

## MEMORANDUM

**TO:** Prospective Pilot Project Participants  
Conference for Food Protection (CFP)  
Uniform Inspection Program Audit Pilot Project

**FROM:** Lee Cornman, John Marcello, and Susan Kendrick

**DATE:** April 10, 2010

**SUBJECT:** **Pilot Project Fact Sheet**

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### **Background**

A Work Group originating with the 2004 Conference has been working with representatives of the Food and Drug Administration to create a multi-tiered process for training and standardizing Food Safety Inspection Officers (FSIOs). The goal of this pilot project is to develop a nationally recognized training and standardization process for FSIOs that can be used as a model by retail food regulatory programs to enhance the effectiveness of food establishment inspections and increase uniformity among regulatory professionals in their assessment of food safety practices in the retail food industry.

Over the past 5 years, the Work Group has used the criteria contained in the *FDA Voluntary National Retail Food Regulatory Program Standards (FDA Program Standards)*, Standard 2 – Trained Regulatory Staff to develop a comprehensive training model for regulatory retail Food Safety Inspection Officers. Jurisdictions using the CFP Field Training process and forms have indicated an overwhelmingly favorable experience.

Results from the follow-up interviews with jurisdictions using the Standard 2 criteria to train their retail food inspection staff indicated support for the development of an audit tool that mirrored the CFP Field Training process. The CFP Work Group is in the process of evaluating approaches regulatory retail food protection programs can implement to assess the effectiveness of the training provided in Standard 2.

The FDA Program Standards apply to the operation and management of regulatory retail food programs NOT practitioners in the field. Self-assessments using the Standards are intended to provide an overall program analysis. The CFP Work Group, therefore, thinks that Standard 4 – Uniform Inspection Program provides the most appropriate place for inclusion of an assessment process.

Standard 4 applies to the jurisdiction's internal policies and procedures established to ensure uniformity among regulatory staff in the interpretation of regulatory requirements, program policies, and compliance/enforcement procedures. It requires that a review of each inspector's work be made during at least two joint on-site inspections, with a corresponding file review of at least the three most recent inspection reports. These

quality assurance assessments provide important feedback that will assist the regulatory jurisdiction in identifying existing strengths and potential areas needing improvement within their existing retail food training program for Food Safety Inspection Officers.

**Purpose and Objectives – Uniform Inspection Program Audit Pilot Project**

The primary objectives of the pilot project will be to evaluate the Uniform Inspection Program Audit Worksheet (included with this pilot project package) as a tool for the quality assurance evaluations conducted as part of Standard 4. Companion documents that include instructions and format for using the Uniform Inspection Audit Worksheet are also included with this pilot project package.

Pilot project participants will:

- Determine the strengths and weakness of the Uniform Inspection Audit Worksheet; instructions; and guidance documents.
- Provide feedback on the ease of use of the documents, including the instructions and format. Are jurisdictions able to use the documents independently without direct supervision or oversight?
- Determine the length of time required to use the documents and complete the audit process.
- Determine whether the audit process is appropriate to assess the FSIO’s knowledge, skills and ability when applying the competencies required during a field inspection.
- Review the 10 inspection program areas and competencies that comprise the Uniform Inspection Program Audit Worksheet for omissions, additions, and items they deem to be not applicable. A detailed description of the 10 inspection program areas and competencies is contained in the Audit Reference Guide included with this pilot project package.
- Determine whether the audit process is properly positioned as part of the Standard 4 criteria. Should it be placed in another part of the Standard or made available as a stand alone tool external to the Program Standards?

**Pilot Project Timeline**

<b>April 2010</b>	Solicitation of interested jurisdictions during the 2010 biennial meeting of the Conference
<b>May 2010</b>	Selection of jurisdictions for Pilot Project (Minimum of 8 jurisdictions desired)
<b>June 2010</b>	Send out Pilot Project packages to selected jurisdictions and notify jurisdictions not selected
<b>June 2010</b>	Conference call with selected jurisdictions (Review Pilot Project objectives, goals, methodology, data collection, etc.)

