VOLUNTARY NATIONAL RETAIL FOOD REGULATORY PROGRAM STANDARDS

CLEARINGHOUSE WORK GROUP
Questions and Answers for Implemented 2011 Standards

[Note: Some of these interpretations were written prior to changes in the Standards which have occurred since 1999. A review of these interpretations has been made for current applicability. Some interpretations are still valid. When interpretations no longer applied because of updated language in the Standards, the interpretation was either eliminated or updated based on the current Standards language.]

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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 then 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 (Updated 2011)

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

3. Local/county Jurisdictions Operating Under State Regulations

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

The State of West Virginia has adopted the *1999 Food Cod*e, 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 & Update 2011)

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.

As of the printing of the *2009 Food Code*, the asterisks have been removed from the Code since a new ranking system of Priority, Priority Foundation, and Code has been established for provisions of the Code. These rankings still hold no relevance to the Standard and have no effect on whether a provision is required for equivalency to the *Food Code*.

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 jurisdictions enrolled in the Standards, 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 & Update 2011)

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.

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

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 "Approved 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 is not likely to cause illness. An example is 2-401-11(B) – where an employee is drinking from an open cup. In our jurisdiction, an inspector's marking this item requires a follow-up inspection. This is causing far too many follow-up inspections and consuming resources unnecessarily. We would like to change the designation in our regulation from a hard and fast "critical" to "swing" for about 28 items so that we can continue to accurately record all violations without triggering follow-up inspections for items that we judge to be non-critical and so that we can maintain a consistent re-inspection policy.

Question/Problem

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

Rationale

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

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

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

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.

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

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 of stringency. An inter-agency policy may or may not be enforceable. If the policy is in writing and documentation from legal counsel in the jurisdiction is provided stating that the policy carries the same weight as regulation so that it carries the same enforceability by means of civil or criminal penalties, then it may be an acceptable means of meeting Standard 1. Some jurisdiction's issue interpretations of their codes that are considered by their legal counsel have the same weight as their code. In the instance where an interpretation or policy has been issued that is as stringent as the *1999 Food Code* and the jurisdiction's legal counsel supports the interpretation in writing as enforceable, then it would meet the Standard. Whether it is in the form of a policy or interpretation, the key resides in the jurisdiction's ability to ensure compliance equal to its ability to ensure compliance with code or regulation. The status of an "inter-agency policy" would need to be assessed by the legal counsel serving each of the various agencies involved if they are not one and the same.

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

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

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" is defined as a penalty being assessed in more than one location for the same circumstance (usually on an inspection form, although the concept is applicable particularly in Standard 1).

In 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-do-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 - Updated 2011)

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 foods have all been associated with foodborne illness in a raw or undercooked state. Standard 1 requires provisions at least as stringent as the 1999 Food Code **(or later – see 2011 version of Standard 1), so a provision that requires an advisory for shellfish only, does not meet the foodborne illness**

intervention for Consumer Advisory in that it would not provide the same protection for consumers.

14. A 7-day versus a 15-day response for request of an administrative hearing.
Keywords: STD-01, regulatory foundation, response, administrative hearing, hearing, time frame

Question/Problem
In section 8-805.10 of the FDA *Food Code*, it requires that a person requesting a hearing in response to an administrative remedy to file that request within 7 calendar days after service. Our state statute that contains what we consider to be the equivalent administrative remedy requires the person requesting the hearing to file that request within 15 days of service. We believe this requirement is equivalent, and the issue of stringency is not at issue.

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

Clearinghouse Work Group Response (11-15-06)

The Clearinghouse agrees that a 15-day time period to request a hearing in response to an administrative remedy meets the intent of Standard 1, Food Code, 8-805.10(A). The purpose of the Standard 1 criterion is to ensure that there is due process, that the establishment is advised of the right of appeal and the time frames for appeal.

15. Details required in a hearing request
Keywords: STD-01, regulatory foundation, response, administrative hearing, hearing, time frame, details

Question/Problem

During a recent audit of Standard 1, an issue arose concerning the comparison between our code and the *FDA Food Code*. Section 8-805.20 requires that the individual responding to a notice of hearing or requesting a hearing make a request in writing and that the request includes the content specified 8-805.20. Standard 1 requires compliance and enforcement "at least as stringent as" the selected provision of the FDA Food Code and

Annex 1 of the Food Code. It is not completely clear as to what is meant by "at least as stringent" with respect to the compliance and enforcement.

