

VOLUNTARY NATIONAL RETAIL FOOD REGULATORY PROGRAM STANDARDS

CLEARINGHOUSE WORK GROUP Questions and Answers May 2002 – September 2006

STANDARD #1

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

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.

Clearinghouse Work Group Response (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

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.

Clearinghouse Work Group Response (02-20-02)

The language of Standard No. 1 currently requires provisions corresponding to all of the 15 identified *Code* provisions, which includes both criminal and civil penalties. According to the criteria established in Standard No. 1, the jurisdiction does not meet the Standard.

The Work Group believes that under some circumstances criminal penalties alone can provide the foundation for effective enforcement. The Work Group is referring this question to the CFP Standards Committee (formerly the Accreditation Committee) for their assessment of the criteria contained in Standard 1, Appendix A, Table A-5.

3. Local/county Jurisdictions Operating Under State Regulations

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

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.

Clearinghouse Work Group Response (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 second 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.

4. Asterisks in Appendix A of Standard #1

Keywords: STD-01, Regulatory foundation, Annex A, superscripts, asterisks, critical items

Annex A that accompanies Standard 1 is confusing in that there is no explanation of the superscripts (asterisks) that appear on some of the line items. What do these mean in terms of meeting the Standard?

Question/Problem

The Program Standard 1, Appendix A needs more clarity pertaining to superscripts and line items. Please explain. We recommend that FDA provide information to assist the user by including information from the *Food Code*, preface 8 (VIII – IX), in the Program Standards Appendix.

Clearinghouse Workgroup Response (11-20-02)

The Workgroup believes that the issue involves the asterisks attached to some of the *Food Code* tag lines that appear in the Appendix A for Standard 1. The asterisks represent the *Food Code* convention that indicates a 'critical item.' The asterisks have no relevance to the Standard itself and do not signify relative importance of one item over another. All of the risk factors and interventions carry equal weight in the attainment of the Standard. This should be resolved, however, if it creates confusion on the part of jurisdictions conducting self-assessment. The Clearinghouse will recommend to FDA that a note explaining the asterisks be added to Appendix A or that the asterisks be removed from the Appendix A for Standard 1 entirely since they have no relative meaning in Standard 1.

5. Access to the Food Code

Keywords: STD-01, Regulatory foundation, Food Code availability

Question/Problem:

Evaluating a program against Standard 1 requires access to FDA *Food Code*. We recommend FDA provide sufficient number of *Food Code* copies to jurisdictions when enrolling in the Program Standards.

Clearinghouse Workgroup Response (11-20-02)

While the Clearinghouse acknowledges that the *Code* is available free-of-charge on the FDA web site and is for sale through the National Technical Services Center, FDA does make limited distribution to jurisdictions through its Regional

Specialists. It seems reasonable that one copy could be made available to each of the enrolled jurisdictions, and the Clearinghouse will forward that recommendation to FDA. You should also know that FDA’s Division of Federal Relations will soon be distributing a CD-ROM set that includes many resource documents, including the *Code*.

6. Phase-in Period for Meeting the Risk Factors/Interventions in Standard #1

Keywords: STD-01, Regulatory foundation, second audit, extended phase-in, phase-in period, risk factors, interventions

This Standard currently requires that a jurisdiction have all 11 of the 11 risk factors/interventions provisions after two self-assessment cycles, essentially six years

Question/Problem

We believe this requirement to meet all eleven of the risk factors/interventions after six years is too stringent. More flexibility to reach compliance is needed.

Recommendation: We recommend that the Clearinghouse extend the phase-in time for compliance with the risk factors and interventions to:

- 9 of 11 in three years (one assessment cycle);
- 9 of 11 in six years (two assessment cycles; and
- 11 of 11 in nine years (three assessment cycles).

Clearinghouse Workgroup Response (11-20-02)

This issue involves extending the period for compliance with all eleven of the risk factors and interventions from two assessment cycles (six years) to three assessment cycles (nine years). Since this is a request for a change in the Standard, the Clearinghouse will recommend that this issue be referred to the CFP Standards Committee for deliberation.

7. Requirement to have all *Code* sections under each heading to meet the Standard.

Keywords: STD-01, Regulatory foundation, recommended formula for compliance, section headings, risk factors

Under the risk factor/intervention category “Approve Source,” there are 18 identified *Food Code* sections. A jurisdiction’s regulation must address each of these in order to meet the Standard for that risk factor.

Question/Problem

Currently some jurisdictions have not included wild mushrooms in their code and, therefore, are unable to meet the requirement for approved source.

Recommendation: We recommend that a formula be developed for each major intervention/risk factor in table A of Appendix A to allow for flexibility in meeting

this standard. So, if a jurisdiction meets 17 of the 18 *Code* provisions in the "Approved Source" section, the intent of the Risk Factor would be met.

Clearinghouse Workgroup Response (11-20-02)

While there may be some merit to the recommendation, the Workgroup foresees an extremely complicated process for determining achievement. Careful consideration will need to be made about whether any overall national benefit will result from the increased complexity, given that there is already a phase-in time for meeting all of the risk factors and interventions. The Clearinghouse Workgroup is referring this issue to the FDA Steering Committee for consideration.

8. Want Alternative Criteria for Demonstrating Control of Risk Factors

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

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?

Recommendation: 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.

Clearinghouse Workgroup Response (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.

9. GRP Requirements Too Stringent

Keywords: STD-01, Regulatory foundation, Good Retail Practices, GRPs, variance for local code, language difference

Question/Problem:

Too much emphasis is placed on GRP's. The 95% requirement is too stringent and does not take into account language differences in local codes, which may not have the same degree of specificity but shares the same intent.

Recommendation: We recommend that the Clearinghouse allow local justification for variance of local codes from the *FDA Food Code* with the condition that the risk factors are NOT compromised.

Clearinghouse Workgroup Response (11-20-02)

It is too early to determine whether any of the Standards are too stringent or too lenient since not enough information has been gathered from the participants. There are currently more than 70 jurisdictions enrolled and conducting self-evaluations for the first time based on the criteria in the Standards. The number of participants grows daily. Many jurisdictions are just beginning to complete the self-assessment process. Any recommended changes to the Standards, made through the CFP, should be made based on empirical data and should reflect the best practices in the food safety community.

10. Compliance and Enforcement Code Sections

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

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 are 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.

Clearinghouse Workgroup Response (02-20-03)

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:

- 1. improper holding temperature;**
- 2. inadequate cooking;**
- 3. contaminated equipment**
- 4. unsafe source; and**
- 5. poor personal hygiene”**

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

- 1. management’s demonstration of knowledge;**
- 2. employee health controls;**
- 3. controlling hands as a vehicle of contamination;**
- 4. time/temperature parameters for controlling pathogens; and**
- 5. 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 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.

11. 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

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)?

Clearinghouse Workgroup Response (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. 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 it's 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.

12. 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

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 questions 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?

Clearinghouse Work Group Response (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' being 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 Appendix A of Standard 1, in Table A-1, there are three 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.

13. Adequacy of Consumer Advisory.

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

If a jurisdiction has a Consumer Advisory, but only for shellfish, could they report compliance with 3-401.11? If not, they won’t meet the standard only because they don’t have Consumer Advisory?

Clearinghouse Work Group Response (2-16-05)

The 1999 Food Code provision that addresses Consumer Advisory is 3-603.11. That provision is quite clear in it’s language to include 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 food 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, 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.

