



DRAFT
Voluntary National Retail Food Regulatory Program Standards

Developed and recommended by the U.S. Food and Drug Administration with input from federal, state, and local regulatory officials, industry, trade associations, academia, and consumers.

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For questions regarding this draft document contact Glenda R. Lewis in the Office of Food Safety, Retail Food and Cooperative Programs Coordination Staff (HFS – 320), CFSAN, Food and Drug Administration, 5100 Paint Branch Parkway, College Park, Maryland 20740 at 301-436-2150.

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INTRODUCTION

Achieving national uniformity among regulatory programs responsible for retail food protection in the United States has long been a subject of debate among the industry, regulators and consumers. Adoption of the FDA Food Code at the state, local and tribal level has been a keystone in the effort to promote greater uniformity. However, a missing piece has been a set of widely recognized standards for regulatory programs that administer the Food Code. To meet this need FDA has developed the Draft Voluntary National Retail Food Regulatory Program Standards (Program Standards) through ideas and input from federal, state, and local regulatory officials, industry, trade and professional associations, academia and consumers on what constitutes a highly effective and responsive retail food regulatory program.

In March of 1996, the FDA hosted a meeting to explore ways in which its retail food protection program could be improved. Participants in the meeting included FDA Retail Food Specialists, FDA headquarters personnel, state and local regulatory officials from the six FDA regions, the president of the Association of Food & Drug Officials, and industry representatives. Following that meeting, FDA established a National Retail Food Team comprised of the Regional Retail Food Specialists, CFSAN personnel and other FDA personnel directly involved in retail food protection. A Retail Food Program Steering Committee was established and tasked with leading the team to respond to the direction given by the participants in the meeting, i.e. providing national leadership, being equal partners, being responsive, and providing communication and promoting uniformity.

The Steering Committee was charged with developing a five-year operational plan for FDA's retail food program. The Steering Committee was also charged with ensuring the operational plan was in keeping with the goals and mission of the President's Food Safety Initiative. FDA solicited input from the regulatory community, industry and consumers in developing the plan. The resulting Operational Plan charted the future of the National Retail Food Program and prompted a reassessment of the respective roles of all stakeholders and how best to achieve program uniformity.

From the goals established in the Operational Plan, two basic principles emerged on which to build a new foundation for the retail program:

- Promote active managerial control of the risk factors most commonly associated with foodborne illness in food establishments, and
- Establish a recommended framework for retail food regulatory programs within which the active managerial control of the risk factors can best be realized.

These principles led to the drafting of standards that encourage voluntary participation by the regulatory agencies at the state, local, and tribal level. The Program Standards were developed with input obtained through a series of meetings over a two-year period including: the 1996 stakeholders meeting, FDA Regional Seminars, meetings with state officials hosted by the Retail Food Specialists, and six Grassroots Meetings held around the country in 1997. Valuable input from industry associations, associations of regulatory officials, and others was also obtained. The Program Standards were provided to the Conference for Food Protection for further input

and to achieve broad consensus among all stakeholders.

In developing the Program Standards, FDA recognized that the ultimate goal of all retail food regulatory programs is to reduce or eliminate the occurrence of illnesses and deaths from food produced at the retail level and that there are different approaches toward achieving that goal. Federal, state, local, and tribal agencies continue to employ a variety of mechanisms with differing levels of sophistication in their attempt to ensure food safety at retail.

While the Program Standards represent the food safety program to which we ultimately aspire, they begin by providing a foundation upon which all regulatory programs can build through a continuous improvement process. The Standards encourage regulatory agencies to improve and build upon existing programs. Further, the Standards provide a framework designed to accommodate both traditional and emerging approaches to food safety. The Program Standards are intended to reinforce proper sanitation (good retail practices) and operational and environmental prerequisite programs while encouraging regulatory agencies and industry to focus on the factors that cause and contribute to foodborne illness.

PURPOSE

The Program Standards serve as a guide to regulatory retail food program managers in the design and management of a retail food regulatory program and provide a means of recognition for those programs that meet these standards. Program manager and administrators may establish additional requirements to meet individual program needs.

The Program Standards are designed to help food regulatory programs enhance the services they provide to the public. When applied in the intended manner, the Program Standards should:

- Identify program areas where an agency can have the greatest impact on retail food safety
- Promote wider application of effective risk-factor intervention strategies
- Assist in identifying program areas most in need of additional attention
- Provide information needed to justify maintenance or increase in program budgets
- Lead to innovations in program implementation and administration
- Improve industry and consumer confidence in food protection programs by enhancing uniformity within and between regulatory agencies

Each standard has one or more corresponding appendices that contain forms and worksheets that facilitate the collection of information needed to fully assess a retail program. Regulatory agencies may use existing, available records or may choose to develop and use alternate forms and worksheets that capture the same information.

SCOPE

The Program Standards apply to the operation and management of a retail food regulatory program that is focused on the reduction of risk factors known to cause or contribute to foodborne illness and to the promotion of active managerial control of these risk factors. The results of a self-assessment against the Standards may be used to evaluate the effectiveness of food safety interventions implemented within a jurisdiction. The Standards also provide a procedure for establishing a database on the occurrence of risk factors that may be used to track the results of regulatory and industry efforts over time.

NEW DEVELOPMENTS

The Program Standards were pilot tested in each of the five FDA regions in 1999. Each regulatory participant reported the results at the 2000 Conference for Food Protection. Improvements to the Standards were incorporated into the January 2001 version based on input from the pilot participants. Further refinements to the Standards were made in subsequent drafts leading up to the endorsement of the March 2002 version of the Program Standards by the 2002 Conference for Food Protection. The April 2003 version contains enhancements to the forms and worksheets in the Appendices to improve their usefulness. The January 2005 version contains revisions to Standard 1, 5, and 9 based on recommendations approved at the 2004 Conference for Food Protection.

In maintaining these standards, FDA intends to allow for and encourage new and innovative approaches to the reduction of factors that are known to cause foodborne illness. Program managers and other health professionals participating in this voluntary program who have demonstrated means or methods other than those described here may submit those to FDA for consideration and inclusion in the Program Standards. Improvements to future versions of the Standards will be made through a process that includes the Conference for Food Protection to allow for constant program enhancement and promotion of national uniformity.

IMPACT ON PROGRAM RESOURCES

During pilot testing of the Program Standards in 1998, some jurisdictions reported that the self-assessment process was time consuming and could significantly impact an agency's resources. Collection, analysis, and management of information for the database were of special concern. However, participating jurisdictions also indicated that the resource commitment was worthwhile and that the results of the self-assessment were expected to benefit their retail food protection program. Advance planning is recommended before beginning the data collection process in order to use resources efficiently. It is further recommended that jurisdictions not attempt to make program enhancements during the self-assessment process. A better approach is to use the self-assessment to identify program needs and then establish program priorities and plans to address those needs as resources become available.

COMMENTS AND INQUIRIES

To promote uniform and reasonable application of these standards, interested persons are invited to submit comments and inquiries to their FDA Regional Retail Food Specialist or to the Retail Food Protection Team in the FDA Center for Food Safety and Applied Nutrition.

DEFINITIONS

The following definitions apply in the interpretation and application of these Standards.

- 1) **Active Managerial Control** - Implementation and supervision of food safety practices to control risk factors by the person-in-charge.
- 2) **Auditor** - An FDA Certified Evaluation Officer (CEO), or any authorized city, county, district, state, federal, tribal or other third party person who has no responsibilities for the day-to-day operations of that jurisdiction and is charged with conducting a verification audit which confirms the accuracy of the self-assessment..
- 3) **Baseline Survey** - Establishment of a database that measures the occurrence of the CDC-identified foodborne illness risk factors within the retail segment of the food industry in accordance with the “FDA Retail Food Program Database of Foodborne Illness Risk Factors Report” and FDA Baseline Data Collection Form.
- 4) **Baseline Survey Update** - data collected to update the initial baseline survey.
- 5) **Candidate** - a regulatory officer whose duties include the inspection of retail food establishments.
- 6) **Compliance and Enforcement** – Compliance includes all voluntary or involuntary conformity with provisions set forth by the regulatory authority to safeguard public health and ensure that food is safe. Enforcement includes any legal and/or administrative procedures taken by the regulatory authority to gain compliance.
- 7) **Direct Regulatory Authority (DRA)** - the organizational level of government that is immediately responsible for the management of the retail program. This may be at the city, county, district, state, federal or tribal level.
- 8) **Enforcement Actions** - actions taken by the regulatory authority such as warning letters, revocation or suspension of permit, court actions, monetary fines, hold orders, destruction of food, etc., to correct a violation found during an inspection.
- 9) **FDA Certified Evaluation Officer (CEO)** - A person, usually a state employee, who has successfully completed the FDA requirements for certification as an evaluator of retail food safety programs.
- 10) **Follow-up Inspection** - an inspection conducted after the initial routine inspection to confirm the correction of a violation(s).
- 11) **Food Code Interventions** – the preventive measures to protect consumer health stated below:
 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.
- 12) **Good Retail Practices (GRP's)** - preventive measures that include practices and procedures to effectively control the introduction of pathogens, chemicals, and physical objects into food, that are prerequisites to instituting a HACCP or Risk Control Plan and are not addressed by the *Food Code* interventions or risk factors.
- 13) **Hazard** - a biological, chemical or physical property that may cause an unacceptable consumer health risk.
- 14) **National Registry Report** - A listing of retail food safety programs that have voluntarily enrolled as participants in the *Voluntary National Retail Food Regulatory Program*

Standards.

- 15) **Person in charge (PIC)** - the individual present at a food establishment who is responsible for the operation at the time of inspection.
- 16) **Program Element** - One of the program areas for which a National Standard has been established such as regulations, training, inspection system, quality assurance, foodborne illness investigation, compliance and enforcement, industry and consumer relations, and program resources.
- 17) **Program Manager** - the individual responsible for the oversight and management of a regulatory retail food program.
- 18) **Quality Records** - Documentation of specific elements of program compliance with the National Standards as specified in each Standard.
- 19) **Risk Control Plan (RCP)** - a short plan based on HACCP principles designed to control a specific risk factor.
- 20) **Risk Factors** - 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.
- 21) **Routine Inspection** - a full review and evaluation of a food establishment's operations and facilities to assess its compliance with Food Safety Law, at a planned frequency determined by the regulatory authority. This does not include reinspections and other follow-up or special investigations.
- 22) **Self-Assessment** - An internal review by program management to determine whether the existing program meets the National Standards.
- 23) **Standardization Inspection** - an inspection used to demonstrate a candidate's knowledge, communication skills, and ability to identify violations of all regulatory requirements and to develop a risk control plan for identified, uncontrolled risk factors.
- 24) **Trainer** - an individual who has successfully completed the training elements outlined in Standard No 2 and is recognized by the program manager as having the field experience and communication skills necessary to train new employees.
- 25) **Training Standard** - a person who has successfully completed the training elements in Steps 1 through 4 as outlined in Standard No 2 and has been recognized by the program manager as having field experience, communication skills, and knowledge of the program policies and procedures necessary to conduct field standardization of other employees.
- 26) **Verification Audit** - A systematic, independent examination by an external party to confirm the accuracy of the Self-Assessment.

STANDARD 1 REGULATORY FOUNDATION

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

Requirement Summary

The regulatory foundation includes provisions for:

1. The public health interventions contained in the *Food Code*;
2. Control measures for the risk factors known to contribute to foodborne illness;
3. Good Retail Practices (GRP's) at least as stringent as the *Food Code*; and
4. Compliance and enforcement at least as stringent as the selected provisions from *Food Code* and Annex 1 of the *Food Code*.

Description of Requirement

A. Food Code Interventions and Risk Factor Control Measures

The regulatory foundation contains 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*. To meet this element of the Standard, regulations must have a corresponding requirement for the *Food Code* sections as listed in Appendix A, Table A-1 and summarized in Table A-2, from #1 'Demonstration of Knowledge' through #11 'Highly Susceptible Populations.' For initial listing, the regulatory foundation must contain at least 9 of the 11 interventions and risk factor controls. In order to meet fully the requirements of the Standard, the regulatory foundation must meet all 11 of the interventions and risk factor controls by the third audit.

B. Good Retail Practices

The regulations contain provisions that address Good Retail Practices that are at least as stringent as those described in the *Food Code*. To meet this element of the Standard, regulations must have a corresponding requirement for 95 percent of the *Food Code* sections as listed in Appendix A, Table A-3 and summarized in Table A-4, from #12 'Personnel' through #37 'Variance for Smoking'.

C. Compliance and Enforcement

The regulations contain provisions that address Compliance and Enforcement requirements that are at least as stringent as those contained in the *Food Code*. To meet this element of the Standard, regulations must have a corresponding requirement for each of the *Food Code* sections as listed in Appendix A, Table A-5, items 1 through 11. For Item 12 pertaining to 'Legal Remedies', a corresponding regulatory requirement must be in place for at least one of the sections pertaining to criminal, injunctive, or civil penalties.

Outcome

The desired outcome of this standard is the adoption of a sound, science-based regulatory foundation for the public health program and the uniform regulation of industry.

Documentation

Documentation

The quality records needed for this standard include:

1. The statute, regulation, rule, ordinance or other prevailing set of regulatory requirements that govern the operation of a retail food establishment; and
2. The completed Appendix A and its accompanying tables.

STANDARD 2 TRAINED REGULATORY STAFF

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

Requirement Summary

The regulatory retail food program inspection staff (Food Safety Inspection Officers - FSIO) shall have the knowledge, skills, and ability to adequately perform their required duties. The following is a schematic of a 5-step training and standardization process to achieve the required level of competency.

STEP 1 – Completion of curriculum courses designated as “Pre” in Appendix B-1 prior to conducting any independent routine inspections.



STEP 2 – Completion of a minimum of 25 joint field training inspections,
AND
successful completion of the jurisdiction’s FSIO Assessment of Training Needs (ATN) similar to the process developed by the Conference for Food Protection. The Assessment of Training Needs Guide and Forms can be access from the CFP web site at

<http://www.foodprotect.org/pdf/GuideConductingAssessmentTrainingNe.pdf>.



STEP 3 – Completion of a minimum of 25 independent inspections
AND
remaining course curriculum (designated as “post” courses) outlined in Appendix B-1.



STEP 4 – Completion of a standardization process similar to the FDA standardization procedures.



STEP 5 – Completion of 20 contact hours of continuing food safety education every 36 months after the initial training is completed.

Description of Requirement

Ninety percent (90 %) of the regulatory retail food program inspection staff (Food Safety Inspection Officers - FSIO) shall have successfully completed the required elements of the 5-step training and standardization process:

- Steps 1 through 4 within 18 months of hire or assignment to the retail food protection program.
- Step 5 every 36 months after the initial 18 months of training.

Step 1: Pre-Inspection Curriculum

Prior to conducting any type of independent field inspections in retail food establishments, the FSIO must satisfactorily complete training in pre-requisite courses designated with a “Pre” in Appendix B-1, for the following curriculum areas:

1. Prevailing statutes, regulations, ordinances (specific laws and regulations to be addressed by each jurisdiction);
2. Public Health Principles;
3. Food Microbiology; and
4. Communication Skills.

There are two options for demonstrating successful completion of these pre-requisite (“Pre”) courses.

OPTION 1:

Successful completion of the FDA ORA U pre-requisite courses/exercises/examinations identified as “Pre” in Appendix B-1
AND
training on the jurisdiction’s prevailing statutes; regulations and/or ordinances.

NOTE: *The estimated contact time for completion of the FDA ORA U pre-requisite (“Pre”) courses is 42 hours.*

OPTION 2:

Successful completion of courses deemed by the regulatory jurisdiction’s food program supervisor or training officer to be equivalent to the FDA ORA U pre-requisite (“Pre”) courses,
AND
training on the jurisdiction’s prevailing statutes, regulations, and/or ordinances,
AND
successful passing of one of the four written examination options (described later in this Standard) for determining whether a FSIO has a basic level of food safety knowledge.

A course is deemed equivalent if it can be demonstrated that it covers at least 80% of the learning objectives of the comparable ORA U course AND verification of successful completion is provided. The learning objectives for each of the listed ORA U courses are available from the web site link at:

<http://www.fda.gov/ora/training/>

NOTE: *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, such as a trainer/food program manager who has first-hand knowledge of employee attendance at the session, keeps the records according to an established protocol. An established protocol can include such items as:*

- *Logs/records that are completed based on sign-in sheets; or*
- *Information validated from the certificate at the time-of-issuance; or*
- *A college transcript with a passing grade or other indication of successful completion of the course; or*
- *Automated attendance records, such as those currently kept by some professional associations and state agencies, or*
- *Other accurate verification of actual attendance.*

Regulatory retail food inspection staff submitting documentation of courses equivalent to the FDA ORA U courses – OPTION 2 – must also demonstrate a basic level of food safety knowledge by successfully passing one examination from the four written examination categories specified herein.

1. The Certified Food Safety Professional examination offered by the National Environmental Health Association; or
2. A state sponsored food safety examination that is based on the current version of the FDA Food Code (and supplement) and is developed using methods that are psychometrically valid and reliable; or
3. A food manager certification examination provided by an ANSI/CFP accredited certification organization; or
4. A Registered Environmental Health Specialist or Registered Sanitarian examination offered by the National Environmental Health Association or a State Registration Board.

NOTE: *Within the context of this Standard, the written examinations are part of a training process; NOT a standardization/certification process. The examinations listed are NOT to be considered equivalent to each other. They are to be considered as training tools and have been incorporated as part of the Standard because each instrument will provide a method of assessing whether a FSIO has attained a basic level of food safety knowledge. Any jurisdiction has the option and latitude to mandate a particular examination based on the laws and rules of that jurisdiction.*

Step 2: Initial Field Training and Experience

The regulatory staff conducting inspections of retail food establishments must conduct a minimum of 25 joint field inspections with a trainer or the jurisdiction’s designated staff member, who has successfully completed all training elements required by this Standard. The 25 joint field inspections are to be comprised of both “demonstration” (trainer led) and “training” (trainee led) inspections and include a variety of retail food establishment types available within the jurisdiction.

Demonstration inspections are those in which the jurisdiction’s trainer and/or designated staff person takes the lead and the candidate observes the inspection process. Training inspections are those in which the candidate takes the lead and their inspection performance is assessed and critiqued by the trainer. The jurisdiction’s trainer is responsible for determining the appropriate combination of demonstration and training inspections based on the candidate’s food safety knowledge and performance during the joint field inspections.

As part of the 25 joint field inspections, the jurisdiction’s trainer will conduct an Assessment of Training Needs (ATN) on those joint inspections performed as “training” inspections where the candidate takes the lead using a process and forms similar to the ones presented in The Guide to Conducting ATN. The ATN is designed not only to assess a Food Safety Inspection Officer’s readiness to conduct independent inspections, but also to provide valuable feedback on the jurisdiction’s food safety training process.

NOTE: *The ATN provides structure to the FSIO performance assessment. The performance assessment is part of a training process that provides both candidate and assessor feedback on specific knowledge, skills and abilities that are important elements of effective retail food, restaurant, and institutional foodservice inspections.*

- *The ATN is NOT intended to be used for certification or licensure purposes.*
- *Regulatory jurisdictions are NOT to use the ATN for administrative purposes including but not limited to, job classifications, promotions, or disciplinary actions up to and including termination.*

FSIOs must successfully complete the ATN prior to conducting independent inspections and re-inspections of retail food establishments in risk categories 2, 3, and 4 as presented in Appendix B-3 (taken from Annex 5, Table 1 of the 2005 FDA Food Code) need to provide web site for this info. The jurisdiction’s trainer/food program manager can make a determination as to the FSIO’s readiness to conduct independent inspections of risk category 1 establishments as defined in Appendix B-3 at any time during the training process.

NOTE: *The criterion for conducting a minimum of 25 joint field training inspections is intended for new employees or employees new to the food safety program. In order to accommodate an experienced FSIO, the supervisor/training officer can include a signed statement or affidavit in the employee’s training file explaining the background or experience that justifies a waiver of this*

requirement. In lieu of the 25 joint field inspections, an ATN of experienced FSIOs must be conducted to determine any areas in need of improvement. An individual corrective action plan should be developed outlining how any training deficiencies will be corrected and the date when correction will be achieved.

Step 3 – Independent Inspections and Completion of ALL Curriculum Elements
Within 18 months of hire or assignment to the regulatory retail food program, Food Safety Inspection Officers must complete a minimum of 25 independent inspections of retail food, restaurant, and/or institutional foodservice establishments.

- If the jurisdiction’s establishment inventory contains a sufficient number of facilities, the FSIO must complete 25 independent inspections of food establishments in risk categories 3 and 4 as described in Appendix B-3.
- For those jurisdictions that have a limited number of establishments which would meet the risk category 3 and/or 4 criteria, the FSIO must complete 25 independent inspections in food establishments that are representative of the highest risk categories within their assigned geographic region or training area.

In addition, all coursework identified in Appendix B-1, for the following six curricula areas, must be completed within this 18 month time frame.

1. Prevailing statutes, regulations, ordinances (all courses for this element are part of the pre-requisite curriculum outlined in Step 1);
2. Public health principles (all courses for this element are part of the pre-requisite curriculum outlined in Step 1);
3. Communication skills (Step 1);
4. Food microbiology (some of the courses for this element are part of the pre-requisite curriculum outlined in Step 1);
5. Epidemiology; and
6. HACCP.