Under our State law, whenever a party is subject to or impacted by a local public health or environmental services department action, such as through the issuance of a Notice of Violation & Demand for Compliance, Cease & Desist Order, Compliance Order, permit or license denial or other similar compliance and enforcement action, the agency is required by law and as a matter of due process to notify the impacted party of the right to a hearing on the matter. At that point the impacted party can request a hearing or not. Should the impacted party request a hearing, State laws dictate that the request for hearing be made in writing within a specified time period. Other than making the request in writing within the timeframe allowed, there are no other requirements that correspond to those found in 8-805-20(B)(1) and (2) and 8-805.20(C)(1) and (2).

It seems somewhat incongruous that while there is nothing in the *Food Code* that mandates an individual respond to a notice of hearing, should one elect to do so, then the requirements contained in 8-805.20(A)(1), (2), (3), and (4), and 8-805.20(C)(1) and (2) kick in. Under the *Food Code* provisions, should a respondent not include all the required particulars in a request, what would be the result? Would a hearing be denied?

Rationale

We maintain that just because we don't require an individual in a request for hearing to provide a statement of defense, mitigation, denial, or explanation concerning each allegation of fact contained in an original compliance and enforcement action, that doesn't make our hearing process any less effective or efficient. All of the items addressed in 8-805.20 will ultimately come to light as part of the hearing process. It is the sequence and manner in which they come to light that differs from the *Food Code*. We are pretty much bound to following the process as it is laid out in our statute. The roadmap provided by State statute to jurisdictions in our State specifies a slightly different route from the route the FDA Food Code takes in the area of hearings administration. In the end, however, we arrive at the same destination, and that is our ability to achieve compliance where compliance cannot be achieve by other means. The important thing in our view is 1) the local jurisdiction has a compliance and enforcement remedy that achieves the objective of the corresponding *FDA Food Code* provision with respect to obtaining compliance and 2) the remedy provides the respondent with an

avenue of redress that recognizes due process under the law. To the extent that our statutes and codes meet these criteria with respect to 8-805.20, we believe that we are "at least as stringent as" the *FDA Food Code* in the area of hearings administration.

Clearinghouse Work Group Response (1-17-07)

Your question caused quite a robust discussion among the Clearinghouse Work Group members. The group members have difficulty understanding how your agency as well as the respondent can adequately prepare for the hearing without the kinds of information outlined in the provisions of 8-805.20. However, the group concluded that as long as you can demonstrate that you are producing cases, have hearing outcomes, and achieving the end compliance result, you are meeting your legal requirements and meet the intent of the Food Code language.

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

16. Residential Kitchens used for Processing of Goods Sold at Retail.
Keywords: STD-01, residential kitchens, home cooking, home processing, home kitchens

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

Consider the options below and determine whether any option for residential kitchens would allow the jurisdiction to meet Standard 1.

Option 1: License and inspect residential kitchens under certain preparation and storage guidelines, but limit items to non-TCS baked goods, jellies and jams. This would become an "approved source" and would be allowed for sale in any retail establishments under their regulations for retail.

Option 2: License and inspect residential kitchens under certain preparation and storage guidelines, limit items to non-TCS baked goods, jellies and jams, but require a variance and a HACCP plan, and under those circumstances allow sale at any retail establishment. This option would also be in the regulations for retail.

Option 3: Create a special regulation for residential kitchens (much as other jurisdictions do for Bed and Breakfast establishments). Under this Option, allow only non-TCS baked goods, jellies, and jams, but allow sales only at farmers markets.

Option 4: Same as 3, except sale at all retail establishments, not just farmers markets.

Option 5: Don't license and don't inspect residential kitchens, but require them to register and perhaps pay a fee. Only allow sale at farmers markets, but require labeling stating these foods are not licensed and inspected as per the definition shown under "food establishment."

Option 6: Any of the scenarios above, but only allow sale directly to the consumer in packaged form and labeled with the disclaimer that the product is not inspected under the full food safety regulations.

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

Clearinghouse Work Group Response (01-20-10)

There are several issues which cannot be overcome with any of the options presented for inspecting and permitting residential kitchens for processing of foods for sale to the public. The *Food Code* clearly prohibits the sale of home-cooked foods in paragraph 3-201.11(B). Further, Standard 1 of the Voluntary National Retail Food Program Standards states that a jurisdiction's regulation must be at least as stringent as the *Food Code*.

There are legitimate concerns with inspecting and permitting the processing of foods for sale to the public in residential or home kitchens.

A. Although the operator may strive for good sanitation, there is always a concern regarding the presence of a sick child, hand sanitation

following the handling of soiled diapers, and the presence of the family pet. These issues cannot always be controlled and represent an increased risk of foodborne illness.

