

VOLUNTARY NATIONAL RETAIL FOOD REGULATORY PROGRAM  
STANDARDS

**CLEARINGHOUSE WORK GROUP**  
**Questions and Answers on the Implementation of the Retail Program**  
**Standards<sup>1</sup>**

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<sup>1</sup>Last updated on 4/5/2016 based on the 2015 edition of the Voluntary National Retail Food Regulatory Program Standards.

# INTRODUCTION

The Clearinghouse Work Group was developed to interpret questions about the implementation of the Voluntary National Retail Food Regulatory Program Standards (Retail Program Standards). The members consist of:

- Two FDA Regional Retail Food Specialists;
- One member from the Retail Food Policy Team in the FDA's Center for Food Safety and Applied Nutrition (CFSAN);
- Five state, local, tribal or territorial members (one from each of the five FDA regions); and
- The current CFP Program Standards Committee Chair.

The Clearinghouse Work Group does not make changes to the Retail Program Standards. Proposed changes are considered by the Conference for Food Protection (CFP). It is recommended that questions about enrollment and implementation of the Retail Program Standards be directed to the jurisdiction's assigned FDA Regional Retail Food Specialist. If an interpretation is necessary, then the Specialist will forward the question to the Clearinghouse Work Group.

# ADMINISTRATIVE PROCEDURES

1. Standard Self-Assessment process for decentralized jurisdictions

Keywords: Administrative Procedures Program Assessment, delegation, state, local, MOU, written agreement

2. Must an audit cover all Standards at the same time?

Keywords: Administrative Procedures audits, auditing of standards, timing of audits

## **1. Standard Self-Assessment process for decentralized jurisdictions**

Keywords: Administrative Procedures, Program Assessment, delegation, state, local, MOU, written agreement

### **Issue Description**

#### **Background**

I work for a State regulatory food program. The responsibility for regulatory oversight of retail food and foodservice operations has been passed on to local county agencies through a formal delegation agreement. The State agency, itself, has very little direct regulatory inspection responsibilities within the retail food sector.

My agency has enrolled in the Program Standards. Our staff is able to initiate a self-assessment of our State Program against some of the Standards, including:

- Standard #1 – Regulatory Foundation
- Standard #2 – Trained Regulatory Staff
- Standard #5 – Foodborne Illness Surveillance
- Standard #7 – Industry and Community Relations

Some of the other Standards, however, present significant challenges to our successful completion of a self-assessment because they rely heavily on the structure and process related to direct inspection work. These Standards include:

- Standard #3 – Incorporating the Principles of HACCP into Regulatory Inspections
- Standard #4 – Inspection Uniformity
- Standard #6 – Compliance and Enforcement
- Standard #8 – Program Resources
- Standard #9 – Program Assessment

#### **Question/Problem**

How should State Programs who have delegation agreements with local agencies for direct regulatory inspections of the retail segment of the industry conduct a self-assessment of their own program? What parameters should be used to assess compliance with those Standards listed above that rely substantially on an assessment of the structure and/or process pertaining to on-site inspection work and related files?

#### **Rationale**

None provided.

### **Response from Clearinghouse Work Group (03-20-02)**

In the circumstance that you describe, the application/implementation of the Standards falls into two areas, those areas that are a direct part of your program and those areas that you manage. Legal delegations can be accomplished using several different written instruments such as delegation agreements, contracts for service, or memoranda of understanding. For those pieces of the program that you manage through delegation, you should establish written criteria to be followed by the delegatee in the performance of those delegated duties. You

can meet the Standards in those areas that you have delegated by demonstrating the following elements:

- That criteria exist in your formal delegation document that meets the Standards criteria for those areas,
- That you regularly perform a monitoring, oversight, or audit function of retail food programs that have entered into a delegation agreement or contract with your agency to ensure that the criteria is being met (We suggest that you require by delegation document that the delegatee perform self-assessment and develop plans to bridge gaps in order to make oversight/auditing less resource intensive), and
- That you require the delegatee to develop and implement action plans for correction if it does not meet the criteria in the delegation agreement or contract.

For your self-assessment of delegated program areas, you will determine the presence or absence of these three elements (a. through c. above) for delegated functions. Of course, you also will perform a self-assessment against the other Standards' requirements for pieces of the program that you perform directly.

## **2. Must an audit cover all Standards at the same time?**

Keywords: Administrative Procedures, audits, auditing of standards, timing of audits

### **Issue Description**

#### **Background**

None provided.

#### **Question/Problem**

Since all the Standards may not be met at one time, what is the correct procedure regarding the timing of the Verification Audit? Must all the Standards be audited at the same time? If after our initial self-assessment, we meet additional standards and submit a new Appendix I, does that restart the clock on self-assessment and audit timing?

#### **Rationale**

None provided.

### **Response from Clearinghouse Work Group (01-17-07) Updated 2013**

No, all Standards are not required to be audited at the same time. The self-assessment represents the status of the program against all of the Standards at a specific moment in time. It must occur at least once every sixty (60) months. Following a self-assessment, a jurisdiction may complete one or more action plans which will allow them to 'update' the self-assessment to show that they then meet one or more additional standards. At any time after a jurisdiction claims to have met a standard, either during the self-assessment or in an update to the self-assessment, a jurisdiction is encouraged to immediately obtain a verification audit of those results. This will allow for timely feedback of the self-reported results and timely correction for any misinterpretations that may have occurred. Multiple verification audit dates may exist and be reflected on the web listing. However, the only requirement for continued participation in the Standards and listing on the National Registry is a self-assessment every sixty months followed by a verification audit within 6 months of the self-assessment. Since verification auditors' time must be respected and a time suitable for both parties must be negotiated, it would not be unusual for Standards to be audited on different dates.

For example, a jurisdiction completes its self-assessment in January 2006 and self-reports meeting one Standard. For timely feedback on the self-reported results, the jurisdiction could obtain an audit of this Standard immediately, and is encouraged to do so. Subsequently, in July 2007, the jurisdiction completes action plans resulting in two additional Standards self-reported as being met. As before, the jurisdiction could obtain an audit of these standards immediately. However, the jurisdiction could wait and have an audit completed on all three Standards by the end of January 2008, which is within 6 months from the self-assessment completion date.

# STANDARD 1

## Regulatory Foundation

This standard applies to the regulatory foundation used by a retail food program. Regulatory foundation includes any statute, regulation, rule, ordinance, or other prevailing set of regulatory requirements that governs the operation of a retail food establishment.

1. [State Interpretation of When Otherwise Approved vs. intent of Food Code](#)  
Keywords: STD-01, regulatory foundation, when otherwise approved, interpretations, at least as stringent
2. [Section 8-813.10 Petitions, Penalties, and Continuing Violations](#)  
Keywords: STD-01, Regulatory foundation, compliance, enforcement, civil penalties, criminal penalties
3. [Local/county Jurisdictions Operating Under State Regulations](#)  
Keywords: STD-01, Regulatory foundation, Food Code intervention, local rule, consumer advisory
4. [Want Alternative Criteria for Demonstrating Control of Risk Factors](#)  
Keywords: STD-01, Regulatory foundation, alternative control of risk factors, equivalent risk factors control
5. [Compliance and Enforcement Code Sections](#)  
Keywords: STD-01, Regulatory foundation, compliance, enforcement, critical items, follow-up
6. [Altering a code's or regulation's language through policy](#)  
Keywords: STD-01, regulatory foundation, altering language, changing the code by policy, policy, bare-hand contact, minimize bare-hand contact
7. [Does omitting one provision of the Food Code count against a jurisdiction in more than one risk factor or intervention section in Standard 1?](#)  
Keywords: STD-01, regulatory foundation, food code provision, risk factor, food code intervention, agreement with the code
8. [Adequacy of Consumer Advisory](#)  
Keywords: STD-01, consumer advisory, shellfish advisory, partial consumer advisory
9. [A 7-day versus a 15-day response for request of an administrative hearing](#)  
Keywords: STD-01, regulatory foundation, response, administrative hearing, hearing, time frame
10. [Details required in a hearing request](#)

Keywords: STD-01, regulatory foundation, response, administrative hearing, hearing, time frame, details

11. **Residential Kitchens used for Processing of Goods Sold at Retail**

Keywords: STD-01, residential kitchens, home cooking, home processing, home kitchens

12. **Regulatory Jurisdiction over Highly Susceptible Populations**

Keywords: STD-01, Highly Susceptible Population Establishments



## **1. State Interpretation of When Otherwise Approved vs. intent of *Food Code*.**

Keywords: STD-01, regulatory foundation, when otherwise approved, interpretations, at least as stringent

### **Issue Description**

#### **Background**

The county that I represent has a delegation agreement with the State. Under the delegation agreement the county is required to use the Food Code adopted by the State. The county may develop Food Code provisions that are stricter than the State. In 2001, the State adopted the 1999 FDA Food Code.

Recently the State has issued interpretations on several key provisions within the Food Code. Most notably, Section 3-301.11 Preventing Contamination from Hands. The State adopted the FDA Food Code language verbatim for this Section. Since that time, however, the State has issued an interpretation on what is meant by “when otherwise approved”. This interpretation is less stringent than what FDA has provided as guidance in ANNEX 3 of the FDA Food Code.

The States interpretation of “when otherwise approved” in essence states that if a facility is in compliance with the hand wash provisions within the Food Code and has a system, such as SOPs, to support this practice, then they meet the intent of “when otherwise approved”.

#### **Question/Problem**

My questions is this, if the Food Code adopted in the State specifically meets the language in the *FDA Food Code*, does that meet the intent of complying with this risk based provision in Standard #1, or will the State’s interpretation of the provision (and any other similar types of interpretations) also have to be taken into account when conducting the self-assessment?

#### **Rationale**

We believe that if the Food Code language in the State (thus County) Code is verbatim to the *FDA Food Code* language then our County meets the intent of Standard #1 which is based on a provision by provision comparison of Food Code requirements. If not, how will an auditor be able to assess a jurisdictions compliance with Standard #1 without knowing all the individual Food Code interpretations that may have been issued by the State.

### **Response from Clearinghouse Work Group (02-20-02)**

The jurisdiction has adopted the language in Section 3-301.11 verbatim. For this specific provision, the jurisdiction is in compliance with the assessment criteria contained in Standard No. 1.

The language of Standard No. 1, in both the ‘Requirement Summary’ and the ‘Description of Requirement’ states that a jurisdiction’s regulation, rule, or ordinance must have a provision as least as stringent as the specified provisions of the Food Code. According to the information provided, the jurisdiction has adopted 3-301.11 of the 1999 version verbatim. That meets the stated requirement of Standard No. 1 for the item in question.

The language of 3-301.11 includes a phrase ‘Except . . . as otherwise approved.’ FDA originally anticipated that jurisdictions approving alternatives to the ‘no bare hands contact with ready-to-eat foods’ provision would approve those alternatives that could convincingly address the hazards of fecal/oral contamination and would provide effective management controls to ensure protection of the food. This phrase was intended to allow some flexibility for innovative ideas or advancing technology that might not be foreseen. It was not anticipated that the phrase would be used as a blanket approval for ‘business as usual.’

Later, FDA provided guidance in Annex 3 regarding the kinds of criteria to be used when approving alternative controls to ‘no bare hand contact.’ Standard No. 1 language does not include adherence to guidance or Annex 3 as a condition of meeting the Standard. While the Work Group agrees that the jurisdiction is not meeting the spirit of that provision of the Food Code, it has adopted the regulatory language necessary to protect the public health, which was the goal of Standard 1. It is in the implementation of the regulatory language where the failure occurs. This failure to meet the spirit of the Code cannot be addressed through Standard No. 1. This appears to be a gap in the Standards that was not foreseen and may well need to be addressed. The Standards will doubtless evolve over time with changes and/or additions as stakeholders gain experience and knowledge through their use.

## **2. Section 8-813.10 Petitions, Penalties, and Continuing Violations**

Keywords: STD-01, Regulatory foundation, compliance, enforcement, civil penalties, criminal penalties

### **Issue Description**

#### **Background**

The Statutes in our State do not provide the State and local health jurisdictions the authority to enact or administer civil penalties. The State and local jurisdictions do, however, have provisions for criminal penalties that are equivalent to the *FDA Food Code*.

#### **Question/Problem**

Since criminal penalties are, in most instances, more punitive and stringent than civil penalties, would jurisdictions operating under the limitations of the State statute prohibiting the application of civil penalties by health authorities meet the intent of the *FDA Food Code*?

#### **Rationale**

Since criminal penalties are more stringent than civil penalties, we believe that jurisdictions that do not have authority to enact civil penalties but incorporate criminal penalties at least equivalent to the *FDA Food Code* meet the intent of Standard #1.

### **Response from Clearinghouse Work Group (Updated 2011)**

The CFP modified Standard 1 at the 2003 Biennial meeting and the change became effective in January 2005. Standard 1 Compliance and Enforcement section now requires that only one of the three possible civil, criminal or administrative remedies is necessary to meet the intent of Standard 1

### **3. Local/county Jurisdictions Operating Under State Regulations**

Keywords: STD-01, Regulatory foundation, Food Code intervention, local rule, consumer advisory

#### **Issue Description**

##### **Background**

The State of West Virginia has adopted the *1999 Food Code*, but deleted the Consumer Advisory. The State Code is used throughout the State. We are two local jurisdictions in the State. Currently, it is possible that we might be able to promulgate a local rule that adds the consumer advisory to our county rules; however, that option may be taken away soon.

##### **Question/Problem**

Will we be able to meet Standard #1?

##### **Rationale**

Unless we are able to enact separate provisions, we believe that we will not be able to ever meet Standard #1.

#### **Response from Clearinghouse Work Group (02-20-02)**

For the initial listing, a jurisdiction's regulation must contain at least 9 of the 11 risk factor controls and interventions. For the initial self- assessment, it is possible to meet the criteria in Standard No. 1 without the consumer advisory provision. By the third verification audit, however, the regulatory foundation must meet all 11 of the 11 risk factor controls and interventions.

As a local jurisdiction, you must promulgate a local rule to include the Consumer Advisory in order to get credit for that item or work toward getting the State's regulation changed to include it.

Update (12-31-2012)

The 2004 CFP changed the requirement to 11 of 11 after the third assessments cycle. Further, the CFP changed the frequency of the assessment cycle effective January 2011 from every 36 months to every 60 months. This changes the requirement to attain all eleven of the risk factors and interventions to fifteen (15) years.

#### **4. Want Alternative Criteria for Demonstrating Control of Risk Factors**

Keywords: STD-01, Regulatory foundation, alternative control of risk factors, equivalent risk factors control

##### **Issue Description**

###### **Background**

None provided.

###### **Question/Problem**

Some local codes have adopted standards which control the risk factors but still differ from the FDA *Food Code*. A jurisdiction that has adopted 130F for hot holding may be adequately addressing the risk factor and controlling the public health concern, but would not meet the 135F requirement in the FDA *Food Code*. Another example is with hand washing - suppose the requirement has a hand washing provision but does not identify a time, such as 20 seconds. Does this meet the intent of the risk factor? We recommend a list of questions be developed for each major intervention/risk factor so a jurisdiction that has different language than the *Food Code* has guidance to determine if the intent of the *Code* section is met without compromising it.

###### **Rationale**

None provided.

##### **Response from Clearinghouse Workgroup (11-20-02)**

Standard 1 is very specific in using the model *Food Code* as the criteria for this Standard. Any attempt to try to interpret “adequate” control of risk factors using something other than the *Code* would be to invite debate on any number of issues without having a viable means of arriving at an authoritative final answer. The forum for debate and for establishing what is acceptable in the ‘community of practice’ is the Conference for Food Protection, which represents the entire food safety community. In the example given for hot holding of 130°F versus 135°F, the answer is very clear. The *Food Code* in the future will require 135°F for hot holding, so that anything less than that does not meet the intent of the *Code*; and, therefore, does not meet Standard 1.

The example of the omission of the 20-second time frame in the handwash requirement can be overcome in some cases. Given the amount of debate and attention that the handwash issue received in the CFP during its last two sessions, the *Food Code* and those interpreting it clearly intend that a 20-second minimum time be included as a part of the acceptable procedure. If the 20-second requirement is omitted from a jurisdiction’s adopted regulation language, but the jurisdiction establishes supplemental policies or standard operating procedures that enable it to carry out the intent of the *Code* language, then the Standard can be met.

The recommendation to develop a list of questions for each major intervention and risk factor and to provide alternative language for determining *Code* intent is not practical. Even to provide a list of potential questions would be a daunting task. Additionally, trying to provide alternative language that would meet the intent of the *Code* would only further confuse matters and would compromise the criteria for determining achievement of the Standard.

While developing a list of anticipated questions might not be practical, the Clearinghouse will continue to respond to questions as they are submitted by jurisdictions. It is hoped that this process for answering questions is beneficial in providing guidance to those of you who are conducting your self-assessments.

## 5. Compliance and Enforcement Code Sections

Keywords: STD-01, Regulatory foundation, compliance, enforcement, critical items, follow-up

### Issue Description

#### **Background**

Our jurisdiction has adopted the *Food Code*, and we are working diligently on our self-assessment process. We also have a very aggressive inspection and follow-up inspection schedule that requires a follow-up whenever a critical item is marked. Our problem is this, there are many items in the *Food Code* that are designated as ‘critical,’ and yet failure to comply is not likely to cause illness. An example is 2-401-11(B) – where an employee is drinking from an open cup. In our jurisdiction, an inspector’s marking this item requires a follow-up inspection. This is causing far too many follow-up inspections and consuming resources unnecessarily. We would like to change the designation in our regulation from a hard and fast ‘critical’ to ‘swing’ for about 28 items so that we can continue to accurately record all violations without triggering follow-up inspections for items that we judge to be non-critical and so that we can maintain a consistent re-inspection policy.

#### **Question/Problem**

If we change the critical item designations in our regulation, do we still meet Standard #1?

#### **Rationale**

We believe that we will still meet Standard #1. Our regulatory language is the same as the model *Food Code*, and we cannot find anything in the Standard that requires identical designations or conventions as the *Food Code*. The Standards, in general, focus on risk factors and interventions, which are not identical to ‘critical’ items.

### Response from Clearinghouse Workgroup Response (02-20-03 & Update 2011)

You make some valid points. The *Food Code* definition of a ‘critical item’ is “a provision of this Code that, if in noncompliance, is more likely than other violations to contribute to FOOD contamination, illness, or environmental health HAZARD.” The Standards definition of a ‘risk factor’ is “improper practices or procedures stated below which are most frequently identified by epidemiological investigation as a cause of foodborne illness or injury:

- improper holding temperature;
- inadequate cooking;
- contaminated equipment
- unsafe source; and
- poor personal hygiene”

*Food Code* ‘interventions,’ although they add somewhat to the above list, also overlap with risk factors. “Interventions are:

- management’s demonstration of knowledge;
- employee health controls;
- controlling hands as a vehicle of contamination;
- time/temperature parameters for controlling pathogens; and
- consumer advisory.”

So there exist two concepts that are not entirely in sync with one another. Critical items are not risk factors or interventions per se since their definition also includes food and environmental contamination.