All courses for each of the curriculum areas must be successfully completed within 18 months of hire or assignment to the regulatory retail food program in order for FSIOs to be eligible for the Field Standardization Assessment.

NOTE: *The estimated contact time for completion of the FDA ORA U “post” courses is 16 hours. The term “post” refers to those courses in Appendix B-1 that were not included as part of the pre-requisite coursework. This includes all the courses in Appendix B-1 that do not have the designation “Pre” associated with them. All courses in Appendix B-1 must be successfully completed prior to conducting field standardizations.*

As with the pre-requisite inspection courses, the coursework pertaining to the above six curriculum areas can be successfully achieved by completing the ORA U courses/exercises/exams listed under each curriculum area OR by completing courses, deemed by the regulatory jurisdiction’s food program supervisor or training officer to be equivalent to the comparable FDA ORA U courses.

A course is deemed equivalent if it can be demonstrated that it covers at least 80% of the learning objectives of the comparable ORA U course AND verification of successful completion can be provided. The learning objectives for each of the listed ORA U courses are available from the FDA web site: <http://www.fda.gov/ora/training/>

Step 4 – Food Safety Inspection Officer – Field Standardization Within 18 months of employment or assignment to the retail food program, staff conducting inspections of retail food establishments must satisfactorily complete four joint inspections with a “training standard” using a process similar to the ‘FDA Standardization Procedures.’ The standardization procedures shall determine the inspector’s ability to apply the knowledge and skills obtained from the training curriculum, and address the five following performance areas:

1. Risk-based inspections focusing on the factors that contribute to foodborne illness;
2. Good Retail Practices;
3. Application of HACCP;
4. Inspection equipment; and
5. Communication.

NOTE: *The field standardization criteria described in Step 4 is intended to provide a jurisdiction the flexibility to use their own regulation or ordinance. In addition, the reference to using standardization procedures similar to the FDA Procedures for Standardization of Retail Food Inspection Training Officers, is intended to allow the jurisdiction the option to develop its own written protocol to ensure that personnel are trained and prepared to competently conduct inspections. Any written standardization protocol must include the five performance areas outlined above in Step 4.*

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 regulatory differences can be noted and discussed during the exercises, thereby enhancing the knowledge and understanding of the candidate. The scoring and assessment tools presented in the FDA standardization procedures can be used without modification regardless of the Food Code enforced in a jurisdiction. The scoring and assessment tools are, however, specifically tied to the standardization inspection form and other assessment forms that are a part of the FDA procedures for standardizations.

FDA’s standardization procedures are based on a minimum of 8 inspection. However to meet Standard #2, a minimum of 4 standardization inspections must be conducted.

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 candidate’s 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 versed 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.

The five performance areas target the behavioral elements of an inspection. The behavioral elements of an inspection are defined as the manner, approach and focus which targets the most important public health risk factors, and communicates vital information about the inspection in a way that can be received, understood and acted upon by management. The goal of standardization is to assess not only technical knowledge but also an inspector's ability to apply his or her knowledge in a way that ensures the time and resources spent within a facility offer maximum benefit to both the regulatory agency and the consuming public. Any customized standardization procedure must continue to meet these stated targets and goals.

Continuing standardization (re-standardization) shall be maintained by performing four joint inspections with the "training standard" every three years.

Should a jurisdiction fall short of having 90% of its retail food program inspection staff successfully complete the Program Standard #2 criteria within the 18 month time frame, a written protocol must be established to provide a remedy so that the Standard can be met. This protocol would include a corrective action plan outlining how the situation will be corrected and the date when the correction will be achieved.

Step 5 – Continuing Education and Training

A FSIO must accumulate 20 contact hours of continuing education in food safety every 36 months after the initial training (18 months) is completed. Within the scope of this standard, the goal of continuing education and training is to enhance the FSIO's knowledge, skills, and ability to perform retail food and foodservice inspections. The objective is to build upon the FSIO's knowledge base. Repeated coursework should be avoided unless justification is provided to, and approved by, the food program manager and/or training officer. .

Training on any changes in the regulatory agency's prevailing statutes, laws and/or ordinances must be included as part of the continuing education (CE) hours within six months of the regulatory change. Documentation of the regulatory change date and date of training must be included as part of the individual's training record.

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

1. Attendance at FDA Regional seminars / technical conferences;

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

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

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

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

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

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

9. Reading technical publications related to food safety.

Documentation must accompany each activity submitted for continuing education credit.

Examples of acceptable documentation include:

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

NOTE: *The key to a document's acceptability is that someone with responsibility, such as a training officer or supervisor, who has first-hand knowledge of employee's continuing education activities, keeps the records according to an established protocol similar to that presented in Step 1 for assessing equivalent courses*

Outcome

The desired outcome of this Standard is a trained regulatory staff with the skills and knowledge necessary to conduct quality inspections.

Documentation

The quality records needed for this standard include:

1. Certificates or proof of attendance from the successful completion of all the course elements identified in the Program Standard curriculum (Steps 1 and 3);
2. Documentation of field inspection reports for twenty-five each joint and independent inspections (Steps 2 and 3);
3. Certificates or other documentation of successful completion of a field training process based on an Assessment of Training Needs;
4. Certificates or other records showing proof of satisfactory standardization (Step 4);
5. Contact hour certificates or other records for continuing education (Step 5);
6. Signed documentation from the regulatory jurisdiction's food program supervisor or training officer that food inspection personnel attended and successfully completed the training and education steps outlined in this Standard.
7. Date of hire records or assignment to the retail food program; and
8. Summary record of employees' compliance with the Standard.

The Standard 2, Program Self-Assessment and Verification Audit Form is designed to document the findings from the self-assessment and the verification audit process for Standard 2.

STANDARD 3

INSPECTION PROGRAM BASED ON HACCP PRINCIPLES

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

Requirement Summary

An inspection program that focuses on the status of risk factors, determines and documents compliance, and targets immediate- and long-term correction of out-of-control risk factors through active managerial control.

Description of Requirement

Program management:

1. Implements the use of an inspection form that is designed for:
 - a) The identification of risk factors and interventions.
 - b) Documentation of the compliance status of each risk factor and intervention (i.e. a form with notations indicating IN compliance, OUT of compliance, Not Observed, or Not Applicable for risk factors)
 - c) Documentation of all compliance and enforcement activities and
 - d) Requires the selection of IN, OUT, NO, or NA for each risk factor.
2. Develops and uses a process that groups food establishments into at least three categories based on potential and inherent food safety risks.
3. Assigns the inspection frequency based on the risk categories to focus program resources on food operations with the greatest food safety risk.
4. Develops and implements a program policy that requires:
 - a) On-site corrective actions* as appropriate to the type of violation.
 - b) Discussion of long-term control** of risk factor options, and
 - c) Follow-up activities.
5. Establishes and implements written policies addressing code variance requests related to risk factors and interventions.
6. Establishes written policies regarding the verification and validation of HACCP plans when a plan is required by the code.

Outcome

The desired outcome of this standard is a regulatory inspection system that uses HACCP principles to identify risk factors and to obtain immediate- and long-term corrective action for recurring risk factors.

Documentation

The quality records needed for this standard include:

1. Inspection form that requires the selection of IN, OUT, NO, or NA,
2. Written process used for grouping establishments based on food safety risk and the inspection frequency assigned to each category,
3. Policy for on-site correction and follow-up activities,
4. Policy for addressing code variance requests related to risk factors and interventions,
5. Policy for verification and validation of HACCP plans required by code, and
6. Policy requiring the discussion of food safety control systems with management when out of control risk factors are recorded on subsequent inspections.

*Note: **On-site** corrective action as appropriate to the violation would include such things as:

- a. Destruction of foods that have experienced extreme temperature abuse,
- b. Embargo or destruction of foods from unapproved sources,
- c. Accelerated cooling of foods when cooling time limits can still be met,
- d. Reheating when small deviations from hot holding have occurred,
- e. Continued cooking when proper cooking temperatures have not been met.
- f. Initiated use of gloves, tongs, or utensils to prevent hand contact with ready-to-eat foods, or
- g. Required hand washing when potential contamination is observed.

Note: **Long-term control of risk factors requires a commitment by managers of food establishments to develop effective monitoring and control measures or system changes to address those risk factors most often responsible for foodborne illness. Risk control plans, standard operating procedures, buyer specifications, menu modification, HACCP plans and equipment or facility modification may be discussed as options to achieve the long-term control of risk factors.

STANDARD 4

UNIFORM INSPECTION PROGRAM

This standard applies to the jurisdiction's internal policies and procedures established to ensure uniformity among regulatory staff in the interpretation of regulatory requirements, program policies and compliance / enforcement procedures.

Requirement Summary

Program management has established a quality assurance program to ensure uniformity among regulatory staff in the interpretation and application of laws, regulations, policies, and procedures.

Description of Requirement

- 1) Program Management implements an on-going quality assurance program that evaluates inspection uniformity to ensure inspection quality, inspection frequency and uniformity among the regulatory staff. The quality assurance program shall:
 - A. Be an on-going program.
 - B. Assure that each inspector:
 1. Determines and documents the compliance status of each risk factor and intervention (i.e., IN compliance, OUT of compliance, Not Observed, or Not Applicable is noted on the inspection form) through observation and investigation;
 2. Completes an inspection report that is clear, legible, concise, and accurately records findings, observations and discussions with establishment management;
 3. Interprets and applies laws, regulations, policies and procedures correctly;
 4. Cites the proper local code provisions for CDC-identified risk factors and Food Code interventions;
 5. Reviews past inspection findings and acts on repeated or unresolved violations;
 6. Follows through with compliance and enforcement;
 7. Obtains and documents on-site corrective action for out-of-control risk factors at the time of inspection as appropriate to the type of violation;
 8. Documents that options for the long-term control of risk factors were discussed with establishment managers when the same out-of control risk factor occurred on consecutive inspections. Options may include but are not limited to risk control plans, standard operating procedures, equipment and/or facility modification, menu modification, buyer specifications, remedial training, or HACCP plans;
 9. Verifies that the establishment is in the proper risk category and that the required inspection frequency is being met; and
 10. Files reports and other documentation in a timely manner.

- C. Describe the actions that will be implemented when the program analysis identifies deficiencies in quality or consistency in any program aspect listed in 1) B.
- 2) The quality assurance program must achieve an overall inspection program performance rating for each of the ten measured aspects [Items1-10] of at least 75% using the following self-assessment procedure and the appropriate Table in Supplement to Standard 4 (Appendix D).

An assessment review of each inspector's work shall be made during at least two joint on-site inspections, with a corresponding file review of at least the three most recent inspection reports of the same inspected establishments, during every self-assessment period.

Outcome

A quality assurance program exists that ensures uniform, high quality inspections.

Documentation

The quality records needed for this standard include:

1. A written procedure that describes the jurisdiction's quality assurance program that meets the criteria under the Description of Requirement section 1) B., including corrective actions for deficiencies, and
2. Documentation that the program achieves a 75 percent performance rating on each aspect using the self-assessment procedures described above and in Supplement to Standard 4 (Appendix D).

STANDARD 5

FOODBORNE ILLNESS AND FOOD DEFENSE PREPAREDNESS AND RESPONSE

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

Requirement Summary

The program has an established system to detect, collect, investigate and respond to complaints and emergencies that involve foodborne illness, injury, and intentional and unintentional food contamination.

Description of Requirement

1. Investigative Procedures

- a. The program has written operating procedures for responding to and /or conducting investigations of foodborne illness and injury. The procedures clearly identify the roles, duties and responsibilities of program staff and how the program interacts with other relevant departments and agencies. The procedures may be contained in a single source document or in multiple documents.
- b. The program maintains contact lists for individuals, departments, and agencies that may be involved in the investigation of foodborne illness, injury or contamination of food.
- c. The program maintains a written operating procedure or a Memorandum of Understanding (MOU) with the appropriate epidemiological investigation program/department to conduct foodborne illness investigations and to report findings. The operating procedure or MOU clearly identifies the roles, duties and responsibilities of each party.
- d. The program maintains logs or databases for all complaints or referral reports from other sources alleging food-related illness, injury or intentional food contamination. The final disposition for each complaint is recorded in the log or database and is filed in or linked to the establishment record for retrieval purposes.
- e. Program procedures describe the disposition, action or follow-up and reporting required for each type of complaint or referral report.
- f. Program procedures require disposition, action or follow-up on each complaint or referral report alleging food-related illness or injury within 24 hours.

- g. The program has established procedures and guidance for collecting information on the suspect food's preparation, storage or handling during on-site illness, injury, or outbreak investigations
- h. Program procedures provide guidance for immediate notification of appropriate law enforcement agencies if at any time intentional food contamination is suspected.
- i. Program procedures provide guidance for the notification of appropriate state and/or federal agencies when a complaint involves a product that originated outside the agency's jurisdiction or has been shipped interstate.

2. Reporting Procedures

- a.—Possible contributing factors to the illness, injury or intentional food contamination are identified in each on-site investigation report.
- b.—The program shares final reports of investigations with the state epidemiologist and reports of confirmed outbreaks with CDC.-

3. Laboratory Support Documentation

- a. The program has a letter of understanding, written procedures, contract or MOU acknowledging, that a laboratory(s) is willing and able to provide analytical support to the jurisdiction's food program. The documentation describes the type of biological, chemical, radiological contaminants or other food adulterants that can be identified by the laboratory. The laboratory support available includes the ability to conduct environmental sample analysis, food sample analysis and clinical sample analysis.
- b. The program maintains a list of alternative laboratory contacts from which assistance could be sought in the event that a food-related emergency exceeds the capability of the primary support lab(s) listed in paragraph 3.a. This list should also identify potential sources of laboratory support such as FDA, USDA, CDC, or environmental laboratories for specific analysis that cannot be performed by the jurisdiction's primary laboratory(s).

4. Trace-back Procedures

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

5. Recalls

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

- b. When the jurisdiction has the responsibility to request or monitor a product recall, written procedures equivalent to 21 CFR, Part 7 are followed.
- c. Written policies and procedures exist for verifying the effectiveness of recall actions by firms (effectiveness checks) when requested by another agency.

6. Media Management

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

7. Trend Analysis

- a. At least once per year, the program conducts a review of the data in the complaint log or database and the illness and injury investigations to identify trends and possible contributing factors that are most likely to cause illness or injury. These periodic reviews of multiple complaints and contributing factors may suggest a need for further investigations and may suggest steps for illness prevention.
- b. The review is conducted with prevention in mind and focuses on, but is not limited to, the following:
 - 1) Multiple complaints on the same establishment;
 - 2) Multiple complaints on the same establishment type;
 - 3) Multiple complaints implicating the same food;
 - 4) Multiple complaints associated with similar food preparation processes;
 - 5) Number of laboratory-confirmed, food-related outbreaks;
 - 6) Number of non-laboratory-confirmed but epidemiologically linked, food-related outbreaks;
 - 7) Contributing factors most often identified;
 - 8) Number of complaints involving real and alleged threats of intentional food contamination; and
 - 9) Multiple complaints involving the same agent and any complaints involving unusual agents.
- c. 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.

Outcome

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.

Documentation

The quality records required to meet this standard include:

1. Logs or databases of alleged food related illness, injury complaints maintained and current.
2. Collection forms specified in the operating procedures.
3. Investigation reports of alleged food related illness, injury, or incidents. Reports are retrievable by implicated establishment name.
4. The written procedures, contracts or MOU's with the supporting laboratories.
5. The procedure addressing the trace-back of food products implicated in an illness, outbreak, or contamination event.
6. 21 CFR, Part 7, or written procedures equivalent to 21 CFR, Part 7 for recalls.
7. Completed copies of the annual trend analysis (after 12 months of data).
8. Current written media policy/procedure and contact person.
9. The contact list for communicating with all relevant agencies.
10. Portions of any emergency response relevant to food safety and security.

STANDARD 6 COMPLIANCE AND ENFORCEMENT

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

Requirement Summary

Compliance and enforcement activities result in follow-up actions for out-of-control risk factors and timely correction of code violations

Description of Requirement

Compliance and enforcement encompasses all voluntary and regulatory actions taken to achieve compliance with regulations. Voluntary corrective action includes, but is not limited to, such activities as on-site corrections at time of inspection, voluntary destruction of product, risk control plans and remedial training. Enforcement action includes, but is not limited to, such activities as warning letters, re-inspection, citations, administrative fines, permit suspension and hearings. Compliance and enforcement options may vary depending on state and local law.

The program must demonstrate credible follow-up for each violation noted during an inspection, with particular emphasis being placed on risk factors that most often contribute to foodborne illness and *Food Code* interventions intended to prevent foodborne illness. The resolution of out-of-compliance risk factors and/or food code interventions must be documented in each establishment record. The essential program elements required to meet this standard are:

1. A written step-by-step procedure that describes how compliance and enforcement tools are to be used to achieve compliance.
2. Inspection report form(s) that record and quantify the compliance status of risk factors and interventions (i.e., IN compliance, OUT of compliance, Not Observed, or Not Applicable).
3. Documentation on the establishment inspection report form or in the establishment file that compliance and/or enforcement action was taken to achieve compliance at least 80 percent of the time when out-of-control risk factors or interventions are recorded on a routine inspection measured using the procedures in Supplement to Standard 6, Appendix F.
4. Compliance and enforcement actions that follow the step-by-step procedure.

Outcome

The desired outcome of this standard is an effective compliance and enforcement program that is implemented consistently to achieve compliance with regulatory requirements.

Documentation

The quality records needed for this standard include:

1. A copy of the written step-by-step enforcement procedures.
2. Inspection form that meets the criteria.
3. Documentation that compliance and enforcement action was taken 80 percent of the time using the worksheet and procedures in Supplement to Standard 6, Appendix F, when out-of-control risk factors or code interventions are recorded on routine inspections.
4. A reference “Key” which identifies the major risk factors and Food Code interventions on the jurisdiction's inspection report form. [Note: A jurisdiction will not be penalized under Standard No. 6 for sections of the Food Code which have not yet been adopted].

STANDARD 7 INDUSTRY AND COMMUNITY RELATIONS

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

Requirement Summary

The jurisdiction documents participation in forums that foster communication and information exchange among the regulators, industry and consumer representatives.

The jurisdiction documents outreach activities that provide educational information on food safety.

Description of Requirement

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.

2. Educational Outreach

Outreach encompasses industry and consumer groups as well as media and elected officials. Outreach efforts may include industry recognition programs, web sites, newsletters, FightBAC™ campaigns, food safety month activities, food worker training, school-based activities, customer surveys or other activities that increase awareness of the risk factors and control methods to prevent foodborne illness. Outreach activities may also include posting inspection information on a web site or in the press.

Agency participation in at least one activity in each of the above categories annually is sufficient to meet this standard.

Outcome

The desired outcome of this standard is enhanced communication with industry and consumers through forums designed to solicit input to improve the food safety program. A further outcome is the reduction of risk factors through educational outreach and cooperative efforts with stakeholders.

Documentation

Quality records needed for this standard reflect activities over the most recent three-year period and include:

1. Minutes, agendas or other records that forums were conducted,
2. For formal, recurring meetings, such documents as by-laws, charters, membership criteria and lists, frequency of meetings, roles, etc.,
3. Documentation of performed actions or activities designed with input from industry and consumers to improve the control of risk factors, or
4. Documentation of food safety educational efforts.

Statements of policies and procedures may suffice if activities are continuous, and documenting multiple incidents would be cumbersome, i.e., recognition provided to establishments with exemplary records or an on-going web site.

STANDARD 8 PROGRAM SUPPORT AND RESOURCES

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

Requirement Summary

The program provides funding, staff and equipment necessary to accomplish compliance with the Voluntary National Retail Food Regulatory Program Standards.

Description of Requirement

The program budget provides the necessary resources to develop and maintain a retail food safety program that meets the following criteria:

1. Staffing Level

A staffing level of one full-time equivalent (FTE) devoted to food for every 280 – 320 inspections performed*. Inspections for purposes of this calculation include 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.

A process should exist for the regulated food establishments to be grouped into at least three categories based on food safety risk (See Standard 3). The number of inspections assigned per FTE should be adjusted within the 280 – 320 range depending upon the composition of low- to high –risk establishments in the assigned inventory. When an FTE is divided between program areas, the total number of food inspections planned for that FTE should be adjusted to compensate for the additional training time required to maintain competency in multiple program areas. An adjustment of planned inspections per FTE should also occur when food establishments are geographically dispersed due to increased travel time.

2. Inspection Equipment

Inspection equipment of each inspector to include head covers, thermocouples, flashlights, sanitization test kits, heat sensitive tapes or maximum registering thermometers, necessary forms and administrative materials. The following equipment must be available for use by inspectors when needed: computers, cameras, black lights, light meters, pH meters, foodborne illness investigation kits, sample collection kits, data loggers and cell phones.

3. Administrative Program Support

Equipment for administrative staff to include computers, software and/or items necessary to support the record keeping system utilized by the program. A system is in place to collect, analyze, retain and report pertinent information.

4. Trained Regulatory Staff

Training and training documentation for all regulatory staff to meet the level specified in Standard No. 2.