Standard #2

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

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

The criteria in Standard #2 require 25 joint training inspections with a trainer who has successfully completed all training elements required in the Standards.

Question/Problem

Can the requirement for 25 joint training inspections be waived for candidates who have had a significant number of years of experience in the field conducting field inspections? 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 joint training 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 exercise, could be developed and implemented.

Clearinghouse Work Group Response (02-20-02)

The language in Standard No. 2 regarding the 25 joint training inspections was intended for new employees or employees new to the food safety program. In order to accommodate an experienced food inspector, the supervisor can include a simple statement or affidavit in the employee's training file explaining their background or experience that justifies a waiver of this requirement. You are correct in stating that the standardization component is the test for competency and should reveal any problem. However, as you suggested, should an experienced inspector for whom a training waiver has been granted fail the standardization component, a corrective action plan must be developed and implemented.

2. Recognized Credentials and Their Relationship to Standard 2 Curriculum

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

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.

Clearinghouse Work Group Response (02-20-02)

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 determination of whether the Standard or elements of the Standard have been met.

3. Determining Training Component Equivalency

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

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?

Clearinghouse Work Group Response (02-20-02)

The submitter is correct in that the Standard does not provide specific guidance on the quality or length of class required for equivalency. Originally a sample training plan (formerly called the Level 1 Training Plan) was included as an attachment to Appendix B that accompanies Standard No. 2., and the sample plan was intended to serve as a general guide. However, it was a very lengthy document that caused trouble when attempting to download the appendix. A decision was made to post the sample training plan on the Web as a separate

document and refer readers of Standard 2 to the appropriate site, still with the intention that it be used as general guidance. The sample training plan is now Appendix K and will be posted with the Standards in the future.

In the sample training plan, the module for microbiology, for example, recommends a half-day of on-site orientation to a laboratory and eight contact hours of microbiology. The FDA filmed satellite course on microbiology is offered as an alternative to a live course. Currently, FDA basic food safety courses are being developed as interactive web-based courses and will be available soon to jurisdictions at no cost. The intention of providing only general guidance was to give jurisdictions some flexibility in designing their training programs and to allow training from a wide variety of sources. It may well be that this is insufficient guidance.

Currently there are over 70 jurisdictions enrolled in self-assessment. The FDA is planning to gather feedback from those jurisdictions. This area of training is one area where information from the jurisdictions about how they view an equivalency measure is needed. There are many ways to go about measuring equivalency, but none of them are simple. Establishing specific course objectives, contact hours, or performance standards for the knowledge gained in order to measure equivalency will be a large task. This may well be a task for stakeholder group, another FDA work group or a CFP committee to tackle. The Clearinghouse Work Group recommends another look at this issue after the jurisdictions have reported back on their experiences.

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

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?

Clearinghouse Work Group Response (03-20-02)

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.

The Clearinghouse Work Group will ask the CFP Standards Committee to look at the issue of logs/training records and take under consideration the amount of information to be kept, what information elements must be kept, and for how long.

5. Who Must Meet Standard 2

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

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?

Clearinghouse Work Group Response (03-20-02)

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

Question/Problem

The Standards do not allow flexibility for standardizations to be conducted to a jurisdiction's own food code when the standardizer and the candidate are from the same jurisdiction.

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

Clearinghouse Workgroup Response (05-20-02)

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, generally, upon the jurisdiction's own regulation or ordinance, with some cautions and explanations provided in the following paragraphs.

FDA's standardization of jurisdiction officials is and will continue to be based upon the FDA Food Code since it represents the national technical and scientific criteria for food safety in the food service and retail food setting and promotes uniformity across the nation. The FDA standardization process, along with the Food Code as a model, furthers the goal of national uniformity. It is certainly the intention of the Standards that jurisdictions adopt the Food Code as faithfully as possible. The Food Code continues to be a primary means of promoting regulations based on science, providing the same level of protection to consumers across the country, and providing a level playing field for the industry.

The specific goal of Standard 2, however, is to ensure that personnel are trained and prepared to competently conduct inspections within their jurisdiction. This is further demonstrated by the curriculum component number 1 of Standard 2 that includes “prevailing statutes, regulations, ordinances; . . .,” meaning those prevailing in the jurisdiction. Standard 2 further states that a jurisdiction’s field standardization must be similar to the *FDA Procedures for Standardization and Certification of Retail Food Inspection/Training Officer*. This means that it must include eight joint standardization inspections, be conducted by a “training standard,” determine the inspector’s ability to apply the knowledge and skills obtained from the training curriculum, and address the five performance areas. The five performance areas to be addressed are spelled out in the Standard as follows:

1. Conducting risk-based inspections,
2. Recognizing good retail practice requirements,
3. Applying HACCP principles to the inspection process,
4. Demonstrating knowledge and use of essential inspection equipment, and
5. Communicating in an effective manner.

The five performance areas target the behavioral elements of an inspection. The behavioral elements of an inspection being defined as the manner, approach and focus of an inspection which targets efforts to the most important public health risk factors and communicates vital information about the inspection to management in a way that it can be received, understood and acted upon. The goal of standardization is to assess not only technical knowledge but also an inspector’s ability to applying his or her technical knowledge in a way that targets time and resources spent in a facility to most benefit the regulatory agency and the consuming public. A customized standardization procedure must still meet the standardization goals.

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*. Usually regulation’s differences 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 ‘*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 procedures. Jurisdictions that change the limits of the standardization form to fit a local regulation are cautioned that a redesign of the scoring assessment of the candidate's performance on the field inspections and other exercises is also necessary, and this sometimes proves to be a very difficult task.

7. Number of Joint Inspections for Field Training

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

Question/Problem

Twenty-five joint inspections for field training of new or newly assigned inspectors is too many. It needs to be reevaluated and justified.

Recommendation: We recommend to the CFP the reevaluation and justification of the number of joint inspections for field training. We recommend a significant reduction of the number of joint inspections for field training (currently 25) to something like 10, and they should cover a variety of risk levels.

Clearinghouse Workgroup Response (11-20-02)

Standard 2 requires that field personnel perform a number of separate training activities and pass a performance measure to assure initial and continued competency in the performance of food safety inspections. An academic training curriculum, the twenty-five joint training inspections and the twenty-five independent inspections are intended to ensure adequate preparation for field standardization and ultimately for the performance of their duties as food inspectors. These are each designed as separate activities. While the submitter of the problem feels that twenty-five joint inspections are too many, other managers and trainers feel that the number may be too few. While more would be better, twenty-five was chosen because it represents an amount of work that can be performed in a reasonable time period for most jurisdictions, probably two weeks or less. The joint inspections are intended to be practical field training that gives the new employee an opportunity to ask questions and the supervisor/trainer an opportunity to train, observe, and assess future training needs of the employee. Twenty-five inspections do not appear to be an unreasonable training module. In addition, twenty-five joint inspections represent an amount of one-on-one training during which a reasonably intelligent person can assimilate the details of the duties being required of them and to encounter a wide variety of situations that exist in the work environment. The twenty-five independent inspections performed before standardization then allows for a sufficient amount of individual work for the employee to gain confidence and to identify questions or issues that will inevitably arise once they are conducting inspections on their own. Also, note that the training is not required to be done by an 'FDA standardized officer.' The Standard says that the joint inspections must be done with a trainer who has successfully completed

the training elements of the Standard. This can be a supervisor or other designated individual. The Clearinghouse believes that the training element for new or newly assigned employees should remain as currently stated

8. Number of Inspections in the Standardization Exercise

Keywords: STD-02, Trained regulatory staff, field standardization, number of inspections for standardization, standardization inspections

Question/Problem

The number of inspections for field standardization is too many due to limited standardized staff resources and travel considerations.