You are correct in stating that there is nothing in Standard 1 which directly links to 'critical items.' One inference might be drawn in the Compliance and Enforcement chapter of the *Food Code*, in section 8-405.11, which is a requirement for part C of Standard 1. That section requires correction at the time of the inspection for critical violations of the *Code*. It might be argued that if you change items from 'fixed critical' to 'swing critical' then your regulation is no longer as stringent the *Code* since you would no longer be required to obtain immediate corrective action all *Food Code* critical items. It could be argued on the other side that this is an implementation issue and not a regulatory foundation issue. Section 8-405.11 is broader than the Standard 6 for Compliance and Enforcement which requires immediate corrective action of out of control risk factors and interventions.

The Clearinghouse Workgroup would hate to see you make changes in your critical item designations until the Conference for Food Protection reaches agreement on the changes that are necessary in the *Food Code* designations. There is wide disagreement on the critical items issue, with opinion ranging from 'make no changes' to 'eliminate the concept entirely.' The CFP Inspection Forms committee will in 2004 again tackle the issue of critical items in an attempt to reach consensus while incorporating either critical items or risk factors into their model form. If CFP makes a recommendation accepted by FDA, you could then accordingly make changes to your regulation and maintain uniformity with the national model.

A more immediate solution to your dilemma would be to make minor changes to your compliance and enforcement policy. To maintain your high standards in this area, you could continue to require on-site corrective action with documentation on the inspection form for all critical item violations; this would maintain conformance with 8-405-11. You could then impose the requirement for follow-up inspections only for out of control risk factors and interventions that contribute to foodborne illness. You would still meet Standard 6 for Compliance and Enforcement, provided the other criteria in that Standard are met, and you would eliminate the unnecessary follow-up to violations you feel do not warrant the resource expenditure.

This response is still a valid interpretation and suggested solution since the change in the ranking of provisions to Priority, Priority Foundation and Core.



## **6. Altering a code's or regulation's language through policy.**

Keywords: STD-01, regulatory foundation, altering language, changing the code by policy, policy, bare-hand contact, minimize bare-hand contact

### **Issue Description**

#### **Background**

None provided.

#### **Question/Problem**

If a jurisdiction adopts into their code, “minimize bare hand contact with ready-to-eat foods” and later issues an inter-agency policy requiring a change in the enforcement strategy to be identical with the Food Code (1999) prohibiting BHC with RTE foods unless otherwise approved, does the jurisdiction meet 3-301.11(b)?

#### **Rationale**

None provided.

### **Response from Clearinghouse Workgroup (9-15-04)**

This is similar to a question answered by the Clearinghouse in 02-20-02 (State Interpretation of When Otherwise Approved vs. intent of *Food Code*). Generally speaking, the judgment should be based on the language in the written code or regulation. Having said that, there are several things that should be considered by an auditor in making this judgment of stringency. An inter-agency policy may or may not be enforceable. If the policy is in writing and documentation from legal counsel in the jurisdiction is provided stating that the policy carries the same weight as regulation so that it carries the same enforceability by means of civil or criminal penalties, then it may be an acceptable means of meeting Standard 1. Some jurisdiction's issue interpretations of their codes that are considered by their legal counsel have the same weight as their code. In the instance where an interpretation or policy has been issued that is as stringent as the *1999 Food Code* and the jurisdiction's legal counsel supports the interpretation in writing as enforceable, then it would meet the Standard. Whether it is in the form of a policy or interpretation, the key resides in the jurisdiction's ability to ensure compliance equal to its ability to ensure compliance with code or regulation. The status of an 'inter-agency policy' would need to be assessed by the legal counsel serving each of the various agencies involved if they are not one and the same.

It should also be noted that a change to Standard 1 was approved at the 2004 Conference for Food Protection allowing the Standard to be met with 9 of the 11 risk factors and interventions until the third audit.

**7. Does omitting one provision of the Food Code count against a jurisdiction in more than one risk factor or intervention section in Standard 1?**

Keywords: STD-01, regulatory foundation, food code provision, risk factor, food code intervention, agreement with the code

**Issue Description**

**Background**

None provided.

**Question/Problem**

What percentage of food code sections have to agree verbatim? Can a double debit exist? (For example, “demonstration of knowledge” also includes the issue of no bare hand contact which is in a separate risk factor/intervention section in the Code as organized in Appendix A of Standard 1.)

(Similar to question above) In the case of a jurisdiction in which you look only at 11 criteria for Person In Charge instead of 12, is there a chance for double debit? (For example, if there is no ‘no bare hand contact’ provision, would you also debit Demonstration of Knowledge?) If you do not double debit, can this be explained better in the Standard/Audit Manual?

**Rationale**

None provided.

**Response from Clearinghouse Work Group (2-16-05)**

There is no requirement for regulatory foundation language to agree verbatim with the *Food Code*. The Standard requires “provisions that are at least as stringent as the public health interventions and the provisions that control risk factors known to contribute to foodborne illness contained in the Food Code.

It was never the intention of any of the Standards to create a situation for a ‘double debit.’ A ‘double debit’ is defined as a penalty being assessed in more than one location for the same circumstance (usually on an inspection form, although the concept is applicable particularly in Standard 1).

In Standard 1, there are four Code sections listed as being requirements for the intervention titled, “Demonstration of Knowledge.” The section in question is 2-103.11(K), which requires the person in charge to ensure that employees are preventing cross-contamination of ready-to-eat food with bare hands by properly using suitable utensils such as deli tissue, spatulas, tongs, single-use gloves, or dispensing equipment. If a jurisdiction has not included section 3-301.11(B), which is the primary requirement for no bare hands contact, then obviously 2-103.11(K) would not be included either. In order to avoid the situation of a ‘double debit,’ the Clearinghouse agrees that the ‘debit’ should be marked in the location that represents the source of the omission or the root cause of the situation. In this case the risk factor/intervention that is missing is the element of ‘protection from contamination’ that is represented by the bare hands contact issue, or section 3-301.11(B). If all other required aspects of ‘demonstration of knowledge’ are present so that a person in charge is held

accountable to know the rules/regulations under which they operate, then the demonstration of knowledge element is met.

## **8. Adequacy of Consumer Advisory.**

Keywords: STD-01, consumer advisory, shellfish advisory, partial consumer advisory

### **Issue Description**

#### **Background**

None provided.

#### **Question/Problem**

If a jurisdiction has a Consumer Advisory, but only for shellfish, could they report compliance with 3-603.11? If not, they won't meet the standard only because they don't have Consumer Advisory?

#### **Rationale**

None provided.

### **Response from Clearinghouse Work Group (2-16-05 - Updated 2011)**

Under 3-603.11, it is clear that the language includes such foods as beef, eggs, fish, lamb, milk, pork, poultry or shellfish that is raw, undercooked, or not otherwise processed to eliminate pathogens when offered in a ready-to-eat form. These foods have all been associated with foodborne illness in a raw or undercooked state. Standard 1 requires provisions at least as stringent as the 1999 Food Code (or later – see 2011 version of Standard 1), so a provision that requires an advisory for shellfish only, does not meet the foodborne illness intervention for Consumer Advisory in that it would not provide the same protection for consumers.

**9. A 7-day versus a 15-day response for request of an administrative hearing.**

Keywords: STD-01, regulatory foundation, response, administrative hearing, hearing, time frame

**Issue Description**

**Background**

None provided.

**Question/Problem**

In section 8-905.10 of the FDA *Food Code*, it requires that a person requesting a hearing in response to an administrative remedy to file that request within 7 calendar days after service. Our state statute that contains what we consider to be the equivalent administrative remedy requires the person requesting the hearing to file that request within 15 days of service. We believe this requirement is equivalent, and the issue of stringency is not at issue.

**Rationale:**

Our state and local laws address administrative and judicial remedies and provide for due process for a wide range of food establishment compliance and enforcement issues and activities. While our 15-day time period for response is not strictly the same as the 7 days contained in the corresponding FDA *Food Code* citation, we believe this meets the intent of the Food Code language. The exact length of the period for response is not a material difference.

**Response from Clearinghouse Work Group (11-15-06)**

The Clearinghouse agrees that a 15-day time period to request a hearing in response to an administrative remedy meets the intent of Standard 1, Food Code, 8-905.10. The purpose of the Standard 1 criterion is to ensure that there is due process, that the establishment is advised of the right of appeal and the time frames for appeal.

## 10. Details required in a hearing request

Keywords: STD-01, regulatory foundation, response, administrative hearing, hearing, time frame, details

### Issue Description

#### **Background**

None provided.

#### **Question/Problem**

During a recent audit of Standard 1, an issue arose concerning the comparison between our code and the *FDA Food Code*. Section 8-905.20 requires that the individual responding to a notice of hearing or requesting a hearing make a request in writing and that the request includes the content specified 8-905.20. Standard 1 requires compliance and enforcement ‘at least as stringent as’ the selected provision of the FDA Food Code and Annex 1 of the Food Code. It is not completely clear as to what is meant by ‘at least as stringent’ with respect to the compliance and enforcement.

Under our State law, whenever a party is subject to or impacted by a local public health or environmental services department action, such as through the issuance of a Notice of Violation & Demand for Compliance, Cease & Desist Order, Compliance Order, permit or license denial or other similar compliance and enforcement action, the agency is required by law and as a matter of due process to notify the impacted party of the right to a hearing on the matter. At that point the impacted party can request a hearing or not. Should the impacted party request a hearing, State laws dictate that the request for hearing be made in writing within a specified time period. Other than making the request in writing within the timeframe allowed, there are no other requirements that correspond to those found in 8-905.20.

It seems somewhat incongruous that while there is nothing in the *Food Code* that mandates an individual respond to a notice of hearing, should one elect to do so, then the requirements contained in 8-905.20 kick in. Under the *Food Code* provisions, should a respondent not include all the required particulars in a request, what would be the result? Would a hearing be denied?

#### **Rationale**

We maintain that just because we don’t require an individual in a request for hearing to provide a statement of defense, mitigation, denial, or explanation concerning each allegation of fact contained in an original compliance and enforcement action, that doesn’t make our hearing process any less effective or efficient. All of the items addressed in 8-805.20 will ultimately come to light as part of the hearing process. It is the sequence and manner in which they come to light that differs from the *Food Code*. We are pretty much bound to following the process as it is laid out in our statute. The roadmap provided by State statute to jurisdictions in our State specifies a slightly different route from the route the FDA Food Code takes in the area of hearings administration. In the end, however, we arrive at the same destination, and that is our ability to achieve compliance where compliance cannot be achieved by other means. The important thing in our view is 1) the local jurisdiction has a

compliance and enforcement remedy that achieves the objective of the corresponding *FDA Food Code* provision with respect to obtaining compliance and 2) the remedy provides the respondent with an avenue of redress that recognizes due process under the law. To the extent that our statutes and codes meet this criteria with respect to 8-805.20, we believe that we are 'at least as stringent as' the *FDA Food Code* in the area of hearings administration.

**Response from Clearinghouse Work Group (1-17-07)**

Your question caused quite a robust discussion among the Clearinghouse Work Group members. The group members have difficulty understanding how your agency as well as the respondent can adequately prepare for the hearing without the kinds of information outlined in the provisions of 8-905.20. However, the group concluded that as long as you can demonstrate that you are producing cases, have hearing outcomes, and achieving the end compliance result, you are meeting your legal requirements and meet the intent of the Food Code language.

The provisions in the *Food Code Annex 1* are intended for a regulatory authority's use in reviewing its statutory authority to be sure it covers the necessary constitutional protections. As a general recommendation, you may want to consider the development of an 'election of rights' packet to be mailed to persons receiving an adverse administrative determination. The packet could include instructions regarding the kinds of information to be provided along with the request for hearing. This could be done as an internal operating procedure without impacting the State statute and would provide help both you and the respondent better prepare for the hearing.

## 11. Residential Kitchens used for Processing of Goods Sold at Retail.

Keywords: STD-01, residential kitchens, home cooking, home processing, home kitchens

### Issue Description

#### **Background**

A jurisdiction currently licenses and inspects residential kitchens that prepare and sell foods at retail. They are currently in the process of updating their regulations and would like to explore various options to find an appropriate means of allowing preparation in residential kitchens that would allow them to meet Standard 1.

#### **Question/Problem**

The Food Code currently prohibits ‘home-cooked’ foods under paragraph 3-201.11(B). See also the definition of a ‘food establishment.’ Is there a situation where a jurisdiction can regulate processing of food for sale at retail in residential kitchens that would allow the jurisdiction to meet Standard 1?

#### **Rationale**

None provided.

### Response from Clearinghouse Work Group (01-20-10)

The wording in paragraph 3-201.11 (B) states “FOOD prepared in a private home may not be used or offered for human consumption in a FOOD ESTABLISHMENT.” Next, we must look at the exemptions to the definition of a FOOD ESTABLISHMENT.

Specifically, in Section 1-201.10 FOOD ESTABLISHMENT (3), the definition of a FOOD ESTABLISHMENT does not include:

- (a) *An establishment that offers only prePACKAGED FOODS that are not TIME/TEMPERATURE CONTROL FOR SAFETY FOODS;*
- (b) *A produce stand that only offers whole, uncut fresh fruits and vegetables;*
- (c) *A FOOD PROCESSING PLANT, including those that are located on the PREMISES of a FOOD ESTABLISHMENT*
- (d) *A kitchen in a private home if only FOOD that is not TIME/TEMPERATURE CONTROL FOR SAFETY FOOD is prepared for sale or service at a function such as a religious or charitable organization’s bake sale if allowed by LAW and if the CONSUMER is informed by a clearly visible placard at the sales or service location that the FOOD is prepared in a kitchen that is not subject to regulation and inspection by the REGULATORY AUTHORITY;*
- (e) *An area where FOOD that is prepared as specified in Subparagraph (3)(d) of this definition is sold or offered for human consumption;*
- (f) *A kitchen in a private home, such as a small family day-care provider; or a bed-and-breakfast operation that prepares and offers FOOD to guests if the home is owner occupied, the number of available guest bedrooms does not exceed 6, breakfast is the only meal offered, the number of guests served does not exceed 18, and THE CONSUMER is informed by statements contained in published advertisements, mailed brochures, and placards posted at the registration area*



*that the FOOD is prepared in a kitchen that is not regulated and inspected by the REGULATORY AUTHORITY; OR*  
*(g) A private home that receives catered or home-delivered FOOD.*

Each of these paragraphs provides an exemption to the definition of a FOOD ESTABLISHMENT and, therefore, would exempt these situations from the regulations that apply to FOOD ESTABLISHMENTS.

Next, we must look at the relevant language of what is included in the definition of a FOOD ESTABLISHMENT. Specifically, any “operation that stores, prepares, packages, serves, vends, or otherwise provides FOOD for human consumption . . ., and relinquishes possession of FOOD to a CONSUMER directly, or indirectly through a delivery service . . .” is included in the definition of a FOOD ESTABLISHMENT. This means that any operation that prepares food for direct sale to consumers such as at a farmers market or over the internet is to be regulated as a FOOD ESTABLISHMENT.

In summary, only jurisdictions which allow the sale of foods from residential kitchens that meet one of the specific exemptions allowed under the *Food Code* in the definition of “FOOD ESTABLISHMENT” in Section 1-201.10, FOOD ESTABLISHMENT (3) can meet Standard 1.

## **12. Regulatory Jurisdiction over Highly Susceptible Populations**

Keywords: STD-01, Highly Susceptible Population Establishments

### **Issue Description**

#### **Background**

The Oregon Department of Agriculture (ODA) is responsible for inspections at retail food stores and has their own code. The Oregon Department of Health and the local health departments conduct inspections in all other food service operations such as restaurants, bed and breakfast operations and highly susceptible population facilities using the related Food Code provisions. Because ODA has no regulatory authority in highly susceptible population facilities, the corresponding FDA Food Code Sections were not included in their code because they cannot enforce them and it could be confusing to their retail food store operations. However the Standard 1 Self-Assessment requires that to fully meet Standard 1 a jurisdiction must have a corresponding requirement to all the Food Code Interventions and Risk Factor Control Measures, which includes Highly Susceptible Populations. In this case, the responsibility and regulatory authority for HSP is held by another state agency yet there is no option for a "not applicable" designation. Does the jurisdiction need to include unenforceable code language to fully meet the Standard or can they indicate 'Not Applicable' with an explanation of the responsibility of their sister agency in the state?

#### **Question/Problem**

Standard 1 Question: If a jurisdiction does not have regulatory authority over highly susceptible population facilities and therefore does not include the corresponding FDA Food Code sections in their own code, can they indicate "not applicable" on the self-assessment for Standard 1 for these sections?

#### **Rationale**

None provided.

### **Response from Clearinghouse Workgroup (10-18-12)**

The Food Code recognizes that more stringent preventative controls are necessary to prevent foodborne illness in facilities that serve a Highly Susceptible Population (HSP). Therefore certain parts of the Food Code specify more stringent controls that are only applicable to food establishments that serve an HSP such as various subparagraphs in Section 2-201.11 and the entirety of Section 3-801.11. In the case where a state's legislative body provides regulatory authority to adopt and enforce regulations pertaining to HSP establishments to a different food regulatory agency, the agency without regulatory authority for HSP establishments does not need to adopt Food Code provisions that pertain only to facilities for which it lacks regulatory authority.

The intent of Standard 1 is to ensure a sound regulatory foundation which includes stricter requirements for establishments that serve an HSP. In this situation, the regulations that apply to HSP establishments exist but another State Agency has responsibility. The Program Standards Clearinghouse (Clearinghouse) does not think the agency without regulatory authority for HSP establishments should be prevented from meeting Standard 1 because they have no authority over HSP establishments. To address this situation in the self-assessment

process, a self-assessor will need to note the situation in the Self-Assessment Worksheet Part I. The worksheet, Section 11, requires the assessor answer either, Yes – Full Intent is Met, Partial Compliance, and No – Is Not Met. The Clearinghouse recommends the self-assessor check the box indicating “YES - Full Intent Is Met” in the section and note in the “Jurisdiction’s Corresponding Code Section, Rule, Etc.” column, the name of the Agency that has HSP establishment responsibility plus the corresponding Agency provisions. During the verification audit, the auditor should select another randomly selected number if line 91 of the worksheet is randomly selected.

# STANDARD 2

## Trained Regulatory Staff

This Standard applies to the essential elements of a training program for regulatory staff.