5. Inspection Program Based on HACCP Principles

Staff to meet all of the requirements in Standard No. 3, inspection based on HACCP principles.

6. Uniform Inspection Program

Administrative and supervisory staff to administer and monitor a uniform inspection program based on HACCP principles that meet Standards No. 3 and 4.

7. Foodborne Illness and Food Defense Preparedness & Response

Staff and resources to maintain a foodborne illness investigation and response system that meets Standard No. 5.

8. Compliance & Enforcement

A program that demonstrates follow-through on all compliance and enforcement actions initiated according to the written step-by-step procedures required in Standard No. 6.

9. Industry & Community Relations

An industry and consumer relations program as specified in Standard No. 7.

10. Program Assessment

Sufficient staff and resources to conduct regular program self-assessment and risk factor surveys as specified in Standard No. 9.

11. Accredited Laboratory

Funds to provide access to accredited laboratory resources in support of the program as specified under these nine Standards.

The essential program elements required to demonstrate compliance with this standard are:

- A. Full-time equivalent (FTE) personnel to inspections accomplished ratio as described in section 1.
- B. Inspection equipment assigned or available as described in section 2.
- C. Equipment and/or supplies required for administering the program as described in Section 3.
- D. A full and accurate completion of Appendix H for Standards 1-7 and Standard 9 whether or not those standards are met.

Outcome

The desired outcome of this standard is that resources are available to support a risk-based retail food safety program designed to reduce the risk factors known to contribute to foodborne illness.

Documentation

The quality records needed for this standard include:

- 1. Documentation of FTE to inspections ratio,
- 2. Inventory of assigned and available inspection equipment,
- 3. Documentation and demonstration of records system and adequacy of support,
- 4. The completed Appendix H

*NOTE: An average workload figure of 150 establishments per FTE with two inspections per year was originally recommended in the 1976 Food Service Sanitation Manual, the standard originating from a book entitled, "Administration of Community Health Services." Annex 4 of the Code since 1993 has included a recommendation that 8 to 10 hours be allocated for each establishment per year to include all the activities reflected here in the definition of an inspection. The range of 280 – 320 broadly defined inspections per FTE is consistent with these previous recommendations. A measure of resources defined as inspections per FTE rather than establishments per FTE allows for the same unit of measure to be used for any jurisdiction regardless of the frequency of routine inspections conducted among the various priority categories.

STANDARD 9 PROGRAM ASSESSMENT

This standard applies to the process used to measure the success of jurisdictions in meeting the *Voluntary National Retail Food Regulatory Program Standards 1 through 9* (hereafter referred to as the National Standards) and their progress in reducing the occurrence of foodborne illness risk factors. Additionally, it applies to the requirements for recognition by the Food and Drug Administration of those jurisdictions meeting the National Standards.

Requirement Summary

1. For listing on the FDA Roll of Participating Jurisdictions, a jurisdiction must assure:
 - A. That the program manager conducts an initial *self-assessment* within 12 months of the date of enrollment in the National Registry and every 36 months thereafter; and,
 - B. That a *verification audit* is conducted within 36 months of the initial *self-assessment*. Subsequent verification audits are conducted every 36 months thereafter.
2. For achievement of Standard 9, a jurisdiction must assure:
 - A. That a survey and report on the occurrence of foodborne illness risk factors and the use of *Food Code* interventions is completed within the 36-month period between the self-assessment and the verification audit; and
 - B. A survey on the occurrence of foodborne illness risk factors and *Food Code* interventions is conducted at least once every five years thereafter to measure trends specific to the occurrence of the risk factors and interventions.
3. Reporting by means of the FDA National Registry Report form.

Description of Requirement

For Listing on the FDA Roll of Participating Jurisdictions, a jurisdiction must assure that:

1. Self-Assessment

The program manager, or a designated representative, conducts an initial *self-assessment* of the retail food safety program within 12 months of the date of enrollment in the National Registry and every 36 months thereafter. The *self-assessment* will determine:

- A. The compliance status with each of the National Standards by completing the Appendix documents (hereafter referred to as the worksheets) or documents containing equivalent summary information for each Standard, and
- B. Whether the *quality records* specified as requirements in each of the National Standards have been established, identified, and maintained. If the quality records for a specific program element are incomplete or provide inadequate information upon which to make a determination or to enable a verification audit, that standard is not

met.

2. Verification Audit

The first *verification audit* is conducted within 36 months the initial *self-assessment*. An individual as defined in the definitions shall complete the verification audit. Subsequent verification audits are conducted every 36 months thereafter. Verification audits confirm and report on the accuracy of the *self-assessment* and the occurrence of risk factors and *Food Code* interventions survey reports. During the *verification audit*, the auditor will:

- A. Review the *quality records* and confirm that the *self-assessment* accurately reflects the current program compliance status in each of the program elements, and
- B. Confirm that the occurrence of risk factors survey collection procedures and survey tools similar to Appendix J have been used and that the conclusions are supported by the data.

3. Achievement of Standard 9

A jurisdiction must assure that a survey and report on the occurrence of foodborne illness risk factors and the use of *Food Code* interventions is completed within the 36-month period between the self-assessment and the verification audit. The survey information is updated at least once in every 5 years to measure trends specific to the occurrence of the risk factors and *Food Code* interventions. The subsequent surveys and reports will determine whether there has been a net change in the occurrence of the risk factors and use *Food Code* interventions.

A data collection instrument similar to the FDA model form referenced in 2.B., using the IN, OUT, NA, and NO convention, is required. Failure to use this convention skews the data toward either IN compliance or OUT of compliance. The FDA data collection instrument is not intended as an inspection form. However, jurisdictions that have developed an inspection form using the IN, OUT, NA and NO convention may use that inspection form as a survey instrument. Refer to the Data Collection Manual to understand the statistical limitations and restrictions if using an inspection form or a data collection form different from the FDA data collection instrument. If the jurisdiction uses a different form, the data may be difficult to compare with the data from the FDA national foodborne illness risk factor study or with data from other jurisdictions.

4. Reporting

The FDA National Registry Report (Standards Appendix I) will be completed and submitted to the appropriate FDA Regional office within 30 days following completion of the self-assessment, survey report on the occurrence of foodborne illness risk factors and *Food Code* interventions, verification audits, and/or survey of risk factor occurrence updates. The FDA National Registry listing will be updated using data contained in this report. A current Release and Permission to Publish Form must accompany each FDA National Registry Report.

Outcome

The desired outcome of this Standard is to enable managers to measure their program against national criteria. The process identifies program elements that may require improvement or be deserving of recognition.

Documentation

The quality records required for this standard include:

1. The completed Appendices (worksheets) for each Standard and supporting records,
2. Survey reports on the occurrence of risk factors and *Food Code* interventions,
3. Verification audit reports,
4. FDA National Registry Report, and
5. Affidavit of Permission to Publish.

Appendix A - Supplement to Standard No. 1 – Regulatory Foundation

See instructions at end of each Table

PART I

Table A- Major Interventions and Risk Factors

Major Interventions/Risk Factor	
Section 1. Demonstration of Knowledge	
Code Section	
2-101.11	Assignment
2-102.11	Demonstration
2-103.11	Person in Charge
Section 2. Employee Health	
Code Section	
2-201.11	Responsibility of PIC to Require Reporting by Food Employees/Applicants
2-201.12	Exclusions and Restrictions
2-201.14	Responsibility of a Food Employee or an Applicant to Report to the PIC
2-201.15	Reporting by the Person in Charge
Section 3. Consumer Advisory	
Code Section	
3-603.11	Consumer Advisory (Consumption of Animal Foods that are Raw, Undercooked, or Not Otherwise Processed to Eliminate Pathogens)
Section 4. Approved Source	
Code Section	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
Code Section	All shellfish from NSSP listed sources / no recreationally caught shellfish received or sold
3-201.14	Fish
3-201.15	Molluscan Shellfish
Code Section	Game and wild mushrooms approved by regulatory authority
3-201.16	Wild Mushrooms
3-201.17	Game Animals
Code Section	Received at proper temperatures / protected from contamination during transport and receiving / safe and unadulterated food
3-202.11	Temperature
3-202.15	Package Integrity
3-101.11	Safe, Unadulterated, and Honestly Presented
Code Section	Shellstock tags retained for 90 days from the date the container is emptied
3-202.18	Shellstock Identification
3-203.12	Shellstock, Maintaining Identification
Code Section	Written documentation of parasite destruction
3-402.11	Parasite Destruction

3-402.12	Records, Creation, and Retention	
Code Section	CCP monitoring records maintained in accordance with HACCP plan	
3-502.12	Variance Requirement	
Section 5. Time/Temperature		
Code Section		
3-401.11	Cooking; Raw animal Foods	
3-401.12	Microwave Cooking	
3-403.11	Reheating for Hot Holding	
3-501.14	Cooling*	
3-501.16	Potentially Hazardous Food, Hot and Cold Holding	
3-501.17	Ready-to-Eat, Potentially Hazardous Food, Date Marking	
3-501.18	Ready-to-Eat, Potentially Hazardous Food, Disposition	
3-501.19	Time as a Public Health Control*	
Section 6. Protection from Contamination		
Code Section		
3-302.11	Packaged/Unpackaged Food - Separation, Packaging, and Segregation	
3-304.11	Food contact with Equipment and Utensils	
3-306.14	Returned Food and Reservice of Food	
3-701.11	Discarding/ Reconditioning Unsafe, Adulterated, or Contaminated Food	
4-501.111	Manual Warewashing Equipment, Hot Water Sanitization Temperatures	
4-501.112	Mechanical Warewashing Equipment, Hot Water Sanitization Temperatures	
4-501.113	Mechanical Warewashing Equipment, Sanitization Pressure	
4-501.114	Chemical Sanitization - Temperature, pH, Concentration, and Hardness	
4-501.115	Manual Warewashing Equipment, Chemical Sanitization Using Detergent Sanitizers	
4-601.11	Equipment, Food-Contact Surfaces, Nonfood-Contact Surfaces, and Utensils?	
4-602.11*	Equipment Food-Contact Surfaces and Utensils	
4-602.12	Cooking and Baking Equipment	
4-702.11*	Before Use After Cleaning	
4-703.11*	Hot Water and Chemical	
Section 7. Control of Hands as a Vehicle of Contamination		
Code Section		
2-301.11	Clean Condition	
2-301.12	Cleaning Procedure	
2-301.14	When to Wash	
2-301.15	Where to Wash	
2-301.16	Hand Sanitizers	
3-301.11	Preventing Contamination from Hands	
5-203.11	Handwashing Facilities (Numbers/Capacities)	
5-204.11	Handwashing Facilities (Location/Placement)	
5-205.11	Using a Handwashing Facility	
6-501.18	Maintaining and Using Handwashing Facilities	
6-301.11	Handwashing Cleanser, Availability	
6-301.12	Hand Drying Provision	

6-301.13	Handwashing Aids and Devices, Use Restrictions	
Section 8. Good Hygienic Practices		
Code Section		
2-401.11	Eating, Drinking, or Using Tobacco	
2-401.12	Discharges from the Eyes, Nose, and Mouth	
2-301.12	Cleaning Procedure	
Section 9. Chemical		
Code Section		
3-202.12	Additives	
3-302.14	Protection from Unapproved Additives	
7-207.11	Restriction and Storage	
7-207.12	Refrigerated Medicines, Storage	
7-208.11	Storage (First Aid Supplies)	
7-209.11	Storage	
7-101.11	Identifying Information, Prominence	
7-202.11	Restriction	
7-202.12	Conditions of Use	
7-203.11	Poisonous or Toxic Material Containers	
7-204.11	Sanitizers, Criteria	
7-204.12	Chemicals for Washing Fruits and Vegetables, Criteria	
7-204.13	Boiler Water Additives, Criteria	
7-204.14	Drying Agents, Criteria	
7-205.11	Incidental Food Contact, Criteria	
7-206.11	Restricted Use Pesticides, Criteria	
7-206.12	Rodent Bait Stations	
7-206.13	Tracking Powders, Pest Control and Monitoring	
7-301.11	Separation	
Section 10. Conformance with Approved Procedures		
Code Section		
8-103.12	Conformance with Approved Procedures (Variance, HACCP plans)	
Section 11. Highly Susceptible Populations		
Code Section		
3-801.11	Pasteurized Foods, Prohibited Reservice, and Prohibited Food	

***** End of Table A-1. *****

Instructions for Table A-1

Evaluate your jurisdiction's code, regulation or ordinance against each *Food Code* section grouped by interventions and risk factors listed in Table A-1 above. To obtain credit for the intervention/risk factor, each of the code sections must be checked in the block of the right hand column. A check mark indicates that your code/regulation contains language at least as stringent as the main requirements in the corresponding *FDA Food Code* section. For example, under the section "Good Hygienic Practices," each of the 3 items must have a check in the right-hand column indicating that your code/regulation meets the intent of all three *Food Code* sections.

Note: If your code requirement is as stringent or more stringent than the *Food Code* requirement, you receive credit for that section. For example, if your code/regulation requires the PERSON IN CHARGE to demonstrate knowledge of the Code by being a certified FOOD protection manager who has shown proficiency through passing a test that is part of an ACCREDITED PROGRAM but does not provide other options for demonstration of knowledge, consider this as meeting 2-102.11. You would then place a check mark in the right-hand column adjacent to 2-102.11

Table A- Regulatory Foundation Summary –Interventions and Risk Factors

Major Food Code Interventions and CDC-identified Risk Factors		
	<i>Description</i>	<i>PASS/FAIL</i>
1	Demonstration of Knowledge	
2	Employee Health	
3	Consumer Advisory	
4	Approved Sources	
5	Time/Temperature	
6	Protection from Contamination	
7	Control of Hands as a Vehicle of Contamination	
8	Good Hygienic Practices	
9	Chemical	
10	Conformance with Approved Procedures	
11	Highly Susceptible Populations	
Assessment of _____ (regulatory agency) Conformance with Interventions / Risk Factors		Overall Rating
		PASS ↑
		FAIL ↑

Instructions for Table A-2

1. Use the information from Table A-1 to complete this table. Determine a PASS or FAIL rating for each of the eleven (11) Interventions/Risk Factors by reviewing the check marks on Table A-1. If all of the *Code* sections listed under an Intervention/Risk Factor have a check mark in the right-hand column on Table A-1, give yourself a PASS rating for that item on Table A-2.

If any of the *Code* section provisions are missing, as indicated by a blank in the right-hand column of Table A-1, indicate FAIL for that Intervention/Risk Factor. For example: Under “Approved Source,” if your code/regulation does not address mushroom species picked in the wild, the right-hand column adjacent to 3-201.16 on Table A-1 would be blank. Therefore, the “Approved Source” Intervention/Risk Factor on Table A-2 would be marked as FAIL.

2. For initial participation and listing purposes, if you have achieved a PASS rating on at least 9 of the 11 items on Table A-2, you receive an overall PASS rating for the Interventions/Risk Factors. By the second scheduled audit, you must achieve a PASS rating on 11 of the 11 items in order to receive a overall PASS rating for the Interventions/Risk Factors portion of Standard 1.

PART II

Table A-3 Regulatory Foundation – Good Retail Practices

Section 12. Personnel				
FOOD CODE CHAPTER	CORRESPONDING CODE SECTION, RULE, ETC.	YES, FULL INTENT IS MET.	PARTIAL COMPLIANCE. LIST WHAT IS NOT COVERED. USE ADDITIONAL SHEETS FOR EXPLANATIONS/COMMENTS.	NO, COMPLIANCE IS NOT MET WITH THIS ITEM. INDICATE THE SITUATION.
2-302.11				
2-303.11				
2-304.11				
2-402.11				

Section 13. Food & Food Protection				
FOOD CODE CHAPTER	CORRESPONDING CODE SECTION, RULE, ETC.	YES, FULL INTENT IS MET.	PARTIAL COMPLIANCE. LIST WHAT IS NOT COVERED. USE ADDITIONAL SHEETS FOR EXPLANATIONS/COMMENTS.	NO, COMPLIANCE IS NOT MET WITH THIS ITEM. INDICATE THE SITUATION.
3-202.16				
3-202.17				
3-202.19				
3-203.11				
3-302.12				
3-302.13				
3-305.13				
3-501.11				
3-601.11				
3-601.12				
3-602.12				
6-404.11				

Section 14. Plant Food cooking for Hot Holding				
FOOD CODE CHAPTER	CORRESPONDING CODE SECTION, RULE, ETC.	YES, FULL INTENT IS MET.	PARTIAL COMPLIANCE. LIST WHAT IS NOT COVERED. USE ADDITIONAL SHEETS FOR EXPLANATIONS/COMMENTS.	NO, COMPLIANCE IS NOT MET WITH THIS ITEM. INDICATE THE SITUATION.
3-401.13				

Section 15. Protection from Contamination				
FOOD CODE CHAPTER	CORRESPONDING CODE SECTION, RULE, ETC.	YES, FULL INTENT IS MET.	PARTIAL COMPLIANCE. LIST WHAT IS NOT COVERED. USE ADDITIONAL SHEETS FOR EXPLANATIONS/COMMENTS.	NO, COMPLIANCE IS NOT MET WITH THIS ITEM. INDICATE THE SITUATION.
3-302.15				
3-303.11				
3-303.12				
3-304.11				
3-305.11				
3-305.12				
3-305.14				
3-306.11				
3-306.12				
3-306.13				
3-307.11				

Section 16. Facilities / Methods To Control Product Temperature				
FOOD CODE CHAPTER	CORRESPONDING CODE SECTION, RULE, ETC.	YES, FULL INTENT IS MET.	PARTIAL COMPLIANCE. LIST WHAT IS NOT COVERED. USE ADDITIONAL SHEETS FOR EXPLANATIONS/COMMENTS.	NO, COMPLIANCE IS NOT MET WITH THIS ITEM. INDICATE THE SITUATION.
3-501.11				
4-301.11				

Section 17. PHF Properly Thawed				
FOOD CODE CHAPTER	CORRESPONDING CODE SECTION , RULE, ETC.	YES, FULL INTENT IS MET.	PARTIAL COMPLIANCE. LIST WHAT IS NOT COVERED. USE ADDITIONAL SHEETS FOR EXPLANATIONS/COMMENTS.	NO, COMPLIANCE IS NOT MET WITH THIS ITEM. INDICATE THE SITUATION.
3-501.12				
3-501.13				

Section 18. Dispensing of Food / Utensils Properly Stored				
FOOD CODE CHAPTER	CORRESPONDING CODE SECTION , RULE, ETC.	YES, FULL INTENT IS MET.	PARTIAL COMPLIANCE. LIST WHAT IS NOT COVERED. USE ADDITIONAL SHEETS FOR EXPLANATIONS/COMMENTS.	NO, COMPLIANCE IS NOT MET WITH THIS ITEM. INDICATE THE SITUATION.
3-304.12				
4-204.13				
4-204.14				

Food Equipment

Section 19. Thermometers Provided and Conspicuous

FOOD CODE CHAPTER	CORRESPONDING CODE SECTION , RULE, ETC.	YES, FULL INTENT IS MET.	PARTIAL COMPLIANCE. LIST WHAT IS NOT COVERED. USE ADDITIONAL SHEETS FOR EXPLANATIONS/COMMENTS.	NO, COMPLIANCE IS NOT MET WITH THIS ITEM. INDICATE THE SITUATION.
4-203.11				
4-203.12				
4-204.112				
4-302.12				

Section 20. Food and Nonfood Contact Surfaces: Designed, Constructed, Maintained, Installed, Located, Operated, Cleanable

FOOD CODE CHAPTER	CORRESPONDING CODE SECTION , RULE, ETC.	YES, FULL INTENT IS MET.	PARTIAL COMPLIANCE. LIST WHAT IS NOT COVERED. USE ADDITIONAL SHEETS FOR EXPLANATIONS/COMMENTS.	NO, COMPLIANCE IS NOT MET WITH THIS ITEM. INDICATE THE SITUATION.
3-304.16				
3-304.17				
4-101.11				
4-101.12				
4-101.13				
4-101.14				
4-101.15				
4-101.16				
4-101.17				
4-101.18				
4-101.19				
4-101.110				
4-101.111				
4-102.11				
4-201.11				

Section 20. Food and Nonfood Contact Surfaces: Designed, Constructed, Maintained, Installed, Located, Operated, Cleanable				
FOOD CODE CHAPTER	CORRESPONDING CODE SECTION, RULE, ETC.	YES, FULL INTENT IS MET.	PARTIAL COMPLIANCE. LIST WHAT IS NOT COVERED. USE ADDITIONAL SHEETS FOR EXPLANATIONS/COMMENTS.	NO, COMPLIANCE IS NOT MET WITH THIS ITEM. INDICATE THE SITUATION.
4-202.12				
4-202.13				
4-202.14				
4-202.15				
4-202.16				
4-202.17				
4-204.12				
4-204.15				
4-204.16				
4-204.17				
4-204.18				
4-204.19				
4-204.110				
4-204.111				
4-204.121				
4-204.122				
4-204.123				
4-205.10				
4-302.11				
4-401.11				
4-402.11				
4-402.12				
4-501.11				
4-501.12				
4-501.13				
4-502.11				