Recommendation: We recommend to the CFP the reduction of inspections for field standardization, e.g. six.

Clearinghouse Workgroup Response (11-20-02)

The number of inspections required for standardization is an issue that has been discussed and agonized over by many people. Remember that the standardization process is a performance measure. It differs considerably from joint training inspections in that the candidate is not allowed to receive technical information regarding observations from the ‘standard’ during a standardization inspection. The fact that the candidate and the ‘standard’ must have comparable results within a percentage range makes this a testing process. The fewer the number of inspections, the more difficult it will become for the candidate to perform satisfactorily during the standardization and the more critical individual inspections and individual technical items become. Fewer inspections in the process will raise the performance bar. Standardization must represent a reasonably challenging measure, but it must not be so stringent a measure that a competent individual cannot succeed. The Clearinghouse Workgroup believes that eight (8) should remain the minimum number of Standardization inspections.

9. Training Plan in Appendix K

Keywords: STD-02, trained regulatory staff, training plan, Appendix K, training guidance

Question/Problem

There is confusion as to whether Appendix K is for guidance only or if it will be used to evaluate a jurisdiction for compliance with the Standard. The training modules in “K” are too narrow and need to be expanded.

Recommendation: We recommend that the Clearinghouse clarify whether Appendix K is for guidance only or if it is to be used as an evaluation tool for compliance. We recommend additional related courses to “K” be added, such as: interpersonal skills;

pesticides/toxicology; equipment and mechanics; foreign languages; cultural diversity; personal safety; H₂O/ww systems; information technology.

Clearinghouse Response (11-20-02)

Standard 2 is clear in stating that Appendix K is provided as an example. It is not intended for use as an evaluation measure, but is provided as an illustration of a good, comprehensive program. Appendix K was developed jointly by the program managers for the states of the FDA Southwest Region and has been used by many of those states for training staff for a number of years.

10. Criteria for the Education/Training Requirements

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

Question/Problem

The Education and Training Requirement in Standard #2 provides no details or guidance as to content. We need more guidance for designing our curriculum, and information about how to measure course equivalency.

Recommendation: We recommend to the Clearinghouse the clarification of the Continued Education and Training requirement so it relates to curriculum requirements. Suggested wording to add to the first paragraph of Element #4 at the end of the 2nd sentence: "...following activities that relate to the components of curriculum in Element #1".

Clearinghouse Response (11-20-02)

It is true that the Standard does not provide any details about the content for each of the curriculum elements. Currently, jurisdictions have maximum flexibility in designing or assembling training in each of the six elements to meet the intent of that portion of the Standard. Those of you who have been in the food safety profession for a number of years may remember the origins of the Managers Certification program. Manager Certification started out in the early 1980's with a specific course outline and a specific number of classroom hours that had to be devoted to each topic. Then the issue of who would qualify the individual training courses as meeting the requirements arose. Then the issue of whether or not the same knowledge could be conveyed in a shorter amount of time surfaced. The good concept that started out in the early 1980's fairly simply was finally resolved to everyone's satisfaction at the 2002 Conference for Food Protection with passage of the issue approving of the certifying process for training providers.

Also, during the 2002 CFP, five issues were submitted that involved the training and certification of health officials. The issues were combined, approved as amended, assigned to a committee for assessment and for review of Standard 2, and charged to return with recommendations to the 2004 Conference. It is not

possible to know what the committee will recommend regarding the training and certification of health officials. At this time, the Clearinghouse Workgroup believes that the best course of action is to wait for the recommendations of the committee and actions of the CFP.

11. Training Time-Frame Requirements for Standard 2

Keywords: STD-02, trained regulatory staff, time frame, time frame for training

Question/Problem

We understand the requirement for 100% of all employees new to the food program to complete the following training requirements:

- Within 18 months of employment or reassignment to the program, an employee must complete the prescribed course curriculum and field standardization.
- Within 12 months of employment or reassignment to the program, an employee must complete field training of 25 joint inspections and 25 independent inspections in preparation for work standardization.

Our question is this, if we have an employee who fails for some reason to meet the requirements within the specified time frame, how long does this count as a failure of the Program to meet the Standard? Does this mean that our Program can never meet Standard 2? Or can we pass the Standard at the point when the employee completes the requirement or when one or two successful audits have been completed after the occurrence?

Recommendation/Rationale

We believe that the intent of the Standard is to ensure that employees receive timely and appropriate training in order to conduct inspections in a knowledgeable and competent manner. Since life is unpredictable, it seems unreasonable to set a standard that can never be met after an initial failure. It seems that the Standard needs two additional components. First, it seems that some criteria other than 100% for pass/fail needs to be considered. For example, require 98 or 95 percent of staff to meet the requirement for program success, with some accommodation for an extremely small staff. This would allow for unforeseen events that might prevent an employee from completing the program despite best efforts. Second, some process should be established to allow for remedy of a failure in order to achieve success. For example, if during self-assessment, I discover several employees have not met the established time frames; but I can provide a commitment to have the training completed in a certain time and the training is in fact completed in that time, then I should be able to claim meeting Standard 2.

Clearinghouse Work Group Response (08-21-02)

When a jurisdiction falls short of meeting Standard 2, several things should be instituted to provide a remedy so that the Standard can be met.

First, a documented explanation must be made regarding why the employee or employees were not able to meet the criteria within the time frame criteria of the Standard. While the timeframe is intended to be a ‘time certain,’ everyone acknowledges that at times unforeseen events may prevent us from meeting our intended goals.

Second, a corrective action plan must be developed outlining how the situation will be corrected and the date when the correction will be achieved.

When the action plan is completed and these conditions have been met, the jurisdiction can then be assessed as meeting the Standard.

12. Proof of Training for Long-tenured Employees

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

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 addresses 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.

Clearinghouse Work Group Response (08-21-02)

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.

13. ORA-U Courses That Satisfy Standard 2 Requirements

Keywords: STD-02, trained regulatory staff, ORA-U, web-based courses, face-to-face courses, meeting training requirements, identifying courses

Question/Problem

Several jurisdictions have asked FDA to identify which of its web-based and face-to-face courses satisfy the course requirements for new and newly assigned employees under Standard 2. Several members of the FDA Clearinghouse in coordination with FDA’s Division of Human Resource Development reviewed the available FDA courses and provided the following list for consideration.

Clearinghouse Workgroup Response (09-16-03)

The Clearinghouse members reviewed the list of identified courses and believe the time commitment to be reasonable. The course list is attached. This list can be used as a model, both for jurisdictions wishing to use the FDA courses to meet the requirements and for those who wish to develop their own in-house courses or to use courses from other sources to meet Standard 2. All the web-based courses under a single topic should be viewed together as one module for purposes of meeting the requirement for that topic. For example, the time commitment for the microbiology requirement would include all fifteen of the web-based courses equaling 21.5 hours, or approximately 2 ¾ days, in microbiology.

See the course list below.

The course numbering in the list below reflects the FDA course numbering under each of its web-based modules.