1. **Number of Joint Training Inspections Required in Standard #2**  
Keywords: STD-02, Trained regulatory staff, joint training inspection, number of training inspections
2. **Recognized Credentials and Their Relationship to Standard 2 Curriculum**  
Keywords: STD-02, Trained regulatory staff, equivalent credentials, Registered Environmental Health Specialist certificate
3. **Determining Training Component Equivalency**  
Keywords: STD-02, Trained Regulatory Staff, training plan, equivalent time, equivalent training, qualifying training, qualifying course
4. **Documents that Serve in Lieu of Training Certificates**  
Keywords: STD-02, Trained regulatory staff, documentation, training certificates, training documentation, training logs, alternatives to certificates
5. **Who Must Meet Standard 2**  
Keywords: STD-02, Trained regulatory staff, plan review personnel, inspection staff, who must be trained, training
6. **Code Criteria for Standardization**  
Keywords: STD-02, Trained regulatory staff, code for standardization, prevailing statutes, regulations, or ordinances, standardization process
7. **Criteria for the Education/Training Requirements**  
Keywords: STD-02, trained regulatory staff, curriculum design, course equivalency, curriculum, course content
8. **Proof of Training for Long-tenured Employees**  
Keywords: STD-02, trained regulatory staff, proof of training, long-term employees, documentation of training
9. **Age of training records**  
Keywords: STD-02, trained regulatory staff, documentation of training, age of training records, records, documentation, valid training
10. **New employee vs. new to the food program**  
Keywords: STD-02, trained regulatory staff, new employees, new to food program

11. **Kinds of continuing education that qualifies**  
Keywords: STD-02, trained regulatory staff, continuing education
12. **Standardization of ‘old’ employees**  
Keywords: STD-02, trained regulatory staff, old employees, standardization, existing staff, current staff
13. **Dilution of field standardization**  
Keywords: STD-02, trained regulatory staff, standardization, dilution, cascade
14. **Is there a requirement for a ‘roster’ of employees including hire date?**  
Keywords: STD-02, trained regulatory staff, roster, documentation, list, Appendix B
15. **Mutual standardization by two parties in different jurisdictions**  
Keywords: STD-02, number of inspections, cross standardization, mutual standardization
16. **Field Training for a Food Safety Inspection Officer (FSIO)**  
Keywords: STD-02, FSIO, Risk Category 1 Food Establishments
17. **Standardization of a Training Standard**  
Keywords: STD-02, Training Standard, Standardization

## **1. Number of Joint Training Inspections Required in Standard 2**

Keywords: STD-02, Trained regulatory staff, joint training inspection, number of training inspections

### **Issue Description**

#### **Background**

The criteria in Standard #2 require 25 joint training inspections with a trainer who has successfully completed Steps 1-3. After the joint training inspections, the trainee must complete 25 independent inspections before beginning the standardization process.

#### **Question/Problem**

Can the requirement for 25 joint training inspections be waived for candidates who have prior experience in the field conducting field inspections? Similarly, can the requirement for 25 independent inspections be waived for candidates who have prior experience?

#### **Rationale**

We believe that Standard #2, as written, was intended to serve as a template for new employees entering the food program. Many of our field personnel have conducted hundreds of inspections independently. We believe that joint field training inspections of these candidates are an inefficient use of time. For experienced candidates, we believe the 25 joint training inspections and 25 independent inspections can be waived and an assessment of their inspection competency be made through the standardization component. If candidates with experience do not successfully complete their standardization, then a corrective action plan, that may include joint field training exercises, could be developed and implemented.

### **Response from Clearinghouse Work Group (02-20-02 - Updated 2011)**

The 25 joint training inspections and the 25 independent inspections were intended for new employees or employees new to the food safety program. The joint inspections and independent inspections are an important component of a comprehensive training program that prepares Food Safety Inspection Officers (FSIO's) for their work in the field. The inspections provide an opportunity to learn and apply the jurisdictions regulations, policies, and procedures while conducting field work, as well as an opportunity to gain experience working with, and communicating with, regulated establishments. Additionally, the joint inspections and independent inspections help prepare the FSIO for successful completion of standardization.

In situations where an incoming employee is an experienced Food Safety Inspection Officer, the retail food regulatory program may decide that the joint inspections are not necessary. In order to accommodate an experienced FSIO, the supervisor can include a simple statement or affidavit in the employee's training file explaining their background or experience that justifies a waiver from conducting 25 joint inspections.

In situations where the joint inspection requirement has been waived due to prior experience, waiving the requirement for 25 independent inspections may also be appropriate. In order to accommodate this, the supervisor can include a simple statement or affidavit in the

employee's training file explaining their background or experience that justifies a waiver from conducting 25 independent inspections.

When considering whether to waive the requirement for joint inspections and independent inspections, consideration should be given to the following:

1. Quality and quantity of the prior experience;
2. Did the prior experience occur with a regulatory authority that:
  - a. Uses different regulations?
  - b. Has different policies and procedures?
  - c. Has oversight for different types of facilities?
3. The jurisdiction's ability to implement a follow-up action plan if the Standardization process reveals deficiencies or if the Standard terminates the exercise because the level of agreement will not be reached.

In situations where the joint inspection number is reduced from the required 25, a lower number of joint field training inspections can be acceptable for that particular FSIO provided there is written documentation, such as the completion of the CFP Field Training Plan to support the exception.

## **2. Recognized Credentials and Their Relationship to Standard 2 Curriculum**

Keywords: STD-02, Trained regulatory staff, equivalent credentials, Registered Environmental Health Specialist certificate

### **Issue Description**

#### **Background**

The criteria in Standard #2 require a candidate to satisfactorily complete training that includes the following curriculum components:

- prevailing statutes, regulations, ordinances;
- public health principles;
- communication skills;
- microbiology;
- epidemiology; and
- HACCP

#### **Question/Problem**

Does a candidate, who has obtained certification as a Registered Environmental Health Specialist, through a recognized national organization (such as NEHA) meet the intent of this Standard?

#### **Rationale**

We believe that having a credential as a Registered Environmental Health Specialist, does not, in and of itself, meet the intent of the Standard. We believe that the intent of the Standard is to ensure that the candidate has specific training in each of the describe disciplines. Credentials as a Registered Environmental Health Specialist, though encouraged, may not include curriculum specific to the disciplines described above.

### **Response from Clearinghouse Work Group (02-20-02 – Updated 2011)**

The Work Group agrees that a credential cannot be taken as prima fascia evidence that the training requirements are met. Specific curriculum components must be examined in order to make a determination of whether the Standard or elements of the Standard have been met. Criteria for determining course equivalency with the ORA-U courses were added to later versions of the Standards. Self-assessors and auditors should consult the latest version of Standard 2.



### **3. Determining Training Component Equivalency**

Keywords: STD-02, Trained Regulatory Staff, training plan, equivalent time, equivalent training, qualifying training, qualifying course

#### **Issue Description**

##### **Background**

The criteria in Standard #2 require a candidate to satisfactorily complete training that includes the following components:

- prevailing statutes, regulations, ordinances;
- public health principles;
- communication skills;
- microbiology;
- epidemiology; and
- HACCP

The Standard, however, does not specifically prescribe the amount of contact time a candidate needs to fulfill the training requirements in any of the disciplines.

##### **Question/Problem**

Is attending a one-hour presentation on food microbiology at a national conference sufficient to meet this requirement? How is one to equate the quality and length of training for equivalency? Besides documentation in the form of certificates and documentation of attendance, what criteria are to be used to demonstrate a candidate's knowledge of the disciplines? Are there specific contact hours that need to be associated with each of the disciplines?

##### **Rationale**

None provided.

#### **Response from Clearinghouse Work Group (Updated 2011)**

The 2009 and later versions of the Standards provide criteria for determining equivalency with the FDA ORA-U required courses. See Standard 2

#### **4. Documents that Serve in Lieu of Training Certificates**

Keywords: STD-02, Trained regulatory staff, documentation, training certificates, training documentation, training logs, alternatives to certificates

##### **Issue Description**

###### **Background**

I serve as the staff development and training officer for a large county health district. I am responsible for keeping records of staff attendance at training workshops and courses. Several of my staff are having difficulty locating their certificates related to their attendance at FDA State Training Branch courses. Some of these course were satellite broadcasts, other were classroom sessions. As their training officer, I have kept an internal log of their attendance at these and other courses.

###### **Question/Problem**

Since my position responsibilities include maintenance and verification of attendance at training workshops and courses, can my Department records be used to verify staff's attendance at these training workshops and courses or must they be able to produce the actual FDA certificate from the course?

###### **Rationale**

None provided.

##### **Response from Clearinghouse Work Group (3-20-02)**

Department records can be used to verify training attendance under certain circumstances. While certificates issued by course sponsors are the ideal proof of attendance, other official documentation can serve as satisfactory verification of attendance. The key to a document's acceptability is that someone with responsibility keeps the records according to an established protocol. Someone such as yourself who is the training officer, or a supervisor who has first-hand knowledge of the employees' attendance at the sessions, can serve as the recordkeeper. By established protocol, we mean logs/records that are completed based on on-site sign-in sheets, have information validated from a certificate at the time of issuance, or other accurate verification of actual attendance. The National Environmental Health Association is keeping automated attendance records for their courses; and in the future, FDA will offer an individual transcript of courses taken through ORA U. These kinds of official automated records kept by course sponsors are acceptable also. Keep in mind when establishing a records system that a Standards Auditor must be able to verify that the various elements of Standard 2 have been accomplished for each applicable employee and within timeframes for new or reassigned employees. Now that documentation of training efforts is so important to regulators, it is more important than ever for employees to retain course certificates as their personal proof of attendance should questions arise, and they should be encouraged to do so regardless of other available records systems.

## **5. Who Must Meet Standard 2?**

Keywords: STD-02, Trained regulatory staff, plan review personnel, inspection staff, who must be trained, training

### **Issue Description**

#### **Background**

In our department, some of the Environmental Health Specialists have been assigned to the plan review program. Their responsibilities include review of plans for both new construction and remodeling of existing facilities. In the course of their duties they conduct plumbing inspections, rough-in equipment inspections, pre-opening inspections and other construction related verifications. Their responsibilities do NOT include operational inspections to assess a facilities adherence to Food Code critical limits pertaining to food storage, preparation and processes.

#### **Question/Problem**

Are the Environmental Health Specialists (EHS) assigned specifically to the plan review program, who do not conduct regular inspections, required to meet the standardization criteria in Standard #2?

#### **Rationale**

None provided.

### **Response from Clearinghouse Work Group (3-20-02)**

The Work Group gives a cautious, qualified "no" when answering whether EHS personnel assigned to plan review only are required to meet the standardization criteria in Standard 2. If a person's duties are strictly limited to construction inspections only, then standardization is not wholly job-related and is not required. In this situation, these positions have a similar relationship to the program as do administrators and other support personnel and take on a function similar to that of a building inspector. There is some concern expressed, though, that without the on-going (maintenance) responsibilities in operations required by the standardization procedures that these inspectors may lose familiarity with developing trends in food operations and, therefore, lose effectiveness in design and equipment evaluation critical to new and remodeled construction.

If the plan review personnel in question conduct inspections of operating facilities even on a limited basis, as back up to other field personnel, in crisis situations, for compliance or other reasons, or if they rotate assignments with inspectional personnel, then they must meet the standardization criteria in Standard 2.

## 6. Code Criteria for Standardization

Keywords: STD-02, Trained regulatory staff, code for standardization, prevailing statutes, regulations, or ordinances, standardization process

### Issue Description

#### **Background**

None provided.

#### **Question/Problem**

Is there flexibility for a Jurisdiction to use its own Food Code where the Standard and the Candidate are from the same Jurisdiction?

#### **Recommendation**

Recommend that the Clearinghouse provide the option for standardization to a jurisdictions own food code, provided that the jurisdiction's food code meets the criteria in Standard #1 - Regulatory Foundation.

### Response from Clearinghouse Work Group (5-20-02; Updated 2011)

This question points out a possible misunderstanding of this portion of Standard 2. It is the intention of Standard 2 that standardization exercises within a jurisdiction can be based upon the jurisdiction's own regulation or ordinance,

The specific goal of Standard 2 is to ensure that personnel are trained and prepared to competently conduct inspections within their jurisdiction. This is demonstrated by the curriculum component number 1 of Standard 2 that includes "prevailing statutes, regulations, ordinances; . . ." meaning those prevailing in the jurisdiction.

It should be noted that it is possible and highly beneficial to use the *FDA Food Code*, standardization forms and procedures even when a jurisdiction has adopted modifications to the *Food Code*. Differences between a local/state Code and the *FDA Food Code* can be noted and discussed during the exercises, and thereby enhance the knowledge and understanding of the candidate. For example, it is valuable for a candidate to assess the foods offered for sale in a facility and to make a determination of whether or not the facility would be required under the *FDA Food Code* to post a 'Consumer Advisory' whether or not the jurisdiction has adopted that requirement. The value derived is an increased awareness of the foods that may pose a particular risk to some individuals. Additionally, use of the FDA standardization form ensures a broad knowledge of the regulations that might not be tested using a condensed inspection form format.

One further advantage exists in using the "FDA Procedures for Standardization and Certification of Retail Food Inspection/Training Officers" and its accompanying forms verbatim. The scoring and assessment tools presented in the 'FDA Procedures' can be used without modification. The scoring and assessment tools are specifically tied to the standardization inspection form and other assessment forms that are a part of the FDA procedures involving 8 joint inspections.

Jurisdictions that modify the limits of the standardization process by reducing the minimum number of inspections from 8 to 4 are cautioned that a redesign of the scoring assessment of the candidates' performance on the field inspections is required. This sometimes proves to be a very difficult task. A jurisdiction must consider both the food safety expertise of its staff, as well as the availability of personnel skilled in statistical analysis before it decides to modify the minimum number of standardization inspections. The jurisdiction's standardization procedures need to reflect a credible process and the scoring assessment should facilitate consistent evaluation of all candidates.

## **7. Criteria for the Education and Training Requirements**

Keywords: STD-02, trained regulatory staff, curriculum design, course equivalency, curriculum, course content

### **Issue Description**

#### **Background**

None provided.

#### **Question/Problem**

Standard 2 states that food safety inspection officers must complete pre- and post-coursework before Standardization. Are there different methods to satisfy this criterion?

#### **Recommendation**

None provided.

### **Response from Clearinghouse Work Group (Updated 2011)**

Standard 2 provides two options for meeting the training curriculum

1. Successful completion of FDA ORA U courses specified in the Standard and provided in documents that accompany the Standard. The course objectives are provided on ORA U's web site; or
2. Completion of courses deemed by the jurisdiction's supervisor or training officer to be equivalent by:
  - a. Demonstration that it meets at least 80% of the learning objectives of the comparable ORA U course, and
  - b. Passing either of the CPFS exam offered by NEHA, A state-sponsored food safety exam developed using methods that are psychometrically valid and reliable, a food manager certification exam provided by an ANSI/CFP accredited organization, or a Registered Environmental Health Specialist or Registered Sanitarian exam.

## **8. Proof of Training for Long-tenured employees**

Keywords: STD-02, trained regulatory staff, proof of training, long-term employees, documentation of training

### **Issue Description**

#### **Background**

None provided.

#### **Question/Problem**

The Clearinghouse stated in a previous response that the time frames for training and fieldwork were designed with new employees in mind. We have many employees who have been performing the job in a competent manner for many years. Since we made no prior attempt to keep department records of all their training, we have a lot of missing documentation for these experienced employees. Can we have each of these long-time employees sign an affidavit for their training file stating the training courses taken in the past? We believe this affidavit, along with successful standardization, and continuing education from this point forward should be sufficient to meet the intent of the Standard for experienced employees.

#### **Rationale**

We believe that the intent of Standard 2 is to ensure that employees receive timely and appropriate training in order to conduct inspections in a knowledgeable and competent manner. It would be a waste of resources to send experienced employees to basic training courses that they have already attended simply because they cannot produce documents, which at the time of their original attendance were not required to be kept. Standardization, the quality assurance program, and continuing education requirements should detect any work performance problems that can then be addressed through performance improvement plans. An affidavit of attendance from the employee should suffice. As an alternative, the Standard might need to 'grandfather' employees hired before 2002.

### **Response from Clearinghouse Work Group (08-21-02 – Updated 2011)**

The Work Group agrees that the intent of Standard 2 is to ensure that employees receive timely and appropriate training in order to conduct inspections in a knowledgeable and competent manner. The requirements for standardization in Standard 2 and the Quality Assurance element in Standard 4 are designed to detect performance problems and allow for correction. Given these things and the fact that jurisdictions were not required to retain evidence of training for individual employees in the past, some accommodation for employees who have previously taken the training but can no longer produce the documents should be made. We agree that a sworn affidavit from the employee, placed in the file, regarding training that has already been completed will suffice.

The proposal for 'grandfathering' certain employees from the requirement would need to be submitted as a proposed change to the Standard through the CFP. Grandfathering, however, suggests an exemption from the requirement of the Standard, and the Work Group expressed strong opposition to exempting any employee from the requirements. All employees, no

matter how much field experience they have, must be held to the basic training and education requirements.

More experienced employees who fail to meet the Standardization and quality assurance elements of Standard 2 should receive an assessment of their performance using the guidance provided in the CFP Field Training Manual which was added in 2009. This assessment would give guidance regarding additional training needed by these employees.



## **9. Age of Training Records**

Keywords: STD-02, trained regulatory staff, documentation of training, age of training records, records, documentation, valid training

### **Issue Description**

#### **Background**

None provided.

#### **Question/Problem**

How old can training records be? If the past training occurred 25 years ago, is that training still valid?

#### **Rationale**

None provided.

### **Response from Clearinghouse Work Group (02-16-05)**

The Standard does not place an age limit to qualified training, so training in the curricula areas obtained 25 years ago is still valid for purposes of meeting the Standard. The purpose of the continuing education requirement is to aid food regulatory personnel in staying current with newer developments related to job performance in food areas. Original training plus continuing education units help ensure that staff has the knowledge and skills to perform their inspection functions.

## **10. New employee vs. New to the food program**

Keywords: STD-02, trained regulatory staff, new employees, new to food program

### **Issue Description**

#### **Background**

None provided.

#### **Question/Problem**

Can you clarify New Employee versus New To Food Program?

#### **Rationale**

None provided.

### **Response from Clearinghouse Work Group (02-16-05)**

New employee vs. new to food program: The phrase is intended to include any employee who has not previously worked in the retail food inspection area for your jurisdiction. A new employee would include any employee newly hired from outside the jurisdiction. If the employee comes from another jurisdiction where he or she worked in the food program area and brings his/her proof-of-training records or is able to obtain and provide those, then those records can be used to meet the requirement if the training applies. Training on certain topics such as 'prevailing statutes, regulations and ordinances' may meet the requirements if the employee is coming from a jurisdiction operating under the same statutes, regulations, etc. The new employee may require new training or additional training if the employee is coming from a jurisdiction with very different statutes, regulations, etc. 'Employees newly assigned to the food program' is intended to cover employees who may already work within the jurisdiction, but in a program area other than food. No matter the longevity of the employee within the jurisdiction, training in the required topic areas must be provided if the employee is newly assigned to the food area and has no documentation of having previously received the required training.

## **11. Kinds of continuing education that qualifies**

Keywords: STD-02, trained regulatory staff, continuing education

### **Issue Description**

#### **Background**

None provided.

#### **Question/Problem**

The Standard doesn't stipulate all the subject areas that qualify as continuing education. Can qualifying training include workplace violence, Spanish language, sewage control, wastewater training, etc. that may relate to job performance but not specifically food related? Why not include the RS training as acceptable?

#### **Rationale**

None provided.

### **Response from Clearinghouse Work Group (02-16-05)**

The Standard gives examples of four types of qualifying continuing education: 1) regional seminars/technical conferences, 2) Professional symposiums/college courses, 3) workshops, 4) food-related training provided by government agencies. Although the language could be clearer, the types listed imply food-related topics. The Standard does not address other kinds of training. The purpose of the Standard is not to make well-rounded employees but rather to ensure that staff has the skills and knowledge to conduct quality food inspections. All the Standards relate to the food program specifically; therefore, the Clearinghouse agrees that other types of training, while beneficial, do not qualify toward meeting the Standard.

The question of Register Sanitarian credentials and other certificate conferring programs such as the Registered Environmental Health Specialist was addressed in an earlier Clearinghouse response (02-20-03). Credentials cannot be taken as prima facie evidence that the training requirements have been met. Individual curriculum components must be examined, just as they would be for a college degree program, in order to make a determination as to which, if any, of the training elements of the Standard have been met.