Section 20. Food and Nonfood Contact Surfaces: Designed, Constructed, Maintained, Installed, Located, Operated, Cleanable				
FOOD CODE CHAPTER	CORRESPONDING CODE SECTION, RULE, ETC.	YES, FULL INTENT IS MET.	PARTIAL COMPLIANCE. LIST WHAT IS NOT COVERED. USE ADDITIONAL SHEETS FOR EXPLANATIONS/COMMENTS.	NO, COMPLIANCE IS NOT MET WITH THIS ITEM. INDICATE THE SITUATION.
4-601.11 (B)(C)				
4-602.13				
4-603.11				
4-603.17				
4-902.11				
4-902.12				

Section 21. Warewashing Facility: Designed, Constructed, Installed, Located, Operated, Cleanable, Used				
FOOD CODE CHAPTER	CORRESPONDING CODE SECTION, RULE, ETC.	YES, FULL INTENT IS MET.	PARTIAL COMPLIANCE. LIST WHAT IS NOT COVERED. USE ADDITIONAL SHEETS FOR EXPLANATIONS/COMMENTS.	NO, COMPLIANCE IS NOT MET WITH THIS ITEM. INDICATE THE SITUATION.
4-203.13				
4-204.113				
4-204.114				
4-204.115				
4-204.116				
4-204.117				
4-204.118				
4-204.119				
4-204.120				
4-301.12				
4-301.13				
4-302.13				
4-302.14				
4-501.14				

Section 21. Warewashing Facility: Designed, Constructed, Installed, Located, Operated, Cleanable, Used				
FOOD CODE CHAPTER	CORRESPONDING CODE SECTION, RULE, ETC.	YES, FULL INTENT IS MET.	PARTIAL COMPLIANCE. LIST WHAT IS NOT COVERED. USE ADDITIONAL SHEETS FOR EXPLANATIONS/COMMENTS.	NO, COMPLIANCE IS NOT MET WITH THIS ITEM. INDICATE THE SITUATION.
4-501.15				
4-501.16				
4-501.17				
4-501.18				
4-501.19				
4-501.110				
4-501.116				
4-603.12				
4-603.13				
4-603.14				
4-603.15				
4-603.16				

Section 22. Wiping Cloths, Linens, Napkins, Gloves, Sponges: Properly Used, Stored				
FOOD CODE CHAPTER	CORRESPONDING CODE SECTION, RULE, ETC.	YES, FULL INTENT IS MET.	PARTIAL COMPLIANCE. LIST WHAT IS NOT COVERED. USE ADDITIONAL SHEETS FOR EXPLANATIONS/COMMENTS.	NO, COMPLIANCE IS NOT MET WITH THIS ITEM. INDICATE THE SITUATION.
3-304.13				
3-304.14				
3-304.15				
4-101.16				
4-801.11				
4-802.11				
4-803.11				
4-803.12				
4-901.12				

Section 22. Wiping Cloths, Linens, Napkins, Gloves, Sponges: Properly Used, Stored				
FOOD CODE CHAPTER	CORRESPONDING CODE SECTION, RULE, ETC.	YES, FULL INTENT IS MET.	PARTIAL COMPLIANCE. LIST WHAT IS NOT COVERED. USE ADDITIONAL SHEETS FOR EXPLANATIONS/COMMENTS.	NO, COMPLIANCE IS NOT MET WITH THIS ITEM. INDICATE THE SITUATION.
4-903.11				
4-903.12				

Section 23. Storage, Handling of Clean Equipment, Utensils				
FOOD CODE CHAPTER	CORRESPONDING CODE SECTION, RULE, ETC.	YES, FULL INTENT IS MET.	PARTIAL COMPLIANCE. LIST WHAT IS NOT COVERED. USE ADDITIONAL SHEETS FOR EXPLANATIONS/COMMENTS.	NO, COMPLIANCE IS NOT MET WITH THIS ITEM. INDICATE THE SITUATION.
4-901.11				
4-903.11				
4-903.12				
4-904.11				
4-904.12				
4-904.13				

Section 24. Single-Service / Single-Use Articles: Storage, Dispensing, Use, No Reuse				
FOOD CODE CHAPTER	CORRESPONDING CODE SECTION, RULE, ETC.	YES, FULL INTENT IS MET.	PARTIAL COMPLIANCE. LIST WHAT IS NOT COVERED. USE ADDITIONAL SHEETS FOR EXPLANATIONS/COMMENTS.	NO, COMPLIANCE IS NOT MET WITH THIS ITEM. INDICATE THE SITUATION.
4-502.12				
4-502.13				
4-502.14				
4-903.11				
4-903.12				
4-904.11				

Water

Section 25. Safe Water Source, Hot and Cold Under Pressure, Adequate Quantity				
FOOD CODE CHAPTER	CORRESPONDING CODE SECTION , RULE, ETC.	YES, FULL INTENT IS MET.	PARTIAL COMPLIANCE. LIST WHAT IS NOT COVERED. USE ADDITIONAL SHEETS FOR EXPLANATIONS/COMMENTS.	NO, COMPLIANCE IS NOT MET WITH THIS ITEM. INDICATE THE SITUATION.
5-101.11				
5-102.11				
5-102.12				
5-102.13				
5-102.14				
5-103.11				
5-103.12				
5-104.11				
5-104.12				

Section 26. Plumbing: Installed, Maintained				
FOOD CODE CHAPTER	CORRESPONDING CODE SECTION , RULE, ETC.	YES, FULL INTENT IS MET.	PARTIAL COMPLIANCE. LIST WHAT IS NOT COVERED. USE ADDITIONAL SHEETS FOR EXPLANATIONS/COMMENTS.	NO, COMPLIANCE IS NOT MET WITH THIS ITEM. INDICATE THE SITUATION.
5-101.12				
5-201.11				
5-202.11				
5-202.12				
5-202.15				
5-203.13				
5-204.13				
5-205.13				
5-205.14				
5-205.15				

Section 26. Plumbing: Installed, Maintained				
FOOD CODE CHAPTER	CORRESPONDING CODE SECTION, RULE, ETC.	YES, FULL INTENT IS MET.	PARTIAL COMPLIANCE. LIST WHAT IS NOT COVERED. USE ADDITIONAL SHEETS FOR EXPLANATIONS/COMMENTS.	NO, COMPLIANCE IS NOT MET WITH THIS ITEM. INDICATE THE SITUATION.
5-301.11				
5-302.11				
5-302.12				
5-302.13				
5-302.14				
5-302.15				
5-302.16				
5-303.11				
5-303.12				
5-303.13				
5-304.11				
5-304.12				
5-304.13				
5-304.14				

Section 27. Cross Connection, Back Siphonage, Backflow Prevention				
FOOD CODE CHAPTER	CORRESPONDING CODE SECTION, RULE, ETC.	YES, FULL INTENT IS MET.	PARTIAL COMPLIANCE. LIST WHAT IS NOT COVERED. USE ADDITIONAL SHEETS FOR EXPLANATIONS/COMMENTS.	NO, COMPLIANCE IS NOT MET WITH THIS ITEM. INDICATE THE SITUATION.
5-202.13				
5-202.14				
5-203.14				
5-204.12				
5-205.12				

Toilet Facilities

Section 28. Number, Convenient, Accessible, Designed, Installed				
FOOD CODE CHAPTER	CORRESPONDING CODE SECTION, RULE, ETC.	YES, FULL INTENT IS MET.	PARTIAL COMPLIANCE. LIST WHAT IS NOT COVERED. USE ADDITIONAL SHEETS FOR EXPLANATIONS/COMMENTS.	NO, COMPLIANCE IS NOT MET WITH THIS ITEM. INDICATE THE SITUATION.
5-203.12				
6-302.10				
6-402.11				

Section 29. Toilet Rooms Enclosed, Self-closing Doors; Fixtures, Good Repair, Clean, Proper Waste Receptacles				
FOOD CODE CHAPTER	CORRESPONDING CODE SECTION, RULE, ETC.	YES, FULL INTENT IS MET.	PARTIAL COMPLIANCE. LIST WHAT IS NOT COVERED. USE ADDITIONAL SHEETS FOR EXPLANATIONS/COMMENTS.	NO, COMPLIANCE IS NOT MET WITH THIS ITEM. INDICATE THE SITUATION.
5-501.17				
6-202.14				
6-301.20				
6-302.11				
6-501.19				

Sewage

Section 30. Sewage and Waste Water Disposal				
FOOD CODE CHAPTER	CORRESPONDING CODE SECTION, RULE, ETC.	YES, FULL INTENT IS MET.	PARTIAL COMPLIANCE. LIST WHAT IS NOT COVERED. USE ADDITIONAL SHEETS FOR EXPLANATIONS/COMMENTS.	NO, COMPLIANCE IS NOT MET WITH THIS ITEM. INDICATE THE SITUATION.
5-401.11				
5-402.10				
5-402.11				
5-402.12				
5-402.13				

Section 30. Sewage and Waste Water Disposal				
FOOD CODE CHAPTER	CORRESPONDING CODE SECTION, RULE, ETC.	YES, FULL INTENT IS MET.	PARTIAL COMPLIANCE. LIST WHAT IS NOT COVERED. USE ADDITIONAL SHEETS FOR EXPLANATIONS/COMMENTS.	NO, COMPLIANCE IS NOT MET WITH THIS ITEM. INDICATE THE SITUATION.
5-402.14				
5-402.15				
5-403.11				
5-403.12				

Garbage & Refuse Disposal

Section 31. Containers or Receptacles: Covered, Adequate Number, Insect / Rodent Proof, Frequency of Removal, Clean. Area Properly Constructed, Necessary Implements, Supplies				
FOOD CODE CHAPTER	CORRESPONDING CODE SECTION, RULE, ETC.	YES, FULL INTENT IS MET.	PARTIAL COMPLIANCE. LIST WHAT IS NOT COVERED. USE ADDITIONAL SHEETS FOR EXPLANATIONS/COMMENTS.	NO, COMPLIANCE IS NOT MET WITH THIS ITEM. INDICATE THE SITUATION.
5-501.10				
5-501.11				
5-501.12				
5-501.13				
5-501.14				
5-501.15				
5-501.16				
5-501.18				
5-501.19				
5-501.110				
5-501.111				
5-501.112				
5-501.113				
5-501.114				
5-501.115				

Section 31. Containers or Receptacles: Covered, Adequate Number, Insect / Rodent Proof, Frequency of Removal, Clean. Area Properly Constructed, Necessary Implements, Supplies				
FOOD CODE CHAPTER	CORRESPONDING CODE SECTION , RULE, ETC.	YES, FULL INTENT IS MET.	PARTIAL COMPLIANCE. LIST WHAT IS NOT COVERED. USE ADDITIONAL SHEETS FOR EXPLANATIONS/COMMENTS.	NO, COMPLIANCE IS NOT MET WITH THIS ITEM. INDICATE THE SITUATION.
5-501.116				
5-502.11				
5-502.12				
5-503.11				
6-202.110				
6-405.10				

Physical Facility

Section 32. Floors, Walls, Ceilings: Designed, Constructed, Maintained, Clean				
FOOD CODE CHAPTER	CORRESPONDING CODE SECTION , RULE, ETC.	YES, FULL INTENT IS MET.	PARTIAL COMPLIANCE. LIST WHAT IS NOT COVERED. USE ADDITIONAL SHEETS FOR EXPLANATIONS/COMMENTS.	NO, COMPLIANCE IS NOT MET WITH THIS ITEM. INDICATE THE SITUATION.
6-101.11				
6-102.11				
6-201.11				
6-201.12				
6-201.13				
6-201.14				
6-201.15				
6-201.16				
6-201.17				
6-201.18				
6-202.17				
6-202.18				
6-501.11				

Section 32. Floors, Walls, Ceilings: Designed, Constructed, Maintained, Clean				
FOOD CODE CHAPTER	CORRESPONDING CODE SECTION, RULE, ETC.	YES, FULL INTENT IS MET.	PARTIAL COMPLIANCE. LIST WHAT IS NOT COVERED. USE ADDITIONAL SHEETS FOR EXPLANATIONS/COMMENTS.	NO, COMPLIANCE IS NOT MET WITH THIS ITEM. INDICATE THE SITUATION.
6-501.12				
6-501.13				
6-501.17				

Section 33. Lighting, Ventilation, Dressing Rooms / Designated Areas Maintained				
FOOD CODE CHAPTER	CORRESPONDING CODE SECTION, RULE, ETC.	YES, FULL INTENT IS MET.	PARTIAL COMPLIANCE. LIST WHAT IS NOT COVERED. USE ADDITIONAL SHEETS FOR EXPLANATIONS/COMMENTS.	NO, COMPLIANCE IS NOT MET WITH THIS ITEM. INDICATE THE SITUATION.
4-202.18				
4-204.11				
4-301.14				
6-202.11				
6-202.12				
6-303.11				
6-304.11				
6-305.11				
6-403.11				
6-501.14				
6-501.110				

Section 34. Premises Maintained Free of Litter, Unnecessary Articles, Cleaning and Maintenance Equipment Properly Stored				
FOOD CODE CHAPTER	CORRESPONDING CODE SECTION, RULE, ETC.	YES, FULL INTENT IS MET.	PARTIAL COMPLIANCE. LIST WHAT IS NOT COVERED. USE ADDITIONAL SHEETS FOR EXPLANATIONS/COMMENTS.	NO, COMPLIANCE IS NOT MET WITH THIS ITEM. INDICATE THE SITUATION.
6-202.11				
6-202.19				
6-306.10				
6-501.15				
6-501.16				
6-501.113				
6-501.114				

Section 35. Complete Separation from Living / Sleeping Quarters; Laundry				
FOOD CODE CHAPTER	CORRESPONDING CODE SECTION, RULE, ETC.	YES, FULL INTENT IS MET.	PARTIAL COMPLIANCE. LIST WHAT IS NOT COVERED. USE ADDITIONAL SHEETS FOR EXPLANATIONS/COMMENTS.	NO, COMPLIANCE IS NOT MET WITH THIS ITEM. INDICATE THE SITUATION.
4-301.15				
4-401.11 (C				
4-803.13				
6-202.111				
6-202.112				

Section 36. Presence of Insects / Rodents Minimized, Outer Openings Protected, Animals As Allowed				
FOOD CODE CHAPTER	CORRESPONDING CODE SECTION , RULE, ETC.	YES, FULL INTENT IS MET.	PARTIAL COMPLIANCE. LIST WHAT IS NOT COVERED. USE ADDITIONAL SHEETS FOR EXPLANATIONS/COMMENTS.	NO, COMPLIANCE IS NOT MET WITH THIS ITEM. INDICATE THE SITUATION.
2-403.11				
6-202.13				
6-202.15				
6-202.16				
6-501.111				
6-501.112				
6-501.115				

Section 37. Variance for Smoking for Preservation, Curing, Brewing Alcoholic Beverages, Using Additives as Preservatives, or Using Reduced Oxygen to Package Food				
FOOD CODE CHAPTER	CORRESPONDING CODE SECTION , RULE, ETC.	YES, FULL INTENT IS MET.	PARTIAL COMPLIANCE. LIST WHAT IS NOT COVERED. USE ADDITIONAL SHEETS FOR EXPLANATIONS/COMMENTS.	NO, COMPLIANCE IS NOT MET WITH THIS ITEM. INDICATE THE SITUATION.
3-502.11				

Instructions for Table A-3

To complete Table A-3, do the following: Evaluate your jurisdiction's code or ordinance against each *Food Code* section grouped by topics under the major section headings numbered 12 through 37 above. If your code/regulation has language meeting the full intent of the corresponding model *Food Code* section, place a check mark in column 3. Columns 4 and 5 are intended to serve as an analytical tool to help you identify gaps in your current code/regulation and to plan for future revisions.

Starting with Section Heading 12 entitled Personnel, count the total number of check marks in column 3 under this heading and transfer this number to column 2 of Table A-4. Do this for each of the numbered section headings until all the information is transferred to Table A-4.

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Table A-4 REGULATORY FOUNDATION SUMMARY - GOOD RETAIL PRACTICES

Section Number	Good Retail Practices		
	Number Identified as "Yes" (column 3 - of Table A-3 worksheet)	<i>Maximum No. of "Yes" possible</i>	<i>Description</i>
12		4	Personnel
13		12	Food & Food Protection
14		1	Plant Food Cooking for Hot Holding
15		11	Protection from Contamination
16		2	Facilities/Methods to Control Product Temperature
17		2	PHF Properly Thawed
18		3	Dispensing Food/Utensils Properly Stored
19		4	Food Equipment
20		47	Food and Non-food Contact Surfaces
21		26	Warewashing Facilities: Designed, etc.
22		11	Wiping cloths, Linens, Napkins, Gloves/Used
23		6	Storage, Handling of Clean Equip / Utensils
24		6	Single-Service/Single-Use Articles
25		9	Safe Water Source, Hot / Cold Under Pressure
26		24	Plumbing: Installed, Maintained
27		5	Cross Connection, Back Siphonage, Backflow Pre
28		3	Toilet Facilities: Number, convenient, Accessible
29		5	Enclosed, Self-closing Doors; Fixtures, Good repair
30		9	Sewage and Waste Water Disposal
31		21	Garbage and Refuse Disposal: covered, number
32		16	Floors, Walls, Ceilings; Designed, Constructed
33		11	Lighting, Ventilation, Dressing Rooms
34		7	Premises Maintained, Free of Litter, etc.
35		5	Complete Separation from Living/Sleeping Quarters
36		7	Presence of Insects / Rodents Minimized
37		1	Variances
Total of col. 2 _____		258	
		(____ / 258) * 100% =	→ _____ %

Instructions for Table A-4

- Starting with Section Heading 12 entitled Personnel, count the total number of check marks in column 3 under this heading and transfer this number to column 2 of Table A-4. Do this for each of the numbered section headings until all the information is transferred to Table A-4.
- Total the numbers in column 2 of Table A-4 and record this number in the blank provided for the total in the bottom section of Table A-4.

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3. Divide this number by 258 and multiply by 100 to determine the percentage of the Good Retail Practices provisions contained in your code/regulation. (_____ %)

A percentage equal to or greater than 95% is considered acceptable for meeting the Regulatory Foundation requirements for Sections 12 through 37.

Appendix A

Table A-5 REGULATORY FOUNDATION SUMMARY – COMPLIANCE AND ENFORCEMENT

Compliance and Enforcement Food Code Chapter 8			
Description of Compliance or Enforcement Action	Food Code Section	<i>Your Corresponding Statute, Code, Regulation or Ordinance section</i>	<i>Full intent of the main provisions of the Food Code sections are met ("Yes" / "No")</i>
1. Hold orders, embargo, and Destruction of food	8-801.10		
	8-803.10		
	8-803.30		
2. Permit / License required ; Right to deny	8-301.11		
	8-304.20		
3. Plan Review / Pre-operational inspection	8-201.11		
4. Inspection authority / right to access	8-402.20		
5. Restriction / Exclusion of Employees; Information Authority	8-501.20		
	8-501.30		
	8-501.10		
6. Authority to Require HACCP plans	8-201.13		
7. Granting of Variances -- or -- Variances prohibited	8-103.11		
	8-103.12		
	8-103.10		
8. Timely Correction of Critical Violations	8-405.11		
	8-405.20		
	8-406.11		
9. Imminent Health Hazard (Summary Suspension)	8-804.10		
	8-404.12		
	8-404.12		
10. License suspension / revocation	8-805.10		
	8-805.20		
11. Institution of Proceedings	8-810.10		
12. Legal Remedies			
a. Criminal Proceedings	8-811.10		
b. Petitions for Injunction	8-812.10		
c. Civil Penalties provided	8-813.10		
13. Additional Requirements	8-102.10		

Instructions for Table A-5

1. For each *Food Code* section listed in column 2, review your code, regulation, rule, or statute for corresponding language.
2. List your corresponding code/regulation section in column 3.
3. Evaluate your code/regulation to determine whether it meets the full intent of the main requirements of the FDA *Food Code* section. If it does, mark “yes” in the last column. If it does not meet the full intent, mark “no” in the last column.
4. To obtain credit for the numbered Compliance and Enforcement item, each of the supporting code sections must be marked “yes” in the last column. For example, to get credit for 2. Permit/License required, both code sections must be marked “yes.”

Passing for the "Compliance and Enforcement" component requires a "Yes" for each of the 15 Compliance and Enforcement requirements.

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**PART IV
Appendix A**

Criteria	YES	NO
1. Your jurisdiction's code, ordinance, rule, or regulation meets the requirement of Standard 1, Regulatory Foundation, for the Major Interventions / Risk Factors.		
2. Your jurisdiction's code, ordinance, rule, or regulation meets the Good Retail Practices requirements of Standard No. 1, Regulatory Foundation.		
3. Your jurisdiction's code, ordinance, rule, regulation or statute meets the Compliance and Enforcement requirements of Standard No. 1, Regulatory Foundation.		

Use the information in Tables A-1 through A-5 to determine the correct answer each of the above questions. A “yes” affirmation to each statement is required to meet Standard No. 1.

