program maintains a list of alternative laboratory contacts		
from which assistance could be sought in the event that a food-		
related emergency exceeds the capability of the primary support		
lab(s) listed in paragraph 3.a. This list should also identify		
potential sources of laboratory support such as FDA, USDA, CDC,		
or environmental laboratories for specific analysis that cannot be		
performed by the jurisdiction's primary laboratory(s).		
4. Trace-back Procedures		
a. Program management has an established procedure to address		
the trace-back of foods implicated in an illness, outbreak or		
intentional food contamination. The track-back procedure provides		
for the coordinated involvement of all appropriate agencies and		
identifies a coordinator to guide the investigation. Trace-back		
reports are shared with all agencies involved and with CDC.		
5. Recalls		

a. Program management has an established procedure to address		
the recall of foods implicated in an illness, outbreak, or intentional		
food contamination.		
b. When the jurisdiction has the responsibility to request or		
monitor a product recall, written procedures equivalent to 21 CFR,		
Part 7 are followed.		
c. Written policies and procedures exist for verifying the		
effectiveness of recall actions by firms (effectiveness checks) when		
requested by another agency.		
6. Media Management		
a. The program has a written policy and procedure that defines a		
protocol for providing information to the public regarding a		
foodborne illness outbreak or food safety emergency. The		
policy/procedure should address coordination and cooperation		
with other agencies involved in the investigation. A media person		
is designated in the protocol.		
7. Data Review and Analysis		
a. At least once per year, the program conducts a review of the		
data in the complaint log or database and the illness and food-		
related injury investigations to identify trends and possible		
contributing factors that are most likely to cause illness or injury.		
These periodic reviews of multiple complaints and contributing		
factors may suggest a need for further investigations and may		
suggest steps for illness prevention.		
b. The review is conducted with prevention in mind and focuses on		
but is not limited to, the following: 1) Multiple complaints on the		
same establishment;		
2) Multiple complaints on the same establishment type;		
3) Multiple complaints implicating the same food;		
4) Multiple complaints associated with similar food preparation		
processes;		
5) Number of confirmed foodborne disease outbreaks;		
6) Number of foodborne disease outbreaks and suspect foodborne		
disease outbreaks;		
7) Contributing factors most often identified;		
8) Number of complaints involving real and alleged threats of		
intentional food contamination; and		

9) Number of complaints involving the same agent and any		
complaints involving unusual agents when agents are identified.		
c. In the event that there have been no illness or food-related injury		
outbreak investigations conducted during the twelve months prior		
to the trend analysis, program management will plan and conduct a		
mock foodborne illness or food defense investigation to test		
program readiness. The mock investigation should simulate		
response to an actual illness outbreak and include on-site		
inspection, sample collection and analysis. A mock investigation		
must be completed at least once per year when no illness outbreak		
investigations occur.		

General notes Pertaining to the Program Self-Assessment or the Verification Audit			

## **Standard 6: Compliance and Enforcement**

## **Program Self-Assessment and Verification Audit Form** (January 2017)

Click the below hyperlink link to open the online PDF verison of Standard 6

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## PROGRAM SELF-ASSESSMENT (SA) SUMMARY

Printed Name of the Person who conducted the SA:	
Self-Assessor's Title:	
Jurisdiction Name:	Enter this field data on the 'Jurisdiction Name' field on the 'Self-Assessment Summary' worksheet page.
Jurisdiction Address:	
Phone / Fax / E-mail:	
Date the Standard 6 Self-Assessment was Completed:	
SA indicatesthe Jurisdiction MEETS the Standard 6 criteria:	NO

I affirm that the information represented in the Self-Assessment of Standard 6 is true and correct

Signature of the Self-Assessor:

## **VERIFICATION AUDIT (VA) SUMMARY**

Printed Name of the Person who conducted the VA:	
Verification Auditor's Title:	
Auditor's Jurisdiction Name:	
Auditor's Jurisdiction Address:	
Phone / Fax / E-mail:	
Date the Verification Audit of Standard 6 was Completed:	
VA indicates the Jurisdiction MEETS the Standard 6 criteria:	

I affirm that the information represented in the Verification Audit of Standard 6 is true and correct