The candidate qualifies for one contact hour of continuing education for each clock hour of participation in any of the following nine activities that are related specifically to food safety or food inspectional work:

1. Attendance at FDA Regional seminars / technical conferences;
2. Professional symposiums / college courses;
3. Food-related training provided by government agencies (e.g., USDA, State, local);
4. Food safety related conferences and workshops; and
5. Distance learning opportunities that pertain to food safety, such as:
  - a. Web-based or online training courses (e.g., additional food safety courses offered though ORA U, industry associations, universities); and
  - b. Satellite Broadcasts.

A maximum of ten (10) contact hours may be accrued from the following activities:

6. Delivering presentations at professional conferences;
7. Providing classroom and/or field training to newly hired FSIOs, or being a course instructor in food safety; or
8. Publishing an original article in a peer-reviewed professional or trade association journal/periodical.

Contact hours for a specified presentation, course, or training activity will be recognized only one time within a 3-year continuing education period.

NOTE: Time needed to prepare an original presentation, course, or article may be included as part of the continuing education hours. If the FSIO delivers a presentation or course that has been previously prepared, only the actual time of the presentation may be considered for continuing education credit.

A maximum of four (4) contact hours may be accrued for:

9. Reading technical publications related to food safety.

Documentation must accompany each activity submitted for continuing education credit. Examples of acceptable documentation include:

- certificates of completion indicating the course date(s) and number of hours attended or CE credits granted;
- transcripts from a college or university;
- a letter from the administrator of the continuing education program attended;
- a copy of the peer-reviewed article or presentation made at a professional conference; or
- documentation to verify technical publications related to food safety have been read including completion of self-assessment quizzes that accompany journal articles, written summaries of key points/findings presented in technical publications, and/or written book reports.

## **12. Standardization of ‘old’ employees**

Keywords: STD-02, trained regulatory staff, old employees, standardization, existing staff, current staff

### **Issue Description**

#### **Background**

None provided.

#### **Question/Problem**

The Standard requires completion of standardization procedure within 18 months – is this only for new hires? If standardization took three years, including some “old” employees, would the jurisdiction not meet the standard?

#### **Rationale**

None provided.

### **Response from Clearinghouse Work Group (02-16-05, updated 07-31-13)**

For new hires and employees assigned to the food program on or after the date of program enrollment: Standardization must be completed within 18 months of hire or assignment. After initial standardization, Standard 2 states that employees must maintain their standardization by performing six joint inspections with the “training standard” every three years.

For FSIO’s assigned to the food program before the date of program enrollment: Staff assigned to the food program prior to the date of enrollment may or may not have been standardized using the methods and/or 18 month timeline outlined in Standard 2. In order to meet Standard 2, staff that were assigned to the food program prior to the date of program enrollment must successfully complete the standardization process outlined in Standard 2 within 18 months from the date of enrollment. This must be completed prior to the self-assessment being conducted. If these employees have not been standardized by the initial self-assessment (12 months after enrollment), then the jurisdiction does not meet Standard 2. In order to meet Standard 2 for the 2nd self-assessment (60 months after the initial self-assessment), the self- assessor should verify that:

1. These employees have been standardized (at some point between the initial self-assessment and the 2nd self-assessment) and are maintaining their standardized status (as described in Standard 2) and,
2. New hires and employees assigned to the food program on or after the date of program enrollment have completed the standardization process within 18 months and continue to maintain their standardized status (as described in Standard 2).

### 13. Dilution of field standardization

Keywords: STD-02, trained regulatory staff, standardization, dilution, cascade

#### Issue Description

##### **Background**

None provided.

##### **Question/Problem**

In field standardization (particularly when done by a local health department), is the “field standard” allowed to complete their required standardizations by going out with their own local staff? If so, is this too much dilution? If not, where do the resources come from to get these standardizations done? Can this be clarified better?

##### **Rationale**

None provided.

#### Response from Clearinghouse Work Group (02-16-05)

The Standard 2 criteria for standardization states that the standardization inspections must be completed with a ‘training standard’ using a process similar to the *FDA Procedures for Standardization and Certification of Retail Food Inspection/Training Officers*. The term ‘training standard’ is defined in the Standards to be “a person who has successfully completed the training elements outlined in Standard No 2; has received further training by an FDA Standardized Inspection or Training Officer; and represents the regulatory agency position on all issues.” This implies that the standardization process is limited by the number of FDA-standardized Inspection or Training Officers available. It has recently been verbalized by some parties that the FDA standardization process is limited to three levels of cascade: level 1 – FDA standardizes State Training Officers; level 2 – The State Training Officers standardize other state officers or city or county training officers; and level 3 –these State-Standardized Officers can standardize one more levels of inspectors. However, this has not been a consistent interpretation or practice across the country. In addition, there is no written policy or procedure that limits the process to three levels of cascade.

The *FDA Procedures for Standardization and Certification of Retail Food Inspection/Training Officers* originally targeted state officials who were the primary clients of the FDA Food Specialists. However, the *FDA Procedures for Standardization and Certification of Retail Food Inspection/Training Officers*, in the Introduction, **Section 1-104 Scope**, states that the procedures are intended as a model process for states, tribes, territorial governments, local municipalities, and other governing bodies that directly regulate food establishments and have food safety regulatory responsibilities at retail. So the source document for standardization implies that the standardization process is intended to cascade down to field personnel at the lowest levels of government wherever retail food inspections are performed. In addition, the FDA has broadened the mission of the FDA Food Specialists to include some services to city, county, and local jurisdictions in response to the Standards initiatives. And indeed, if the Standards are to be applied to all jurisdictions, then a process must be established to make standardization available to all field inspectors at all levels of government.

The CFP clarified Standard 2 by distinguishing between the Standardization process for a person who will be standardizing other employees and those employees who will be conducting inspections only. The process for those who will use the skills for conducting inspections require only 4 standardization inspections versus 8 for those who will be training other employees. See the 2011 version of Standard 2.

[NOTE: The phrase “a process similar to the FDA Procedures. . .” was clarified in a previous Clearinghouse response. See ‘*Code Criteria for Standardization*’ 03-20-02]

#### **14. Is there a requirement for a ‘roster’ of employees including hire date**

Keywords: STD-02, trained regulatory staff, roster, documentation, list, Appendix B

##### **Issue Description**

###### **Background**

None provided.

###### **Question/Problem**

What type of documentation may be used to show conformance with Standard 2? For instance, in Standard 2, must a jurisdiction use the training record worksheet provided in the self-assessment instructions?

###### **Rationale**

None provided.

##### **Response from Clearinghouse Work Group (02-16-05 – Updated 2011)**

The Retail Program Standards are published with sample forms and worksheets. However, jurisdictions may use alternative forms and worksheets so long as they capture the same information identified on the sample forms and worksheets.



## **15. Mutual standardization by two parties in different jurisdictions**

Keywords: STD-02, number of inspections, cross standardization, mutual standardization

### **Issue Description**

#### **Background**

As an FDA Specialist, I have an enrolled county with a staff of two people. They have been standardized by a state standardizing officer, but the state procedure uses only six inspections in the process. A clearinghouse response issued 05-20-02 stated that the standardization must include eight joint inspections in order to be similar to the FDA procedures. So they each need two more standardization inspections in order to meet the requirements of Standard 2. They have asked if they can standardize each other since they are both state-standardized and would be, in theory, able to standardize their own staff if they had a bigger group. The plan would mean that each person would serve as the 'standard' on 2 inspections of the other candidate, and then they would switch and do 2 more.

#### **Question/Problem**

If these described joint inspections are acceptable for standardization under Standard 2, would they also meet the requirements for joint field inspections under Standard 4?

#### **Rationale**

This proposal has merit and should be acceptable. It would facilitate uniformity because they would be going out together and able to make sure they are both focusing and making judgments in a consistent manner.

### **Response from Clearinghouse Work Group (8-16-06)**

The Clearinghouse agrees that the proposal to complete two additional standardization inspections to meet the required eight inspections by alternately serving as the 'standard' meets the intent of the Standardization process. This process will foster uniformity between the two inspectors who find themselves in a unique position because of the size of their staff. Small jurisdictions have special challenges in meeting the Standards requirements, and leeway must be given for creative solutions such as this one.

As to whether standardization inspections can also be used as a part of the field inspection evaluation measure for Standard 4, see the Clearinghouse response under Standard 4, question 4, answered on 2-16-5.

## **16. Field Training for a Food Safety Inspection Officer (FSIO)**

Keywords: STD-02, FISO, Risk Category 1 Food Establishment

### **Issue Description**

#### **Background**

In our department we have several Environmental Health Specialists who are assigned to inspect only Risk Category 1 retail food establishments. Examples of these types of establishments are: convenience stores, drug stores, and retail food stores with no deli or food prep. Training for this staff includes all of the requirements of Standard 2, except joint field training. The joint training includes joint inspections of category 1 establishments only.

The Appendix B-2 CFP Field Training Plan and Log for our staff conducting inspections of Risk Category 1 establishments has been designed to include competencies for category 1 inspections types only. It makes sense then to train them in this category of inspections. Should they advance to conducting inspections in the other categories, additional training and joint inspections would be added to their training plan and training conducted to meet those requirements?

We feel it is the best use of our resources to train staff specifically to the types of inspections assigned to the inspection staff.

#### **Question/Problem**

Is it acceptable for staff that only conducts Category 1 inspections to only complete joint field training in category 1 establishments? It is our understanding that the joint inspection part of training can only be in Risk Category 2, 3, or 4 establishments.

### **Response from Clearinghouse Work Group (10-10-2014)**

The purpose of Standard 2 is to ensure Food Safety Inspection Officers (FSIOs) have the knowledge, skills and abilities to adequately perform their duties. The Standard requires a training program with five components:

1. Pre-Inspection (Step 1)
2. Initial Field Training and Experience (Step 2)
3. Independent Inspections and Completion of All Curriculum Elements (Step 3);
4. Field Standardization (Step 4); and
5. Continuing Education and Training (Step 5).

Standard 2 prescribes specific guidance that a training program must implement in order for an enrolled jurisdiction to achieve conformance. In order to achieve conformance, ninety percent (90 %) of the retail food regulatory program inspection staff (Food Safety Inspection Officers - FSIO) must successfully complete the required elements of the 5-step training and standardization process within 18 months of assignment to the retail food regulatory program.

With respect to facility type, Standard 2 prescribes the following:

1. For the Initial Field Training: The 25 joint field inspections are to be comprised of both “demonstration” (trainer-led) and “training” (trainee-led) inspections and include

- a variety of retail food establishment types available within the jurisdiction. FSIOs must successfully complete a joint field training process, similar to that presented in the *CFP Field Training Manual*, prior to conducting independent inspections and re-inspections of retail food establishments in risk categories 2, 3, and 4 as presented in Appendix B-3.
2. For the Independent Inspections: If the jurisdiction's establishment inventory contains a sufficient number of facilities, the FSIO must complete 25 independent inspections of food establishments in risk categories 3 and 4 as described in Appendix B-3. For those jurisdictions that have a limited number of establishments which would meet the risk category 3 and/or 4 criteria, the FSIO must complete 25 independent inspections in food establishments that are representative of the highest risk categories within their assigned geographic region or training area.
  3. For Field Standardization: Within 18 months of employment or assignment to the retail food program, staff conducting inspections of retail food establishments must satisfactorily complete four joint inspections with a "training standard" using a process similar to the "FDA Standardization Procedures." Successful completion of field standardization, and re-standardization, requires selection of establishments in risk category 2, 3, or 4.

Standard 2 requires that the independent inspections and field standardization be conducted in risk category establishments higher than category 1. If staff members were only trained in risk category 1 establishments, they may be ill equipped to deal with menu changes, process changes, and equipment changes that result in a more complex operation. FSIOs need exposure to a variety of different food establishments to be able to determine if the food establishment is properly categorized, determine the compliance status of Risk Factors and Good Retail Practices (GRPs), determine appropriate immediate corrective action if needed, and promote active managerial control over the risk factors using various strategies. These actions require highly trained, competent professionals.

## **17. Standardization of a Training Standard**

Keywords: STD-02, Training Standard, Standardization

### **Issue Description**

#### **Background**

None provided.

#### **Question/Problem**

A FSIO is standardized to meet Standard 2 (four standardization inspections were conducted). Subsequently, that FSIO has a need to standardize other FSIOs. Prior to standardizing other FSIO's, does that FSIO (standardized with four inspections) need to be re-standardized with an additional eight inspections by a training standard?

### **Response from Clearinghouse Work Group (10-10-2014)**

In order to achieve conformance with Standard 2, staff conducting inspections of retail food establishments must satisfactorily complete four joint inspections with a "training standard" using a process similar to the *FDA Procedures for Standardization of Retail Food Safety Inspection Officers*. The jurisdiction's "training standard" must meet all the requirements for conducting field standardizations as presented in the definition section of the Standards.

A "Training Standard" is defined as an individual who has successfully completed the following training elements AND standardization elements in Standard 2 and is recognized by the program manager as having the field experience and communication skills necessary to train new employees. The training and standardization elements include:

1. Satisfactory completion of the prerequisite curriculum;
2. Completion of a field training process similar to that contained in Appendix B-2 CFP Field Training Manual;
3. Completion of a minimum of 25 independent inspections and satisfactory completion of the remaining course curriculum; and
4. Successful completion of a standardization process based on a minimum of eight inspections that includes development of HACCP flow charts, completion of a risk control plan, and verification of a HACCP plan, similar to the FDA standardization procedures.

As the Standard is currently written, the primary difference between a standardized FSIO and a training standard is the number of standardization inspections required. A standardized FSIO must complete 4 standardization inspections, while a training standard must complete 8 standardization inspections. In both cases, the *FDA Procedures for Standardization of Retail Food Safety Inspectors* allows up to 12 months to complete the standardization process. Thus, an individual who has successfully completed 4 standardization inspections could complete an additional four standardization inspections with a Training Standard within the same 12-month period in order to be recognized as a training standard.

# STANDARD 3

## Inspection Program Based on HACCP Principles

This Standard applies to the utilization of HACCP principles to control risk factors in a retail food inspection program.

1. **Guidance for Short- and Long-term Compliance Policy**  
Keywords: STD-03, HACCP-Based Inspection Program, good compliance policies on-site corrective actions, long-term control, policies, policy examples, on-site correction, long-term correction, short-term compliance, long-term compliance
2. **Better Guidance for Establishment Risk Categories**  
Keywords: STD-03, HACCP-Based Inspection Program, risk categories, Annex 4, determining risk categories, priority categories, inspection priorities, inspection categories
3. **Variance policy**  
Keywords: STD-03, HACCP-Based Inspection Program, variance policy, requirement for variance, variance
4. **Multiple Inspection Forms**  
Keywords: STD-03, HACCP-Based Inspection Program, multiple inspection forms, IN, OUT, NA, NO, low-risk firms, priority, multiple forms
5. **Design and Use of a State Inspection form to Conform with the Program Standards**  
Keywords: STD-03, Inspection Program Based on HACCP Principles; STD-04, Uniform Inspection Program; and STD-06, Compliance and Enforcement, inspection forms, inspection uniformity, risk-based inspection; IN, OUT, NA, NO, low-risk firms, priority

## **1. Guidance for short-term and long-term compliance policy**

Keywords: STD-03, HACCP-Based Inspection Program, good compliance policies on-site corrective actions, long-term control, policies, policy examples, on-site correction, long-term correction, short-term compliance, long-term compliance

### **Issue Description**

#### **Background**

None provided.

#### **Question/Problem**

There is a lack of guidance in the area of policy development concerning short- and long-term compliance issues. Are resources available to assist a jurisdiction that is attempting to develop compliance and enforcement policies?

#### **Recommendation**

None provided.

### **Response from Clearinghouse Work Group (11-20-02 Updated 2013)**

FDA has partnered with FOODSHIELD to enable jurisdictions to post and share templates, policies and other helpful information to assist one another in working on and achieving conformance with Standards. If a regulator wishes to join this network, they should contact their assigned FDA Regional Retail Food Specialist. Their assigned FDA Regional Retail Food Specialist can be found by going to [www.fda.gov/RetailProgramStandards](http://www.fda.gov/RetailProgramStandards) and clicking on “Directory of FDA Regional Retail Food Specialists”.

## **2. Better guidance for establishment risk categories**

Keywords: STD-03, HACCP-Based Inspection Program, risk categories, Annex 4, determining risk categories, priority categories, inspection priorities, inspection categories

### **Issue Description**

#### **Background**

None provided.

#### **Question/Problem**

Standard 3 states that jurisdictions must develop and use a process that groups food establishments into at least three categories based on potential and inherent food safety risks. Are there resources or guidance available to help a jurisdiction develop establishment risk categories?

#### **Recommendation**

None provided.

### **Response from Clearinghouse Work Group (11-20-02)**

There is guidance for determining risk categories provided in Annex 4 of the *Food Code*. In addition, this may be another area where the jurisdictions, themselves, may be able to provide good examples for others to use. (please see response to Question 1 for Standard 3).

### **3. Variance Policy**

Keywords: STD-03, HACCP-Based Inspection Program, variance policy, requirement for variance, variance

#### **Issue Description**

##### **Background**

None provided.

##### **Question/Problem**

Does the variance policy referenced in step 5 of Standard 3 have to address the jurisdiction's specific code requirements and sections for a variance?

##### **Recommendation**

None provided.

#### **Response from Clearinghouse Work Group (2-16-05)**

If a jurisdiction has a variance requirement written into its code, it is a good idea to reference the appropriate sections in the policy; however, there is no requirement to do so. The policy should provide any details or procedures not specified in the code language. For jurisdictions that did not include a variance process in its code language, details such as those included in 1999 Food Code in sections 8-103.10, 8-103.11, and 8-103.12 and through to 8-201.14 should be spelled out in the policy.



#### **4. Multiple Inspection Forms**

Keywords: STD-03, HACCP-Based Inspection Program, multiple inspection forms, IN, OUT, NA, NO, low-risk firms, priority, multiple forms

##### **Issue Description**

###### **Background**

None provided.

###### **Question/Problem**

Suppose a jurisdiction has an electronic inspection system with different forms that can be selected for different types of establishments. The forms do not have default answers, but all the questions regarding risk factors and interventions do not appear on the forms for low-risk firms. The forms for medium- and high-risk firms have IN, OUT, NA and NO since these are the firms where risk factors and interventions apply. The low-risk forms do not have the IN, OUT, NA and NO since the jurisdiction does not want to dedicate time going through questions for those firms where the activities don't occur and the risk factors don't apply. The system does allow for 'upgrading' a firm to a new form when the nature of its business changes. Would this meet the Standard? Can the Standard 3 requirement for a form showing the IN, OUT, NA, and NO for the risk factors and interventions be met by using a different form for high- and medium-risk firms from the form used for low-risk firms?

###### **Recommendation**

None provided.

##### **Response from Clearinghouse Work Group (2-16-05)**

Assuming that the jurisdiction's method of priority categorization restricts the low-priority firms to those in which no potential risk factors occur and no interventions are necessary, then the system would be acceptable. The key to acceptability of this system, however, is not the fact that an establishment is in a low-risk category, but that none of the potential risk factors and interventions apply to its operation. Standard 3 does not require that IN compliance, OUT of compliance, Not Applicable, and Not Observed be marked for every inspection item, only for the risk factors and Food Code interventions. So having a secondary form for use when no risk factors or interventions apply to that particular establishment would not violate the intent of the Standard. Also, a policy, procedure or system should be in place that establishes a way to determine when conditions in an establishment change such that they require the form containing the IN, OUT, NA, and NO and that the switch to that form occurs.