- February 2011** Interim conference call with jurisdictions  
(Review of data received to date, overview of progress, solicitation of questions, reminder of deadlines, etc.)
- August 2011** Completion of field component of Pilot Project and collection of completed pilot project feedback forms from jurisdictions
- October 2011** Convene conference call focus group of jurisdiction representatives to review Pilot Project outcomes
- November 2011** CFP Work Group review, analysis, summary and development of Pilot Project results into Conference report and Issue
- December 2011** Submit final Work Group report and any Issues for consideration at the 2012 biennial meeting of the Conference.

## **Methodology**

### **A. Selection of pilot project participants**

The CFP is soliciting agencies to participate in the Uniform Inspection Program Audit Pilot Project. To be considered for the pilot project, agencies must:

- Have at least one FSIO who has completed the retail food program training requirements included in Steps 1 through 3 of Standard 2 – Trained Regulatory Staff; and
- Conduct a quality assurance assessment of at least one FSIO within the pilot project period following the criteria contained in Standard 4 – Uniform Inspection Program using the Uniform Inspection Program Audit Worksheet; and
- Make a commitment to meet the pilot project timelines, reporting protocols and conference calls, and
- Permit publication of the jurisdiction’s participation in the pilot project report presented at the 2012 Conference for Food Protection meeting (absent any specific information from the Uniform Inspection Program Audit Worksheets).

### **B. Distribution of Pilot Project Package**

All selected jurisdictions will receive an Electronic Pilot Project Package containing the following materials:

- Pilot Project Fact Sheet;
- Application to Participate;
- Guide to the Uniform Inspection Program Audit;
- Audit Worksheet
- Audit Reference Guide;
- Audit Results Summary and FSIO Training Plan; and the

- FDA Voluntary National Retail Food Regulatory Program Standards (April 2009).  
The two Standards referenced in the pilot project package are:
  - Standard 2 – Trained Regulatory Staff
  - Standard 4 – Uniform Inspection Program

C. Launch of Pilot Project:

Pilot Project will be initiated with a conference call of all participating jurisdictions during the month of June 2010. The purpose of the conference call will be to provide an overview of the Pilot Project objectives, goals, timeline, methodology, participant expectations, data collection, and other reporting criteria.

D. Interim Progress Review of Pilot Project:

An interim project conference call will be conducted with all pilot participants during the month of January 2011. The purpose of this goal is to check on each jurisdiction's progress in meeting the pilot projects objectives and answer any questions that have arisen during the course of the project.

E. Data Collection and Reporting:

The design of the pilot project data collection instrument will include:

- A pilot project feedback form designed to solicit information from participants.
- Demographical information
- Focus Group(s) designed to solicit additional anecdotal information and recommendations

The pilot project data collection instrument will be distributed to jurisdictions the are selected for the study.

Participating jurisdictions agree to complete a pilot project feedback form at the end of the study. Data from the form will be analyzed and summarized to determine whether the Uniform Inspection Program Audit is appropriately designed to provide feedback on a jurisdiction's training program. In addition, data will be evaluated to determine whether the implementation of the audit process is properly positioned within Standard 4 criteria.

Additionally, a conference call will be conducted with a representative sampling of pilot project jurisdictions to review and clarify the study's conclusions.

**Description of Pilot Project Program Materials**

Pilot Project Fact Sheet (this cover memo)

The Pilot Project Fact sheet outlines the:

- Background information on the project;
- Pilot Project Purpose and Objectives;
- Pilot Project Time Line;
- Methodology (including selection of pilot project participants);
- Description of the pilot project materials, and
- Pilot Project Coordinator contact information.

#### Guide to the Uniform Inspection Program Audit

The Guide is the Pilot Project core document and provides:

- An overview of the Uniform Inspection Program Audit process
- A discussion on how the audit process is to be used within the context of Standard 4 – Uniform Inspection Program, *FDA Voluntary National Retail Food Regulatory Program Standards*
- Guidelines to assist FSIOs preparing for the inspection program audit process,
- Step-by-step instructions for conducting the uniform inspection program audit using the Standard 4 criteria.

#### Uniform Inspection Program – Audit Worksheet

A blank Audit Worksheet is provided for jurisdictions to make multiple copies of the form to meet their specific program needs. The Audit Worksheet contains the 10 uniform inspection program components that are to be evaluated during the file review/joint field inspections with FSIOs of selected establishments.