SORTING FDA ORA-U WEB & FACE-TO-FACE COURSES BY CURRICULUM AREAS

**CONTAINED IN
PROGRAM STANDARD #2
TRAINED REGULATORY STAFF**

1. Prevailing Statutes, Regulations, Ordinances

ORA-U Web Courses – *(This curriculum element is intended to be specific to each jurisdiction’s prevailing statutes, regulations and ordinances. Beginning in 2004, ORA-U will begin the development of web courses on the FDA Food Code. These courses can serve as a foundation for most jurisdictions with the understanding that each regulatory authority will need to develop adjunct training to reflect their applicable rules.*

While none of the web courses could meet the full intent of this requirement, nevertheless, the courses listed below may contain program elements that have been incorporated into a jurisdiction’s regulations either directly or by reference. Review of these ORA-U courses is encouraged and elements that relate to a jurisdiction’s regulatory foundation should be included as part of their training programs.)

- Course #1 – Basic Food Law for State Regulators (60 minutes)
- Course #5 – Basics of Inspections: Beginning and Inspection (90 min.)
- Course #6 – Basics of Inspections: Issues and Observations (90 min.)
- Course #9 – Courtroom Testimony (60 min.)
- Course #10 – Destruction and Reconditioning (60 min.)
- Course #11 – Evidence and Proof (60 min.)
- Course #19 – Food and Drug Law: FDA Jurisdictions (60 min.)
- Course #20 – Food and Drug Law: Prohibited Actions (60 min.)
- Course #21 – Food and Drug Law: Criminal Acts Violations (45 min.)
- Course #22 – Food and Drug Law: Judicial Actions (60 min.)
- Course #23 – Food and Drug Law: Imports and Exports (60 min.)
- Course #24 – Food Labeling
- Course #39 – Food Microbiology Control 11: Good Manufacturing Practices (90 min)

FDA Face-to-Face Courses – *(These face-to-face courses do meet the intent of the training objectives in Program Standard #2. Though the curriculum in these face-to-face courses may not directly reflect all the rules within a jurisdiction, the overall content provides a substantial part of regulatory foundation that transcends all regulatory retail food programs. Each regulatory authority may need to develop adjunct training to reflect their applicable rules where they differ from the Food Code.)*

- Food Code FD1012
- Food Code Train-the-Trainer FD2013
- Preparation for Retail Food Standardization FD 3016

2. Public Health Principles

ORA-U Web Courses

Course #53 – Public Health Principles (90 min.)

3. Communication Skills

ORA-U Web Courses

Under Development – Communication Skills for Regulators

4. Microbiology

ORA-U Web Courses

Course #25 – Food Microbiological Control 1: Overview of Microbiology (60 min.)

Course #26 – Food Microbiological Control 2A: Gram-Negative Rods (60 min.)

Course #27 – Food Microbiological Control 2B: Gram-Positive Rods & Cocci (90 min.)

Course #28 – Food Microbiological Control 3: Foodborne Viruses (60 min.)

Course #29 – Food Microbiological Control 4: Foodborne Parasites (90 min.)

Course #30 – Food Microbiological Control: Mid-Series Exam (30 min.)

Course #31 – Food Microbiological Control 5: Controlling Growth Factors (90 min.)

Course #32 – Food Microbiological Control 6: Control by Refrigeration & Freezing (60 min.)

Course #33 – Food Microbiological Control 7A: Control by Thermal Processing (90 min.)

Course #34 – Food Microbiological Control 7B: Control by Pasteurization (90 min.)

Course #35 – Food Microbiological Control 7C: Control by Retorting (90 min.)

Course #36 – Food Microbiological Control 8: Technology-based Food Processes (120 min.)

Course #37 – Food Microbiological Control 9: Natural Toxins (90 min.)

Course #38 – Food Microbiological Control 10: Aseptic Sampling (90 min.)

Course #39 – Food Microbiological Control 11: Good Manufacturing Practices (90 min.)

Course #40 – Food Microbiological Control 12: Cleaning and Sanitizing (90 min.)

5. Epidemiology

ORA-U Web Courses

Course #41 – Foodborne Illness Investigations 1: Collecting Surveillance Data (90 min.)

Course #42 – Foodborne Illness Investigations 2: Beginning an Investigation (90 min.)

- Course #43 – Foodborne Illness Investigations 3: Expanding the Investigation (90 min.)
- Course #44 – Foodborne Illness Investigations 4: Conducting a Food Hazard Review (90 min.)
- Course #45 – Foodborne Illness Investigations 5: Epidemiological Statistics (90 min.)
- Course #46 – Foodborne Illness Investigations 6: Final Report (30 min.)

FDA Face-to-Face Courses

Fundamentals of Foodborne Illness Investigations FD1025

6. HACCP

ORA-U Web Courses

- Course #2 – Basics of HACCP: Overview of HACCP (60 min.)
- Course #3 – Basics of HACCP: Prerequisite Programs and Preliminary Steps (60 min.)
- Course #4 – Basics of HACCP: The Principles (60 min.)

FDA Face-to-Face Courses

Managing Retail Food Safety FD2015

14. Age of training records.

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

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

Clearinghouse Work Group Response (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 have the knowledge and skills to perform their inspection functions.

15. New employee vs. new to the food program.

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

Can you clarify New Employee versus New To Food Program?

Clearinghouse Work Group Response (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 in certain topics such as ‘prevailing statutes, regulations and ordinances’ may apply 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.

16. Kinds of continuing education that qualify.

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

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?

Clearinghouse Work Group Response (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 topic. The Standard does not address other kinds of training; however, the purpose of the Standard is not to make well-rounded employees but to ensure that staff have 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 fascia 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.

17. Time frame on Standardization.

Keywords: [STD-02, trained regulatory staff, standardization, time frame for standardization](#)

What if a jurisdiction trains and standardizes their staff, but can only get the job done in 24 months instead of 18 months? How can we ever meet the standard?

Clearinghouse Work Group Response (02-16-05)

It is usually best to frame questions to the Clearinghouse with some background information so that the question can be given a context. We will examine this question from two different perspectives in hopes of accurately interpreting the question.

First would be the situation where the staff standardizations generally get accomplished with the 18-month time frame, with the exception of an employee or two where some circumstance prevented the standardization from taking place on schedule. This question was previously answered by the Clearinghouse on 08-21-02. In this situation, the standardization element can be met by fulfilling two conditions: 1) a documented explanation must be made for the file regarding why the employee or employees were not able to be standardized within the time frame, and 2) a corrective action plan with the date by which the standardization will be completed. After the standardization is completed, the jurisdiction can be assessed as meeting the Standard.

The second situation would be one in which the jurisdiction consistently does not meet the training and standardization time frames for new and newly assigned employees. The Clearinghouse agrees that this second situation does not meet the spirit of the Standard; and, therefore, the Standard is not met until a system is in place that will enable the jurisdiction to provide the required training and standardization within the 18-month time frame, except for those rare occasions when unforeseen circumstances intervene.

Standardization is an on-going process where restandardizations occurs on a three-year cycle for each employee. So as a general rule, if at the time of the self-assessment and audit, the jurisdiction can show that each inspection staff member has a currently valid standardization certificate, then the Standard is met since the goal of the Standard is to have knowledgeable staff with the skills and abilities to perform quality inspections.

18. Standardization of ‘old’ employees

Keywords: [STD-02, trained regulatory staff, old employees, standardization, existing staff, current staff](#)

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?