## **5. Design and use of State inspection forms to conform with Program Standards**

Keywords: STD-03, Inspection Program Based on HACCP Principles; STD-04, Uniform Inspection Program; and STD-06, Compliance and Enforcement, inspection forms, inspection uniformity, risk-based inspection; IN, OUT, NA, NO, low-risk firms, priority

### **Issue Description**

#### **Background**

Much of the criteria contained in Standards #3, 4, and 6 are predicated on the inspection program containing risk-based approaches. The intent of designing inspection forms with the four options was to ensure that the inspector examined and evaluated items related to the factors most often associated with foodborne illness.

#### **Question/Problem**

The inspection report must use IN, OUT, NA, NO. Can an electronic version of this report default to IN compliance?

#### **Recommendation**

Some facts about the proposed inspection form:

- Rather than clearly marking an observation as "IN", the form leaves the assumption that if no points are taken, or nothing is marked, the item is "IN".
- "NO" and "NA" are options for observations on items to which they do not apply
- Not many counties are on electronic forms, so an automatic default to "OUT" or blocking inappropriate "NA" and "NO" would not be blocked.

### **Response from Clearinghouse Work Group (3-21-08)**

The intent of the use of IN, OUT, NA and NO is that the inspector must choose from the options. An important item to remember is that this is required for risk factors and interventions only and is not required for all GRPs. Also, an option that is not appropriate need not be included. This is the same system/format as the FDA Risk Factor Study data collection form.

The requirement for an inspection form showing IN, OUT, NA, and NO for the risk factors and interventions can be met by using a different form from the model form in the Annex of the FDA Food Code (Form 3-A), however, the need for the inspector to make a decision about the compliance status of the risk factors and interventions must be maintained.

The importance of the NO is that an inspector could time their next routine inspection to ensure they observe the practice that was not observed during the time of this inspection. Two common examples would be cooling or reheating Time/Temperature Control for Safety Food (TCS). These processes generally occur over a period of time and often require two data points or measurements over time to determine compliance. Additionally, selecting NO may alert staff that the establishment does not cool foods in the morning or does not reheat foods in the evening.

Based on the discussion above, an electronic form that defaults to "IN compliance", would not meet the intent of (part 1 of) Standard 3.

# STANDARD 4

## Uniform Inspection Program

This standard 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.

1. **Citing Code Provisions during Inspections**

Keywords: STD-04, Uniform Inspection Program, code citation, quality assurance, quality assurance elements, quality assurance aspects, code provisions

2. **Completion of Assessment Protocols**

Keywords: STD-04, Uniform Inspection Program, quality assurance program, gaps, identifying gaps, self-assessment, self-assessment process, self-assessment of Standard 4, field review, field visits, aspects, field evaluations

3. **Use of Standardization Inspections for Field Evaluation Inspections under Standard 4**

Keywords: STD-04, Uniform Inspection program, standardization inspections, field evaluation inspections, quality assurance, quality assurance inspections, field evaluations, performance measurement

4. **Consultant Inspectional Agencies**

Keywords: STD-04, STD-06, Consultant, delegation, enforcement

## 1. Citing Code provisions during inspections

Keywords: STD-04, Uniform Inspection Program, code citation, quality assurance, quality assurance elements, quality assurance aspects, code provisions

### Issue Description

#### **Background**

Standard #4 requires an on-going quality assurance program that evaluates inspection uniformity to ensure inspection quality, inspection frequency and uniformity among the regulatory staff. The assessment protocol defines 10 areas for evaluating each candidate. Area #4 requires the assessment of the candidate to ensure that the proper local code provisions for the CDC-identified risk factors and Food Code interventions are cited during inspections.

#### **Question/Problem**

Is the expectation of this component of the quality assurance evaluation that the candidates cite the specific code section number for each of the violations recorded on the inspection report?

#### **Rationale**

While we recognize the importance of understanding the regulatory foundation for all violations cited during inspections, the citing of specific section numbers for each violation recorded on the inspection form seems unduly arduous. The FDA, in its own *Food Code* standardization process does not require this level of documentation. Instead a reference sheet is used that associates a section number with the specific out-of-compliance observation.

To further complicate this assessment, many jurisdictions have condensed the FDA Food Code Standardization form into fewer items under each of the risk factor. The 5- page FDA Standardization form, while a good data collection tool, is not considered a good communication tool for prioritizing critical areas with the target audience – retail food protection managers/operators. State and local jurisdictions are exploring methods to condense the form and still maintain a meaningful assessment of risk factors as identified in FDA's Baseline. This often leads to consolidating items to shorten the inspection form.

Consolidating items under broad risk categories present the challenge of assessing which provision of the Food Code the candidate actually cited when noting the violation. The FDA Standardization form can be used to illustrate this point. In FDA's reference sheet for citing specific sections of the Food Code, six (6) separate sections of the Food Code are listed under:

#### Food from Approved Source

- A. All food from regulated food processing plants/no home prepared or canned foods.

3-201.11 Compliance with food law  
3-201.12 Food in a hermetically sealed container

3-201.13	Fluid milk and milk products
3-202.13	Shell eggs
3-202.14	Eggs and milk products, pasteurized
5-101.13	Bottled drinking water

The candidate is only required to make a determination of whether “A” above is “IN”, “OUT”, Not Observed (“NO”), or Not Applicable (“NA”). The candidate is not required to assess which one of the Sections applies unless specifically asked to do so by the Standard.

FDA has recognized the difficulty with citing specific code provisions within its own standardization procedure. We believe that the assessment of this component should be the jurisdiction’s development of a reference sheet much as FDA uses for citing specific sections of the Code. Assessing specific candidates' abilities to cite the appropriate section of their code as it pertains to observed violation should be a component of the 2 field inspections conducted by the candidate and the programs quality assurance officer.

**Response from Clearinghouse Work Group (2-20-02)**

The submitter raises several issues that need clarification.

Standard No. 4 does not dictate a particular form to be used in routine inspections. Certain provisions of Standard No. 3 and Standard No. 6 require that the risk-control factors and risk interventions be identified as "in, out, not applicable, or not observed." Those provisions aside, there are no prohibitions against combining items on a routine inspection form. When several provisions of the local code are combined under one item, it is a very good idea that a reference sheet be made available to inspectors; otherwise, uniformity of marking becomes very difficult to achieve. The reference sheet should clearly list the provisions that have been combined under each item heading or number.

Standard No. 4 is made up of two parts. The first requirement is for an on-going quality assurance program that assures quality inspections in the ten identified aspects and describes the actions that will be implemented when deficiencies in any of the ten are identified. The second requirement describes the measurement that will be used to determine whether the quality assurance program in place is successful. The Standard does not dictate the specifics of the quality assurance program itself.

One of the quality aspects of Standard No. 4 is that each inspector is able to cite the proper local code provisions for the CDC-identified risk factors and Food Code interventions, but accuracy in citing all local code provisions (Good Retail Practices) is not required. This is a reasonable requirement in that the legal process used for enforcement in the majority of jurisdictions requires that a firm accused of a violation of a regulation or code must be charged against a particular provision of that regulation or code. It is reasonable to expect that an inspector with the responsibility and authority to charge a violation should know, or be able to identify, the specific charge that they are making. For example, when an inspector cites a firm for serving home-canned foods, he/she should know that the proper citation is the one related specifically to "hermetically sealed containers." Standard No. 4 requires that you

address and assure in some fashion that your inspectors are able to do this, but does not dictate your process.

The process for measuring the success of your quality assurance program is described in the *Standard 4: Self-Assessment Instructions and Worksheet* document. This procedure involves two on-site inspections during every self-assessment period (three years). A file review of the three most recent inspection reports of the same establishments must accompany the field exercise in order to be able to judge the quality aspects:

5. Repeat violations;
6. Follow up on compliance and enforcement;
8. Discussion and documentation of long-term corrective options; and
- 9 Assignment of the firm to the proper priority category and inspection frequency.

Notice that the file review does not specifically target aspect 4. - Citing of proper local code provisions. Determinations of whether the inspector is able to cite proper local code provisions may be addressed during the one-on-one, on-site inspections, standardizations exercises, or other methods the jurisdiction deems appropriate.

There is just a final caution that it may not be wise to rely on the measurement/testing process of Standard No. 4 as your sole check for quality. While it is practical and acceptable to combine this QA check as a part of the standardization process, they are intended to serve separate purposes. When FDA personnel standardize state and local officials, the submitter is correct in stating that citing the specific provision is not required. That is because most jurisdictions that have adopted the *Code* use a different paragraph numbering system that is compatible with their own regulations or laws. However, in the FDA internal personnel standardization process, individual *Code* section and paragraph citing is required. It is recommended that during your internal standardization process you include a verification of the knowledge of specific local code provisions.

## **2. Completion of Assessment Protocols**

Keywords: STD-04. Uniform Inspection Program, quality assurance program, gaps, identifying gaps, self-assessment, self-assessment process, self-assessment of Standard 4, field review, field visits, aspects, field evaluations

### **Issue Description**

#### **Background**

Much of the criteria contained in Standard 4 are predicated on an inspection program containing risk-based approaches outlined in earlier Standards - in particular Standard #3. Our initial review of Standard #4 indicates that many of the 10 items contained as part of the Quality Assurance Program have not as yet been integrated into our retail food program. Some of these items include:

- Documents compliance status of risk factor/interventions;
- Obtains & documents on-site corrective action for risk factors appropriate to the violation;
- Documents offered options for long-term control of risk factors; and
- Verifies that the establishment is in the proper risk category.

Since our retail food program is lacking some key components, the assessment protocol outlined in Standard #4 can not be completed as designed. Assessing staff's consistency in these areas through joint on-site inspections and corresponding file reviews seems premature until all the components are in place.

#### **Question/Problem**

Our internal self-assessment process has revealed significant gaps in our quality assurance program. Several components contained in Standard #4's criteria must be developed and integrated into our program before a meaningful field and file review can be performed against all the 10 components that should be included in a Quality Assurance Program.

For this initial self-assessment, is it sufficient to note the gaps within our current quality assurance program as rationale for why we do not meet Standard #4 or must we also complete a field and file review for each of our staff? If we are to continue on with a field and file review, against what criteria do we assess compliance with the Q.A. components we already have in place?

#### **Rationale**

None provided.

### **Response from Clearinghouse Work Group (03-20-02)**

If a cursory look at a Standard compared to your program is sufficient to reveal gaps that prevent you from meeting the Standard and provides a rationale for your conclusion, then it is not necessary for you to proceed further. No one wants you to spend time that is not productive. You only need go as far as necessary to identify the gaps you would need to fill to help you establish a plan for ultimately meeting the Standard.

### **3. Use of standardization inspections for Field Evaluation Inspections under Standard 4**

Keywords: STD-04, Uniform Inspection program, standardization inspections, field evaluation inspections, quality assurance, quality assurance inspections, field evaluations, performance measurement

#### **Issue Description**

##### **Background**

None provided.

##### **Question/Problem**

In order to achieve conformance with Standard 4, field assessments (and an associated file review) must be conducted with food safety inspection officers. Can this field assessment process occur at the same time as a Standardization inspection?

##### **Rationale**

None provided.

#### **Response from Clearinghouse Work Group (02-16-05)**

Yes, Standardization inspections may also be used as the field component of Standard 4's effectiveness measure. Whether this is appropriate or not will depend on a jurisdiction's standardization process, and so this practice will need to be evaluated on a case by case basis. There are specific performance elements that are to be evaluated during the Standard 4 field assessment inspections. These include such things as reviewing and acting on repeated or unresolved previous violations, following through on compliance and enforcement actions, obtaining immediate corrective actions and effectively communicating inspectional findings to the establishment's management. Some jurisdictions do not include all of these aspects of a regular inspection in a standardization inspection in order to shorten the time needed to complete the process. If all of the elements to be measured under Standard 4 are not a part of the standardization inspection process, then it would not be appropriate to conduct these field evaluations simultaneously. However, if the standardization inspections include all the pertinent elements of a regular inspection so that all ten of the elements of Standard 4 can be evaluated, there is nothing to prohibit these inspections from being conducted at the same time.



#### **4. Consultant Inspectional Agencies**

Keywords: STD-04, STD-06, Consultant, delegation, enforcement

##### **Issue Description**

###### **Background**

Government agency A is enrolled in the Program Standards. Government agency A conducts inspections based on the most current published FDA Food Code and uses the Inspection Report Form in Annex 7 of the Food Code. Government agency A also has written procedures for compliance and enforcement. However, legal authority for requiring compliance and enforcement belongs to Government Agency B. Therefore, inspection results are recorded by Agency A, and provided to Agency B. In addition to the inspection results, Agency A also provides consultation and recommended corrective actions to Agency B. Agency A recommends corrective actions that are consistent with Standard 4 and Standard 6. Agency B is responsible for determining when compliance and enforcement actions are necessary, and is responsible for implementing compliance and enforcement actions. Agency B may or may not implement compliance and enforcement actions that are consistent with Standard 4 and Standard 6.

###### **Question/Problem**

Can a government agency achieve conformance with Standard 4 if they lack the legal basis to require immediate onsite compliance and/or lack the legal basis to implement an enforcement action when immediate onsite compliance is not possible?

###### **Rationale**

None provided.

##### **Response from Clearinghouse Work Group (02-16-05)**

In order to achieve conformance with Standard 4, a government agency must have the legal authority to require immediate on-site compliance for imminent health hazards and priority items, and must be able to take enforcement action when immediate on-site compliance is not possible.

When conducting a self-assessment for Standard 4, the government agency must review food safety inspection officer's performance against the ten quality elements listed in Standard 4. The following two quality elements pertain to compliance and enforcement:

1. Follows through with compliance and enforcement.
2. Obtains and documents on-site corrective action for out-of-control risk factors at the time of inspection as appropriate to the type of violation.

The ability to require immediate on-site compliance for imminent health hazards and priority items, and the ability to take enforcement action when immediate on-site compliance is not possible, is necessary for staff members to achieve these quality elements. Without this ability, food safety inspection officers will be unfairly penalized for not achieving these performance elements. Alternatively, an agency will never be able to assess achievement of these performance elements, thus basing a determination of conformance with Standard 4 on the assessment of only eight performance elements instead of all ten performance elements.

This is less stringent than the level of achievement necessary for a jurisdiction that must assess performance of all ten performance elements. In this case, the jurisdiction cannot fully meet the Standard.

It is important to note that even if an enrolled jurisdiction cannot achieve conformance with Standard 4 due to the lack of legal authority for compliance and enforcement, they can still use the applicable performance elements in Standard 4 to evaluate inspection performance. These results can be useful for continually improving a food safety program.

# STANDARD 5

## Foodborne Illness and Food Defense Preparedness and Response

This standard applies to the surveillance, investigation, response, and subsequent review of alleged food-related incidents and emergencies, either unintentional or deliberate, which results in illness, injury and outbreaks.

1. **Final Outbreak Reports**

Keywords: STD-05, foodborne illness reports, foodborne illness, illness reports, CDC, complaints, complaint reports, reports, report distribution

2. **Complaints received by a jurisdiction other than foodborne illness complaints**

Keywords: STD-05, complaints, risk, other complaints, prioritizing complaints

3. **County independent of state on recall policy**

Keywords: STD-05, recalls, recall, recall policy, conducting recalls

4. **Must the trend analysis required in Standard 5 include all the data from a complaint log or database or will an analysis of all data from the epidemiology data base be sufficient to meet the intent of the Standard?**

Keywords: STD-05, trend analysis, complaints, complaint logs, complaint database, analysis

5. **What triggers the need for a mock foodborne illness investigation?**

Keywords: STD-05, foodborne illness, investigation, mock investigation, table top, illness investigation

## **1. Final Outbreak Reports**

Keywords: STD-05, foodborne illness reports, foodborne illness, illness reports, CDC, complaints, complaint reports, reports, report distribution

### **Issue Description**

#### **Background**

None provided.

#### **Question/Problem**

The second paragraph under “Description of Requirement” in Standard 5 discusses follow-up on complaints of alleged food-related illness or injury. At the end of that paragraph, it says “the final report of the investigation is shared with the state epidemiologist and the Centers for Disease Control and Prevention.” Are all complaint follow-ups to be reported to the epidemiologist and CDC or only those that meet the definition of a foodborne illness?

#### **Rationale**

None provided.

### **Response from Clearinghouse Work Group (03-20-02; Updated 2011)**

The final reports of investigations that meet the definition of a foodborne illness should be shared with the state epidemiologist and CDC. The paragraph does seem to mix “apples and oranges.” The intention is for you to record all complaints of alleged illness or injury, to perform an assessment of the complaint to determine appropriate follow-up, and to link that information to the establishment record for retrieval purposes in order to identify patterns and trends. In some instances an investigation may be performed and a short report written on complaints that do not meet the official definition of a foodborne illness. You are not required to share work reports of that nature with the state epidemiologist and CDC. For all investigations that meet the definition of a foodborne illness, a final report is to be written and shared with the state epidemiologist and CDC.

## **2. Complaints received by a jurisdiction other than foodborne illness complaints**

Keywords: STD-05, complaints, risk, other complaints, prioritizing complaints

### **Issue Description**

#### **Background**

None provided.

#### **Question/Problem**

Where is it required that a jurisdiction must prioritize and respond to complaints based on risk? An example is hair in food or a child throwing up in a restaurant.

#### **Rationale**

None provided.

### **Response from Clearinghouse Work Group (02-16-05; Updated 2011)**

Standard 5 does not specify that complaints need to be prioritized according to risk. It addresses the logging of and response to all alleged food-related illness or injury, but other types of complaints are not required to be logged or prioritized to meet the Standard.

### **3. County independent of State on recall policy**

Keywords: STD-05, recalls, recall, recall policy, conducting recalls

#### **Issue Description**

##### **Background**

None provided.

##### **Question/Problem**

If a county has a policy about how they work with the state on recalls, but the state does not have a policy similar to 21 CFP, Part C, and the county does not have authority for conducting recalls, can the county meet Standard 5?

##### **Rationale**

None provided.

#### **Response from Clearinghouse Work Group (02-16-05)**

Yes, as long as the county's policy covers its own responsibilities and has procedures for conducting effectiveness check of actions by firms when requested by cooperating agencies.

**4. Must the trend analysis required in Standard 5 include all the data from a complaint log or database or will an analysis of all data from the epidemiology data be sufficient to meet the intent of the Standard.**

Keywords: STD-05, trend analysis, complaints, complaint logs, complaint database, analysis

**Issue Description**

**Background**

None provided.

**Question/Problem**

Under the Trend Analysis section, it states that at least once per year, the program must conduct a review of the data in the complaint log or database and the illness and 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. The review should be conducted with prevention in mind and focuses on, but is not limited to, the following:

- Multiple complaints on the same establishment;
- Multiple complaints on the same establishment type;
- Multiple complaints implicating the same food;
- Multiple complaints associated with similar food preparation processes;
- Number of laboratory-confirmed, food-related outbreaks;
- Number of non-laboratory-confirmed but epidemiologically linked, food-related outbreaks;
- Contributing factors most often identified;
- Number of complaints involving real and alleged threats of intentional food contamination; and
- Multiple complaints involving the same agent and any complaints involving unusual agents.