Table 7 - Program Self-Assessment and Verification Audit Table for Standard 6

Standard Sub-Elements Criteria	SA MET	Self-Assessor's Comments	VA MET	If NO, why criterion not met
1. Compliance and Enforcement Procedure				
a. The jurisdiction's has a written step-by-step compliance and				
enforcement procedure that describes what actions and tools				
(forms/documents/interventions) are to be used to achieve				
compliance.				
b. The jurisdiction's inspection form(s) record and quantify the				
compliance status of foodborne illness risk factors, Food Code				
interventions and other serious code violations.				
2. Assessment of Effectiveness				
a. The jurisdiction has written documentation that verifies the				
review of the effectiveness of the staff's implementation of the				
program's compliance and enforcement procedure that includes a				
selection of establishment files for review in accordance with the				
Standard criteria.				
b. The jurisdiction has written documentation verifying that at least	-			
80 percent of the sampled files follow the agency's step-by-step				
compliance and enforcement procedures and actions were taken to				
resolve out-of-compliance risk factors recorded on the selected				
routine inspection in accordance with the Standard criteria.				

General notes Pertaining to the Program Self-Assessment or the Verification Audit		

## **Standard 7: Industry and Community Relations**

## **Program Self-Assessment and Verification Audit Form** (January 2017)

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## PROGRAM SELF-ASSESSMENT (SA) SUMMARY

Printed Name of the Person who conducted the SA:	
Self-Assessor's Title:	
Jurisdiction Name:	Enter this field data on the 'Jurisdiction Name' field on the 'Self-Assessment Summary' worksheet page.
Jurisdiction Address:	
Phone / Fax / E-mail:	
Date the Standard 7 Self-Assessment was Completed:	
SA indicatesthe Jurisdiction MEETS the Standard 7 criteria:	NO
7 00 1 1 1 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0	1 1-

I affirm that the information represented in the Self-Assessment of Standard 7 is true and correct

Signature of the Self-Assessor:

## **VERIFICATION AUDIT (VA) SUMMARY**

Printed Name of the Person who conducted the VA:	
Verification Auditor's Title:	
Auditor's Jurisdiction Name:	
Auditor's Jurisdiction Address:	
Phone / Fax / E-mail:	
Date the Verification Audit of Standard 7 was Completed:	
VA indicates the Jurisdiction MEETS the Standard 7 criteria:	

I affirm that the information represented in the Verification Audit of Standard 7 is true and correct

Table 8 - Program Self-Assessment and Verification Audit Table for Standard 7

SA MET	Self-Assessor's Comments	VA MET	If NO, why criterion not met
	SA MET		

General notes Pertaining to the Program Self-Assessment or the Verification Audit	

## **Standard 8: Program Support and Resources**

## **Program Self-Assessment and Verification Audit Form** (January 2017)

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### PROGRAM SELF-ASSESSMENT (SA) SUMMARY

Printed Name of the Person who conducted the SA:	
Self-Assessor's Title:	
Jurisdiction Name:	Enter this field data on the 'Jurisdiction Name' field on the 'Self-Assessment Summary' worksheet page.
Jurisdiction Address:	
Phone / Fax / E-mail:	
Date the Standard 8 Self-Assessment was Completed:	
SA indicatesthe Jurisdiction MEETS the Standard 8 criteria:	NO

I affirm that the information represented in the Self-Assessment of Standard 8 is true and correct

Signature of the Self-Assessor:

## **VERIFICATION AUDIT (VA) SUMMARY**

Printed Name of the Person who conducted the VA:	
Verification Auditor's Title:	
Auditor's Jurisdiction Name:	
Auditor's Jurisdiction Address:	
Phone / Fax / E-mail:	
Date the Verification Audit of Standard 8 was Completed:	
VA indicates the Jurisdiction MEETS the Standard 8 criteria:	

I affirm that the information represented in the Verification Audit of Standard 8 is true and correct