Clearinghouse Work Group Response (02-16-05)

Standardization within 18 months applies to new hires and employees newly assigned to the food program. The Standard criteria go on to require continuing standardization to be maintained by performing six joint inspections with the “training standard” every three years. So the criteria clearly intend that all of the inspection staff achieve and maintain standardization. After initial standardization, the cycle for restandardizations is three years. The measure of achievement for this element of Standard 2 for both the self-assessor and the auditor would be whether all inspection staff who have been assigned to the program for at least 18 months has a valid standardization or restandardizations certificate issued by a training standard.

19. Dilution of field standardization.

Keywords: [STD-02, trained regulatory staff, standardization, dilution, cascade](#)

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?

Clearinghouse Work Group Response (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 Clearinghouse must refer this issue to the FDA Steering Committee for further clarification. It may also be necessary to redefine the term ‘training standard, in Standard 2 to allow the use of additional personnel. If that is the case, then an issue will need to be submitted to the CFP.

[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]

FDA Steering Committee's response (07-21-2006):

The Steering Committee discussed the issue of potential "dilution effect" of standardization and offers the following clarification. The Committee believes that as long as a procedure similar to FDA Procedures for Standardization and Certification of Retail Food Inspection/Training Officers is followed and quality assurance of the standardization staff at all levels is maintained, the number of levels of cascade needed to accomplish the standardization element specified in Standard 2 can be left to the discretion of the enrolled jurisdiction..

[NOTE: The Steering Committee further clarified that the reference to quality assurance in their statement does not mean that a jurisdiction must meet Standard 4 in order to have a qualifying standardization process.]

20. Is there a requirement for a ‘roster’ of employees including hire date?

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

Is there a requirement for a roster of employees, with dates of hire, etc as evidence to meet the first requirement in Standard 2?

Clearinghouse Response (02-16-05)

The quality records for Standard 2 list date-of-hire records and a summary record of employees’ compliance with the Standard similar to Appendix B. The Standards state that jurisdictions are not required to use the appendices, but may use alternative forms as long as they capture the same information as an Appendix. Whether you call the document a roster or not, some sort of consolidated list of employees and their hire dates who were evaluated for

meeting the Standard at the time of the self-assessment must be established and maintained as per Standard 2 and its Appendix B.

21. Mutual standardization by two parties in different jurisdictions

Keywords: STD-02, number of inspections, cross standardization, mutual standardization [Note: This will be question 21 under Standard 2 in the merged Clearinghouse responses.]

Question/Problem

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.

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.

Clearinghouse Work Group Response (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.

22. Who Can Perform Training Needs Assessments under the 2006 Revised Standard 2?

Keywords: STD-02, Training Needs Assessment, TNA, qualifications, trainer [Note: This will be question 22 under Standard 2 in the merged Clearinghouse responses.]

Submitted on behalf of the CFP Certification of Food Safety Regulations Professionals work group.

Question Submitted By:

David Read – Minnesota Department of Agriculture

Revised Program Standard #2 criteria approved at the 2006 Conference for Food Protection

BACKGROUND: Beginning in January, 2007, the criteria in Program Standard #2 – Trained Regulatory Staff will reflect the revisions recommended by the Conference for Food Protection (CFP) Certification of Food Safety Regulations Professionals and unanimously approved by the CFP Assembly of Voting Delegates. One of the more substantive revisions to the Program Standard #2 criteria is the incorporation of an Assessment of Training Needs (ATN) used during joint field training inspection as a tool to assist training officers and food program managers determine when a Food Safety Inspection Officer (FSIO) has the basic knowledge and skills to conduct independent routine inspections. The ATN is intended to be a training tool and not an evaluation or audit instrument. It is focused on ensuring that the FSIO has received the appropriate training from the jurisdiction to acceptably perform specific tasks associated with conducting routine retail food and foodservice inspections.

The Program Standard #2 criteria still contains the requirement that FSIOs successfully complete a standardization process similar to one performed by FDA within 18 months of hire or assignment to the retail food protection program. It is this standardization process that serves as the evaluation instrument for assuring FSIO performance within the context of Program Standard #2.

Question/Problem

Standard #2 clearly specifies that the standardization process must be performed by a trainer or the jurisdiction’s “training standard”. The term “training standard” denotes an individual who has successfully completed all elements of Standard #2 including standardization. It was not the intention, however, of the CFP Certification of Food Safety Regulation Professionals work group to limit the conduction of joint field training inspections or the Assessment of Training Needs to only “training standards”.

In the revised Program Standard #2, the language in Step 2 – Initial Field Training and Experience pertaining to who can conduct the joint field training inspections and Assessment of Training Needs includes FSIOs,

who have successfully completed all training elements required by the Standard.

The intent of the CFP work group was to allow experienced FSIOs that had successfully completed all the criteria in Standard #2, but had not been standardized, to assist the jurisdiction’s trainer and food program manager in the training process for FSIOs newly

hired or assigned to the retail food protection program. For some regulatory retail food programs, particularly large health jurisdictions, the time and resources required to train new employees in an efficient and effective manner far exceed those that can be provided by “training standards” available to the jurisdiction. The regulatory retail food protection program’s management should be provided the opportunity to use staff that has demonstrated successful competence in the training elements of Program Standard #2, to assist with the joint field training inspections and the Assessment of Training Needs.

The Program Standard #2 criteria still requires all FSIOs to successfully complete standardization within 18 months of hire or assignment to the retail food program. Standardization is the evaluation component of a FSIOs knowledge and skills learned through the training process and it must be performed by the “training standard”.

CLARIFICATION NEEDED: The current language in Step 2 of the revised Program Standards may be mis-interpreted. A written interpretation from the Clearinghouse is needed to confirm the intent of the CFP work group and the Standard criteria to allow staff who have successfully completed all the Standard #2 training elements, but who have not been standardized, to assist with the joint field training inspections and the Assessment of Training Needs for FSIOs newly hired or assigned to the regulatory retail food protection program.

Clearinghouse Work Group Response (8-16-06)

There are 26 terms defined in the Standards. The terms ‘trainer’ and ‘training standard’ are both defined. Currently these definitions read:

- **Trainer – an individual who has successfully completed the training elements outlined in Standard No. 2 and is recognized by the program manager as having the field experience and communication skills necessary to train new employees.**
- **Training Standard – 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.**

The original framers intended to make a distinction between trainers and those who had progressed to the next step and completed Standardization.

The phrase ‘trainer who has successfully completed all training elements required by this standard’ is used in the original version of Standard No. 2 as the person qualified to conduct the field training consisting of 25 joint field inspections. In Step 2 of the 2006 version of Standard No. 2, that same phrase is used as the person qualified to conduct the field training and the term ‘trainer’ is consistently used throughout the description of the Assessment of Training Needs process. From the language of the Standard and further confirmed by the CFP Certification of Food Safety Regulations Professionals Work Group, there was no intent to require the field training or Assessment of Training Needs to be performed only by Standardized Training Officers.

Some confusion occurred because of language inadvertently inserted in Appendix B-2 of the revised Standard No. 2 stating that standardization was required for those conducting an Assessment of Training Needs. The appendices accompanying Standard 2 were constructed in a short time period in order to meet deadlines for the 2006 CFP meeting. The CFP Work Group recognizes that there are a few errors in those documents. The CFP Certification of Food Safety Regulations Professionals Work Group clarified the issue of qualification for ATN assessors via conference calls held with jurisdictions participating the Assessment of Training Needs pilot and issued a Question and Answer document on 8-3-06 stating that it is not their intent to require Standardized Officers to conduct the ATNs. All of the documents contained in the Appendices to Standard 2 will be corrected and resubmitted to the next CFP following the conclusion of the Assessment of Training Needs pilot.