The trend analysis areas in 1 - 4 above seem to indicate that all foodborne illness complaints should be taken into account in the analysis, even if the complaints were unsubstantiated or that were not resulting from outbreaks (i.e. sporadic cases of foodborne illness). If a jurisdiction, either on its own or in cooperation with a sister agency, issues a report(s) that summarizes the total number of foodborne illness complaints for each establishment, and in that report, conducts trends for items 2 - 9 using only outbreak data, is the intent of the Standard met?

**Rationale**

None provided.

### **Response from Clearinghouse Work Group (08-16-06; Updated 2011)**

In reviewing the language of the Standard No. 5 as a whole, including the section on trend analysis, there is very little room for interpretation. It is clear that the intent is for the analysis to include all complaints and not just outbreak data.

The Clearinghouse members agreed that a jurisdiction's investigative procedures and protocols should include all the elements as described in 1.a. through 1.i., including the handling and response to all complaints. The Clearinghouse engaged in a further discussion regarding whether an analysis as described in 7.a. through 7.c. of all unsubstantiated complaints and sporadic illnesses was practical, feasible and/or of value, but was unable to reach a consensus. This question requires broader input from regulators, and any change to the Standard 5 language to eliminate the requirement for analysis of complaint data would require action by the CFP. The Clearinghouse will recommend that the question be forwarded for reviewed by the CFP Program Standards Committee.

CFP addressed this issue, and Standard 5 was altered in 2007 to rename this section as 'review and analysis.' The review is to include all complaints, not just outbreak data; although this kind of information does not lend itself to analysis per se. All unsubstantiated complaints and sporadic illnesses are to be reviewed to determine whether a pattern exists or whether factor is at work in the community which may not be recognized as relating to a confirmed outbreak.



## **5. What triggers the need for a mock foodborne illness investigation?**

Keywords: STD-05, foodborne illness, investigation, mock investigation, table top, illness investigation

### **Issue Description**

#### **Background**

None provided.

#### **Question/Problem**

In the version of Standard 5 that was passed in 2006, under the heading of Trend Analysis, item c. states:

“In the event that there have been no illness or injury outbreak investigations conducted during the twelve months prior to the trend analysis, program management will plan and conduct a mock foodborne illness 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.”

Must a jurisdiction have a full investigation that results in samples taken and a full report sent to CDC to avoid a mock investigation? Or is a smaller investigation sufficient to avoid the mock investigation requirement? What triggers the need for a mock investigation?

#### **Rationale**

None provided.

### **Response from Clearinghouse Work Group (08-16-06)**

The Standard 5 language states that the purpose of the mock investigation is to “test the program readiness” to respond to an outbreak. The desired outcome for Standard 5 is that a food regulatory program has a systematic approach for the detection, investigation, response, documentation and analysis of alleged food-related incidents that involve illness, injury, unintentional or deliberate food contamination. Any event that activates communication between the various parties with a role/responsibility in an outbreak investigation and demonstrates that the system can respond if needed would serve to test the readiness of the system. If the system’s readiness has been demonstrated, then there would be no need for a mock exercise.

# STANDARD 6

## Compliance and Enforcement

This standard applies to all compliance and enforcement activities used by a jurisdiction to achieve compliance with regulations.

1. **Determining Conformance with a Standard**  
Keywords: STD-06, Compliance and Enforcement, compliance protocol, risk-based enforcement, self-assessment, extent of self-assessment, cursory review
2. **Files with No Risk Factor/Intervention Violation on the Start-Point Inspection**  
Keywords: STD-06, Compliance and Enforcement, start-point, start-point inspection, random selection, random files selection
3. **Standardization Inspection/exercise used as a Start Point Inspection or any inspection as part of the file review**  
Keywords: STD-06, Compliance and Enforcement, Use of Standardization Inspections
4. **Determining conformance with a Standard**  
Keywords: STD-06, Compliance and Enforcement, compliance protocol, risk-based enforcement; timely correction for compliance
5. **Consultant Inspectional Agencies**  
Keywords: STD-06, STD-04, Consultant, delegation, enforcement

## **1. Determining conformance with the Standard**

Keywords: STD-06, Compliance and Enforcement, compliance protocol, risk-based enforcement, self-assessment, extent of self-assessment, cursory review

### **Issue Description**

#### **Background**

Much of the criteria contained in Standard #6 are predicated on the inspection program containing risk-based approaches outlined in earlier Standards - in particular Standard #3. Our initial review of Standard #6 indicates that much of the criteria rely on forms that record and quantify status of risk factors/interventions and other serious violations.

Since our current program is lacking a definitive step-by-step compliance and enforcement process based on the occurrence and correction of risk factors and interventions, the assessment protocol outlined in Standard #6 cannot be completed as designed. Assessing staff's consistency in these areas through file reviews seems premature until all the components are in place.

#### **Question/Problem**

Our internal self-assessment process has revealed significant gaps in our compliance and enforcement program. Several risk-based components contained in Standard #6's criteria must be developed and integrated into our program before a meaningful file review can be performed against all the criteria contained in the Compliance and Enforcement Standard.

For this initial self-assessment, is it sufficient to note the gaps within our current compliance and enforcement program as rationales as to why we do not meet Standard #6 or must we also complete a file review of randomly selected establishments. If we are to continue on with a file review, against what criteria do we assess compliance with the Compliance and Enforcement program components we already have in place?

#### **Rationale**

None provided.

### **Response from Clearinghouse Work Group (03-20-02)**

This question is similar to a prior one concerning Standard 4, and the response applies regardless of the Standard in question. If a cursory look at a Standard compared to your program is sufficient to reveal gaps that prevent you from meeting the Standard and provides a rational for your conclusion, then it is not necessary for you to proceed further. No one wants you to spend time that is not productive. You only need go as far as necessary to identify the gaps you would need to fill and to establish a strategic plan for ultimately meeting the Standard.

## **2. Files with no Risk Factor or Intervention violation on the start-point inspection**

Keywords: STD-06, Compliance and Enforcement, start-point, start-point inspection, random selection, random files selection

### **Issue Description**

#### **Background**

None provided.

#### **Question/Problem**

It is not clear how to mark files drawn for review that do not have a risk factor or Food Code intervention violation on the 'start-point inspection.' Should the self-assessor keep drawing files until he/she finds the requisite number of files with violations on the start-point inspection or are files without a violation considered as 'passing' files?

#### **Rationale**

None provided.

### **Response from Clearinghouse Work Group (Updated 2011)**

The fourth oldest inspection can be used as the 'start point' if no risk factor violation was identified on the third oldest inspection. Sampling and instructions have also been updated and clarified. See the most recent version of Standard 6 and the worksheets and guidance documents on the website.

### **3. Standardization Inspection/exercise used as a Start Point Inspection or any inspection as part of the file review**

Keywords: STD-06, Compliance and Enforcement, Use of Standardization Inspections

#### **Issue Description**

##### **Background**

None provided.

##### **Question/Problem**

Under Standard 6 may a standardization inspection be used for one of the 3 inspections or does one need to use the inspection before the standardization inspection? In the audit manual it states "the start-point inspection will be the third oldest routine inspection in the establishment's file at the time of the review. If it shows a violation of one of the risk factor or Food Code interventions, an X is placed under the appropriate food borne illness risk factor or Food Code intervention heading if a violation was noted on the start-point inspection." My question is since a standardization inspection focuses on risk factors and interventions, could it count toward meeting this standard?

##### **Rationale**

None provided.

#### **Response from Clearinghouse Work Group (April 2013)**

The Program Standards serve as a guide to regulatory food protection program managers in the design and management of a regulatory food protection program and provide a means of recognition for those programs that meet these standards. These standards are designed to help regulatory food protection programs enhance the services they provide to the public, and therefore the specific criteria that comprise each standard establishes a high bar for performance.

In addition to establishing specific performance criteria, the Program Standards also provide a specific methodology for assessing a jurisdiction's performance against the individual criteria in each Program Standard. Using a common, specific methodology enables jurisdictions in different parts of the country to use the same common yardstick when measuring the success of their program relative to the performance criteria in each Program Standard.

Standard 6 focuses on outcomes from the jurisdiction's compliance and enforcement program. Specifically, it establishes that a jurisdiction's compliance and enforcement program should achieve compliance at least 80% of the time when out-of-control risk factors or interventions are observed during a routine inspection. There are numerous methods that could be used to assess a jurisdiction's compliance and enforcement program against this criterion. Therefore, FDA developed a specific methodology to ensure that Standard 6 could be uniformly interpreted and self-assessed by different jurisdictions across the nation.

There are three considerations that support the current methodology for assessing Standard 6:

- It is not reasonable for the self-assessor to review each establishment file in the inventory. Therefore the methodology must incorporate a smaller sample size of establishment files and inspections;
- The sample of establishment files and regulatory inspections must be representative of the inventory of establishment files and regulatory inspections. In other words, it is important that the results from assessing the sample can be extrapolated to the entire inventory; and
- The methodology must provide for a simple, common yardstick that can be used by different jurisdictions to assess their regulatory inspections relative to the criteria in Standard.

In light of the first consideration: The methodology in Standard 6 recognizes that a self-assessor can not review a jurisdiction's entire inventory of establishment files and regulatory inspections. Therefore a protocol was established so that a smaller sample could be assessed.

In light of the second consideration: The bulk of inspections in jurisdiction's inventory will be routine regulatory inspections. In order to extrapolate the results from the self-assessment to the jurisdiction's entire inventory, it is necessary to review inspections that are similar in nature to the bulk of the inspections that comprise the inventory. Standardization inspections tend not to be representative of routine regulatory inspections for two key reasons:

- Standardization inspections involve two inspectors, the Candidate and the Standard, whereas typically one Standardized inspector performs routine, regulatory inspections.
- The purpose of Standardization is for the Standard to evaluate the Candidate. This is different than a routine, regulatory inspection. The focus in a Standardization inspection is on the Candidate's performance and not the establishment's compliance with provisions of the Food Code. Standardization is part of a jurisdiction's training program which is assessed in Standard 2, not Standard 6.

Because of these reasons, Standardization inspections tend not to be representative of most routine regulatory inspections conducted in a jurisdiction. As a result, incorporating Standardization inspections into a self-assessment of Standard 6 may yield results that do not provide an accurate picture of the enforcement and compliance actions in a jurisdiction.

In light of the third consideration: The focus of Standard 6 is enforcement and compliance. Most, if not all, enforcement and compliance action stems from routine regulatory inspections. This is consistent regardless of the state or locality. Therefore the Standard seeks to focus attention on these types of inspections, which represent the bulk of inspectional activity in most regulatory food protection programs.

Incorporating Standardization inspections into the assessment of Standard 6 takes the focus away from routine regulatory work. Moreover, it introduces a degree of variation between jurisdictions because there are significant differences in how Standardization inspections are conducted throughout the United States. Some of these differences include:

- Some jurisdictions leave a written report with the establishment after the Standardization inspection, while others do not.

- Some jurisdictions do not conduct Standardization inspections.
- Some jurisdictions require enforcement and compliance action after a Standardization inspection, while others do not.

Because of these differences, incorporating Standardization inspections into the Standard 6 self-assessment would result in inconsistent assessment of Standard 6 by different jurisdictions.

Although the Clearinghouse recognizes that due to staff and resource limitations, Standardization inspections have been used as regulatory inspections in some manner, the Standards are Standards of excellence and the ability to meet or not meet a Standard is not reason enough to interpret a lesser criteria to be used. Additionally, Standard 8 addresses Program Support and Resources and as such can be used to identify gaps in staffing needs and address them.

Due to the intent of Standardization, some of the differences between a Standardization inspection and a routine inspection, the variability that may exist in how a jurisdiction may handle post-Standardization compliance and the potential problems of delineating whose observations are considered regulatory, Standardization inspections shall not be used to determine compliance with Standard 6.

#### **4. Determining conformance with a Standard**

Keywords: STD-06, Compliance and Enforcement, compliance protocol, risk-based enforcement; timely correction for compliance

##### **Issue Description**

###### **Background**

None provided.

###### **Question/Problem**

The State has recently revised their scoring protocol to address the new Food Code risk designations of core, priority foundation, and priority. Core items will be cited as a violation, however they will be non-debitable and not require any compliance timeline. Standard 6 does not prescribe the type of regulatory action required for violations, however it does require "credible follow-up for each violation" be demonstrated. If core items are marked as violations with no other associated compliance or enforcement actions, would this meet Standard 6?

###### **Rationale**

None provided.

##### **Clearinghouse Work Group Response (10-18-12)**

The Food Code states that Code provisions are either appropriate for citing and debiting on an inspection report or they are not. A Code provision that is cited as a violation is considered debitable and therefore requires a time frame for correction. This includes Core Item violations, as per Section 8-406.11 of the Food Code.

Within the context of the Food Code, Core Items by definition are items usually related to general sanitation, operational controls, sanitation standard operating procedures, facilities or structures, equipment design, or general maintenance. Non-debitable provisions of the Code provide further information for consideration, such as provision for an exception or for an allowance to comply via an alternative method. Exceptions and allowances often contain conditions of compliance, i.e., conditions that must be met in order for the exception or allowance to convey.

If a jurisdiction chooses to use a non-debitable status for Core Items, it would mean that none of the Core Items would be capable of being debited or cited on an inspection form as a violation. That is not the intent of the Food Code in having a non-debitable status.

Code sections considered as non-debitable should not be cited as violations. If a Code section is cited as a violation, compliance or enforcement action should be taken as recommended in Section 8-406.11. Implementing the recommendation in 8-406.11 is one aspect of meeting Standard 6. By not requiring a time frame for correcting Core Items, a jurisdiction does not meet the intent of 8-406.11 and therefore does not meet part of Standard 6.



## 5. Consultant Inspectional Agencies

Keywords: STD-06, STD-04, Consultant, delegation, enforcement

### Issue Description

#### **Background**

Government agency A is enrolled in the Program Standards. Government agency A conducts inspections based on the most current published FDA Food Code and uses the Inspection Report Form in Annex 7 of the Food Code. Government agency A also has written procedures for compliance and enforcement. However, legal authority for requiring compliance and enforcement belongs to Government Agency B. Therefore, inspection results are recorded by Agency A, and provided to Agency B. In addition to the inspection results, Agency A also provides consultation and recommended corrective actions to Agency B. Agency A recommends corrective actions that are consistent with Standard 4 and Standard 6. Agency B is responsible for determining when compliance and enforcement actions are necessary, and is responsible for implementing compliance and enforcement actions. Agency B may or may not implement compliance and enforcement actions that are consistent with Standard 4 and Standard 6.

#### **Question/Problem**

Can a government agency achieve conformance with Standard 6 if they lack the legal basis to require immediate onsite compliance and/or lack the legal basis to implement an enforcement action when immediate onsite compliance is not possible?

#### **Rationale**

None provided.

### Clearinghouse Work Group Response (12-19-13)

In order to achieve conformance with Standard 6, a government agency must have the legal authority to require immediate on-site compliance for imminent health hazards and priority items, and must be able to take enforcement action when immediate on-site compliance is not possible.

When conducting a self-assessment for Standard 6, the government agency must take a random sample of establishment files. The inspections contained within each establishment file must be reviewed to verify that the appropriate compliance and enforcement action was taken. In instances where the government agency conducts inspections at establishments for which it lacks legal authority to require onsite compliance and take enforcement action, these establishment files should be excluded from the random sample of establishment files.

In other words, conformance with Standard 6 should only be assessed using establishment files for which the government agency has the legal authority to require onsite compliance and take enforcement action. Therefore, a government agency cannot achieve conformance with Standard 6 if, at all inspected establishments, the agency lacks legal authority to require immediate on-site compliance for imminent health hazards and priority items, or lacks the legal authority to take enforcement action when immediate on-site compliance is not possible.

# STANDARD 7

## Industry and Community Relations

This standard applies to industry and community outreach activities utilized by a regulatory program to solicit a broad spectrum input into a comprehensive regulatory food program, communicate sound public health food safety principles, and foster and recognize community initiatives focused on the reduction of foodborne disease risk factors.

1. **Could CFP Participation Be Used to Meet This Standard?**

Keywords: STD-07, Industry and Community Relations, CFP, participation, industry relations

2. **District Health Department participation in State-level food advisory committees for compliance with the first part of Standard 7 (referenced below).**

Keywords: STD-07, Industry and Community Relations, industry and consumer interaction, food advisory boards, task forces, or committees.

3. **Holding separate regulatory, industry and public stakeholder meetings**

Keywords: STD-07, Industry and Community Relations, industry and consumer interaction, separate meetings

4. **Use of web based or social media for fostering stakeholder communication and feedback**

Keywords: STD-07, Industry and Community Relations, communication, information exchange

## **1. Could CFP participation be used to meet this Standard?**

Keywords: STD-07, Industry and Community Relations, CFP, participation, industry relations

### **Issue Description**

#### **Background**

None provided.

#### **Question/Problem**

Would participation in CFP via a board, committee or council constitute meeting the requirements of the Standard where it states, “or other forums for presenting food safety strategies” in that the representative brings information and strategies from their jurisdiction and takes back information to their jurisdiction?

#### **Rationale**

None provided.

### **Response from Clearinghouse Work Group (02-16-05)**

No, the intent of Standard 7 is to foster communication and understanding between the jurisdiction and its own industry and consumer constituency. You are encouraged to participate in the CFP to the fullest extent possible since, as you say, representatives bring their perspectives to the Conference and take strategies back to their own jurisdictions. It is important to have the widest representation possible at the Conference because of the parliamentary-style decision making. The number of participant positions at CFP is limited, however, and thus not all industry and consumers are represented. It is important to have channels for open dialogue between each regulatory jurisdiction and its regulated industry and with the public whose health interests it protects. The establishment of community-focused interaction is the goal of Standard 7.

## **2. District Health Department participation in State-level food advisory committees for compliance with the first part of Standard 7**

Keywords: STD-07, Industry and Community Relations, industry and consumer interaction, food advisory boards, task forces, or committees.

### **Issue Description**

#### **Background**

*Industry and Consumer Interaction:* The jurisdiction sponsors or actively participates in meetings such as food safety task forces, advisory boards or advisory committees. These forums shall present information on food safety, food safety strategies and interventions to control risk factors. Offers of participation must be extended to industry and consumer representatives.

#### **Question/Problem**

The Idaho Food Protection Program has sponsored the "Idaho Food Safety Advisory Committee" (IFSAC) for the past few years. IFSAC consists of industry, academia, state regulatory, consumers, and other stakeholders. There has only been limited involvement by local regulatory agencies. A few of Idaho's 7 District Health Departments have formed their own food safety advisory committees and they have worked well. However, in the more rural parts of the state, the formation and maintenance of such a committee is proving to be quite difficult.

Question: If the IFSAC were to expand and include participants from each of the District Health Departments, could each District then claim that they met the first part of Standard 7?

#### **Rationale**

The intent of Standard 7 is to foster communication and understanding between the jurisdiction and its own industry and consumer constituency. Further, it is important to have channels for open dialogue between each regulatory jurisdiction and its regulated industry and with the public whose health interests it protects. The establishment of community-focused interaction is the goal of Standard 7.

### **Response from Clearinghouse Work Group (03-21-08)**

Including participants from each of the District Health Departments on the State Food Advisory Committee would meet the intent of Standard #7.