APPENDIX B - [Supplement to Standard No. 2 - Trained Regulatory Staff](#)

B-1: Curriculum for Retail Food Safety Inspection Officers

B-2: Guide To Conducting an Assessment of Training Needs

Attachment A – Assessment of Training Needs – Field Training Worksheet

Attachment B - Documentation of Successful Completion – Field Training Process

B-3: Risk Categorization for Food Establishments

B-4: Training Record Summary

Appendix B-1
Program Standard #2
Curriculum for Retail Food Safety Inspection Officers

For state, local & tribal regulators to register on-line for free access to web courses, go to:
<http://www.fda.gov/ora/training/>

Pre-requisite (“Pre”) curriculum courses

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

PUBLIC HEALTH PRINCIPLES

Public Health Principles (90) FDA36

MICROBIOLOGY

Food Microbiological Control (series):

1. Overview of Microbiology (60) MIC01
- 2A. Gram-Negative Rods (60) MIC02
- 2B. Gram-Positive Rods & Cocci (90) MIC03
3. Foodborne Viruses (60) MIC04
4. Foodborne Parasites (90) MIC05
Mid-Series Exam (30) MIC16
5. Controlling Growth Factors (90) MIC06
6. Control by Refrigeration & Freezing (60) MIC07
- 7A. Control by Thermal Processing (90) MIC08
- 7B. Control by Pasteurization (90) MIC09
10. Aseptic Sampling (90) MIC13
12. Cleaning & Sanitizing (90) MIC15

PREVAILING STATUTES, REGULATIONS, ORDINANCES

Basic Food Law for State Regulators (60) FDA35

Basics of Inspection:

Beginning an Inspection (90) FDA38

Issues & Observations (90) FDA39

An Introduction to Food Security Awareness (60) FD251
(ORA U internet site)

2005 Food Code*

NOTE: Specific state/local laws & regulations to be addressed by each jurisdiction

COMMUNICATION SKILLS

Communication Skills for Regulators*

Curriculum (“Post”) courses

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

MICROBIOLOGY

Food Microbiological Control (series):

- 7C. Control by Retorting (90) MIC10
8. Technology-Based Food Processes (120) MIC11
9. Natural Toxins (90) MIC12

HACCP

Basics of HACCP (series):

1. Overview of HACCP (60) FDA16
2. Prerequisite Programs & Preliminary Steps (60) FDA17
3. The Principles (60) FDA18

EPIDEMIOLOGY

Foodborne Illness Investigations (series):

1. Collecting Surveillance Data (90) FI01
 2. Beginning the Investigation (90) FI02
 3. Expanding the Investigation (90) FI03
 4. Conducting a Food Hazard Review (90) FI04
 5. Epidemiological Statistics (90) FI05
 6. Final Report (30) FI06
-

“Application” Courses and “Hands-On” Training

To provide application of skills and transfer of web instruction to the jurisdiction’s work environment, although not required at this time, it is recommended that FSIOs complete one of the following three options within 18 months of hire or assignment to the regulatory retail food program:

1. **Classroom Course: Application of the Basics of Inspection/Investigation FD170** (class schedule available at www.afdo.org/ or course content available on CD via FDA’s Division of Human Resource Development’s lending library.)
2. **Courses developed by State or local regulatory jurisdictions or other entities** containing learning objectives and exercises equivalent to Option 1 above.
3. **Discussions Questions & Exercises *** (conducted in the office or during the 25 joint inspections)

* Under construction

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

Estimated total hours for “Pre” courses are 42 hours.

Estimated total hours for “Post” courses are 16 hours.

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Estimated total hours for completion of all Program Standard #2 coursework are 54 hours

**A GUIDE TO CONDUCTING
AN
ASSESSMENT OF TRAINING NEEDS**

**REGULATORY RETAIL FOOD SAFETY
INSPECTION OFFICERS**

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- I. Preparing for the Assessment of Training Needs.....
- II. Conducting the Assessment of Training Needs.....
- III. Completing the Documentation of Successful Completion.....

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A Guide to Conducting an Assessment of Training Needs

Retail Food, Restaurant, and Institutional Foodservice Regulatory Food Safety Inspection Officers

BACKGROUND

The Conference for Food Protection (CFP) has progressed through several stages in the development of a nationally recognized process for training and standardizing regulatory Food Safety Inspection Officers (FSIO) responsible for inspections of institutional foodservice, restaurant, and retail food establishments. Research conducted by the CFP work group charged with addressing this issue revealed that existing training and standardization programs for FSIOs are as varied as the number of regulatory jurisdictions throughout the country. What has been lacking is a nationally recognized training and standardization process for FSIOs that can be used as a model to enhance the effectiveness of regulatory retail food program inspections and increase uniformity among regulatory professionals in their assessment of industry's food safety practices.

The CFP Program Standards Committee was charged with using the FDA Voluntary National Retail Food Regulatory Program Standards, Standard #2 – Trained Regulatory Staff, as a model for developing a multi-tiered approach for training and standardizing FSIOs. The CFP Program Standards Committee assembled a work group to address this specific charge. The criteria contained in the 5-step training and standardization process presented in Program Standard #2 reflects this multi-tiered approach. An innovative and critical component of this multi-tiered process is the inclusion of an Assessment of Training Needs (ATN) as part of the joint field training inspections in Step 2 of the Standard.

INTRODUCTION AND PURPOSE

Training is most effective when it is delivered within the context or environment within which the individual would be expected to apply the knowledge and skills required of the job task. For FSIOs, the appropriate training environment is one that mirrors the actual experience of inspecting retail food, restaurant, and/or institutional foodservice establishments.

The primary purpose of the ATN as described in Program Standard #2 is to establish a structured approach (a national model) for field training of regulatory retail food program inspection staff that is to be part of a continuous improvement process. New hires and/or individuals newly assigned to the regulatory retail food program require consistent training related to the knowledge, skills, and abilities (KSA) that not only involve technical food safety principles, but also include competencies in the areas of oral and written communication.

Consistent and on-going feedback on key inspection related performance elements is the cornerstone of the ATN process. No one inspection/training exercise is used to determine a FSIOs readiness to conduct independent retail food and foodservice inspections. Rather

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the ATN process and forms are designed to enable the candidate to demonstrate a consistent pattern of behavior in KSAs identified as important for conducting effective regulatory retail food program inspections.

The ATN has been designed to evaluate specific performance elements within 6 categories:

- I. Pre-Inspection;
- II. Inspection Observations and Performance;
- III. Sample Collection and Evidence Development;
- IV. Oral Communication;
- V. Written Communication; and
- VI. Professionalism

The performance elements for each of the 6 categories were derived from research of current regulatory retail food program training curriculums and competency areas. The CFP work group reviewed training programs/competencies developed by the State of California; Florida Department of Business and Professional Regulations; Massachusetts Department of Public Health; New York Department of Health; North Carolina Department of Environment and Natural Resources; and the Rhode Island Department of Health. Other resources included the Southwest Region Training Plan that has appeared as Appendix K in previous versions of the *FDA National Voluntary Retail Food Regulatory Program Standards* and FDA's Level I Investigator Performance Audit criteria.

Each of the performance elements included in the ATN received a comprehensive review by the CFP work group comprised of psychometricians and representatives from state and local regulatory retail food programs; industry trade associations; retail food and foodservice operations; and academia. The performance elements were assessed by the CFP work group to ascertain their:

- Importance to conducting effective regulatory retail food and foodservice inspections;
- Measurement criteria that would be used to assess the FSIO's KSAs to perform the task; and
- Frequency the item being assessed occurs during retail food and foodservice inspection work.

The ATN forms and protocol contained in this document represent the culmination of the research and review by subject matter experts that comprise the CFP Program Standards work group assigned the charge of developing a training and standardization protocol for state and local regulatory retail food program inspection staff. The ATN protocol and forms are still considered working documents. Enhancements will be based on input from regulatory, industry, academia and consumer stakeholder groups through a process that includes the Conference for Food Protection to allow for on-going program improvement and promotion of national uniformity.

Flexibility has been built into the ATN to allow regulatory jurisdictions the ability to

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customize training so that it reflects a jurisdiction's administrative policies, sampling procedures, and inspection protocol. Instructions on how to use, and if appropriate, customize the process to specific jurisdictional needs are presented later in this document.

ASSESSMENT OF TRAINING NEEDS

The Assessment of Training Needs (ATN) provides forms to assist food program managers/trainers with a structured approach for determining whether a FSIO has the required knowledge, skills, and abilities to perform specific competencies related to retail food and foodservice inspections.

- A **Field Training Worksheet** provides a representative baseline of competencies (criteria) expected to be performed by regulatory retail food program FSIOs. It is to be used during joint field training inspections.
- The **Documentation of Successful Completion** provides verification that the FSIO has successfully demonstrated the ability to perform all the required competencies (criteria) needed to conduct independent retail food and foodservice inspections. It is completed once at the end of the joint field training process.

These forms are an integral part of a training process that provides both the candidate and the trainer feedback on specific elements of effective institutional foodservice, restaurant, and retail food store inspections.

- The ATN is NOT intended to be used for certification, audit, or licensure purposes.
- Regulatory jurisdictions are NOT to use the ATN for administrative purposes including but not limited to job classifications, promotions, or disciplinary actions up to and including termination.

Used for its intended purpose, the ATN addresses a significant gap in existing regulatory retail food training programs. It provides a structure for preparing a FSIO to conduct independent retail food and foodservice inspections. It is NOT a test or audit but an on-going field assessment of training that focuses on a candidate's continuous improvement.

In addition, the ATN provides critical feedback to program managers and trainers on the effectiveness of their retail food training and orientation process. Competencies (criteria) that are not consistently performed well by FSIOs may be an indication that the regulatory jurisdiction has significant gaps in their training program, coursework, or materials used to prepare staff for field inspections. The ATN provides a framework for assessing and strengthening existing regulatory retail food training programs.

The ATN provides regulatory retail food protection programs with performance elements upon which to make sound assessments of a FSIO's understanding of their job responsibilities, as well as their ability to consistently apply those knowledge elements within the environment of retail food and foodservice inspections.

WHO MUST COMPLETE THE FIELD TRAINING PROCESS?

All new employees or individuals new to the regulatory retail food protection program must complete a field training process similar to the one presented in this document. The Program Standard #2 criteria require a FSIO to complete specified pre-requisite coursework prior to conducting independent inspections. Program Standard #2 does not

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stipulate any pre-requisite coursework (curriculum) for participating in the ATN.

Completion of pre-requisite coursework, particularly training in the jurisdiction's prevailing statutes, regulations, and/or ordinances should be considered when making a determination as to when to begin the ATN process. In addition, it is highly recommended that an appropriate number of demonstration (trainer-led) inspections be conducted prior to the ATN to provide the candidate an opportunity to observe an experienced FSIO perform specific inspection elements that will be included in the field training process. The jurisdiction's trainer, or designated staff member, is responsible for determining when the ATN process should be initiated.

An ATN should be conducted when an experienced FSIO joins, or is assigned to, the regulatory retail food program staff. In order to accommodate experienced FSIOs, the Program Standard #2 criteria allows a waiver of the 25 joint inspections if the food program manager/trainer includes a signed statement or affidavit in the employee's training file explaining the background and/or experience that justifies the waiver. In lieu of the 25 joint field training inspections, an ATN is required to determine if any performance elements are in need of improvement.

WHO CAN CONDUCT AN ASSESSMENT OF TRAINING NEEDS?

The management of the regulatory retail food protection program has the discretion of deciding who will serve as the assessor and conduct the ATN. The jurisdiction's assessor, or designated staff member, must have completed all the training and standardization elements (Steps 1 – 4) required in Program Standard #2 – Trained Regulatory Staff.

FIELD TRAINING FORMS AND PROTOCOL

Two forms are used during the Assessment of Training Needs:

- Retail Food, Restaurant, and Institutional Foodservice – Food Safety Inspection Officer, **Field Training Worksheet**, and
- Retail Food, Restaurant, and Institutional Foodservice – Food Safety Inspection Officer, **Documentation of Successful Completion**.

The Field Training Worksheet is to be used as a training tool during the joint field training inspections. The Documentation of Successful Completion is used at the end of the joint field training inspection process to document a FSIO's successful completion of the field training process and readiness to conduct independent retail food and foodservice inspections.

Field Training Worksheet

Overview of the Field Training Worksheet The Field Training Worksheet is presented in Attachment A to Appendix B-2 and contains a representative baseline of competencies (criteria) expected to be performed by state, local, and tribal FSIOs. As its name implies, the Field Training Worksheet is the form that is to be used during joint field training inspections to provide the FSIO continuous feedback as to their strengths/weaknesses for specific performance elements. All performance elements that are applicable to the FSIO's inspection responsibilities must be evaluated during the Assessment of Training Needs (ATN).

Description of the Header Information on the Field Training Worksheet The Field Training Worksheet contains basic header information that should be completed for each joint field inspection for which it is used.

Establishment Name: The full name of the establishment where the ATN is conducted.

Establishment Address: The full address of the establishment where the ATN is conducted.

Permit #: The regulatory jurisdiction's food permit number or identification code for the establishment where the ATN is conducted.

Date: The date the ATN is conducted at the establishment.

Time In: The time the ATN is started at the selected establishment.

Time Out: The time the ATN is completed at the selected establishment.

NOTE: A pilot project to evaluate the ATN process is planned for 2006-2007. An important component of that project will be to obtain data on the amount of time needed to perform a field ATN. From that data, jurisdictions will have a basis for developing work plans that incorporate the appropriate amount of time to conduct field training of regulatory retail food protection program staff.

Food Safety Inspection Officer Name (FSIO): The name of the trainee FSIO being trained.

FSIO's Agency: The name of jurisdiction for which the FSIO (trainee) is employed.

Assessor's Name: The name of the trainer or the jurisdiction's designated individual who has completed all the Program Standard #2 training and standardization requirements (Steps 1-4) performing the evaluation of the FSIO on the performance elements that comprise the Field Training Worksheet.

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Assessor's Agency: The regulatory jurisdiction where the assessor is employed. The assessor may work for a different jurisdiction than the FSIO being trained.

Performance Elements The Field Training Worksheet includes 6 inspection training areas in which a FSIO must demonstrate acceptable performance.

- I. Pre-Inspection
- II. Inspection Observations and Performance
- III. Sample Collection and Evidence Development
- IV. Oral Communication
- V. Written Communication
- VI. Professionalism

The FSIO (trainee) must take the lead during joint field training inspections when an ATN is being performed. Taking the lead means the FSIO is responsible for:

- Initiating contact with the person in charge;
- Explaining the purpose of the inspection;
- Directing the inspection process;
- Establishing a dialogue with the person in charge/employees;
- Making the observations of food safety practices within the establishment;
- Obtaining immediate corrective actions for contributing factors to foodborne illness;
- Preparing the inspection report; and
- Conducting the exit interview with the person in charge.

The Field Training Worksheet contains 25 “performance elements” sorted among the 6 inspection training areas.

Summary of FSIO Performance Elements for the 6 Inspection Training Areas

I. Pre-Inspection – (3 Performance Elements)

- Has successfully completed the pre-requisite training (“Pre”) courses as specified in the *FDA Voluntary National Retail Food Regulatory Program Standards: Standard #2 – Trained Regulatory Staff*.
- Has the required equipment and forms to conduct the inspection.
- Reviews the establishment file for the previous inspection report and, if applicable, any documents or complaints on file.

II. Inspection Observations and Performance – (7 Performance Elements)

- Provides identification as a regulatory official to the person in charge, confirming agency authority for the inspection, and stating the purpose of the visit.
- Has knowledge of the jurisdiction’s laws, rules, and regulations required for conducting retail food/foodservice inspections.
- Uses a risk-based inspection methodology to assess regulations related to employee practices and management procedures essential to the safe storage, preparation and service of food.
- Obtains immediate corrective action for out of compliance employee practices and management procedures essential to the safe storage, preparation and service of food.
- Correctly assesses the compliance status of other regulations (Good Retail Practices) that are included in the jurisdiction’s prevailing statutes, regulations and/or ordinances.
- Verifies correction of out of compliance observations identified during the previous inspection.

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- Correctly uses inspection equipment during the joint inspection.

III. Sample Collection and Evidence Development – (3 Performance Elements)

- Photographs taken support the regulatory findings or conditions observed.
- Uses an aseptic food sample collection method consistent with criteria established by laboratory serving the jurisdiction.
- Uses an aseptic water sample collection method consistent with criteria established by the laboratory serving the jurisdiction.

IV. Oral Communication – (6 Performance Elements)

- Asks questions and engages in a dialogue with the person in charge/employees to obtain information relevant to the inspection.
- Provides the person in charge/employees with accurate answers to inspection-related questions or admits not knowing the answer.
- Uses available means (e.g., interpreter, drawings, demonstrations, diagrams) to overcome language or communication barriers.
- Follows the jurisdiction’s policy with regard to disclosure of confidential information.
- Uses effective communication and conflict resolution techniques to overcome inspection barriers.
- Conducts the exit interview explaining out of compliance observations and identifying corrective actions and timelines for all noted violations.

V. Written Communication – (3 Performance Elements)

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

VI. Professionalism – (3 Performance Elements)

- Maintains a professional appearance consistent with the jurisdiction’s policy (e.g., clean outer clothing, hair restraint).
- Demonstrates proper sanitary practices as expected from a food service employee.
- Only reports substantiated findings as violations.

Performance elements appear in the **shaded areas** of the tables on the Field Training Worksheet in Attachment A.

Preparing to Conduct an Assessment of Training Needs

A. Reviewing the Performance Elements

Though the overwhelming majority of the 25 identified performance elements apply to every jurisdiction, there may be a few instances where select performance elements may not be part of a FSIO’s job responsibilities. For example, FSIOs in some jurisdictions may not have responsibility for collecting aseptic food or water samples.

In preparing to conduct an ATN, the assessor/trainer should identify those performance elements that are not applicable to the FSIO’s job responsibilities within the jurisdiction. These performance elements can be removed from the Field Training Worksheet or the assessor/trainer may simply choose to circle “not applicable “ (NA) in the adjoining box on the Field Training Worksheet as depicted in the following illustration..

2. Uses an aseptic food sample collection method consistent with criteria established by laboratory serving the jurisdiction.	A	NI	NO	NA
---	---	----	----	----

If the performance element is part of the FSIO’s job responsibility it must be assessed. Performance elements that are applicable to the FSIO’s job tasks can not be arbitrarily removed or deleted from the Field Training Worksheet.

B. Specific Competencies/Criteria for each Performance Element.

The specific competencies/criteria listed under each performance element are intended to serve as examples of observations that can be used to assess a FSIO during joint field training inspections.

As an example, six specific criteria are provided for assessing the FSIO’s use of inspection equipment.

Performance Element

Correctly uses inspection equipment during the joint inspections.

Specific Competencies/Criteria for Assessing the Performance Element

- Used temperature measuring devices/probes in accordance with manufacturer’s instructions.
- Cleaned and sanitized (alcohol swabs) temperature measurement probes to prevent food contamination.
- Used infrared thermometer in accordance with manufacturer’s instructions. Verifies any out of compliance product temperatures registered on the infrared with a thermocouple.
- Used maximum registering thermometer or heat sensitive tapes in accordance with manufacturer’s instructions to verify final rinse dishwasher temperature.
- Used chemical test strips in accordance with manufacturer’s instructions to measure sanitizer concentrations in manual and mechanical dishwashing operations; wiping cloth solutions; and spray bottle applicators.
- Used flashlight to assess observations in areas with no or low light.

Some of the criteria listed for a performance element may not be applicable to a FSIO within a given jurisdiction. In the example above, infrared thermometers may not be part of the standard issued equipment for inspection staff. The FSIO would not, therefore, be responsible for using this type of equipment. If this were the case, the assessor/trainer would mark this criteria not applicable (NA) as depicted in the following illustration.

7. Correctly uses inspection equipment during the joint inspections.	A	NI	NO	NA
Used temperature measuring devices/probes in accordance with manufacturer’s instructions.				
Cleaned and sanitized (alcohol swabs) temperature measurement probes to prevent food contamination.				
Used infrared thermometer in accordance with manufacturer’s instructions. Verified any out of compliance product temperatures registered on the infrared with a thermocouple.				X

Conversely, there may be criteria not listed under the performance element that are important for a jurisdiction to include. The Field Training Worksheet has been designed to allow the addition of “OPTIONAL” criteria. For example, a jurisdiction may issue pH

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test kits to all FSIOs for product assessments during inspections. If this is the case, a jurisdiction may want to include an evaluation of the use of pH test kits in accordance with manufacturer’s instructions as part of the Field Training Worksheet as depicted in the following illustration.

7. Correctly uses inspection equipment during the joint inspections.	A	NI	NO	NA
Used temperature measuring devices/probes in accordance with manufacturer’s instructions.				
Cleaned and sanitized (alcohol swabs) temperature measurement probes to prevent food contamination.				
Used infrared thermometer in accordance with manufacturer’s instructions. Verified any out of compliance product temperatures registered on the infrared with a thermocouple.				
Used maximum registering thermometer or heat sensitive tapes in accordance with manufacturer’s instructions to verify final rinse dishwasher temperature.				
Used chemical test strips in accordance with manufacturer’s instructions to measure sanitizer concentrations in manual and mechanical dishwashing operations; wiping cloth solutions; and spray bottle applicators.				
Used flashlight to assess observations in areas with no or low light.				
OPTIONAL (Jurisdiction specific items): Used pH test kits in accordance with manufacturer’s instructions.				
Comments:				

C. Determine the Appropriate Number of Assessments for each FSIO

The level of preparedness and time needed to assimilate knowledge from on-the-job training will vary with each FSIO. The jurisdiction’s trainer, or designated staff member, is responsible for determining the number of ATNs that will be performed during the joint field training inspections. A sufficient number of field ATNs must be conducted during trainee-led joint field training inspections to properly assess a FSIO’s performance for each of the applicable performance elements and competencies/criteria.