In addition, the Clearinghouse will formulate a recommendation to clarify the language and intent of the Standard further by refining the definitions of ‘trainer’ and ‘training Standard’ in an issue to be submitted to the next CFP meeting. The definitions should clarify that a trainer is required to complete Steps 1 through 3, while a training standard is required to complete Steps 1 through 4. Also, in light of the FDA Steering Committee’s decision on the standardization dilution question (see Clearinghouse Work Group Questions and Answers, Standard 2, question 11, Steering Committee’s response of 7-21-06), the definition of ‘training Standard’ should be further changed to remove the restriction for standardization to be performed by an FDA-Standardized Inspection Officer.

Standard #3

1. Change the Term HACCP in Standard 3.

Keywords: STD-03, HACCP-Based Inspection Program, risk factors, risk control, HACCP, Standard 3 title

Question/Problem

The term “HACCP” doesn’t convey the clear intent of identifying and controlling risk.

Recommendation: Recommend to the Clearinghouse that Standard #3 wording be revised to eliminate acronyms by replacing HACCP with “Risk Control” in the Standard 3 title.

Clearinghouse Workgroup Response (11-20-02)

The language in the title of this Standard uses the term “HACCP Principles,” which was intended to distinguish the concept from a pure HACCP process. The intent of the Standard is for the inspection program to focus on the control

of risk factors, which in most instances coincides with hazards or hazard control points under the HACCP concept. Further, the inspection program is intended to support or enhance an establishment's own management systems or encourage the development of one if it is lacking entirely. Industry management systems are, for the most part, based on HACCP principles. The term HACCP is generally recognized and understood by industry and by food safety officials. The Clearinghouse Workgroup does not support changing the title as recommended.

2. Risk-Base Inspection Form

Keywords: STD-03, HACCP-Based Inspection Program, risk-based inspection form, Annex 7 form, recommended inspection form, CFP model inspection form, model inspection form, CFP form

Question/Problem

Most jurisdictions don't utilize a risk-based inspection form. We recommend to FDA that the CFP Model Inspection Form replace the present inspection report form in Annex 7 of the *Food Code*. This will encourage use of the new form.

Clearinghouse Workgroup Response (11-20-02)

The CFP Model Inspection Form has not completed the approval process as yet. Jurisdictions are currently being asked to pilot the form to identify any improvements that are needed or to identify any flaws that need to be corrected. When that process is completed and the CFP votes its final approval, the FDA will consider endorsing the form and placing it in Annex 7 of the Food Code as a model.

3. 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

Question/Problem

There is a lack of guidance in the area of policy development concerning short- and long-term compliance issues.

Recommendation: We recommend to FDA that it provide representative examples of acceptable policies addressing the following: on-site corrective actions; long-term risk factor control; follow-up activities.

Clearinghouse Working Group Response (11-20-02)

This issue will be referred to the FDA for consideration. While most jurisdictions want the flexibility to develop their own policies given that compliance and enforcement procedures are controlled in different legal documents among jurisdictions, there is no reason why good examples cannot be provided. Many jurisdictions will be approaching the conclusion of the self-

assessments in March of 2003. The Clearinghouse Workgroup will recommend to FDA that it provide examples on their internet website of good compliance policies as they become available.

4. 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

Question/Problem:

There is a lack of clear criteria in defining risk categories. This results in the loss of uniformity and consistency. FDA should provide more definitive guidance and criteria for determining risk categories/classification.

Clearinghouse Workgroup Response (11-20-02)

There is guidance for determining risk categories provided in Annex 4 of the *Food Code*. The Clearinghouse Workgroup agrees, however, that better guidance is needed. In addition, this may be another area where the jurisdictions, themselves, may be able to provide good examples for others to use. In any regard, this is an area where consensus opinion of the jurisdictions would be very helpful. The Clearinghouse recommends referring this issue to the CFP Program Standards Committee for deliberation.

5. Variance policy

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

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?

Clearinghouse Work Group Response (02-16-05)

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.

6. Multiple Inspection Forms

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

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?

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?

Clearinghouse Work Group Response (02-16-05)

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.

STANDARD #4

1. Citing Code Provisions during Inspections

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

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.

Clearinghouse Work Group Response (02-20-02)

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 the procedure described in Appendix D. 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.

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

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:

- *Document 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?

Clearinghouse Working Group Response (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. Spreadsheet with Embedded Formulas

Keywords: STD-04, Uniform Inspection program, software, self-assessment software, spreadsheet for Standard 4

Question/Problem

No current uniform software exists to document achievement of Standard #4. We recommend that FDA develop software for use with Standard 4 needed for consistency, convenience, and uniformity.

Clearinghouse Workgroup Response (11-20-02)

The Clearinghouse group's understanding of this request is for a spreadsheet with mathematical formulas embedded in the columns and/or rows to calculate compliance according to the completed tables and charts provided in the Appendices to Standard 4. We believe that there may be jurisdictions that have developed such spreadsheets and are willing to share those tools with others. The Workgroup will recommend that FDA seek such a tool from participating jurisdictions.

4. 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

The measurement of field performance inspections under Standard 4 should be taken from routine inspections – not standardization inspections, due to the fact that standardizations are more critical in marking than normal inspections. The goal is to evaluate routine work not standardization.

Clearinghouse Work Group Response (02-16-05)

There is nothing in the Standard that prohibits the use of standardization inspections from being 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 ten specific components 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, follow 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 ten 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.

5. Inspection Forms (IN, OUT, NA, NO).

Keywords: STD-04, Uniform Inspection program, inspection form, IN, OUT, NO, NA

There should be an explanation regarding the need for inspection forms to include the IN, OUT, NA, and NO at the beginning of each pertinent Standard (Standards 3, 4, and 6) for which these markings are required

Clearinghouse Workgroup Response (02-16-05)

Yes, we agree that the language needs to be clearer regarding this requirement. We will forward language to the CFP Standards Committee to be put into an issue for the 2006 Conference for Food Protection meeting.

STANDARD #5

1. Final Outbreak Reports

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

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?

Clearinghouse Work Group (03-20-02)

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

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.

Clearinghouse Work Group Response (02-16-05)

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

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?

Clearinghouse Work Group Response (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 base be sufficient to meet the intent of the Standard?

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

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.
- 1) 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?

Clearinghouse Work Group Response (8-16-06)

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.

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

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

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?

Clearinghouse Work Group Response (8-16-06)

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

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

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 rationale 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?

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 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 and to establish a strategic plan for ultimately meeting the Standard.

2. Risk Categories for Establishments

Keywords: STD-06, Compliance and Enforcement, risk categories, risk priorities, inspection priority

Question/Problem:

Risk categories for prioritizing establishment inspections need to be established and put into the Program Standards Guidelines.

Clearinghouse Workgroup Response (11-20-02)

The Workgroup agrees. See response to Standard #3, Problem 4.

3. Spreadsheet with Embedded Math Formulas

Keywords: STD-06, Compliance and Enforcement, spreadsheet, embedded formulas, standardized reporting, collection format

Question/Problem

There is a need for a standardized reporting and collecting format for Standard #6.