### **3. Holding separate regulatory, industry and public stakeholder meetings**

Keywords: STD-07, Industry and Community Relations, industry and consumer interaction, separate meetings

#### **Issue Description**

##### **Background**

A jurisdiction may be in the process of conducting public meetings pertaining to the adoption of a new Food Code. They intend on meeting with industry, regulatory, and consumer groups but plan to hold 3 separate public meeting for each of these stakeholder groups.

##### **Question/Problem**

Does the jurisdiction meet the intent of the Industry and Community Relations criteria of Standard 7 if the meetings with regulatory, industry and the public are held separately?

##### **Rationale**

None provided.

#### **Response from Clearinghouse Workgroup Response (2-1-12)**

Standard 7 states that invitations for participation in meetings must be extended to all stakeholders including industry, consumers and regulatory with the intent to foster enhanced communication and information exchange. The desired outcome as stated is to solicit broad stakeholder input to improve the jurisdiction's food safety program. The specific question posed is based on public meetings which would by definition be open to all.

Standard 7 does not prohibit a jurisdiction from holding multiple separate meetings to facilitate private group dialogue and development on program issues. It does not require the use of a consensus process that might necessitate that all parties be present at the same time, only that the jurisdiction hold meetings that provide quality feedback from regulators, industry and consumer groups. The Standard requires an invitation to industry and consumer representatives annually to ensure open discourse and feedback so that program decisions are not made in a vacuum. Although the CH encourages efforts to bring the stakeholders together for these meetings to better understand each others interests, separate meetings would be acceptable.

#### **4. Use of web-based or social media for fostering stakeholder communication and feedback**

Keywords: STD-07, Industry and Community Relations, communication, information exchange

##### **Issue Description**

###### **Background**

Standard 7 requires participation in forums that foster communication and information exchange among regulators, industry and consumers representatives. Item #1 under the "Description of Requirement – Industry and Consumer Interaction" specifically states that the jurisdiction sponsor or actively participate in meetings for this purpose. The stated desired outcome is to enhance communication with industry and consumers through forums designed to solicit input to improve the food safety program. With the increasing use of web based communication, availability of general department electronic mailboxes and social media, are face to face meetings the only forum that can be recognized as meeting this requirement. Would an option on a program's website for "contact us" or "please provide feedback" or similar communication meet the intent of this for both industry and consumers and perhaps even enhance communication since regular participation at face to face meetings is often challenging for industry members and almost non existent for consumers, despite invitations and solicitations for involvement?

###### **Question/Problem**

Would other types of web based or social media be acceptable such as web based feedback options, general program electronic mailboxes, social media (Face Book, LinkedIn, Twitter accounts, etc) if they are 2 way communications forums open to industry, consumers, and regulatory in lieu of traditional face to face meetings?

###### **Rationale**

None provided.

##### **Response from Clearinghouse Workgroup Response (12-14-11)**

The Clearinghouse agrees that a strict requirement limited to public meetings may be locking out growing trend that could be useful for program feedback and communication. Web-based social media is a significant means of communication for younger people in the community if not fully embraced by all. Since this Standard was written over 10 years ago, it may be time to consider this aspect as an important venue for public communication. However, the criteria would need to be developed and, if accepted, would involve changes to the current Standard 7 language, a task beyond the scope of the Clearinghouse.

The Clearinghouse recommends that the question be referred to the FDA Program Standards Workgroup for consideration as either meeting the existing intent with additional language or as a new requirement including:

- View of social media as supporting the intent of “#1 Industry and Consumer Interaction” requirements in Standard 7

- Criteria for adding web-based communication or social media option – demonstrating 2 way communication, responses, possible real time requirements or trending for response, required documentation for various possibilities.
- Effect on audit forms, language of the Standard
- FOI issues for documentation of communication records that might be required
- Use of email voting

The Clearinghouse believes that it is too early to determine whether a Standard should be made more stringent or lenient. Information should be gathered from the current participants, and then recommendations for change can be based on experiential data gathered from across the country from both large and small jurisdictions. The Clearinghouse does not recommend action on this item at the present time. However, any CFP participant can submit issues to alter the Standards through the CFP process.

# STANDARD 8

## Program Support and Resources

This standard applies to the program resources (budget, staff, equipment, etc.) necessary to support an inspection and surveillance system that is designed to reduce risk factors and other factors known to contribute to foodborne illness.

1. **Is inspection write-up and data entry part of the direct inspection time?**

Keywords: STD-08, Program Support and Resources, administrative time, report writing, data entry

2. **Why is the FTE Ratio not tied to Number of Establishments?**

Keywords: STD-08, Program Support and Resources, FTE ratio, number of inspections, number of establishments, comparing staff ratios

3. **Administrative Time**

Keywords: STD-08, Program Support and Resources, FTE ratio, number of establishments, comparing staff ratios, administrative time, report time.



## **1. Is inspection write-up and data entry part of the direct inspection time?**

Keywords: STD-08, Program Support and Resources, administrative time, report writing, data entry

### **Issue Description**

#### **Background**

None provided.

#### **Question/Problem**

Standard 8 establishes a recommended FTE-to-Inspection ratio for retail food regulatory programs. Does the FTE-to-Inspection ratio account for the inspector's time required to complete the inspection write-up and data entry?

#### **Rationale**

None provided.

### **Response from Clearinghouse Work Group (02-16-05)**

Office time used for reports, data entry and other types of paperwork are administrative functions and are not considered a part of productive time. The built-in allowance for administrative overhead is the reason that productive hours or full-time equivalent hours are less than the total employee time available. Also, depending on the process for generating reports and data entry, the administrative time required for these functions can vary greatly. Jurisdictions with highly automated systems might require much less administrative time than others. The measurement criteria are for productive time used for critical regulatory functions in the establishment that can be applied to any jurisdiction regardless of administrative process.

## 2. Why is the FTE ratio not tied to number of establishments?

Keywords: STD-08, Program Support and Resources, FTE ratio, number of inspections, number of establishments, comparing staff ratios

### Issue Description

#### **Background**

None provided.

#### **Question/Problem**

Why is the Standard 8 staffing level element based on the FTE-to Inspection ratio instead of an FTE-to-Establishment ratio?

#### **Rationale**

None provided.

### Response from Clearinghouse Work Group (02-16-05)

A jurisdiction that inspects each establishment once per year and one that inspects each establishment three times per year would require different ratios under the FTE-to-Establishment figure in order to achieve approximately the same average inspection time per visit. The Standard 8 criteria is established so that the same unit of measure can be used for any jurisdiction regardless of the frequency of routine inspections conducted among the various priority categories. Annex 4 of the 1993 Food Code, recommended that 8 to 10 hours of staff time be allocated for each establishment per year to include all the activities included in the definition of an inspection in Standard 8: routine inspections, re-inspections, complaint investigations, outbreak investigations, compliance follow-up inspections, risk assessment reviews, process reviews, variance process reviews and other direct establishment contact time such as on-site training. The criterion of 280 to 320 broadly defined inspections per FTE is consistent with these previous figures.

To illustrate, assume that the average FTE equals 1200 productive hours:

- From the 1976 Code, 150 establishments/per FTE was the recommendation. The recommendation was 2 routine inspections per year, then allowing for the other on-site inspectional and assessment work to equal 8 hours X 150 establishments = 1200 hours, or 1 FTE/150 establishments.
- From the 1993 Code, the recommendation was 8 to 10 hours per establishment. Working from the other direction, one FTE of 1200 hours / by 8 hours per establishment = 150 establishments per FTE. Or one FTE of 1200 hours / by 10 hours per establish = 120 establishments per FTE.
- \*From Standard 8, assuming an average activity time of 4 hours per on-site activity, then 4 hours X 280 activities (broadly defined as inspections) per person = 1120 productive hours; 4 hours X 320 activities = 1280 productive hours per person. This represents a reasonable range of 1120 to 1280 hours or one FTE per every 280 to 320 inspectional activities.

This last measure does not dictate a required number of routine inspections. It therefore allows for an inspection frequency for different establishment categories based on safety prioritization. It also allows the same unit of measure to be applied to all jurisdictions regardless of their procedures and processes; and therefore, represents better national Standard criteria for measuring inspectional staffing levels.

### 3. Administrative Time

Keywords: STD-08, Program Support and Resources, FTE ratio, number of establishments, comparing staff ratios, administrative time, report time.

#### **Issue Description**

##### **Background**

None provided.

##### **Question/Problem**

How do you show administrative time necessary to support the Standards?

##### **Rationale**

None provided.

#### **Response from Clearinghouse Work Group (02-16-05)**

Except for the specified requirements for Full-Time Equivalents (FTEs) for field work and the specified equipment for each inspector, Standard 8 is intended as a guide for a program to self-analyze general program needs and the administrative support necessary to function properly. There are no identified criteria or minimum levels for the support of the other Standards or overall administration of the program. It is intended that by completing the Standard 8 worksheet, a manager would look realistically at his or her environment and identify the elements that hinder achievement of a quality program.

There are two examples to illustrate this concept:

- For Standard 1, it may not be funding or staffing that prevents a jurisdiction from meeting the requirements for regulatory foundation: Rather, it may well be a lack of industry or health board support.
- For Standard 3, the obstacle may be a lack of technology in the form of adequate computer systems or it may be the lack of clerical staff to support the records and reporting system currently in use.

Once the obstacle to achieving a Standard is identified, then appropriate strategies to overcome the obstacle may be developed. The area of administrative support is too broad and too diverse for any one formula to be proposed. You are encouraged to look realistically at all program needs, identify short falls, and garner support by articulating those needs along with proposals for improvements to those with the power to help.

# STANDARD 9

## Program Assessment

This Standard applies to the process used to measure the success of jurisdictions in meeting the *Voluntary National Retail Food Regulatory Program Standards 1 through 9* (hereafter referred to as the National Standards) and their progress in reducing the occurrence of foodborne illness risk factors.

1. **Facility Types to be Included in Baseline Surveys**  
Keywords: STD-09, Program Assessment, sample size, baseline, baseline survey, survey, risk factor survey. Facility type.
2. **Baseline Survey Sample Size**  
Keywords: STD-09, Program Assessment, sample size, baseline, baseline survey, survey, risk factor survey
3. **Baseline Surveys – Use of lower confidence levels than recommended in the FDA Data Collection Manual**  
Keywords: STD-09, Program Assessment, baseline survey, risk factor survey, survey, confidence level
4. **Survey Reports – The use of the number 32 as a reporting cut off for out of compliance elements**  
Keywords: STD-09, Program Assessment, baseline survey, risk factor survey, survey, cut off, out of compliance
5. **Cooperation within a state on Risk Factor Surveys**  
Keywords: STD-09, Program Assessment, baseline survey, risk factor survey, survey, cooperation, joint survey
6. **Can jurisdictions combine to create one single baseline?**  
Keywords: STD-09, Program assessment, baseline survey, risk factor survey, survey, cooperation, joint survey, combined survey
7. **Appropriate auditor for the risk factor survey**  
Keywords: STD 9, auditor, conflict of interest, risk factor survey

## **1. Facility types to be included in Baseline Surveys**

Keywords: STD-09, Program Assessment, sample size, baseline, baseline survey, survey, risk factor survey, facility type.

### **Issue Description**

#### **Background**

Our jurisdiction is considering limiting our baseline survey data collection to only one of the facility types that we regulate. We are thinking of surveying only the full service restaurants since it is the more complex segment of the industry and includes the majority of our permitted establishments. There are two reasons for limiting the scope of our survey. The first reason is to conserve the expenditure of resources during these tight budget times. The second reason is that we would like to gain some experience in the methodology and surveying techniques before we put too many resources into the process only to discover that changes need to be made in the process.

#### **Question/Problem**

If we limit the scope of our data collection survey to only one of the facility types that we regulate, will we still meet the intent of Standard 9?

#### **Rationale**

We believe that we will meet the intent of Standard 9 by surveying only one facility type. The Standard does not spell out which facility types must be surveyed. It simply requires that baseline data be collected and that additional data be collected on subsequent three-year cycles. Further FDA did not collect information on all of the potential facility types in existence or that might be regulated by a jurisdiction. Therefore, we should be free to select the scope of the survey that meets our needs.

### **Response from Clearinghouse Work Group (Updated 2011)**

Standard 9 was changed based on the 2004 CFP recommendation so that a risk factor study need only be completed once every five years. In later revisions it was clarified that surveys of the various facility types can be conducted independently over the 5-year evaluation period as long as all the facility types under the jurisdiction's authority are surveyed within the recurring survey cycle. The Standard was also revised to allow regular inspection data to be used in determining the occurrence of risk factors the risk factors most in need of priority attention.

## 2. Baseline Survey sample size

Keywords: STD-09, Program Assessment, sample size, baseline, baseline survey, survey, risk factor survey

### Issue Description

#### **Background**

At the Program Standards workshop, information was presented related to determining a jurisdiction's sample size to ensure a valid Baseline measurement of CDC identified foodborne illness risk factors. In order to ensure a comparable baseline with FDA, a jurisdiction that has 100 or more establishments in any of the 9 categories was instructed to sample at least 100 of those establishments in each category for a valid sample size. If a category had less than 100, the jurisdiction was expected to sample all the facilities within that category.

#### **Question/Problem**

Aren't the sample size parameters presented above unnecessarily high given the fact that FDA's sample size for any of the nine categories did not exceed 100 and there is a national study comprising about one million establishments? Is there an alternative to this suggested model that would provide a statistically valid confidence level given the much smaller total number of establishments within any given jurisdiction?

#### **Rationale**

While we are awaiting feedback from the work group, we strongly believe that a statistically valid baseline is achievable from a sample size that is significantly less than what the FDA has presented as a model.

### Response from Clearinghouse Work Group (Updated 2011)

Statisticians within FDA's Division of Mathematics have re-examined this issue and determined that smaller sample sizes can be used to attain a statistically valid confidence level for the establishment of a Baseline of Occurrence of Foodborne Illness Risk Factors. The following presents the Division of Mathematics current guidance on assuring sample sizes for Baseline measurements is statistically meaningful. For complete guidance on conducting a baseline and ensuring comparability with FDA national study, see "Developing a Baseline on the Occurrence of Foodborne Illness Risk Factors – Data Collection Instruction Manual," available from your Regional Food Specialist.

See Appendix A for the document titled *Sample Size Recommendations for Local Government Retail Food Safety Baselines*.

### **3. Baseline Surveys – Use of lower confidence levels than recommended in the FDA Data Collection Manual**

Keywords: STD-09, Program Assessment, baseline survey, risk factor survey, survey, confidence level

#### **Issue Description**

##### **Background**

None provided.

##### **Question/Problem**

I am the director of a jurisdiction that is participating in the Standards, and I have completed my self-assessment. Although I would like to conduct a risk factor baseline survey, I have very limited resources. The FDA Data Collections Manual recommends sample sizes that will result in a 95 percent confidence level. It seems that if I am willing to accept a lower confidence, for example 80 or 90 percent, I can collect fewer samples. This will allow me to conduct my survey using fewer person hours.

##### **Rationale**

I realize that I would not be able to compare my results with the FDA National data. I also realize that the results would not be as reliable using a lower confidence level; however, I think the information I gather will be sufficient to help me tweak my program to gain some improvements. I'm not sure I need the scientific justification of a 95 percent confidence level. If I'm willing to accept the lower confidence levels, are there other reasons why I shouldn't reduce sampling to stretch my resources?

#### **Response from Clearinghouse Work Group (07-15-03; Updated 2011)**

There are a number of issues to be considered here. In a nut shell, the statistics show that although you may be able to reduce sample size somewhat, your ability to measure trends over time is greatly compromised. You will lose precision to a degree that you may not be able to detect increases or decreases in compliance of risk factors in future surveys. Indeed, upward trends in compliance may even be mistaken for downward trends. The complete mathematical explanation for this phenomenon that argues against using confidence levels lower than 95 percent (95%), as outlined in the "FDA Data Collection Manual," is included as an answer addendum at the end of this Clearinghouse response.

The surveys are intended to track over time the occurrence of risk factors known to cause or contribute to foodborne illness. The idea is that the information uncovered will allow you to focus your efforts in selected areas where compliance is low in order to achieve significant improvement. Future surveys would then reveal whether your efforts and strategies were successful in changing the occurrence of the selected risk factors. If your survey is conducted in such a way that you are unable to identify changing trends in risk factor occurrence, then the purpose of the survey is defeated. You may conserve resources used to conduct the surveys, but if the information gathered does not serve the intended purpose, then the resources will have been wasted.



An initial baseline survey and future risk factor surveys can be a tremendously powerful tool to demonstrate the usefulness of your program to the Board of Health, City Council or whatever body has influence over your budget and resources. For the first time, there exists an effectiveness measure for a public health program. It has always been difficult to justify preventive programs, especially during austere economic times. The surveys allow you to identify areas that represent potential problems affecting consumer health and the well being of the community at large. You can then develop logical strategies to reduce the risk in those specific problem areas and to demonstrate the positive impact of your program. Conducted properly, risk factor surveys can provide tangible justification for your food program in a way never before possible. This being the case, your surveys should be conducted in such a way as to maintain the highest integrity and maximum usefulness of the survey results. For these reasons the Clearinghouse cannot recommend the use of lower confidence levels. However, see the latest version of Standard 9 since facility types now do not have to be surveyed in the same year and regular inspection data may now also be used as an alternative to conducting a specific data collection.

See Appendix B for the document titled *Discussion of the Impact of Confidence Levels on Data Precision.*

#### **4. Survey Reports – The use of the number 32 as a reporting cut-off for Out-of-compliance elements.**

Keywords: STD-09, Program Assessment, baseline survey, risk factor survey, survey, cut off, out of compliance

##### **Issue Description**

###### **Background**

None provided.

###### **Question/Problem**

In the *Report of the FDA Retail Food Program Database of Foodborne Illness Risk Factors*, it appears that the risk factors with out-of-compliance observations of at least 32 was a cut off mark for reporting and prioritizing the results. I cannot find an explanation of why 32 was used as the cut off. Is there a statistical significance to this number? And does this figure apply to all jurisdictions conducting risk factor studies as well?

###### **Rationale**

None provided.

##### **Response from Clearinghouse Work Group (07-15-03)**

The rationale for choosing 32 Out-of-Compliance observations as the cut off point for determining what individual data items deserved priority attention is discussed on page 22 of the mentioned report. Basically FDA analysts sorted the data items by number of OUT-of-Compliance observations, ranking them in order from the one with the highest number to the one with least number of Compliance observations. The analysts then looked for a point in the list of ranked data items after which the number of OUT observations began to decrease more rapidly or were farther apart. This ‘natural break’ was the cut off value used for each facility type.

This approach appears to have worked well for the FDA Baseline. However, this is not the only approach that can be used and other approaches may be appropriate for individual jurisdictions conducting a risk factor survey. For example, with the possibility of different sample size requirements and different observation rates for different facility types, state and local jurisdictions may decide to choose different cutoff points for highlighting data items in need of priority attention for each of the facility types.

The recipe used in the FDA Baseline Report for identifying data items needing priority attention does not use the OUT-OF-COMPLIANCE percentage (rate). Instead the approach only considers the number of OUT-OF-COMPLIANCE observations as the criterion. This means that individual data items with high OUT-OF-COMPLIANCE rates but with few observations, will not be highlighted using the FDA approach.

The goal of conducting repeated baselines survey over time is to measure trends on the occurrence of foodborne illness risk factors. Note that progress is measured in terms of the amount of increase in the overall percent of IN COMPLIANCE observations for all data items combined. This is done separately for each facility type. (This is the ratio of total “IN”

observations for all data items combined to the total of “IN” observations plus total “OUT” observations for all data items combined.).