B. Home processors cannot usually meet all the requirements of the local food safety regulations, which is the reason for desiring a special procedure for inspection and licensing of residential kitchens. The creation of special regulations and a special inspection process creates a loophole in the food safety program, which is designed to protect the consuming public from undue risk.

C. The equipment such as ovens, refrigerators available in residential or home kitchens is not designed to produce, cool and hold volumes of prepared foods. The lack of commercial equipment creates an added contributing risk factor to foodborne illness.

D. There are legal concerns associated with inspecting private homes, as well as staff safety issues.

The Clearinghouse approached the question by looking at specific language in the *Food Code* without addressing each option as presented individually. It will be easier to articulate what is allowed under the *Food Code* since there could be endless unstated scenarios, and each one would need to be evaluated against the regulatory language. Look first at the wording in paragraph 3-201.11 (B). It states "FOOD prepared in a private home may not be used or offered for human consumption in a FOOD ESTABLISHMENT." Next, we must look at the exemptions to the definition of a FOOD ESTABLISHMENT.

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

(a) ***An establishment that offers only prePACKAGED FOODS that are not POTENTIALLY HAZARDOUS (TIME/TEMPERATURE CONTROL FOR SAFETY) FOODS;***

(b) A produce stand that only offers whole, uncut fresh fruits and vegetables;

(c) A FOOD PROCESSING PLANT

(d) A kitchen in a private home if only FOOD that is not POTENTIALLY HAZARDOUS (TIME/TEMPERATURE CONTROL FOR SAFETY), FOOD is prepared for sale or service at a function such as a religious or charitable organization's bake sale if allowed by LAW and if the CONSUMER is informed by a clearly visible placard at the sales or service location that the FOOD is prepared in a kitchen that is not subject to regulation and inspection by the REGULATORY AUTHORITY;

(e) An area where FOOD that is prepared as specified in Subparagraph (3)(d) of this definition is sold or offered for human consumption;
(f) A kitchen in a private home, such as a small family day-care provider; or a bed-and-breakfast operation that prepares and offers FOOD to guests if the home is owner occupied, the number of available guest bedrooms does not exceed 6, breakfast is the only meal offered, the number of guests served does not exceed 18, and THE CONSUMER is informed by statements contained in published advertisements, mailed brochures, and placards posted at the registration area that the FOOD is prepared in a kitchen that is not regulated and inspected by the REGULATORY AUTHORITY; OR
(g) A private home that receives catered or home-delivered FOOD.

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

Subparagraph (a) exempts establishments that offer only foods that are prePACKAGED in a licensed FOOD ESTABLISHMENT OR FOOD PROCESSING PLANT and that are not Temperature Control for Safety FOODS. Paragraph (d) is the paragraph that most jurisdictions rely on to allow occasional bake sales for functions sponsored by religious or other organizations such as Girl Scouts and school bands. Paragraph (e) exempts the areas used to prepare the Non Temperature Control for Safety foods for those charitable functions such as church kitchens. Paragraph (f) is the paragraph jurisdictions rely on to exempt small day cares and bed-and-breakfast establishments with limited service from inspection.

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

The question of allowing a home kitchen to prepare and sell food to the public through a VARIANCE with an accompanying HACCP plan was also raised. In a variance request, the requestor must both justify the need for a variance and demonstrate that it can produce food equally as safe as food produced under the Code requirement. Simply wanting to operate a food business from a home kitchen without meeting all of the Code requirements is insufficient justification for use of a variance since no demonstration can

be made that the operation will meet the same level of safety as a commercial kitchen.

In many communities, small processors have access to leasing of either commercial space or incubator kitchens for varying amount of processing time. Some jurisdictions allow small scale food establishments or food processors to operate from another licensed establishment's facility by written agreement. While this does create some logistical concerns such as hours of operation for both businesses and which firm is ultimately responsible should an inspection reveal a violative condition, these issues can be overcome by requirements for a written agreement between the parties, which is acceptable to the jurisdiction. It is recommended that individuals desiring to operate a small business explore these alternative means of meeting Code requirements.

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

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 - Updated 2011)

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 field assessment of skills should be conducted per the new guidelines in the 2011 Standard 2, CFP Field Training Manual. The assessment would help determine where additional training is needed.

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 – Updated 2011)

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

3. Determining Training Component Equivalency

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

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 (Updated 2011)
The 2009 and later versions of the Standards provide criteria for determining equivalency with the FDA ORA-U required courses. See Standard 2

4. Documents that Serve in Lieu of Training Certificates
Keywords: STD-02, Trained regulatory staff, documentation, training certificates, training documentation, training logs, alternatives to certificates

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.