Clearinghouse Workgroup Response (11-20-02)

Since a ‘format’ is included in the Appendix to Standard, it appears that a mathematical spreadsheet for calculating the columns in the worksheet in the Appendix for Standard #6 is being requested. The Workgroup will recommend that FDA collect existing spreadsheets, if they exist, from the participating jurisdictions.

4. 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

Question/Problem

The process for self-assessment against Standard 6 is unclear. It is not clear from the Appendix F worksheet instructions 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?

Clearinghouse Work Group (07-21-04)

While the Standard 6 implies the answer, the Appendix F instruction create some confusion. Standard 6 says in item 3. under the essential program elements required to meet the Standard that there must be ‘documentation on the establishment inspection report form or in the establishment file that compliance and/or enforcement action was taken to achieve compliance at least 80 percent of the time *when* out-of-control risk factors or interventions are recorded on a routine inspection measured using the procedures in Appendix F.’ The ‘when’ in the sentence indicates that the files to be counted are ones where a risk factor/intervention violation exists.

Appendix F says that in order for an establishment file to ‘pass,’ each column marked with a violation at the start-point inspection must have a subsequent “yes” answer to indicate that at least one type of follow-up action was taken. This again clearly defines what constitutes a passing file. The Appendix also goes on to define a ‘failing’ file as a start-point violation without a final resolution.

The confusion occurs when the instructions say to divide the number of files that passed by the number of files reviewed to determine the percentage. This assumes that every file reviewed would have a violation on the start-point inspection and would, therefore, be either a 'pass' or a 'fail' file. This is not the case when the start-point inspection does not reflect a risk factor or intervention violation. Files without a violation at the start-point inspection do not meet either the pass or fail criteria, and using the math formula as described would not demonstrate an 80 percent resolution when violations are identified. The instruction should say to divide the number of files that pass by the number of files showing a risk factor or Food Code intervention on the start-point inspection.

Advice from the FDA Division of Mathematics says that the random draw of files must continue until the assessor finds the requisite number of files that have a start-point violation. Files that do not have a violation at the start-point inspection do not meet the criteria established for the sample. The minimum random draw of files with a start-point violation will be 20 files for jurisdictions with less than 400 establishments and five percent (5%) or 70 files, whichever is less, for jurisdictions with 400 or more establishments. The number of alternate files suggested under the Supplemental Sampling heading in Appendix F should also probably be increased to 50 percent of the original sample size to accommodate the number of files that may be excluded from the draw because of no start point inspection violation.

5. Sample Selection and Pass/Fail Criteria for Standard 6

Keywords: STD-06, Compliance and Enforcement, determining random selection, random files, medium-risk facilities

If the files sampled for measuring Standard 6 are to come only from medium- and high-priority facilities, then why is the number of files sampled determined by all the facilities in the inventory including low-priority firms? Also there appears to be a conflict between the Standard itself and the instructions in Appendix F regarding how to categorize a file that does not have a risk factor violation on the 'start point' inspection. Can you clarify?

Clearinghouse Work Group Response (02-16-05)

Appendix F instructions need to be revised, both to address the question of sampling and sample size and to better explain the pass/fail criteria. We will submit a recommendation to the CFP Standards committee for submitting this as an issue to the 2006 CFP meeting.

STANDARD #7

1. Strengthen Standard #7

Keywords: STD-07, Industry and Community Relations, activities, required activities

Question/Problem

There needs to be more emphasis on interacting with industry and community. How many are feasible? We recommend the Standard be altered to recommend a total of four activities annually (two in each category).

Clearinghouse Workgroup Response (11-20-02)

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.

2. Could CFP Participation Be Used to Meet This Standard?

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

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?

Clearinghouse Work Group Response (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 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.

STANDARD #8

1. Full-time Equivalent to inspection Ratio

Keywords: STD-08, Program Support and Resources, FTE, staffing, staffing requirement, FTE to inspection ratio, inspection ratio

Question/Problem

FTE inspection ratio is not attainable. Develop more realistic criteria. We recommend that FDA approve the innovative grant for the time study to develop realistic data on this issue. We also recommend that CFP Program Standards Committee use the information developed in the time study (still to be approved) to re-evaluate the FTE ration with respect to the number of inspections and/or allowing local staffing formulas.

Clearinghouse Workgroup Response (11-20-02)

About the grant process, a panel of ten or so judges, including experts from outside the FDA organization, rates the innovative grant proposals independently based on the published rating criteria for the grants. Although the panel meets to present and discuss the merits of each proposal, each judge separately scores each proposal on each of the several rating criteria. After each of the judges rates the proposals, the separate ratings from each of the judges are averaged. A separate grant board (FDA uses the National Institutes of Health Grant Board) then ranks the proposals in descending order according to their averaged scores, with the lowest score being the best. Grants are given starting with the proposals at the top of the list and continuing until the pool of grant money available is exhausted.

We agree that a time study of inspections conducted in accordance to the Standards' inspectional requirements and including all the activities in the definition of an inspection in Standard # 8's would be most useful. The time study mentioned in the issue was funded for a grant from FDA. As in all studies, it's usefulness will be determined by the quality of the study design. The report of the study outcome will be reviewed by FDA with great interest. The Clearinghouse expects that important data will be gathered as well from the jurisdictions currently participating in the self-assessment process. As stated in other responses, the Clearinghouse believes that recommendations for changes will need to be based on solid information and should reflect the best practices in the food safety community. The Clearinghouse Workgroup recommends no action at this time.

2. Inspection write-up and data entry should be part of the direct inspection time!

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

The calculations for direct inspection time used to determine full-time equivalent personnel in element 1 of Standard 8 should include the time required to complete the inspection write up and data entry if it is done by the inspector regardless of whether it occurs back in the office or not.

Clearinghouse Work Group Response (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.

3. 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

If we want to use this standard as a tool to get and keep more FTEs, the ratio should be calculated as the number of staff to number of establishments, not to number of inspections, so that we can compare to other jurisdictions.

Clearinghouse Work Group Response (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 staff to establishment figure in order to achieve approximately the same average inspection time per visit. The Standard 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. An average workload figure of 150 establishments per FTE, conducting two inspections per year, was recommended in the FDA 1976 Food Service Sanitation Manual. 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. Remember that the included activities are 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.

Let us illustrate, assuming 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; and 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 a better national Standard criterion for measuring inspectional staffing levels.

4. Administrative Time

Keywords: STD-08, Program Support and Resources, administrative, time, support time

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

Clearinghouse Work Group Response (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 Appendix H, a manager would look realistically at his or her environment and identify the elements that hinder achievement of a quality program. For example, in analyzing the needs 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. Once the obstacle to achieving a Standard is identified, then appropriate strategies to overcome the obstacle may be developed. The obstacle to achieving Standard 3 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. 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

1. Standard Self-Assessment Process for Decentralized Jurisdictions

Keywords: STD-09, Program Assessment, delegation, state, local, MOU, written agreement

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?

Clearinghouse Work Group Response (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:

- a. That criteria exist in your formal delegation document that meets the Standards criteria for those areas,**

- b. 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
- c. 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. Facility Types to be Included in Baseline Surveys

Keywords: STD-09, Program Assessment, facilities, facility, type of facility

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.