The primary purpose of the ATN is to facilitate a continuous improvement learning experience for the FSIO. The ATN is part of a training process NOT an examination/audit process. The ATN provides a structured, disciplined process for preparing a FSIO to conduct independent retail food and foodservice inspections.

D. Choosing Establishments for the Field Training Process

The ideal retail food or foodservice establishment for conducting an ATN is one that will provide an opportunity to observe the greatest number of performance elements and competencies/criteria. The ATNs should be conducted in retail food and foodservice establishments identified in risk categories 2, 3, and 4 as presented in Appendix B-3 (taken from Annex 5, Table 1 of the 2005 FDA Food Code). As a general rule, establishments in risk categories 3 and 4 provide an opportunity to observe a greater number of the performance elements. The majority of the ATNs should be completed in establishments that are representative of the highest risk categories within the jurisdiction

or the FSIO's assigned training area.

Conducting the Assessment of Training Needs

A. Methodology

There is no single “correct” method for conducting an ATN. There are, however, two outcomes that must be achieved regardless of the approach used.

- All performance elements that are specific to the FSIO's job responsibilities must be assessed; and
- The FSIO must demonstrate a consistent pattern of behavior showing they have the knowledge, skills and ability to competently conduct retail food and foodservice inspections.

Two approaches that can be used are:

- Conducting an ATN during every joint field training inspection; or
- Conducting an ATN at set interval points during the joint field training process.

These two approaches are examples only and are not intended to restrict the use of other formats by a jurisdiction. The following summary of strengths-challenges for each approach provides some guidance to regulatory retail food programs on ways to implement the ATN process.

Approach #1: Conducting an ATN during every joint field training inspection

Strengths: This approach provides continual feedback to the FSIO on the performance elements they have mastered and those for which improvement is needed. In the early stages of the joint field inspection process, conducting ATNs can be an important tool in determining whether more demonstration (trainer-led) inspections need to be performed. In later stages of the process, the focus of the training can concentrate on specific performance elements needing improvement.

In addition, this approach will provide important feedback on the jurisdiction's training and orientation program used to prepare FSIOs for their joint field inspections. Performance elements that are consistently not performed well by FSIOs during the joint field training exercises may be an indication of gaps within the jurisdiction's program, coursework requirements, or administrative materials used to prepare staff for field inspections.

Challenges: Using this approach, trainers may focus too much on the assessment, rather than the training, of the FSIO. The ATN process is an integral part of training. It is not an audit or standardization process traditionally used to evaluate a candidate's performance. Continuous instruction is encouraged during each of the field ATNs and trainers should take the opportunity to demonstrate and/or review correct procedures and skills for performance elements that are not

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understood or properly carried out by the FSIO during each joint field inspection.

Moreover, competing program priorities and limited resources may impede a jurisdiction's ability to conduct an ATN during every joint training inspection. At this stage, it is difficult to determine how much time will be needed for the ATN process since it is a new element of the Program Standards #2 criteria. The ATN Field Training Worksheet has been designed, however, to acknowledge that an opportunity may not exist during every inspection to observe all required performance elements. The "Not Observed" (NO) marking option should be used for performance elements that are part of the FSIO's assigned responsibilities but not observed during the inspection.

Approach #2: Conducting an ATN at set interval points during the joint field training process.

Strengths: A trainer may choose to conduct an ATN at set interval points during the joint field inspection process. For example, if 25 joint field inspections (trainee-led) are planned, an ATN could be conducted during every fifth inspection (i.e., inspections 5, 10, 15, 20 and 25). This process provides set checkpoints to assess continuous improvement for specific performance elements. The joint field training inspections conducted between each ATN can be used to enhance a FSIO's knowledge and skills for performance elements in need of improvement.

Challenges: The interval process may not provide as consistent of an assessment of a FSIO's command of specific performance elements as that obtained by conducting an ATN during each joint inspection. The objective of the ATN is to observe a consistent pattern of acceptable performance from the FSIO on each performance element. Depending on the frequency a performance element is observed, an interval approach could reveal fluctuations in performance. It may be difficult, however, for the trainer to determine whether these fluctuations are isolated occurrences or are more reflective of the FSIO's need to enhance their understanding and skills for the specific performance element.

For either of the above approaches, the trainer should continue to conduct ATNs as part of the joint field training process until the FSIO achieves acceptable performance for all the relevant competencies/criteria within each element.

B. Observing Performance Elements

Some of the performance elements on the Field Training Worksheet **frequently occur as part of the inspection process** and will provide multiple opportunities for the trainer to assess the FSIO performance during the course of the joint training inspections. These performance elements include verifying that the FSIO:

- Has successfully completed the pre-requisite ("Pre") training courses as specified in the FDA Voluntary National Retail Food Program Standards: Standard #2 – Trained Regulatory Staff;
- Has the required equipment and forms to conduct the inspection;

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- Reviews the establishment file for the previous inspection report and, if applicable, any documents or complaints on file;
- Provides identification as a regulatory official to the person in charge; confirming agency authority for the inspection and stating the purpose of the visit
- Correctly uses inspection equipment during the joint inspections;
- Conducts the exit interview explaining out of compliance observations and identifying corrective actions and timelines for all noted violations;
- Presents the inspection report and when necessary, cross-referenced documents, to the person in charge; and
- Maintains a professional appearance that is consistent with jurisdiction's policy (e.g., clean outer clothing, hair restraints).

Some of the performance elements, though they frequently occur during field inspections, **will have to be evaluated through the course of the entire joint field training process** in order to assess a consistent pattern of performance on the part of the FSIO. Most of the performance elements fall into this category and include verifying that the FSIO:

- Has knowledge of the jurisdiction's laws, rules, and regulations required for conducting retail food/foodservice inspections;
- Uses a risk-based inspection methodology to assess regulations related to employee practices and management procedures essential to the safe storage, preparation, and service of food;
- Obtains immediate corrective actions for out of compliance employee practices and management procedures essential to the safe storage, preparation, and service of food;
- Verifies correction of out of compliance observations identified during the previous inspection;
- Asks questions and engages in a dialogue with the person in charge/employees to obtain information relevant to the inspection;
- Provides the operator with accurate answers to inspection-related questions or admits not knowing the answer;
- Uses available means (e.g. interpreter, drawings, demonstrations, diagrams) to overcome language or communication barriers;
- Completes inspection form per the jurisdiction's administrative procedures (e.g., observations; corrective actions; public health reasons; applicable code reference; compliance dates);
- Includes with the inspection report any compliance or regulatory documents (e.g., exhibits, attachments, sample forms, embargo forms, destruction forms, suspension notices) identified or cross-referenced in written statements;
- Demonstrates proper sanitary practices as expected from a food service employee; and
- Only reports substantiated findings as violations.

There are, however, some performance elements that are important FSIO inspection responsibilities but will be **difficult to observe** as part of the joint field training process. These performance elements include knowledge and skills to perform very specific tasks or are integral to enhancing the effectiveness of the inspection process and include verifying that the FSIO:

- Photographs support the regulatory findings or conditions observed;

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- Uses an aseptic food sample collection method consistent with criteria established by laboratory serving jurisdiction;
- Uses an aseptic water sample collection method consistent with criteria established by laboratory serving jurisdiction;
- Follows the jurisdiction’s policy in regard to disclosure of confidential information; and
- Uses effective communication and conflict resolution techniques to overcome inspection barriers.

If possible, performance elements are to be assessed in the field inspection environment. If this is not feasible, **field, laboratory, classroom, or office exercises** may be used to assess performance elements that are difficult to observe in the field. Examples of such training exercises may include the:

- FSIO demonstrating aseptic food and/or water sampling in the laboratory;
- Designating a specific field training inspection for the FSIO to demonstrate aseptic collection of a food and/or water sample;
- FSIO photographing a specific object in the office/field/lab;
- FSIO explaining to the assessor/trainer the jurisdiction’s policy in regard to disclosure of confidential information; or
- FSIO explaining to the assessor/trainer the jurisdiction’s policy in regard to conflict resolution. The assessor/trainer may develop scenarios for the FSIO to review and discuss appropriate conflict resolution techniques.

C. Assessing FSIO Training Needs

Each field ATN is just one step in the continuous improvement training process. The Field Training Worksheet provides a framework for identifying a FSIO’s strengths and areas for focused training to improve performance.

A FSIO must be evaluated on each of the performance elements that are applicable to the jurisdiction. Under each performance element there is a list of competencies/criteria that a trainer can use to assess the FSIO. As mentioned earlier in this guidance document, the competencies/criteria listed are intended only to serve as examples.

For each of the competencies/criteria, the assessor determines the FSIO’s performance using one of four markings as depicted in the following illustration:

- **Acceptable (A)** – FSIO meets the performance element criteria
- **Needs Improvement (NI)** – FSIO does not meet the performance element criteria. Written comments must be provided for any criteria needing improvement.
- **Not Observed (NO)** – Performance element criteria is part of the FSIO’s assigned responsibilities but was not observed during the inspection.
- **Not Applicable (NA)** – Performance element criteria is not part of the FSIO’s assigned responsibilities

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7. Correctly uses inspection equipment during the joint inspections.	A	NI	NO	NA
Used temperature measuring devices/probes in accordance with manufacturer’s instructions.				
Cleaned and sanitized (alcohol swabs) temperature measurement probes to prevent food contamination.				
Used infrared thermometer in accordance with manufacturer’s instructions. Verified any out of compliance product temperatures registered on the infrared with a thermocouple.				
Used maximum registering thermometer or heat sensitive tapes in accordance with manufacturer’s instructions to verify final rinse dishwasher temperature.				
Used chemical test strips in accordance with manufacturer’s instructions to measure sanitizer concentrations in manual and mechanical dishwashing operations; wiping cloth solutions; and spray bottle applicators.				
Used flashlight to assess observations in areas with no or low light.				
OPTIONAL (Jurisdiction specific items):				
Comments:				

For a FSIO to successfully demonstrate the required competencies/criteria of the performance element being assessed, none of the applicable and observable criteria for that performance element can indicate “Needs Improvement.” The assessor/trainer must provide written comments that address any criteria needing improvement.

Criteria marked as “Not Observed” (NO) and/or “Not Applicable” (NA) are not to be included in assessing the FSIO’s performance. Only observable criteria are used to assess the FSIO during an ATN.

The Field Training Worksheet is not intended to be used as a “Pass/Fail” evaluation. The ATN is not an examination or audit. It is a structured training approach with defined criteria to prepare a FSIO to conduct independent inspections of retail food and foodservice establishments.

D. Reviewing the Field Training Worksheets with the FSIO

The assessor/trainer should review the results of each completed Field Training Worksheet with the FSIO as soon as possible (ideally after each joint training inspection). The review should include a discussion of both performance elements that were acceptable and those needing improvement. The assessor/trainer should review with the FSIO methods for improving KSAs in performance elements needing improvement. Upon completion of the discussion, both the assessor/trainer and the FSIO sign and date the Field Training Worksheet.

After conducting a minimum of 25 joint field training inspections (or lesser number for an experienced FSIO if authorized by the food program manager/trainer), the trainer will need to make a determination as to whether additional joint field training with the FSIO is needed. A review of all the performance elements is conducted to determine a FSIO’s

readiness to conduct independent retail food and/or foodservice inspections. The Documentation of Successful Completion form is used to verify that the FSIO has successfully demonstrated the required knowledge, skills and abilities to perform all applicable competencies/criteria.

Field Training Process

Documentation of Successful Completion

Purpose of the Documentation of Successful Completion The Field Training Process - Documentation of Successful Completion (DSC) is presented in Attachment B. Since the Assessment of Training Needs is a continuous improvement process, some of the performance elements must be assessed over time. The DSC provides a tool for the assessor/trainer to review the results from all the Field Training Worksheets. It provides verification that the FSIO has achieved an acceptable level of performance in each of the inspection elements.

Descriptions of the Header Information on the Documentation of Successful Completion The DSC contains basic header information that should be verified at the end of the joint field training inspection process.

Date Assessment of Training Needs Began: The date the first Field ATN was conducted.

Date Assessment of Training Needs is Completed: The date the last Field ATN was conducted. Upon completion of the last Field Training Worksheet, the FSIO has demonstrated an acceptable performance for each inspection element.

Print Name – Food Safety Inspection Officer: Print the full name of the FSIO in training.

Signature – Food Safety Inspection Officer: Signature of the FSIO in training indicates acknowledgement of receipt and review of the assessor/trainer's assessment and comments contained in the DSC.

Print Name – Assessor(s): The name of the assessor(s)/trainer(s) responsible for conducting the field ATNs. Some jurisdictions may choose to have all field ATNs performed by a single individual such as a training officer. Other jurisdictions may have multiple individuals conduct the field ATNs. In cases where multiple trainers are used to conduct the ATNs, the names of all trainers should be printed in the header box.

Signature of Assessor: The signature of the assessor should be the food program manager/trainer/or designated staff member who has responsibility for determining when a FSIO is ready to conduct independent retail food and foodservice inspections.

Assessing FSIO Readiness to Conduct Independent Inspections As previously stated,

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the collective results from all the Field Training Worksheets are used to determine a FSIOs readiness to conduct independent inspections. Demonstration of competence in all applicable performance elements and criteria is needed for a FSIO to successfully complete the ATN process.

Almost all performance elements contain judgments or actions that must be successfully demonstrated by the FSIO. It is to be expected that new hires and employees new to the regulatory retail food program will not be perfect on all criteria that comprise a performance element. The assessor/trainer will need to evaluate the progress of the FSIO, as noted on each of the Field Training Worksheets, over the course of the joint field training inspections.

A score is not used to demonstrate competence of a performance element. Rather an assessment of all the ATNs conducted must indicate a consistent pattern of behavior that demonstrates widespread understanding or skill competency in the performance element. A consistent pattern of behavior would be one where the FSIO almost always meets the criterion that comprises a performance element. There should be only a few, if any, instances where the FSIO did not meet the expected criteria.

Acceptable – indicates that the FSIO meets expectations; or in only a few instances is the performance element not met.

Should the FSIO fail to achieve an “Acceptable” evaluation on one or more of the performance elements, the assessor/trainer will develop a **corrective action plan** specific to the areas in need of improvement. Corrective action plans may include, but are not limited to:

- additional joint field training inspections;
- additional field, laboratory, classroom, or office exercises;
- additional coursework;
- review of the jurisdiction’s administrative procedures and/or policies; or
- additional field ATNs.

Once a FSIO achieves an acceptable evaluation on all performance elements they have successfully completed the ATN.

The “Comments” section is designed to be used by the assessor/trainer as a continuous improvement tool. For example, trainers may note a FSIO specific strengths or note items on which inspection knowledge, skills, and abilities, while generally acceptable, can be furthered enhanced.

The DSC is to be reviewed with the FSIO to discuss any items requiring clarification and to share mutual perspectives on the joint field training experience. For the FSIO, the discussion can lay out the next steps in training to prepare for standardization. For the trainer, the discussion can identify strengths and gaps in the jurisdiction’s training process.

After the final discussion, both the FSIO and assessor/trainer sign the form. The DSC form should be kept as part of the FSIO’s training records.

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Step-By-Step Summary – Field Training Process

I. Preparing for the Assessment of Training Needs (ATN)

Regulatory Jurisdiction’s Designated Trainer <i>(Trainer must have successfully completed all Program Standard #2 training and standardization criteria)</i>	Food Safety Inspection Officers <i>(Trainees)</i>
<p>1. Review the guidance in this document for conducting an ATN of regulatory retail food and foodservice inspection officers.</p>	<p>1. Complete all pre-requisite coursework required to prepare for joint field training inspections.</p>
<p>2. Determine if any of the performance elements listed on the Field Training Worksheet are not applicable (NA) to the FSIO job responsibilities.</p> <ul style="list-style-type: none"> ● Mark these performance elements not applicable (NA), or ● Remove them from the Field Training Worksheet. 	<p>2. Review the performance elements included on the jurisdiction’s Field Training Worksheet.</p>
<p>3. Determine if the criteria listed under each performance element is specific to the FSIO job responsibilities.</p> <ul style="list-style-type: none"> ● Indicate on the Field Training Worksheet criteria that is not applicable (NA) ● Criteria marked not applicable (NA) is <u>not</u> to be used as part of the ATN process. 	<p>3. Review the criteria that will be assessed for each of the performance elements that comprise the jurisdiction’s Field Training Worksheet.</p>
<p>4. Determine if any criteria, specific to the regulatory jurisdiction, needs to be added.</p> <ul style="list-style-type: none"> ● New criteria can be added in the “OPTIONAL” section for each of the performance elements. 	<p>4. Participate in an appropriate number of joint field demonstration inspections (trainer-led), as determined by the jurisdiction’s trainer, in preparation for joint field training inspections (trainee-led).</p>
<p>5. Determine the format that will be used to conduct the ATN.</p> <ul style="list-style-type: none"> ● Jurisdiction can determine the appropriate format for conducting the ATN. Some examples include: <ul style="list-style-type: none"> ✓ conducting an ATN during <u>every</u> joint field training inspection (trainee-led); ✓ conducting ATNs at <u>set interval points</u> during the joint field training inspections; or ✓ having the jurisdiction develop an ATN format to meet its specific training needs. ● A <u>sufficient number</u> of field ATNs <u>must</u> be conducted to evaluate the FSIO for <u>each</u> of the performance elements. 	
<p>6. Schedule the field ATN</p> <ul style="list-style-type: none"> ● In retail food and foodservice establishments identified in risk categories 2, 3, and 4 as presented in Appendix B-3 (taken from Annex 5, Table 1 of the 2005 FDA Food Code). 	
<p>7. Complete an appropriate number of joint field demonstration inspections (trainer-led) to prepare the FSIO for joint field training inspections (trainee-led).</p>	

Step-By-Step Summary – Field Training Process

II. Conducting the Assessment of Training Needs (ATN)

<p>Regulatory Jurisdiction’s Designated Trainer <i>(Trainer must have successfully completed all Program Standard #2 training and standardization criteria)</i></p>	<p>Food Safety Inspection Officers <i>(Trainees)</i></p>
<p>1. Explain to the FSIO the format for the ATN. Options may include:</p> <ul style="list-style-type: none"> ● as part of <u>every</u> joint field training inspection; ● at <u>set intervals</u> during the joint field training inspections process; or ● per a jurisdiction-specific format. 	<p>1. Review the regulatory jurisdiction’s format for conducting the ATN. The regulatory jurisdiction’s trainer should provide an orientation to the training process and format.</p>
<p>2. Conduct a sufficient number of field ATNs.</p> <ul style="list-style-type: none"> ● to properly assess a FSIO’s performance for <u>each</u> of the applicable performance elements. ● laboratory, classroom, or office exercises may be used to assess performance elements that are difficult to observe as part of the joint field training inspection process. 	<p>2. Assume the lead during joint field training inspections. FSIO is responsible for:</p> <ul style="list-style-type: none"> ● initiating contact with the person in charge; ● explaining the purpose of the inspection; ● directing the inspection process; ● establishing a dialogue with the management/employees; ● making the observations of food safety practices ● obtaining corrective actions for out of compliance foodborne illness contributing factors, and ● preparing the report and conducting the exit interview. <p>NOTE: The trainer observes the FSIO conducting inspection performance elements and participates only when the inspection process dictates their assistance or intervention.</p>
<p>3. Observe the FSIO (trainee) conducting inspections in retail food and foodservice establishments identified in risk categories 2, 3, and 4 as presented in Appendix B-3 (taken from Annex 5, Table 1 of the 2005 FDA Food Code).</p>	<p>3. Follow the regulatory jurisdiction’s administrative procedures for conducting retail food and foodservice inspections – including use of the jurisdiction’s inspection forms.</p> <ul style="list-style-type: none"> ● FSIO concentrates on the retail food and/or foodservice inspection. ● Only trainer completes the Field Training Worksheet.
<p>4. Use the jurisdiction’s Field Training Worksheet to assess FSIO on <u>each</u> of the applicable and observable performance elements.</p>	<p>4. Meet with the jurisdiction’s trainer to discuss the results of the Field Training Worksheet upon completion of the joint training inspection. The trainer reviews observations documented on the Field Training Worksheet with the FSIO. The FSIO obtains feedback on</p> <ul style="list-style-type: none"> ● areas performed well; ● performance elements needing improvement; and ● FSIO discusses with the trainer options for enhancing their performance for elements needing improvement.
<p>5. Use the criteria under each of the performance elements to assess the FSIO using one of the four markings:</p> <ul style="list-style-type: none"> ● Acceptable (A) – FSIO meets the performance element criteria; ● Needs Improvement (NI) – FSIO does not meet the performance element criteria. Written comments must be provided for any criteria needing improvement. ● Not Observed (NO) – Performance element criteria are part of the FSIO’s assigned responsibilities but were not observed during the joint field training inspection. ● Not Applicable (NA) – Performance element criteria are not part of the FSIO’s assigned responsibilities. 	
<p>6. Review with, or demonstrate to, the FSIO the correct procedure for any performance element criteria marked as needing improvement during the field ATN.</p>	<p>5. Sign the Field Training Worksheet upon completion of the review of the results from the assessment.</p>
<p>7. Conduct a comprehensive review of the Field Training Worksheet with the FSIO. Review should include:</p> <ul style="list-style-type: none"> ● performance elements that the FSIO performed well. ● performance elements needing improvement and corrective action plan for those performance element criteria needing improvement. 	
<p>8. Sign, and obtain the signature of the FSIO, on each Field Training Worksheet. The Field Training Worksheet is retained in the</p>	

FSIO’s training file and used as part of their DSC.