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 jurisdictions own food code, provided that the jurisdiction's food code meets the criteria in Standard #1 - Regulatory Foundation

Clearinghouse Workgroup Response (05-20-02 - Updated 2011)

This question points out a possible misunderstanding of this portion of Standard 2. It is the intention of Standard 2 that standardization exercises within a jurisdiction can be based upon the jurisdiction's own regulation or ordinance, 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. The Program Standard 2 was modified in 2009 and distinguishes between the Standardization process for general staff members who will be conducting field inspections and those staff members who will be standardizing other inspectors. The Standardization process used for staff conducting inspections of retail food establishments must satisfactorily complete four joint inspections with a "training standard" (see current Standard 2 for qualifications of the "training standard") using a process similar to the FDA Standardization Procedures. The procedure must determine the inspector's ability to apply the knowledge and skills obtained from the training curriculum and address the five performance areas as follows:

1. **Conducting risk-based inspections focused on foodborne illness risk factors,**
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 "FDA Procedures" can be used without modification. The scoring and assessment tools are specifically tied to the standardization inspection form and other assessment forms that are a part of the FDA procedures involving 8 joint inspections.

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

7. 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 are too many. It needs to be reevaluated and justified.

Recommendation: We recommend to the CFP the revaluation 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.

Original Clearhouse Response 11-20-02 no longer applicable – Updated 2011 based on 2011 Standard

Standard 2 was altered in 2009 based on work completed by a Conference for Food Protection Committee. Questioners should review the current Standard, the guidance documents provided for self-assessors and auditors, and the CFP Field Training Manual that was prepared as an adjunct to the 2009 Standard 2.

Generally a Food Safety Inspection Officer (FSIO) conducting inspections of retail food establishments during their 18-month training period must conduct a minimum of 25 joint field inspections with a trainer who has successfully completed all training elements, Steps 1 – 3 of Standard 2. Facilities selected for the joint field training inspections should include a variety of retail and foodservice operations that are reflective of all establishment risk categories available in the jurisdiction. The majority of selected establishments, however, should be representative of the highest risk categories within the Food Safety Inspection Officer (FSIOs) assigned geographic area.

If the trainer determines that the FSIO has successfully demonstrated the required performance elements and competencies, as provided in the CFP Field Training Manual, a lower number of joint field training inspections can be acceptable for that particular FSIO provided there is written documentation, such as the completion of the CFP Field Training Plan to support the exception.

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.

See Updated Response of 2011 to Question 6.

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; H_20/ww systems; information technology.

Clearinghouse Response (11-20-02) Updated 2011

[*Earliest versions of Standard 2 are clear in stating that Appendix K is provided as an example. It was not intended for use as an evaluation measure, but was 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 was used by many of those states for training staff for a number of years.*] Appendix K no longer is reference in the Standard 2, nor is it available. See the current Standard 2 requirements and the guidance and example documents in the CFP Field Training Manual, which serves as a tool for meeting and documenting the requirements of Standard 2.

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".

Response Updated (2011)

Updated versions of Standard 2 provide two options form meeting the training curriculum

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

11. 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 – Updated 2011)

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

The proposal for "grandfathering" certain employees from the requirement would need to be submitted as a proposed change to the Standard through the CFP. Grandfathering, however, suggests an exemption from the requirement of the Standard, and the Work Group expressed strong opposition to exempting any employee from the requirements. All employees, no matter how much field experience they have, must be held to the basic training and education requirements.

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

12. 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 has the knowledge and skills to perform their inspection functions.

13. 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 on certain topics such as "prevailing statutes, regulations and ordinances" may meet the requirements if the employee is coming from a jurisdiction operating under the same statutes, regulations, etc. The new employee may require new training or additional training if the employee is coming from a jurisdiction with very different statutes, regulations, etc. "Employees newly assigned to the food program" is intended to cover employees who may already work within the jurisdiction, but in a program area other than food. No matter the longevity of the employee within the jurisdiction, training in the required topic areas must be provided if the employee is newly assigned to the food area and has no documentation of having previously received the required training.

14. Kinds of continuing education that qualifies.

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 has the skills and knowledge to conduct quality food inspections. All the Standards relate to the food program specifically; therefore, the Clearinghouse agrees that other types of training, while beneficial, do not qualify toward meeting the Standard.

The question of Register Sanitarian credentials and other certificate conferring programs such as the Registered Environmental Health Specialist was addressed in an earlier Clearinghouse response (02-20-03). Credentials cannot be taken as

prima 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.

15. 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.