Table 9 - Program Self-Assessment and Verification Audit Table for Standard 8

Standard Sub-Elements Criteria	SA MET	<b>Self-Assessor's Comments</b>	VA MET	If NO, why criterion not met
1. Staffing Level – FTEs per Inspections Performed	<u> </u>			
a. The jurisdiction has written documentation, calculations, or a				
program resource assessment that demonstrated a staffing level of				
one full-time equivalent (FTE) for every 280-320 retail food				
program inspections performed.				
2. Inspection Equipment				
a. The jurisdiction can demonstrate through written records,				
equipment inventories, or actual observations that each retail food				
program inspector has a head cover, thermocouple, flashlight,				
sanitization test kit, heat sensitive tapes or maximum registering				
thermometer and necessary forms and administrative materials.				
b. The jurisdiction has a written procedure for obtaining the use of				
computers, cameras, black lights, light meters, pH meters,				
foodborne illness kits, sample collection kits, data loggers and cell				
phones should this equipment not be part of the agency's general				
equipment inventory.				
3. Administrative Program Support				
a. The jurisdiction has written documentation, calculations or a				
program resource assessment that demonstrates sufficient				
equipment is available to support the record keeping system				
utilized by the program.				
b. The jurisdiction has a system in place to collect, analyze, retain				
and report pertinent information required to manage and				
implement the retail food protection program.				
4. Program Resource Assessment				
a. The jurisdiction has conducted an assessment to determine if the				
agency has the budget, staffing and equipment necessary to meet				
Standard #1 – Regulatory Foundation.				
b. The jurisdiction has conducted an assessment to determine if the				
agency has the budget, staffing and equipment necessary to meet				
Standard #2 – Trained Regulatory Staff.				

c. The jurisdiction has conducted an assessment to determine if the agency has the budget, staffing and equipment necessary to meet Standard #3 – Inspection Program Based on HACCP Principles.	
d. The jurisdiction has conducted an assessment to determine if the agency has the budget, staffing and equipment necessary to meet Standard #4 – Uniform Inspection Program.	
e. The jurisdiction has conducted an assessment to determine if the agency has the budget, staffing and equipment necessary to meet Standard #5 – Foodborne Illness and Food Security Preparedness and Response	
f. The jurisdiction has conducted an assessment to determine if the agency has the budget, staffing and equipment necessary to meet Standard #6 – Compliance and Enforcement.	
g. The jurisdiction has conducted an assessment to determine if the agency has the budget, staffing and equipment necessary to meet Standard #7 – Industry and Community Relations.	
h. The jurisdiction has conducted an assessment to determine if the agency has the budget, staffing and equipment necessary to meet Standard #9 – Program Assessment.	

General notes Pertaining to the Program Self-Assessment or the Verification Audit				

## **Standard 9: Program Assessment**

## **Program Self-Assessment and Verification Audit Form** (January 2017)

Click the below hyperlink link to open the online PDF verison of Standard 9

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### PROGRAM SELF-ASSESSMENT (SA) SUMMARY

Enter this field data on the 'Jurisdiction Name' field on the 'Self-Assessment Summary' worksheet page.
NO

I affirm that the information represented in the Self-Assessment of Standard 9 is true and correct

Signature of the Self-Assessor:

#### **VERIFICATION AUDIT (VA) SUMMARY**

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Printed Name of the Person who conducted the VA:	
Verification Auditor's Title:	
Auditor's Jurisdiction Name:	
Auditor's Jurisdiction Address:	
Phone / Fax / E-mail:	
Date the Verification Audit of Standard 9 was Completed:	
VA indicates the Jurisdiction MEETS the Standard 9 criteria:	
T CO 1 1 1 C	1 10.

I affirm that the information represented in the Verification Audit of Standard 9 is true and correct

Table 10 - Program Self-Assessment and Verification Audit Table for Standard 9

Standard Sub-Elements Criteria	SA MET	<b>Self-Assessor's Comments</b>	VA MET	If NO, why criterion not met
1. Risk Factor Study				
<ul> <li>a. A study on the occurrence of foodborne illness risk factors has been completed and includes data for each facility type regulated by the jurisdiction collected over the study cycle.</li> <li>b. The data collection form includes items pertaining to the following Center for Disease Control and Prevention (CDC)</li> </ul>				
identified contributing factors to foodborne Illness: 1) Food from Unsafe Sources, 2) Improper Holding/Time and Temperature, 3) Inadequate Cooking, 4) Poor Personal Hygiene, and 5) Contaminated Equipment/Protection from Contamination				
c. The data collection form provides for marking actual observations of food practices within an establishment (IN, OUT, NO, and NA).				
2. Report of Analysis and Outcome				
a. A report is available that shows the results of the data collection from the jurisdiction's foodborne illness risk factor study				
b. The report provides quantitative measurements upon which to assess the trends in the occurrence of foodborne illness risk factors over time	5			
3. Intervention Strategy				
a. A targeted intervention strategy designed to address the occurrence of the risk factor(s) identified in their RISK FACTOR STUDY is implemented and the effectiveness of such strategy is evaluated by subsequent RISK FACTOR STUDIES or other similar tools				
b. Documentation is provided of performed interventions, action, or activities designed to improve control of foodborne illness risk factors.				

General notes Pertaining to the Program Self-Assessment or the Verification Audit				