Clearinghouse Work Group Response (07-21-04)

You are correct in stating that Standard 9 does not spell out which facility types must be surveyed. There was recognition by the drafters of the Standard that jurisdictions vary in the number and types of facilities that they regulate. The

Standard’s description of the requirement, however, does specify that the intent of the Standard is to measure trends and to determine whether there has been a net change over time in the occurrence of risk factors and the use of Food Code interventions. The stated outcome further clarifies that this Standard is intended to enable program managers to measure their program against national criteria, and to identify program elements that may require improvement or be deserving of recognition.

The Clearinghouse Workgroup believes that a data collection survey must include, as a minimum, all of the facility types identified in the FDA National Baseline that are regulated by a jurisdiction. As demonstrated in the “Report of the FDA Retail Food Program Database of the Foodborne Illness Risk Factors,” different facility types are likely to have different risk factors in need of priority attention. Surveying only one facility type presents an incomplete picture and will not give a complete measure of trends over time.

In FDA’s national survey, it chose to survey the major facility types for the three industry segments. A direct focus on these industry segments provided a breadth of coverage of general and highly susceptible populations while also covering the vast majority of establishment types. The nine identified facility types are:

Institutions

- 1. Hospitals**
- 2. Nursing Homes**
- 3. Elementary Schools (K-5)**

Restaurants

- 4. Fast Food Restaurants**
- 5. Full Service Restaurants**

Retail Food Stores

- 6. Deli Departments**
- 7. Meat Departments**
- 8. Seafood Departments**
- 9. Produce Departments**

These are the nine facility types for which there is national data; and if you regulate any of these nine facility types, they should be included in a data collection study to meet the intent of Standard 9. You may, if you wish, survey facility types in addition to the nine identified types, but you are not required to go further in your data collection efforts.

Request to Reconsider Previous Interpretation regarding Baseline Surveys. The question of whether all facility types under a jurisdiction’s authority must be included in the baseline survey in order to meet the Standards was answered previously in the affirmative by the Clearinghouse. The Hawaii District Health Office, Placer County Environmental Health, Santa Clara Department of Health, Sonoma County

Environmental Health, and the San Diego County Environmental Health asked the Clearinghouse to reconsider the issue. The group presented in writing a number of reasoned arguments in favor of recognizing the accomplishment of survey's of the largest pool of establishments. They reasoned that intervention strategies developed for a program in response to surveys of full-service establishments (or other largest pool of a jurisdiction's establishments) would have an impact on the other facility types as well, and that future surveys could include other facility types.

ADDITIONAL INFORMATION AND RESPONSE (02-20-05): While the Clearinghouse stands behind its previous interpretation, here are some additional thoughts. Baseline surveys are now considered a part of Standard 9 for purposes of Standards accomplishments. Failure to meet Standard 9 will not have additional consequences that influence participation or enrollment in the Standards as a whole.

There is some sympathy for the point of view that staggered facility-type baselines may have utility as far as conservation of resources: however, there is overall support for requiring a definite point in time where all facility types under the jurisdiction's authority have been included in a survey. Since risk factor surveys need only be completed once every three years (every 5 years as of the 2004 CFP recommendation), there is no reason why the surveys of the various facility types cannot be conducted independently over the 3- or 5-year evaluation period as long as all the facility types under the jurisdiction's authority are surveyed within the recurring survey cycle. This procedure would meet the intent of Standard 9.

3. Baseline Survey Sample Size

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

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 establishment 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 theirs 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.

Clearinghouse Work Group Response (02-20-02)

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 are 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.

**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
Elem. schools	48
Fast food	420
Full service	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 90 100 110 120 130
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Then this no. of observations is needed from the partial sample: 48	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:

150 175 200 225 250 300 350 400 450

Then this no. of observations is needed from the partial sample:

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.

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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 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
Elem. schools	48	33
Fast food	420	87
Full service	360	83
Retail food stores	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.

4. 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

Question/Problem

I am the director of a jurisdiction that is participating in the Standards and 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?

Clearinghouse Work Group Response (07-15-03)

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. In deed, upward trends in compliance may even be mistaken for downward trends. The complete mathematical explanation for these phenomena 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.

Answer addendum

**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 sample 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.

5. 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

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?

Clearinghouse Work Group Response (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.

6. Cooperation within a state on Risk Factor Surveys

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

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/Recommendation

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)

Clearinghouse Work Group Response (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.

- a. The State plans one overall survey by combining all the district inventories and sampling randomly from the single combined inventory.**
- b. Each district will conduct the survey inspections of the facilities in their district that were drawn from the sampling of the combined inventory.**
- c. 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.**
- d. 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.

7. Cooperation within a state on risk factor occurrence surveys.

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

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?

Background

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)

Clearinghouse Work Group Response (08/2004)

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.

- e. The State plans one overall survey by combining all the district inventories and sampling randomly from the single combined inventory.**
- f. Each district will conduct the survey inspections of the facilities in their district that were drawn from the sampling of the combined inventory.**
- g. 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.**
- h. 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.

8. Can jurisdictions combine to create one single baseline?

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

Clearinghouse Work Group Response (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.

9. Avoiding Audits

Keywords: STD-09, Program assessment, audits, avoiding audits

What is to keep a jurisdiction from simply submitting new self-assessments in order to avoid an audit?

Clearinghouse Work Group Response (02-16-05)

First, let us remind the questioner that the National Standards are a voluntary program with the goal of enhancing a vital public health program: There is no motivation to avoid an audit. The process of self-assessment should be an on-going and dynamic process if it is to achieve its goal of continuous improvement. It is highly desirable for every jurisdiction to continually take stock of its status, identify areas for improvement and initiate priority improvement plans. They are also encouraged to submit new National Registry Reports as appropriate to reflect any improvements in the program. This in no way is in conflict with the Standards process. Standard 9 states, "The first verification audit is conducted within 36 months the initial self-assessment. . . . Subsequent verification audits are conducted every 36 months thereafter. Verification audits confirm and report on the accuracy of the self-assessment and the occurrence of risk factors and Food Code interventions survey reports." So the tie between the self-assessment and the audit occurs only at the first self-assessment since there needed to be a way to initiate the cycle. Audits then occur on regular 36-month cycles regardless of the number of updated self-assessments between audits.

10. Action Plans Following an Audit

Keywords: STD-09, Program assessment, action plan, audit, action plans, time frame

The Audit Manual provides for action plans by a jurisdiction for correction of claimed accomplishments not confirmed by the audit. The action plan allows a posted achievement to stand if correction can be accomplished in a reasonable time. What is a reasonable time limit for an action plan – one month, three months, six months?

Clearinghouse Work Group Response (02-16-05)

It is reasonable to believe that an achievement which is claimed by a jurisdiction but not confirmed by an audit is the result of a misinterpretation or misunderstanding of the intent of the Standard by the jurisdiction. The action plan is a means to allow correction to occur without initiating the process of changing the jurisdiction's listing on the web if it believes the correction can be achieved in a reasonable amount of time. This provision is practical since the listings are updated only once per quarter. It is quite possible to make some corrections before the listing could be changed and then changed back following the correction. However, if the jurisdiction believes that the correction will require more effort and take time, it may choose to have the audit-confirmed achievements only reflected in the listing while it works without time constraints to make improvements. The Audit Manual says that an action plan must be negotiated with specific milestones to ensure that the full Standard criteria are met by an established target date, not to exceed one year. One year would be the maximum time allowed, since a newly submitted self-assessment is due no later than one year following an audit, and at that point an action plan would be moot. The periodic self-assessment must accurately reflect the status of the jurisdiction's achievements.