16. 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 CFP clarified Standard 2 by distinguishing between the Standardization process for a person who will be standardizing other employees and those employees who will be conducting inspections only. The process for those who will use the skills for conducting inspections require only 4 standardization inspections versus 8 for those who will be training other employees. See the 2011 version of Standard 2.
[NOTE: The phrase "a process similar to the FDA Procedures. . ." was clarified in a previous Clearinghouse response. See "*Code* Criteria for Standardization" 03-20-02]

17. 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 – Updated 2011)

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. Later versions of the Standards are provided on a resource CD disk, with a number of worksheets that accompany each Standard instead of Appendices. Self-assessors and auditors will find those documents for detailed and useful; however, the worksheets are still intended as tools. A jurisdiction may use its own forms and documents as long as the necessary information is available to an auditor in a reviewable format.

18. Mutual standardization by two parties in different jurisdictions
Keywords: STD-02, number of inspections, cross standardization, mutual standardization

Question/Problem
As an FDA Specialists, 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 join 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.

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

Keywords: STD-02, Training Needs Assessment, TNA, qualifications, trainer

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 successful 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 successful 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 (Updated 2011)

The CFP changed the language in Standard 2 in 2009 and again in 2011 to address and clarify this issue.

20. When do the new provisions of Standard 2 passed at the 2006 CFP become effective? Is there a phase-in period for jurisdictions already in process of meeting Standard 2?

Keywords: STD-02, trained regulatory staff, implementation 2007, new provisions, standardization, ATN, Assessment of Training Needs, field work, training

In my jurisdiction, we are in middle of completing Standard 2 under the 2005 version. That means that individuals among the staff are in various stages of completing the process. The changes in requirements that were passed at the 2006 Conference for Food Protection are significant. The implementation date for these changes is January 1, 2007. Does this mean that we must go back and complete the new requirements, such as an Assessment of Training Needs, with staff members who have already completed the academic, field work training and been standardized under the old procedures?

Question/Problem

If we are required to start over in the process, it will be quite a set-back for our and would mean that much of the work already completed would need to be repeated.

Clearinghouse Work Group Response (11-15-06)

Changes to the Standards are not intended to discourage jurisdictions or to create rework, but to make improvements to the Standards. In providing this interpretation for implementation, the intent is not to micro-manage jurisdictions that are making a good faith effort to meet the Standards. However, guidance needs to be provided for this Standard in order to ensure consistent application among jurisdictions.

Jurisdictions that currently meet Program Standard 2 must implement the new requirements for any new staff hired after 1/1/07 in order to continue meeting the standard.

If the standardization process for a staff or staff members has been initiated prior to January 1, 2007, then the jurisdiction can continue to use the original standard language and format for those employees. If the jurisdiction is currently in the process of training staff and the training/field inspection elements are not completed until after 1-1-07, then an Assessment of Training Needs (ATN) should be conducted prior to standardization. We want to be clear regarding what conducting an ATN means. It does NOT mean that the candidate that has been in training must perform another 25 joint inspections. It simply means that a candidate needs to demonstrate either through a field, lab, or classroom exercise that they can perform the elements on the ATN to an acceptable level.

Many of the performance elements on the ATN will already have been reviewed by the training officer/food program manager as part of their initial field training. For example, it is expected that the candidate will have already demonstrated that they can use their equipment properly, complete the inspection forms, communicate with the operator, etc. The training officer/food program manager can simply check these items acceptable on the ATN since they have already verified the candidate can perform these elements during their initial training. Elements that may not have been evaluated may include such things as the aseptic sampling of food/water samples. The training officer can set up an office or lab exercise for the candidate to demonstrate these skills.

This is a similar situation to the example of the experienced Food Safety Inspection Officer (FSIO) given in Step 2 of Standard 2. In that step, the training officer can waive the need to perform the 25 joint field training inspections by providing a waiver/affidavit in the employee's training file citing the experience/training the FSIO has received that would justify this decision. An ATN is to be performed with the experienced FSIO to ensure they can perform all the elements specific to their job responsibility. There is

no requirement as to how many field inspections are done using the ATN form to accomplish this OR whether the verification is conducted in the field or through an office exercise. The desired result is that the food program manager/training officer has verified that the candidate can perform these elements. The training officer/food program manager may place in the comment section of the ATN that verification of some of the performance elements were made during the initial training period conducted prior to 1-1-07.

The ATN is simply a training tool to assist food program manager/training officers with documenting the process and performance of the elements. It is expected that this guidance will be applicable for only a short period of time during transition between use of the old and new criteria in Standard 2.