Step-By-Step Summary – Field Training Process

III. Completing the Documentation of Successful Completion (DSC)

Regulatory Jurisdiction’s Designated Trainer <i>(Trainer must have successfully completed all Program Standard #2 training and standardization criteria)</i>	Food Safety Inspection Officers <i>(Trainees)</i>
<p>1. Review the Field Training Worksheets conducted during the joint field training process. A review of all the Field Training Worksheets must indicate that the FSIO demonstrated a consistent pattern of:</p> <ul style="list-style-type: none"> • understanding or skill competency for each of the performance elements. • meeting the criteria that comprises a performance element. There should be only a few, if any, instances where the FSIO did not meet the expected criteria. 	<p>1. Review with the trainer the results of the ATN process.</p> <ul style="list-style-type: none"> • The “Comments” section can be used by the trainer as a continuous improvement tool. For example, trainers may note a FSIO’s specific strengths or note items on which inspection KSAs can be furthered enhanced. FSIO should review comments to focus on areas which will enhance their inspection performance.
<p>2. Verify that an assessment of the FSIO has been conducted for all applicable performance elements. Laboratory, classroom, or office exercises may be used to assess performance elements that are difficult to observe during the joint field training inspection process.</p>	<p>2. Should FSIO not receive an “Acceptable” marking for any performance element, a continuous improvement action plan is to be developed with the trainer to address areas needing improvement.</p> <ul style="list-style-type: none"> • The FSIO should adhere to the corrective action plan developed by the trainer until all performance elements receive an “Acceptable” marking.
<p>3. Complete the DSC based on the results compiled from the Field Training Worksheets. A FSIO must achieve an “Acceptable” marking on <u>all</u> the applicable performance elements.</p> <p>Acceptable – indicates that the FSIO meets expectations; in only a few instances is the performance element not met.</p> <ul style="list-style-type: none"> • The “Comments” section can be used by the trainer as a continuous improvement tool. For example, trainers may note a FSIO specific strengths or note items for which inspection KSAs can be further enhanced. 	<p>3. Sign the DSC.</p> <ul style="list-style-type: none"> • Comments on the DSC from the trainer should be used to prepare for Food Code standardization. • Signed DSC will be placed in the FSIO’s training file.
<p>4. Review the DSC with the FSIO. FSIOs that receive an “Acceptable” marking on all applicable performance elements have successfully completed the field training process.</p> <ul style="list-style-type: none"> • Should the FSIO fail to achieve an “Acceptable” evaluation on one or more of the performance elements the trainer will develop a corrective action plan specific for the areas in need of improvement. 	
<p>5. Sign the DSC in the header box titled, “Signature of Assessor.” The trainer signature indicates that the FSIO has successfully completed the field training process.</p>	
<p>6. Obtain the signature of the FSIO on the DSC. The FSIO’s signature indicates that the trainer has reviewed the results of the ATN with them. The DSC should be kept as part of the FSIO’s training records.</p>	

ATTACHMENT A

Assessment of Training Needs

Retail Food, Restaurant, and Institutional Foodservice
Food Safety Inspection Officer

Field Training Worksheet

Establishment Name:	Permit #:	Date:
Establishment Address:	Time In:	Time Out:
Food Safety Inspection Officer (FSIO) Name:	FSIO's Agency:	
Assessor's Name:	Assessor's Agency:	

Acceptable (A) FSIO meets performance element criteria

Needs Improvement (NI) FSIO does not meet the criteria expected for the performance element. Written comments must be provided for any criteria marked as needing improvement.

Not Observed (NO) Performance element criterion is part of the FSIO's assigned responsibilities but was not observed during the inspection.

Not Applicable (NA) Performance element criterion is not part of the FSIO's assigned responsibilities

A sufficient number of joint field training inspections must be conducted to assess a FSIO's performance for each of the applicable performance elements (performance elements are in BOLD font in the shaded area of each Table).

Criteria listed under each performance element are intended to serve as examples of observations that can be used to assess a FSIO's performance. Criteria not specific to the FSIO job responsibilities in a jurisdiction are to be marked "Not Applicable" (NA).

The Field Training Worksheet has been designed to accommodate criteria specific to a jurisdiction's retail food protection program. A space has been provided under each performance element for additional or new criteria specific to a jurisdiction. Under each performance element there is a space titled, "OPTIONAL." The "OPTIONAL" area under each performance element can be used by a jurisdiction to add assessment criteria to meet the specific needs of the regulatory retail food protection program.

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ATTACHMENT A**

I. Pre-Inspection

1. Food Safety Inspection Officer (FSIO) has successfully completed pre-requisite training courses as specified in FDA Voluntary National Retail Food Regulatory Program Standards: Standard #2 – Trained Regulatory Staff.	A	NI
OPTION 1: Completed the FDA ORA-U <u>pre-requisite</u> (“Pre”) courses/examinations AND training on the jurisdiction’s prevailing statutes, regulations, and/or ordinances.		
OPTION 2: Submitted documentation of completing coursework equivalent to the FDA-ORA <u>pre-requisite</u> (“Pre”) curriculum, training on the jurisdiction’s prevailing statutes, regulations, and/or ordinances, AND		
Has certificate or documentation of successfully passing one of the written examination options in Program Standard #2.		
OPTIONAL (Jurisdiction specific items):		
Comments:		

2. Has required equipment and forms to conduct inspection.	A	NI	NA
Necessary inspection forms and administrative materials.			
Lab coat or equivalent protection to cover street clothes.			
Head cover: baseball cap; hair net; or equivalent.			
Calibrated thermocouple temperature measuring device.			
Maximum registering thermometer or temperature sensitive tapes for verifying hot water warewashing final rinse temperature.			
Chemical test kits for chlorine, iodophor and quaternary ammonia sanitizers.			
Flashlight.			
Alcohol swabs.			
OPTIONAL (Jurisdiction specific items):			
Comments:			

3. Reviews establishment file for previous inspection report and, if applicable, any documents or complaints on file.	A	NI	NO	NA
Reviewed previous inspection report noting documented out of compliance observations.				
Reviewed establishment file for complaint reports.				
Reviewed establishment file for documentation indicating a need for a HACCP Plan.				
Reviewed establishment file for documentation of food production or processes operating under a variance issued by the jurisdiction.				
OPTIONAL (Jurisdiction specific items):				

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I. Pre-Inspection (continued)

<i>(continued from previous page)</i>	
Comments:	

II. Inspection Observations and Performance

1. Provides identification as a regulatory official to person in charge, confirming agency authority for inspection, and stating the purpose of visit.	A	NI	NO	NA
Verbally provided name and agency to the person in charge.				
Presented regulatory identification or business card.				
Stated the purpose of the visit.				
Requests and confirmed permission to conduct inspection from the person in charge prior to initiating the inspection.				
OPTIONAL (Jurisdiction specific items):				
Comments:				

2. Has knowledge of jurisdiction’s laws, rules, and regulations required for conducting retail food/foodservice inspections.	A	NI	NO	NA
Verified the correct critical limit and or standard specified in the jurisdiction’s rules/regulations to the observation made.				
Correctly cited the rule/regulation for each out of compliance observation.				
OPTIONAL (Jurisdiction specific items):				
Comments:				

3. Uses a risk-based inspection methodology to assess regulations related to employee practices and management procedures essential to the safe storage, preparation, and service of food.	A	NI	NO	NA
Verified Demonstration of Knowledge of the person in charge.				
Verified approved food sources (e.g., food from regulated food processing plants; shellfish documentation; game animal processing; parasite destruction for certain species of fish intended for raw consumption; receiving temperatures).				
Verified food safety practices for preventing cross-contamination of ready-to-eat food.				
Verified food contact surfaces are clean and sanitized, protected from contamination from soiled cutting boards, utensils, aprons, etc., or raw animal foods.				
<i>(continued on next page)</i>				

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II. Inspection Observations and Performance (continued)

3. Uses a risk-based inspection methodology to assess regulations related to employee practices and management procedures essential to the safe storage, preparation, and service of food.	A	NI	NO	NA
<i>(continued from previous page)</i>				
Verified the restriction or exclusion of ill employees.				
Verified no bare hand contact with ready-to-eat foods (or use of a pre-approved, alternative procedure).				
Verified employee handwashing.				
Verified cold holding temperatures of foods requiring time/temperature control for safety (TCS food), or when necessary, verified that procedures are in place to use time alone to control bacterial growth and toxin production.				
Verified date marking of ready-to-eat TCS food held for more than 24 hours.				
Verified cooking temperatures to destroy bacteria and parasites.				
Verified hot holding temperatures of TCS food or when necessary, that procedures were in place to use time alone to prevent the outgrowth of spore-forming bacteria.				
Verified cooling temperatures of TCS food to prevent the outgrowth of spore-forming or toxin-forming bacteria.				
Verified reheating temperatures of TCS food for hot holding.				
Verified the availability of a consumer advisory for foods of animal origin served raw or undercooked.				
Identified food processes and/or procedures that require a HACCP Plan per the jurisdiction's regulations.				
OPTIONAL (Jurisdiction specific items):				
Comments:				

4. Obtains immediate corrective action for out of compliance employee practices and management procedures (listed in Item 3 above) essential to the safe storage, preparation, and service of food.	A	NI	NO	NA
Notified the person in charge/employee(s) of the out of compliance observations.				
Reviewed corrective actions with the person in charge/employee(s).				
Observed the person in charge/employee(s) immediately take corrective action for out of compliance observations (e.g., movement of food to ensure product temperature or prevent contamination; reconditioning food; restriction/exclusion of ill employees; discarding of food product) in accordance with local jurisdiction's procedures.				
Identified conditions requiring issuance of an embargo/stop sale/food destruction order per jurisdiction's administrative procedures.				
OPTIONAL (Jurisdiction specific items):				
Comments:				

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II. Inspection Observations and Performance (continued)

5. Correctly assesses compliance status of other regulations (not included in Item 4 – Good Retail Practices) that are included in jurisdiction’s prevailing statutes, regulations and/or ordinances.	A	NI	NO	NA
Correctly assessed compliance status of other regulations (not included in Item 4 above - Good Retail Practices) that are included in jurisdiction’s prevailing statutes, regulations and/or ordinances.				
OPTIONAL (Jurisdiction specific items):				
Comments:				

6. Verifies correction of out of compliance observations identified during previous inspection.	A	NI	NO	NA
Verified correction of out of compliance observations identified during previous inspection				
OPTIONAL (Jurisdiction specific items):				
Comments:				

7. Correctly uses inspection equipment during joint inspections.	A	NI	NO	NA
Used temperature measuring devices/probes in accordance with manufacturer’s instructions.				
Cleaned and sanitized (alcohol swabs) temperature measurement probes to prevent food contamination.				
Used infrared thermometer in accordance with manufacturer’s instructions. Verified any out of compliance product temperatures registered on the infrared with a thermocouple.				
Used maximum registering thermometer or heat sensitive tapes in accordance with manufacturer’s instructions to verify final rinse dishwasher temperature.				
Used chemical test strips in accordance with manufacturer’s instructions to measure sanitizer concentrations in manual and mechanical dishwashing operations; wiping cloth solutions; and spray bottle applicators.				
Used flashlight to assess observations in areas with no or low light.				
OPTIONAL (Jurisdiction specific items):				
Comments:				

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III. Sample Collection and Evidence Development

1. Photographs taken support regulatory findings or conditions observed.	A	NI	NO	NA
Photographs taken support regulatory findings or conditions observed.				
OPTIONAL (Jurisdiction specific items):				
Comments:				

2. Uses an aseptic food sample collection method consistent with criteria established by laboratory serving jurisdiction.	A	NI	NO	NA
Used proper hygiene before and during sample process (e.g., washed hands prior to sampling; did not touch sample container opening, inside lip, inside cap or did not blow into the bag to open it up.)				
Used sample collection method specified by the jurisdiction (e.g., original container if available; collection of a representative sample from a large quantity or container).				
Used sterile, leak-proof lidded container or zipper-lock type bags.				
Used a separate sterile utensil to collect each different sample item.				
Labeled all containers with required information (e.g., date, time, location, product name, FSIO initials) with corresponding information noted on inspection report or laboratory forms.				
Initiated written chain of custody including use of evidence seal.				
Stored and transported sample in a clean, refrigerated unit (e.g., ice chest with ice) within the prescribed time period.				
Maintained sample refrigerated or frozen until transport or shipping to laboratory.				
Sample packed and shipped in sterile, leak-proof, insulated container with refrigerant (wet or dry ice) via the most rapid and convenient means available (e.g., courier, bus, express mail).				
OPTIONAL (Jurisdiction specific items):				
Comments:				

3. Uses an aseptic water sample collection method consistent with criteria established by laboratory serving jurisdiction.	A	NI	NO	NA
Used proper hygiene before and during sample process (e.g., washed hands prior to sampling; did not touch sample container opening, inside lip, inside cap or did not blow into the bag to open it up.)				
Sample taken at site closest to source of water (prior to any treatment) if possible, or at a site (post treatment) per jurisdiction's procedures.				
Sample taken from operational fixed type faucet – no swing type or leaking faucets.				
Removed aerator (if present) from faucet prior to sampling.				
Disinfected faucet with bleach or flame.				
Ran water through faucet for several minutes to clear line.				
<i>(continued on next page)</i>				

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III. Sample Collection and Evidence Development (continued)

3. Uses an aseptic water sample collection method consistent with criteria established by laboratory serving jurisdiction.	A	NI	NO	NA
<i>(continued from page 6)</i>				
Used a sterile, leak-proof lidded container, “whirl-pak” or zipper-lock type bag.				
Sample taken from midstream of the flowing faucet.				
Labeled all containers with required information (e.g., date, time, location, product name, FSIO initials) with corresponding information noted on inspection report or laboratory forms.				
Initiated written chain of custody including use of evidence seal.				
Stored and transported sample in a clean, refrigerated unit (e.g., ice chest with ice) within the prescribed time period.				
Maintained sample refrigerated until transport or shipping to the laboratory.				
Sample packed and shipped in sterile, leak-proof, insulated container with refrigerant via the most rapid and convenient means available (e.g., courier, bus, express mail).				
OPTIONAL (Jurisdiction specific items):				
Comments:				

IV. Oral Communication

1. Asks questions and engages in a dialogue with person in charge/employees to obtain information relevant to inspection.	A	NI	NO	NA
Asked open ended questions (questions that can not be answered with “yes” or “no”).				
Did not interrupt when the person in charge/employee was speaking.				
Paraphrased/summarized statements from the person in charge to confirm understanding.				
OPTIONAL (Jurisdiction specific items):				
Comments:				

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IV. Oral Communication (continued)

2. Provides the person in charge/employees with accurate answers to inspection-related questions or admits not knowing the answer.	A	NI	NO	NA
Answered inspection-related questions accurately.				
Admitted not knowing the answer to a question and arranges to contact the establishment with the answer.				
Used trainer as a resource when unsure of an answer.				
OPTIONAL (Jurisdiction specific items):				
Comments:				

3. Uses available means (e.g., interpreter, drawings, demonstrations, diagrams) to overcome language or communication barriers.	A	NI	NO	NA
Avoided using jargon and acronyms, without explanation.				
Used interpreter, drawings, demonstrations, or diagrams to overcome language or communication barriers.				
Checked the person in charge’s understanding of information/instructions by asking the operator to paraphrase or demonstrate the information/instructions.				
OPTIONAL (Jurisdiction specific items):				
Comments:				

4. Follows jurisdiction’s policy in regard to disclosure of confidential information.	A	NI	NO	NA
Explained confidentiality laws, policies and procedures to the person in charge when necessary. (If the need to explain confidential laws did not occur during the joint field training inspections, the FSIO explained confidentiality laws, policies and procedures to the trainer).				
Applied the confidentiality policy per the jurisdictional requirements (e.g., FSIO did not reveal confidential information to the operator during the inspection).				
OPTIONAL (Jurisdiction specific items):				
Comments:				

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IV. Oral Communication (continued)

5. Uses effective communication and conflict resolution techniques to overcome inspection barriers.	A	NI	NO	NA
Identified challenges faced by the person in charge and offered possible solution(s).				
Did not become argumentative (e.g., remained calm and focused).				
Removed himself/herself from a confrontation or threat that may impact personal safety.				
OPTIONAL (Jurisdiction specific items):				
Comments:				

6. Conducts exit interview explaining out of compliance observations and identifying corrective actions and timelines for all noted violations.	A	NI	NO	NA
Explained the public health significance of the inspection observations.				
Reviewed all findings with the person in charge with emphasis on contributing factors to foodborne illness and Food Code Interventions (listed in Section II, Item 3).				
Used foodborne illness data to highlight contributing factors.				
Answered all questions or concerns pertaining to items on the inspection report.				
Provided contact information to the person in charge for follow up questions or additional guidance.				
OPTIONAL (Jurisdiction specific items):				
Comments:				

V. Written Communication

1. Completes inspection form per jurisdiction’s administrative procedures (e.g., observations; corrective actions; public health reason; applicable code reference; compliance dates).	A	NI	NO	NA
Used correct inspection form.				
Completed a legible report.				
Accurately documented observations made during inspection.				
Completed inspection form in accordance with jurisdiction’s administrative procedures.				
Cited correct code provisions/rules/regulations.				
Documented immediate corrective action for out-of-compliance foodborne illness contributing factors and Food Code Interventions (listed in Section II, Item 3).				
Documented time frames for correcting each out of compliance observation.				
Signed completed inspection report.				
<i>(continued on page 10)</i>				

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V. Written Communication (continued)

1. Completes inspection form per jurisdiction’s administrative procedures (e.g., observations; corrective actions; public health reason; applicable code reference; compliance dates).	A	NI	NO	NA
<i>(continued from previous page)</i>				
OPTIONAL (Jurisdiction specific items):				
Comments:				
2. Includes with inspection report any compliance or regulatory documents (e.g., exhibits, attachments, sample forms, embargo forms, destruction forms, suspension notices) identified or cross-referenced in written statements.	A	NI	NO	NA
Referenced attached documents in inspection report.				
Referenced documents are legible.				
Referenced documents are accurate and reflect observations made during the inspection.				
Attached referenced document(s) to the inspection report per jurisdiction’s administrative procedures.				
OPTIONAL (Jurisdiction specific items):				
Comments:				
3. Presents inspection report, and when necessary cross-referenced documents, to person in charge.	A	NI	NO	NA
Presented complete inspection report, with referenced documents when necessary, to person in charge during exit interview.				
Followed jurisdiction’s administrative procedures for delivering written inspection report.				
Obtained signature of person in charge on inspection report.				
OPTIONAL (Jurisdiction specific items):				
Comments:				

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VI. Professionalism

1. Maintains a professional appearance consistent with jurisdiction's policy (e.g., clean outer clothing, hair restraint).	A	NI	NO	NA
Maintained a professional appearance consistent with jurisdiction's policy (e.g., clean outer clothing, hair restraint).				
OPTIONAL (Jurisdiction specific items):				
Comments:				
2. Demonstrates proper sanitary practices as expected from a food service employee.	A	NI	NO	NA
Washed hands as needed (e.g., prior to conducting inspection, after using restroom, after touching dirty surfaces, after touching face/body, after sneezing/coughing).				
Protected bandages on hands, when necessary, to prevent contamination of food or food contact surfaces.				
Did NOT contact ready-to-eat foods with bare hands.				
Did NOT show any obvious signs of illness in accordance with jurisdiction's employee health policy and/or current food code.				
OPTIONAL (Jurisdiction specific items):				
Comments:				
3. Only reports substantiated findings as violations.	A	NI	NO	NA
Only reported findings that were directly observed or substantiated in accordance with jurisdiction's policies and procedures.				
Findings are supported by fact (e.g., are NOT based on hunch or suspicion; are witnessed, are investigated).				
Did NOT note violations without visiting the establishment.				
Did NOT exaggerate details related to findings to support report conclusions.				
Did NOT modify report after leaving the establishment except as allowed by jurisdiction's administrative procedures.				
OPTIONAL (Jurisdiction specific items):				
Comments:				

Assessor Signature: _____ **Date:** _____

FSIO Signature: _____ **Date:** _____

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ATTACHMENT B

Documentation of Successful Completion – Field Training Process

Retail Food, Restaurant, and Institutional Foodservice – Food Safety Inspection Officer

Date Assessment of Training Needs Began:	Date Assessment of Training Needs is Completed:
Print Name – Food Safety Inspection Officer (candidate):	Signature – Food Safety Inspection Officer:
Print Name – Assessor(s):	Signature of Assessor: <i>(Signature indicates FSIO has successfully completed the Field Training Process)</i>

Acceptable (A) FSIO meets expectations; performance element not demonstrated in a few instances
Not Applicable (NA) Performance element not part of the FSIO’s assigned responsibilities

Item	I. Pre-Inspection Performance Elements	A	NA
1	Successfully completed pre-requisite training courses as specified in FDA Voluntary National Retail Food Program Standards: Standard #2 – Trained Regulatory Staff.		
2	Had required equipment and forms to conduct inspection.		
3	Reviewed establishment file for previous inspection report and, if applicable, any documents or complaints on file.		
	Comments		

Item	II. Inspection Observation and Performance Elements	A	NA
1	Provided identification as a regulatory official to person in charge, confirmed agency authority for inspection, and stated purpose of visit.		
2	Had knowledge of jurisdiction’s laws, rules, and regulations required for conducting retail food/foodservice inspections.		
3	Used a risk-based inspection methodology to assess regulations related to employee practices and management procedures essential to the safe storage, preparation and service of food.		
4	Obtained immediate corrective action for employee practices and management procedures (listed in Item 3 above) essential to the safe storage, preparation and service of food.		
5	Correctly assessed compliance status of other regulations (Good Retail Practices).		
6	Verified correction of out of compliance observations identified during previous inspection.		
7	Correctly used inspection equipment during joint inspections.		
Item	Comments		

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Item	III. Sample Collection and Evidence Development Performance Elements	A	NA
1	Photographs taken support regulatory findings or conditions observed.		
2	Used an aseptic food sample collection method consistent with criteria established by laboratory serving jurisdiction.		
3	Used an aseptic water sample collection method consistent with criteria established by laboratory serving jurisdiction.		
Item	Comments		

Item	IV. Oral Communication Performance Elements	A	NA
1	Asked questions and engaged in dialogue with person in charge/employees to obtain information relevant to inspection.		
2	Provided operator with accurate answers to inspection-related questions or admitted he/she did not know the answer.		
3	Used available means (e.g., interpreter, drawings, demonstrations, diagrams) to overcome language or communication barriers.		
4	Followed department policy with regard to disclosure of confidential information.		
5	Used effective communication and conflict resolution techniques to overcome inspection barriers.		
6	Conducted exit interview explaining out of compliance observations and identifying corrective actions and timelines for all noted violations.		
Item	Comments		

Item	V. Written Communication Performance Elements	A	NA
1	Completed inspection forms per jurisdiction’s administrative procedures (e.g., observations; corrective actions; public health reason; applicable code reference; compliance dates).		
2	Included with inspection report any compliance or regulatory documents (e.g., exhibits, attachments, sample forms, embargo forms; destruction forms; suspension notices) identified or cross-referenced in written statements.		
3	Presented inspection report and when necessary, cross-referenced documents, to person in charge.		
Item	Comments		

Item	VI. Professionalism Performance Element	A	NA
1	Had a professional appearance consistent with jurisdiction’s policy (e.g., clean outer clothing, hair restraint).		
2	Demonstrated proper sanitary practices as expected from a food service employee.		
3	Only reported substantiated findings as violations.		
Item	Comments		

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Supplement to Standard #2 - Appendix B-3

2005 FDA Food Code – Annex 5

Table 1.