Overall Baseline IN Compliance percentage for a Facility Type =

$$\frac{\text{(Total number of IN Compliance Observations for all data items)} \times (100\%)}{\text{(Total \# of IN Compliance Observations + Out of Compliance Observations for all data items)}}$$

The reality of this approach is that those individual data items that are seldom observed or are frequently noted as not applicable will have little impact on this score. What affects the overall baseline measurement are the data items that are frequently observed. Practically speaking, this means focusing on the items with the most OUT OF COMPLIANCE observations.

However, there is no reason why states and local jurisdictions cannot also consider items that have high OUT OF COMPLIANCE percentages and simultaneously do not have a large number of observations. If you decide that some of these items represent important problems and you have sufficient resources, you may wish to work on improving these items as well as the problematic data items with many observations. Additionally, if you determine that some items may be improved with very little effort, it may be wise to address these, regardless of how often they occur. Be aware, however, you cannot expect efforts devoted to data items that have low observation rates to have a substantial effect on future baseline measurement trends.

In conclusion, states and local jurisdictions may list as many data items as you like in your reporting and analysis, selecting them in order of the number of OUT-OF-COMPLIANCE observations, and prioritizing the items to be worked on in the same order, based on your resource constraints. This should be done separately for each facility type. The number of items that can be listed is up to your discretion and preferences. You are not required to list the same number for each facility type. The number you choose to work on and the amount of effort you wish to expend on each is up to you.

## 5. Cooperation within a State on Risk Factor Surveys

Keywords: STD-09, Program Assessment, baseline survey, risk factor survey, survey, cooperation, joint survey

### **Issue Description**

#### **Background**

None provided.

#### **Question/Problem**

If a state-wide baseline is conducted, can the enrolled jurisdictions in that state utilize that state-wide baseline to satisfy the criteria for Standard 9 if they participate?

#### **Rationale**

The Food Protection Program in Idaho consists of a state program manager that provides rule implementation and interpretation. The Food Protection Program delegates jurisdictional authority to seven (7) district health departments to issue licenses, conduct inspections, and investigate complaints and potential foodborne illnesses.

All of Idaho's seven health districts have enrolled in the Voluntary Program Standards as well as the Food Protection Program of the State Department of Health and Welfare. In other words, all of Idaho's health jurisdictions that deal with retail food are enrolled in the standards.

Individual baseline studies conducted by the individual health districts will result in some districts collecting data from approximately 50% of all food establishments within the district while other districts would be required to collect data from 28% of all food establishments due to the varying sizes of the districts. This would result in unequal costs to the districts. In some cases, this cost differential will likely prohibit a district from conducting an effective baseline study.

A state-wide baseline would result in a sample size equivalent to 16% of all food establishments in the state. In Idaho, data collected from a state-wide baseline study would be used to develop the goals and objectives of the Food Protection Program for the next several years. These goals and objectives would also be implemented by each of the seven districts.

Given the unique structure of public health delivery in Idaho, we believe that the Clearing house's agreement with this position and affirmative decision on the question posed above does not set any kind of difficult precedent. Rather, it creates a cost-effective way to evaluate potential risks for developing foodborne illness throughout the State of Idaho and optimizes ways to implement effective intervention strategies statewide. In addition, an affirmative decision on the question would be consistent with the following paragraphs from the document "Developing a Baseline on the Occurrence of Foodborne Illness Risk Factors: Data Collection Instruction Manual."

“Jurisdictions may choose to work together on the Baseline to develop a comprehensive establishment inventory. This takes some coordination and cooperation between agencies but often results in a more efficient use of limited resources, particularly travel time associated with data collection at randomly selected facilities located throughout a large region or state.” (Page 10)

“Many jurisdictions have relatively small establishment inventories. Some are one-person health jurisdictions. Small jurisdictions may consider working together to establish a regional baseline. To accomplish this, they would pool their establishment inventories and follow a random selection process. The sample size and selected establishments would have a regional distribution allowing the jurisdictions to collectively determine specific responsibilities for the actual data collection.” (Page 13)

#### **Response from Clearinghouse Work Group (08-18-04)**

The methodology described in the background for this question appears sound in that the proposal follows the guidance given in the Baseline Data Collection Instruction Manual for conducting a state-wide or region-wide study.

- The State plans one overall survey by combining all the district inventories and sampling randomly from the single combined inventory.
- Each district will conduct the survey inspections of the facilities in their district that were drawn from the sampling of the combined inventory.
- The districts will not attempt to analyze the data by district, nor will they compare districts using the data collected since they recognize that collecting the data on a state-wide basis results in a state-wide survey.
- The survey will result in one report that will be used to develop goals and objectives to be applied within all of the participating districts.

The audit criteria for risk factor occurrence surveys require that jurisdictions understand the results and limitations of their surveys and produce meaningful information for improving programs. That requirement will be met in the Idaho proposal.

We have heard throughout the country that conducting a risk factor occurrence survey is difficult because of resource issues. The Clearinghouse Work Group and FDA have been asked to look at ways to overcome this problem. Working together on a state-wide approach is an innovative way to overcome the resource issue and still have a meaningful measurement of the occurrence of risk factors.

This model could be useful for very small jurisdictions. The FDA has encouraged small jurisdictions, especially one- and two-person departments to work together on the Standards. Area-wide risk factor occurrence surveys conducted by a consortium of small jurisdictions working together would be one cost-effective method for smaller jurisdictions to gather the information needed to develop program improvement strategies. As long as accurate conclusions are drawn based on the data and appropriate strategies are developed, there is no reason why this kind of cooperation cannot take place.

The Clearinghouse Work Group accepts the Idaho structure and agrees that each of the participating Idaho districts will meet the intent of Standard 9 related to risk factor occurrence surveys.

**6. Can jurisdictions combine to create one single baseline?**

Keywords: STD-09, Program assessment, baseline survey, risk factor survey, survey, cooperation, joint survey, combined survey

**Issue Description**

**Background**

None provided.

**Question/Problem**

Can jurisdictions combine to create one single baseline?

**Rationale**

None provided.

**Response from Clearinghouse Work Group (02-16-05)**

Yes, refer to the Data Collection Manual Chapters 3 and 4 and Annex IV and VII. The Data Collection Manual gives detailed guidance on sampling and limitations of combining data sets when conducting occurrence of risk factor surveys. Also, see the previous response to a similar question from Idaho.

## **7. Appropriate auditor for the Risk Factor Survey**

Keywords: STD 9, auditor, conflict of interest, risk factor survey

### **Issue Description**

#### **Background**

None provided.

#### **Question/Problem**

The State of Idaho has completed a statewide baseline study. Inspections were completed by the seven (7) individual health districts. The reports were sent to the Food Protection Manager with the State of Idaho. The Food Protection Manager used the Access Database to enter the inspection results from the districts and completed the report using the FDA Study report as a guideline. If the Food Protection Manager did not complete the actual field collection activities, can he be the auditor for the 7 individual health districts for this Standard? If so, can he also get credit for the States Standard 9?

#### **Rationale**

The Food Protection Manager is not the one who actually did the inspections. He is simply the individual who entered the data from the inspections and produced the reports from the Access Database. He then created a report along the lines of the FDA Risk Factor Studies. Please refer to the Clearinghouse Opinion of August, 2004.

### **Response from Clearinghouse Work Group (01-17-07)**

Our understanding of your risk factor survey is that the seven health jurisdictions combined your inventories and made one random selection of facilities to represent a State-wide survey that would be used by each of the seven districts to set goals and directions for the next several years. Your State asked for and got a favorable response for this methodology before embarking on the survey. We see your point that the input of data and constructing of the report by the State Program Manager would not constitute a significant influence on his part over the outcome of the survey. One purpose of the verification audit is to show outside agreement that a jurisdiction's interpretation of the process and outcome was valid. It is also to give validity and credibility to the Standards process and preserves integrity of the system. While we believe that the Program Manager could serve objectively as the auditor, some might view this arrangement as a conflict of interest. For this reason, the Clearinghouse recommends that you obtain a different auditor for this particular element of Standard 9.



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# Appendix A

## **SAMPLE SIZE RECOMMENDATIONS FOR LOCAL GOVERNMENT RETAIL FOOD SAFETY BASELINES**

A Working Paper by W. E. Bing Garthright, Ph.D.,  
HHS/FDA/CFSAN/OSAS/Division of Mathematics

February 7, 2002

Many states, counties, and cities are beginning to plan their own retail food safety baseline measurements, based on the FDA project (“Report of the FDA Retail Food Program Database of Foodborne Illness Risk Factors”, 8/10/2000). These activities will be called “local baselines” for brevity. This working paper will recommend sample sizes for random selection of facilities to inspect, based on analyses done by Bing Garthright and Jerome Schneidman of FDA/CFSAN’s Division of Mathematics.

For a local baseline for some facility types, the inventory of establishments is small enough that sample sizes can be smaller than those used in the FDA’s national assessment. Local requirements should also be satisfied by a slightly less stringent requirement on confidence limits, which will also allow some reduction to sample sizes. These two facts will lead to the recommendations below.

John Marcello, an FDA Regional Retail Food Specialist, has proposed a theoretical profile of a local government inventory as follows:

Hospitals	6
Nursing Homes	36
Elementary Schools	48
Fast Food Restaurants	420
Full Service Restaurants	360
Retail Grocery Stores	180

I will recommend sample sizes for inventories of these sizes and bigger.

The purposes of a local baseline would include these two:

- compare the locality to FDA’s national baseline profile by risk factors;
- identify the subset of the 42 items in the baseline that are most in need of improvement.

Of course states and local governments will want to see whether compliance with risk-based factors is improving or not over periods of several years. The local situation is different from FDA’s however, because local authorities have frequent contact with most of their inventories every year, and so they have many more points for comparison than just a baseline measurement.

The locality will observe its improvements and declines in more detail than a periodic baseline, and will know more rapidly how its efforts are succeeding.

There are many different goals that we could pursue that would lead to different sample size requirements. Pursuing the most difficult goal will automatically provide big enough samples to satisfy the rest. The most difficult goal is to identify those specific baseline items, out of FDA's 42 items, that are most in need of priority attention. Of course everyone wants every risk-related item to be as in compliance as possible, but with limited resources it is good to tackle the factors that are the least in compliance. All of FDA's 42 items are directly connected to risk, so FDA highlighted the least in compliance items in its August 10, 2000 report. The 9 tables numbered 3 through 11 gave items deserving priority attention each of the 9 facility types in our baseline. We expect some degree of similarity in most local baseline results, so we will look at those tables when planning our statistical criteria.

There is no single correct basis for setting a sampling plan for an operation like baseline measurement. We determined by consulting FDA's retail field specialists that some rough guidelines could be derived. In particular, we view an item that is in compliance more than 80 percent of the time to need improvement, but not as a priority; an item in compliance less than 60 percent of the time clearly deserves priority attention.

There is a great body of valuable survey theory that deals with difficulties and complexities in collecting data and getting accurate and precise conclusions. This theory is necessary when the conclusion will be to describe causality in social relations (e.g., children whose parents read more than 3 books per year earn \$10,000 more than the average citizen). Most of this theory is unnecessary for a baseline measurement, which simply gives a measurement of conditions at one particular time. We will define as our completely accurate measurement the data that would result if we conducted baseline measurements at the entire inventory of establishments. We will define the results of sampling a subset of the inventory by how accurately it reflects the data we would get by including the complete inventory. This bypasses many complexities in sampling theory.

If we want to give priority attention to items whose compliance (measured by the whole inventory) is less than 60 percent, then we have to decide what a successful measurement will be. Many approaches are reasonable, but FDA used the following goal when determining its sample sizes relative to prioritizing items:

If a particular baseline item has a compliance rate of no more than 60 percent, we want to have a high probability that our data will show a compliance rate of no more than 70 percent.

This means that we can treat items that score in compliance at less than 60 percent as clear priorities and treat those up to 70 percent as also of special concern. I will call this objective the "60-70 objective", for convenience.

FDA's J. Schneidman has used statistical theory (the hypergeometric distribution) to see how well various sample sizes meet the 60-70 objective.

I suggest a goal of 95% confidence that a particular item with 60% total compliance would not be found to have more than 70% compliance in the randomly selected sample. (This is less demanding than the 98.5% confidence of the 60-70 objective required for the national baseline, but we think it is justified by two facts: the consequences of an error are confined to one locality, and the locality would soon discover any such errors by their follow-up activities.) The table below shows how many compliance observations must result from the sampling in order to achieve this.

Note that in this working paper, the term “observations” refers to findings of “in compliance” or “out of compliance”, but does not include “not applicable” or “not observed”. The table below cannot be used directly, since we can’t predict the number of observations that would be achieved if the entire inventory were attempted.

FOR ONE OF THE 42 ITEMS IN THE BASELINE:

If this no. of observations would result if the entire inventory is attempted:	10	20	30	40	50	60	70	80	90	100	110	120
Then this no. of observations is needed from the partial sample:	9	16	22	28	29	32	38	38	39	42	45	45

If this no. of observations would result if the entire inventory is attempted:	130	150	175	200	225	250	300	350	400	450
Then this no. of observations is needed from the partial sample:	48	48	49	52	55	58	58	58	58	58

How can we adapt the above relationship for observations to the relationship for establishments, using the results of the FDA baseline study? As was noted in Tables 3-to-11 of the FDA baseline study, many items are both applicable and observable at only a fraction of the inspections. This means that, for some particular item in the baseline, the numbers of establishments in the inventory really represent smaller numbers of observations, and so we must take that into account when setting our desired sample sizes.

Tables 3-to-11 record, for the 9 individual facility types, a total of 55 mentions of baseline items that deserve the most priority for improvement. I would expect these tendencies to be reflected to a great extent in most localities, and so we will use them as a guide in judging just how much to “oversample” in order to get adequate numbers of observations for making important decisions.

When an item is much less than 60 percent in compliance, say less than 50 percent, it takes only a very small sample to give a result no more than 70 percent in compliance with 95 percent confidence. We want to take into account the sampling that will do a good job for items that score very near to 60 percent.

There were ten mentions of items that appeared to be between 58-62% in compliance, and they were observed at between 72 and 100 percent of the inspections, with an average of 87 percent of inspections. We want to be able to capture enough observations for all such items, and we know that there will be some sampling error involved that requires that we assume an even lower of level of observation to have high assurance of coverage. Therefore, we will allow for the possibility that only 2/3 (67%) of the inspections yield observations.

For example, suppose a locality has 90 elementary schools. For an item of interest, we would suppose that there would exist a potential for 60 observations (2/3 of 90). For this no. (60) of potential observation, our table above would require a sample of 32 observations. Using the 2/3 rule, we would sample 48 establishments (since 2/3 of 48 is 32).

But the example above is clearly over-simplified, since our sampling of 48 of the 90 schools could conceivably encounter as many as 48 or as few as 18 observations. This involves the second layer of sampling errors, the sampling that coincides with observable items and with non-observable ones. We will accept this oversimplification, however, for several reasons. First, the probabilities suggest that mistakes will be very few. Second, we have picked a hardest case to represent the test that our sampling must satisfy. The FDA baseline items with 58-62% compliance averaged 87 percent observations, much higher than our conservative assumption of 67 percent, and so we have a cushion of over-sampling for these items. Third, 45 out of 55 of the FDA items of concern were noticeably above or below 60 percent in compliance, and therefore we will not need such large samples in order to characterize them correctly. Taken together, with a little smoothing at the upper end, these three reasons cause us to support the following table of samplings based on inventory sizes:

### ESTABLISHMENT INVENTORY SAMPLE SIZES

Inventory Size	< 9	9	10-12	13	14-19	20-24	25-28	29-31	32-36	37-43	44-51
Sample Size	All	8	9	12	14	18	23	24	27	29	33

Inventory Size	52-58	59-73	74-81	82-96	97-103	104-133	134-148	149-163
Sample Size	38	42	44	48	53	57	59	63

Inventory Size	164-186	187-261	262-291	292-328	329-373	374+
Sample Size	68	72	74	78	83	87

This will give the following sample sizes for the theoretical example posed by John Marcello:

<u>Type</u>	<u>Inventory</u>	<u>Sample size</u>
Hospitals	6	6
Nursing Homes	36	27
Elementary Schools	48	33
Fast Food	420	87
Full Service	360	83
Retail Food Service	180	68
Totals	1050	304

This working paper supersedes the sampling scheme that I spelled out in my prepared remarks, delivered in my absence by John Marcello, for the Pacific Northwest Regional Meeting in August of 2001. (The regional meeting remarks would have recommended 390 inspections for the example above.) This paper represents CFSAN's best advice for sample sizes of inspections for local baseline studies.

Postscript: When the tables are used for Retail food stores, they really represent the numbers of each of the four retail food store departments to be measured. It will be necessary to visit more than this number of stores in order to achieve coverage of the less frequently encountered departments. Guidance for this will be developed by FDA's regional specialists and by the Clearinghouse Workgroup for Program Standards.

# Appendix B

## **DISCUSSION OF IMPACT OF CONFIDENCE LEVELS ON DATA PRECISION**

Prepared by Jerome Schneidman, FDA Division of Mathematics

Recall that our original samples sizes for state and local baselines, as presented in the Data Collection Manual, were calculated to give 95% confidence that a data item that was 60% or less in compliance would be found to be no more than 70% in compliance in the sample (pages 48-49). We were asked to explore the effect on sample size, if we reduced the confidence goal from 95% to 80% and 90%, respectively.

### 80% Confidence

Provided the number of establishments in a facility type is no more than 15,951, this yields a sample size of no more than 29 (i.e., 29 or fewer). Assuming nonresponse (not observed or not applicable) similar to what FDA experienced, this could easily lead to only about 20 observations for a data item. Under such a scenario, there would be only 21 possibilities: 0 IN, 1 IN, 2 IN, ..., 19 IN, 20 IN. Similarly, this yields only 21 possibilities for % IN: 0%, 5%, 10%, ..., 95%, 100%. Such limited possibilities for the results give too little information to be of much use. With such a small sample, there will be almost no ability to detect small changes from repeated baselines. In fact, there would be a good chance that a small increase in compliance would erroneously show up as a decrease. We cannot recommend such a small sample size and would urge rejection of using only 80% confidence.

### 90% Confidence

The sample size results are summarized as follows.

Population Size	Sample Size
763 or less	57 or less
764 - 1,311	59
1,312 - 3,591	63
3,592 and above	68

We don't recommend using this either, because such sample sizes will make it more difficult to show or detect small changes from repeated baselines because of loss of precision due to these smaller sample sizes. This difficulty cannot be quantified until the particular data has been collected. We can illustrate using example scenarios.

Example: With these sample sizes, we have 90% confidence that a data item that was 60% or less in compliance would be found to be no more than 70% in compliance in the sample. It is also expected to be more difficult to show a small change from say, 60% IN to 65% IN or 70% IN to 75% IN than with our original samples sizes. Furthermore the probability of detecting such changes from repeated baselines is expected to be less than .90.

Under these sample sizes, jurisdictions will be less likely (it will be more difficult) to detect changes from repeated baselines. With full understanding of these caveats, these smaller

sample sizes could be used; however, we still do not recommend them. If used at all, this 90% confidence level should probably be restricted to very small states and jurisdictions. It is probably not appropriate for jurisdictions with large populations since public health is at issue.