Here is a bulleted summary of how the new Standard 2 requirements are to be implemented beginning 1/1/07:

- **Changes to Standard 2 were approved by the 2006 Conference for Food Protection (CFP). The effective date of these changes is January 1, 2007.**
- **Jurisdictions that currently meet Program Standard 2 will need to implement the changes for any new staff hired after 1/1/07 in order to continue meeting the standard.**
- **Staff members that have completed all of the Standard 2 training but have not been standardized prior to 1/1/07 must successfully complete an Assessment of Training Needs (ATN) prior to standardization inspections. For experienced staff, there is no specific number of inspections that must be performed using the ATN Field Training Worksheet. A Food Safety Inspection Officer (FSIO) need only demonstrate the ability to perform all 25 ATN performance elements. This can be done as part of conducting other types of inspections, through classroom/field/lab exercises, or field training. Once the experienced candidate has demonstrated that they can perform the ATN elements, they are eligible for field standardization. The Field Standardization must include a minimum of 4 inspections using procedures similar to the "FDA Procedure for Standardization."**
- **Staff members that have completed all of the Standard 2 training and standardization elements prior to 1/1/07 meet the intent of the criteria. An Assessment of Training Needs (ATN) does not need to be performed for these staff members.**

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 (Updated 2011)

The CFP Model Inspection Form has completed the CFP approval process and been accepted. The FDA has endorsed the form and placed 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.

7. Design and Use of a State Inspection form to Conform with the Program Standards

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

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

Question/Problem

1. Does the draft inspection form proposed by the State of North Carolina meet the Standards?

Rationale:

North Carolina is a county-based program with state rules and forms. As such, the enrolled counties are directly impacted by this form meeting/not meeting the Programs Standards. Some facts about the proposed inspection form:

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

Clearinghouse history:

Although the Standard only mentions about design of the form to provide the compliance status of IN, OUT, NA, and NO, the original Audit Manual (through its updates to June 2006) has more specific language. It's this more specific language that expresses the original intent of requiring the compliance status on the inspection form to necessitate evaluation and action by the inspector. The Audit manual says:

"The inspection form that the jurisdiction uses must be designed so that an inspector must choose from the four compliance status options for the items identified as contributing risk factors to foodborne illness and public health interventions. "

The key here is that the inspector must choose from the options. This is consistent with the Iowa pda automated system that was designed originally to default to "IN" compliance. The question was brought to the Clearinghouse (CH) for discussion and a reply was given that the program could not default to “IN” compliance. Their immediate solution was to default each question to "OUT” of compliance, requiring the inspector to then take action to change the marking to IN, NA, or NO. They later reprogrammed so that the inspector had to choose the correct option. Another important item to remember is that this is required for risk factors and interventions only and is not required for all

GRPs. Also, an option that is not appropriate need not be included. This is the same system/format as the FDA risk factor survey form.

Clearinghouse Work Group (03-21-08)

The requirement for a form showing the IN, OUT, NA, and NO for the risk factors and interventions can be met by using a different form, however, the draft North Carolina form, as provided (dated January 2008), does not meet Standards 3, 4 and 6. In order to meet these Standards, the addition of a new column to record IN compliance status is needed.

Further suggestions for improving the form include revising the marking instructions to indicate when NA /NO do not apply and to also clearly identify on the form when the NA/NO option is not to be used, i.e., block out the option for marking NA/NO on the inspection form when it does not apply.

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, standardizations exercises, or other methods the jurisdiction deems appropriate.

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

2. Completion of Assessment Protocols

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

Much of the criteria contained in Standard 4 are predicated on an inspection program containing risked 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 rational for your conclusion, then it is not necessary for you to proceed further. No one wants you to spend time that is not productive. You only need go as far as necessary to identify the gaps you would need to fill 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 – Updated 2011)

Language for Standard 3 and Standard 4 were clarified regarding the necessity for IN, OUT, NA and NO at the 2006 Conference for Food Protection meeting. See current versions of the Standards

6. Design and Use of a State Inspection form to Conform with the Program Standards

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

Response: See Standard 3, question #7

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 – Updated 2011)

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

Standard 5 was altered and clarified in 2009.

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.

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 – Updated 2011)

In reviewing the language of the Standard No. 5 as a whole, including the section on trend analysis, there is very little room for interpretation. It is clear that the intent is for the analysis to include all complaints and not just outbreak data. The Clearinghouse members agreed that a jurisdiction's investigative procedures and protocols should include all the elements as described in 1.a. through 1.i., including the handling and response to all complaints. The Clearinghouse engaged in a further discussion regarding whether an analysis as described in 7.a. through 7.c. of all unsubstantiated complaints and sporadic illnesses was practical, feasible and/or of value, but was unable to reach a consensus. This question requires broader input from regulators, and any change to the Standard 5 language to eliminate the requirement for analysis of complaint data would require action by the CFP. The Clearinghouse will recommend that the question be forwarded for reviewed by the CFP Program Standards Committee.