#### Uniform Inspection Program – Audit Reference Guide

The Audit Reference Guide provides examples of applicable FSIO performance areas and competencies for each of the 10 uniform inspection program areas identified in the Standard 4 criteria. The FSIO performance areas and competencies are from the Standard 2 – CFP Field Training Plan

#### Uniform Inspection Program – Audit Results Summary and FSIO Training Plan

The Audit Results Summary and FSIO Training Plan is designed as a template for documenting additional FSIO training needs identified during the audit process. There are two parts to this form:

- Part I – Audit Results Summary
- Part II – FSIO Training Plan

The jurisdiction's designated auditor completes Part I – Audit Results Summary. Any inspection program competencies that were not successfully performed during the establishment file reviews and field inspections are noted on the form by the auditor.

The FSIOs supervisor completes Part II – FSIO Training Plan. If any competencies have been identified by the jurisdiction's auditor as needing improvement, the FSIO's supervisor develops a training plan to address competencies identified as needing improvement. The supervisor consults with the FSIO regarding their training needs so expectations are clearly understood. The FSIO's successful completion of the additional training is recorded on this form. The jurisdiction has the flexibility for addressing these

identified training needs within the context of their own administrative retail food inspection program protocols.

#### Program Standard 2 – Trained Regulatory Staff

The *FDA Voluntary National Retail Food Regulatory Program Standards*, Standard 2 – Trained Regulatory Staff outlines the five-step process for the training and standardization of FSIOs. To participate in the pilot project, FSIOs must have completed Steps 1 through 3, Standard 2 and have conducted independent inspections of retail food and/or foodservice establishments.

#### Program Standard 4 – Uniform Inspection Program

The *FDA Voluntary National Retail Food Regulatory Program Standards*, Standard 4 – Uniform Inspection Program applies to the jurisdiction's internal policies and procedures established to ensure uniformity among regulatory staff in the interpretation of regulatory requirements, program policies, and compliance/enforcement procedures. The Standard 4 criteria outlines 10 inspection program areas that are to be included in a jurisdiction quality assurance assessment of their retail food protection program. The Standard 4 self-assessment criteria provides the framework for the implementation of the Uniform Inspection Program Audit.

### **Application to Participate**

Jurisdictions that would like to participate in the pilot project must complete and submit the enclosed "Application to Participate" form by **May 28, 2010**. Each jurisdiction that submits an application will be notified as to whether they have been selected to participate in the pilot project by **June 4, 2010**. Every effort will be made to accommodate as many jurisdictions as possible. A pilot project conference call(s) will be conducted in June 2010 and will provide participating jurisdictions an overview of the project.

A CD, with all pilot project materials has been included with the set of materials that accompany this cover memo to assist jurisdictions in sharing documents with staff and duplicating the Uniform Inspection Audit worksheet and instructions that will be used in conjunction with the pilot project.

### **Analysis of Data**

The CFP Pilot Project Work Group will analyze the data by tabulating and summarizing all responses to the questionnaire and the focus group meetings. Based on the results of the Pilot Project, the Work Group will determine necessary or recommended changes to be made to the training/Audit documents and/or process.

### **Preparation of Pilot Project Report**

A report of the results of the Pilot Project will be created. The report will include a summary of the results of the data tabulation (including participant list, demographics,

and questionnaire results), a list of recommended changes to the Audit documents and a list of recommended changes to the *FDA Voluntary National Retail Food Regulatory Program Standards* (Standard 2 and/or Standard 4). This report will be submitted to the 2012 biennial meeting of the Conference for Food Protection.

Additionally, Pilot Project results and recommendations will be developed in collaboration with FDA's Division of Human Resource Development to assist in the development of a performance assessment specific to the responsibilities of state, local and tribal retail food safety inspection officers.

### **Pilot Project Coordinators**

Individuals who have questions or would like more information about the pilot project may contact one of the following pilot project coordinators:

Lee Cornman  
850 245-5595

[cornmal@doacs.state.fl.us](mailto:cornmal@doacs.state.fl.us)

John Marcello  
480 829-7396 ext. 35

[john.marcello@fda.hhs.gov](mailto:john.marcello@fda.hhs.gov)

Susan Kendrick  
503 533-0835

[skendric@oda.state.or.us](mailto:skendric@oda.state.or.us)