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

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

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

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 risked 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'scriteria must be developed and integrated into our program before a meaningful file review can be performed against all the criteria contained in the Compliance and Enforcement Standard.

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

Clearinghouse Work Group (03-20-02)

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

2. 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 (Updated 2011)

Standard 6 was altered after this question was asked to allow for the fourth oldest inspection to be used as the "start point" if no risk factor violation was identified on the third oldest inspection. Sampling and instructions have also been updated and clarified. See the most recent version of Standard 6 and the worksheets and guidance documents on the Program Standards Resource Disk.

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 (Updated 2011

Appendix F instructions (now worksheets and guidance documents for Standard 6) were revised at the 2007 CFP, both to address the question of sampling and sample size and to better explain the pass/fail criteria.

6. Design and Use of a State Inspection form to Conform with the Program Standards

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

Response: See Standard 3, question #7

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. However, any CFP participant can submit issues to alter the Standards through the CFP process.

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.

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

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

Standard #7 text:

1. **Industry and Consumer Interaction**

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

Question/Problem

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

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

Rationale:

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

Clearinghouse Work Group (03-21-08)

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

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, rate the innovative grant proposals independently based on the published rating criteria for the grants. Although the panel meets to present and discus 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 funding for a grant from FDA. As in all studies, its 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 better national Standard criteria for measuring inspectional staffing levels.

4. Administrative Time

How do you show administrative time necessary to support the Standards?
Keywords: STD-08, Program Support and Resources, FTE ratio, number of establishments, comparing staff ratios, administrative time, report time.

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, sample size, baseline, baseline survey, survey, risk factor survey. Facility type.

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 (Updated 2011)

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

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

Question/Problem

Aren't the sample size parameters presented above unnecessarily high given the fact that FDA's sample size for any of the nine categories did not exceed 100 and 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 is statistically meaningful. For complete guidance on conducting a baseline and ensuring comparability with FDA national study, see "Developing a Baseline on the Occurrence of Foodborne Illness Risk Factors – Data Collection Instruction Manual," available from your Regional Food Specialist.

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.

<u>FOR ONE OF THE 42 ITEMS IN THE BASELINE:</u>

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**
Then this no. of observations is needed from the partial sample:	**9**	**16**	**22**	**28**	**29**	**32**	**38**	**38**	**39**	**42**	**45**	**45**	**48**

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 that 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 of level of observation to have high assurance of coverage. Therefore, we will allow for the possibility that only 2/3 (67%) of the inspections yield observations.

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

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

ESTABLISHMENT INVENTORY SAMPLE SIZES

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

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

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

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

Type	**Inventory**	**Sample size**
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 I have completed my self-assessment. Although I would like to conduct a risk factor baseline survey, I have very limited resources. The FDA Data Collections Manual recommends sample sizes that will result in a 95 percent confidence level. It seems

that if I am willing to accept a lower confidence, for example 80 or 90 percent, I can collect fewer samples. This will allow me to conduct my survey using fewer person hours.

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

Clearinghouse Work Group Response (07-15-03 – Updated 2011)

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

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

An initial baseline survey and future risk factor surveys can be a tremendously powerful tool to demonstrate the usefulness of your program to the Board of Health, City Council or whatever body has influence over your budget and resources. For the first time, there exists an effectiveness measure for a public health program. It has always been difficult to justify preventive programs, especially during austere economic times. The surveys allow you to identify areas that represent potential problems affecting consumer health and the well being of the community at large. You can then develop logical strategies to reduce the risk in those specific problem areas and to demonstrate the positive impact of your program. Conducted properly, risk factor surveys can provide tangible justification for your food program in a way never before possible. This

being the case, your surveys should be conducted in such a way as to maintain the highest integrity and maximum usefulness of the survey results. For these reasons the Clearinghouse cannot recommend the use of lower confidence levels. However, see the latest version of Standard 9 since facility types now do not have to be surveyed in the same year and regular inspection data may now also be used as an alternative to conducting a specific data collection.

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 samples sizes. Furthermore the probability of detecting such changes from repeated baselines is expected to be less than .90.

Under these sample sizes, jurisdictions will be less likely (it will be more difficult) to detect changes from repeated baselines. With full understanding of these caveats, these smaller sample sizes could be used; however, we still do not recommend them. If used at all, this 90% confidence level should probably be restricted to very small states and jurisdictions. It is probably not appropriate for jurisdictions with large populations since public health is at issue.

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 =

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

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.

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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."

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"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 requires 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 (Update 2011)

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 it 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.

In 2010, the CFP altered Standard 9 to require an audit within 6 months of claiming a Standard as met. The purpose of the audit is to confirm the accuracy of the self-assessment and gives credibility to the claims of the jurisdiction. The real question is "why would a jurisdiction want to claim a Standard as met and then try to avoid an audit?" Surely there is no real desire or intent to deceive.

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.

11. Requirements to meet Standard 9 and the relationship between audits and Standard 9

Keywords: STD-09, audits, criteria for Standard 9, when is audit required, requirements for Standard 9

Question/Problem

The State of Idaho and the seven health districts within the state have each completed their own self assessments. We have also completed a "Statewide" survey on the occurrence of foodborne illness risk factors. When we submitted our Appendix I listing showing that we met Standard 9, we were told that we wouldn't meet Standard 9 until our audits had been completed. Is this a correct interpretation of Standard 9? The January 2005 version of Standard 9 does not seem to support this interpretation.

Rationale

Jurisdictions can submit Appendix I and report the completion of their self assessment and any of the Standards 1 through 8 that they believe they meet. They get credit for this reported completion simply by submitting that they meet it. There is no Verification Audit required at this time. Credit can exist and can be displayed on the National Web Listing for Enrolled Jurisdictions for several years prior to the required Verification Audit. Why should Standard 9 be treated differently?

Clearinghouse Work Group Response (1-17-07)

Standard 9 may be confusing in that it serves two purposes. The first purpose is to outline the administrative process for officially participating in the program and a second purpose gives specific criteria for claiming achievement of Standard 9. The Standard contains two parts. The first part of the Standard simply states the requirements for a jurisdiction to continue to be listed on the FDA Roll of Participating Jurisdictions. The two requirements for listing are 1) to conduct a self-assessment within 12 months of the date of enrollment and then every 36 months thereafter, and 2) to have a verification audit conducted within 36 months of the initial self-assessment and every 36 months thereafter. You are correct in stating that credit is given for self-reported accomplishment of a Standard before the Verification Audit is performed.

The requirement for meeting Standard 9 is simply to conduct a survey on the occurrence of foodborne illness risk factors and Food Code interventions.

Following the initial achievement of Standard 9, to continue meeting Standard 9, a survey must be conducted every five years thereafter. Clarification and separation of these two functions of this Standard was the purpose of the 2005 revision of Standard 9.

Although the Standard still contains language regarding the timing of an initial risk factor survey between self-assessment and a Verification Audit, the question of timing for the first survey is in reality moot. If a jurisdiction does not conduct a risk factor survey, it simply means that they have not yet met the criterion for achievement of Standard 9. So, the Clearinghouse agrees with your interpretation that the only requirement for a jurisdiction to be shown on the National Listing as meeting Standard 9 is to conduct survey of foodborne illness risk factors, write a report of the results and to report that achievement of Standard 9 on the Appendix I.

12. Must an Audit cover all the Standards at the same time?
Keywords: STD-09, audits, auditing of standards, timing of audits

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

Clearinghouse Work Group Response (1-17-07)

No, all Standards are not required to be audited at the same time. The self-assessment represents the status of the program against all of the Standards at a specific moment in time. It must occur at least once every three years. Following a self-assessment, a jurisdiction may complete one or more action plans which will allow them to "update" the self-assessment to show that they then meet one or more additional standards. At any time after a jurisdiction claims to have met a standard, either during the self-assessment or in an update to the self-assessment, a jurisdiction is encouraged to immediately obtain a verification audit of those results. This will allow for timely feedback of the self-reported results and timely correction for any misinterpretations that may have occurred. Multiple verification audit dates may exist and be reflected on the web listing. However, the only requirement for continued participation in the Standards and listing on the National Registry is a self-assessment every fourth year followed by a verification audit within 36 months of the self-assessment. Since verification auditors' time must be respected and a time suitable for both parties must be negotiated, it would not be unusual for Standards to be audited on different dates.

For example, a jurisdiction completes its self-assessment in January 2006 and self-reports meeting one Standard. For timely feedback on the self-reported results, the jurisdiction could obtain an audit of this Standard immediately, and is encouraged to do so. Subsequently, in July 2007, the jurisdiction completes action plans resulting in two additional Standards self-reported as being met. As before, the jurisdiction could obtain an audit of these standards immediately. However, the jurisdiction could wait and have an audit completed on all three Standards by the end of January 2009, which is within the 36 months from the self-assessment completion date.

13. Appropriate auditor for the risk factor survey

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

Question/Problem

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

Rationale

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

Clearinghouse Work Group Response (1-17-07)

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

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