Risk Categorization of Food Establishments

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

Appendix C - Supplement to Standard No. 3 - Inspection Program Based on HACCP Principles

Table C- – Inspection Program Worksheet

Criteria	YES	NO
1. The inspection form in use is designed to: a. identify risk factors and interventions b. document in, out, not observed, and not applicable status c. document compliance and enforcement activities		
	1a.	
	1b.	
	1c.	
2. Your jurisdiction uses a written process that groups food establishments into at least three categories based on potential and inherent food safety risks.	2.	
3. Your jurisdiction assigns an annual inspection frequency to each food establishment based on its assigned food safety risk category.	3.	
4. Your jurisdiction has an implemented, written policy that requires: a. On-site corrective actions b. Discussion of long-term control options c. Follow-up activities		
	4a.	
	4b.	
	4c.	
5. Your jurisdiction has an implemented written policy that addresses code variance requests related to risk factors and interventions.	5.	
6. Your jurisdiction has an implemented written policy for the verification and validation of HACCP plans when a plan is required by the code.	6.	

A “yes” affirmation to each statement is required to meet Standard No. 3. The source documents specified as quality records in Standard No. 3 must be maintained in good order by the regulatory authority to support this summary record and must be made available for purposes of a verification audit.

I affirm that the information represented on this record is true and correct. This jurisdiction meets all the requirements for Standard No. 3, _____YES _____NO

Printed Name and Signature of Self-Assessor

Date

Name and Address of the Jurisdiction

Appendix D - Supplement to Standard No. 4 – Uniform Inspection Program

Use Table D-2 or a similar manual or automated form to document the success of a jurisdiction's quality assurance program in meeting Standard No. 4. In the first column, identify the inspector by name or by a code. In the Establishment ID column, identify the establishment by name or by code. In the "DATE" column, record the dates of the field visit and file review. Items 1 through 10 below summarize the desired activities and competencies of an inspector. Note that some items (such as 5, 6, 8, and 9) cannot be verified without a review of the file for the establishment visited. Place a check mark in the corresponding column of Table D-2 when the activity or competency is verified.

1. Determines and documents the compliance status of each risk factor and intervention (i.e., IN compliance, OUT of compliance, Not Observed, or Not Applicable is noted on the inspection form) through observation and investigation;
2. Completes an inspection report that is clear, legible, concise, and accurately records findings and observations;
3. Interprets and applies laws, regulations, policies and procedures correctly;
4. Cites the proper local code provisions for CDC-identified risk factors and Food Code interventions;
5. Reviews past inspection findings and acts on repeated or unresolved violations;
6. Follows through with compliance and enforcement actions;
7. Obtains on-site corrective action;
8. Discusses and documents discussion of options for implementing food safety systems, when required;
9. Confirms that the facility is assigned to the correct risk category and inspection frequency; and
10. Files reports and other documentation in a timely manner.

NOTE TO AGENCIES HAVING LESS THAN 10 INSPECTORS: When dealing with samples this small, it is statistically necessary to group all the item ratings together, disregarding the score for each individual Item (1) – (10). Agencies having less than 4 inspectors will need to conduct extra inspections with each inspector in order to reach a minimum total of 8 inspections. This is necessary in order to have a sample of inspections large enough to statistically measure the uniformity of your inspection program fairly. Therefore, do not calculate the "% compliance" row for each item at the bottom of Table D-2. Instead use Chart D-1 and Table D-1 to determine the program's rating.

Chart D-1 Method of Calculation For Jurisdictions With Less Than Ten Inspectors		
# of inspectors	# inspections needed	# of items needed to be marked in compliance in order to pass
<4	8 minimum	65 (out of 80 possible Items)
4-9	2 per inspector	4 inspectors = 65 (out of 80 possible Items) 5 inspectors = 82 (out of 100 possible Items) 6 inspectors = 99 (out of 120 possible Items) 7 inspectors = 116 (out of 140 possible Items) 8 inspectors = 133 (out of 160 possible Items) 9 inspectors = 150 (out of 180 possible Items)

Example: For 6 inspectors, there will be 2 field visits per inspector = 12 visits
12 visits X 10 Items per visit = 120 Total Possible Items

These minimum passing scores are comparable to the 75% per aspect passing rate for jurisdictions with 10 or more inspectors.

Table D-1 Calculation of Uniformity for Jurisdictions with Less Than Ten Inspectors	
Period from _____ to _____	
1. Number of inspectors in the jurisdiction	
2. Number of inspections used in the calculation (minimum of 8)	
3. Total number of items marked as correct during joint field visits and corresponding file reviews and recorded on Table D-2.	
4. Total number of possible items based on the number of inspections (10 items times the # of inspections – see Chart D-1, column 3)	
Indicate Pass or Fail as determined by chart D-1, column 3	

Table D-2: Calculation of Uniformity for Jurisdictions with Ten or More Inspectors Period from _____ to _____												
INSPECTOR ID.	Establishment ID	Date	ITEM (1)	ITEM (2)	ITEM (3)	ITEM (4)	ITEM (5)	ITEM (6)	ITEM (7)	ITEM (8)	ITEM (9)	ITEM (10)
1.												
2.												
3.												
4.												
5.												
6.												
7.												
8.												
9.												
10												
% In Compliance												

A check mark indicates the inspector complies with the item. Conduct at least two field visits and file reviews per inspector during each three-year self-assessment period. For each item, compute the Percent In Compliance by dividing the number of checks in each column by the number of field inspections observed and multiplying the result by 100. Each column must show at least a 75% In Compliance rate for the program to conform to the Standard. See instructions on page D-1 for jurisdictions with less than ten inspectors.

EXPLANATION OF THE STATISTICAL MODEL

This is an explanation of the thinking that determined the statistical model relating to the criteria used for evaluating the inspectional performance of jurisdictions. The FDA Program Standards Workgroup and the Retail Food Steering Committee agreed this model to, with guidance from the CFSAN Division of Mathematics.

Evaluation of the performance of large jurisdictions

For large jurisdictions (jurisdictions with 10 or more inspectors) the evaluation is based on direct oversight of two inspections per inspector, with respect to 10 items of performance. If 10 or more inspectors are being evaluated in the program, then we will see 20 or more scores of satisfactory or unsatisfactory for each item. The standard for approval of the inspection performance is a passing score of 75% on each of the 10 items. An individual item receives a passing score if at least 75 percent of the instances of observation are completed in a satisfactory manner. For example, with 10 inspectors, we must have at least 15 (that is 75 percent of 20 inspections) completed correctly for item number 1. Similarly, for item number 2, we would need to see at least 15 inspections done correctly. In order for the program to pass the evaluation successfully with respect to inspection performance, all of the 10 items would be required to show satisfactory completion of at least 15 out of the 20 ratings. For those jurisdictions with more than 10 inspectors, we simply apply the 75 percent rule as we did for the jurisdiction with 10 inspectors. Using two overseen inspections for each inspector, record the observations for each item, figure the percent correct for each item, and round up to the next higher whole number when the percent is not a whole number.

The 75 percent per item rule was determined by the consensus of several highly experienced individuals working in the retail food safety team. We view the set of overseen inspections as a sample from a much larger set of total inspections performed. In this approach to program evaluation, the statistical measure does not evaluate any individual inspector. The emphasis is on the overall performance of the team, with respect to any item. Even if an inspection were observed in which one inspector fails all 10 items, the program would not necessarily fail.

The jurisdiction's quality assurance program, however, must address individual inspector's performance to ensure a standard of uniformity among the team. If each inspection were successful only 75 percent of the time for each item, the team as a whole would almost always fail. This is because they would almost always dip below 75 percent on at least one of the 10 items. For example, a team that scored 70, 70, 70, 75, 75, 75, 75, 80, 80, and 80 on each of the 10 items would be successful 75 percent of the time, but they would fail three times over since three items scored below 75. However, for a team with 10 inspectors exactly, if their chance of getting each item right improved to 88 percent at each inspection, then they would have a much better chance of keeping all 10 results at 75 percent or higher. Under the simple statistical assumption of independent sampling, a team achieving 88 percent at each inspection would pass the evaluation 75 percent of the time. Therefore, this 88 percent level of performance was used as a simple representation of a team that is good enough that we want them to have a good chance of passing, but not so good that they would not find it advantageous to improve.

Evaluation of performance of small jurisdictions

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

of performance at each inspection was the feature of the standard that was kept constant in designing the sample sizes for the smaller jurisdictions

In jurisdictions with less than 10 inspectors, the statistical solution is to group all of the individual ratings, disregarding the individual items. For 5 inspectors we would review $5 \times 2 = 10$ inspections, with respect to all 10 items combined. This gives 100 observations. It is not possible to make a total observation test mimic exactly a 10 item test, but the minimum passing rates will be about as stringent as the 75 percent for each of 10 aspects test.

For 4 to 9 inspectors, conduct two co-inspections for each inspector. Chart D-1 shows the lowest total passing score out of the complete set of combined items that would give at least a 75 percent chance of passing for a team with an 88 percent chance of getting any particular observation correct. For a team of three or less, it is recommended that extra oversight inspections be performed to produce a total of 8 inspections. This is an intuitive judgment call that any set smaller than 8 could randomly turn out to be odd enough to produce an unfair rating.

Appendix E - Supplement to Standard No. 5 - Foodborne Illness and Food Defense Preparedness and Response

Criteria	YES	NO
1. Investigation Procedures		
a. The program has written operating procedures for responding to and/or conducting investigations of foodborne illness and injury that clearly identify the roles, duties and responsibilities of program staff and how the program interacts with other relevant departments and agencies. (The procedures may be contained in a single source document or in multiple documents.)	a.	
b. The program maintains contact lists for individuals, departments, and agencies that may be involved in the investigation of foodborne illness, injury or contamination of food.	b.	
c. The program maintains a written operating procedure or a memorandum of Understanding (MOU) with the appropriate epidemiological investigation program/department to conduct foodborne illness investigations and to report findings. The operating procedure or MOU clearly identifies the roles, duties, and responsibilities of each party.	c.	
d. The program maintains logs or databases for all complaint or referral reports from other sources alleging food-related illness, injury or intentional food contamination. The final disposition for each complaint is recorded in the log or database and is files in or linked to the establishment record for retrieval purposes.	d.	
e. Program procedures describe the disposition, action or follow-up and reporting requirement for each type of complaint or referral report.	e.	
f. Program procedures require disposition, action or follow-up on each complaint or referral report alleging food-related illness or injury within 24 hours.	f.	
g. The program has established procedures and guidance for collecting information on the suspect foods' preparation, storage or handling during on-site illness, injury, or outbreak investigations.	g.	
h. Program procedures provide guidance for immediate notification of appropriate law enforcement agencies if at any time intentional food contamination is suspected.	h.	

<p>i. Program procedures provide guidance for the notification of appropriate state and/or federal agencies when a complaint involves a product that originated outside the agency’s jurisdiction or has been shipped interstate.</p>	<p>i.</p>	
<p>2. Reporting Procedures</p>		
<p>a. Possible contributing factors to the illness, injury or intentional food contamination are identified in each on-site investigation report.</p>	<p>a.</p>	
<p>b. The program shares final reports of investigations with the state epidemiologist and reports of confirmed outbreaks with CDC.</p>	<p>b.</p>	
<p>3. Laboratory Support Documentation</p>		
<p>a. The program has a letter of understanding, written procedures, contract or MOU acknowledging that a laboratory(s) is willing and able to provide analytical support to the jurisdiction’s food program. The documentation describes the type of biological, chemical, radiological contaminants or other food adulterants that can be identified by the laboratory. The laboratory support available includes the ability to conduct environmental sample analysis, food sample analysis and clinical sample analysis.</p>	<p>a.</p>	
<p>b. The program maintains a list of alternative laboratory contacts from which assistance could be sought in the event that a food-related emergency exceeds the capability of the primary support lab(s) listed in paragraph 3.a. This list should also identify potential sources of laboratory support such as FDA, USDA, CDC, or environmental laboratories for specific analysis that cannot be performed by the jurisdiction’s primary laboratory(s).</p>	<p>b.</p>	
<p>4. Trace-back Procedures</p>		
<p>a. Program management has an established procedure to address the trace-back of foods implicated in an illness, outbreak or intentional food contamination. The track-back procedure provides for the coordinated involvement of all appropriate agencies and identifies a coordinator to guide the investigation. Trace-back reports are shared with all agencies involved and with CDC.</p>	<p>a.</p>	
<p>5. Recalls</p>		
<p>a. Program management has an established procedure to address the recall of foods implicated in an illness, outbreak or intentional food contamination.</p>	<p>a.</p>	
<p>b. When the jurisdiction has the responsibility to request or monitor a product recall, written procedures equivalent to 21 CFP, Part 7 are followed.</p>	<p>b.</p>	

<p>c. Written policies and procedures exist for verifying the effectiveness of recall actions by firms (effectiveness checks) when requested by another agency.</p>	<p>c.</p>	
<p>6. Media Management</p>		
<p>a. The program has a written policy and procedure that defines a protocol for providing information to the public regarding a foodborne illness outbreak or food safety emergency. The policy/procedure should address coordination and cooperation with other agencies involved in the investigation. A media person is designated in the protocol.</p>	<p>a.</p>	
<p>7. Trend Analysis</p>		
<p>a. At least once per year, the program conducts 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.</p>	<p>a.</p>	
<p>b. The review is conducted with prevention in mind and focuses on, but is not limited to, the following:</p> <ul style="list-style-type: none"> i. Multiple complaints on the same establishment; ii. Multiple complaints on the same establishment type; iii. Multiple complaints implicating the same food; iv. Multiple complaints associated with similar food preparation processes; v. Number of laboratory-confirmed, food-related outbreaks; vi. Number of non-laboratory-confirmed but epidemiologically linked, food-related outbreaks; vii. Number of complaints involving real and alleged threats of intentional food contamination; and viii. Multiple complaints involving the same agent and any complaints involving unusual agents. 	<p>b.</p>	

<p>c. 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.</p>		
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A ‘yes’ affirmation to each statement is required to meet Standard 5. If an appendix item contains multiple questions, then all questions must be answered in the affirmative in order to meet that element of the Standard.

The source documents, such as the various policies and procedures, that support this summary record must be maintained in good order by the regulatory authority and must be made available upon request for purposes of a verification audit.

I affirm that the information represented on this record is true and correct. This jurisdiction meets all the requirements for Standard No. 5, _____Yes _____NO

Signature of Self-assessor

Date

Printed Name of Self-assessor and Title

Name and Address of Jurisdiction

Appendix F - Supplement to Standard No. 6 - Compliance and Enforcement

Work Sheet Instructions

This Standard applies to all voluntary and regulatory activities used by a jurisdiction to achieve compliance with regulatory requirements. The desired outcome is an effective compliance and enforcement program that consistently follows through on documented violations and achieves compliance. The sequence and type of follow-up activity a particular jurisdiction elects to use may vary. However, when an out-of-control risk factor or intervention is documented on an inspection report, the expectation is that actions taken to correct the violation will also be documented in the establishment file. For the purposes of self-assessment, follow-up actions have been divided into three types.

- On-site corrective action that occurs at the time of a routinely scheduled inspection,
- Follow-up action that occurs after the routine inspection, such as re-inspections, training, risk control plans, and informal conferences, and
- Enforcement activities such as fines, permit suspension, hearings, mandated training, restriction of operations, embargo, etc.

The measure of success for a compliance and enforcement program under Standard 6 is based on a review of randomly selected establishment files to determine whether documented violations have been resolved satisfactorily in the establishment.

In order to track documented violations through the compliance and enforcement process for a period of time long enough to determine resolution, a fixed point in time must be chosen as the starting point. It is expected that follow-up or subsequent inspections of that facility should show correction of the violations documented at the starting point. The Standard 6 measure uses a concept called the 'start-point inspection.'

The 'start-point inspection' will be the third oldest routine inspection in the establishment's file if it shows a violation of one of the risk factors or *Food Code* interventions. If no risk factor or *Food Code* intervention violation is shown on that inspection, then the fourth oldest routine inspection may be used if it shows a risk factor or *Food Code* intervention violation. The third oldest routine inspection is determined by starting from the most recent routine inspection in the establishment's file and working backward chronologically. The fourth oldest routine inspection would be the one prior to the third oldest. If no violation of a risk factor or *Food Code* intervention is documented on the third or fourth oldest routine inspection, then no 'start-point inspection' exists for that establishment.

A sampling of files will be reviewed for compliance and enforcement performance based on the 'start-point inspection' concept. The following section provides instructions for the proper construction of a list of sample files and a required alternate list of sample files.

SELECTING THE SAMPLE

The method used to select the sample is to be uniformly applied and must provide a sample that is representative of the total number of retail food establishments in the community. A method of simple random sampling can be used on the principle that all retail food establishments in the inventory are equally exposed to selection.

Jurisdictions with less than 400 total establishments will select at least 20 files for review. Jurisdictions with over 400 establishments will select a sample equal to 5% of the total establishments up to a maximum of 70 files. This initial selection of sample files will be the initial sample and will be the first files reviewed. Sample selection using a table of random numbers or a random number generator is the preferred method of sample selection and can be used with a card file, ledger, list, or automated data system. However, two alternative sample selection techniques acceptable for retail food program self-assessments are presented here.

1. Method 1. The first alternative technique to the use of a random number generator requires that each establishment be identified by a card or strip of paper having the establishment's name and address, permit number, file number, or other means of positive identification. These identifying cards or slips of paper are thoroughly mixed and the establishment files to be reviewed are drawn one at a time until the required number is obtained.

2. Method 2. The second alternative technique to the use of a random number generator utilizes a card file, ledger, list or data processing record system. When this procedure is used, all the establishments in the program must be subject to sampling. The frequency interval may be determined by dividing the total number of retail food establishments by the number of files needed in the sample. (For example, if there are 800 establishments within the jurisdiction, a sample of 40 would be needed (5% of 80). The frequency interval would be 800 divided by 40, or 20. Thus every 20th establishment shall be selected to make up the initial sample.) In order to maintain the desired random quality of the sample, the card file, ledger, list or data processing record system should be entered or listed in a random fashion. To establish a starting point when using a frequency interval of 20, write numbers 1 – 20, inclusive, on separate strips of paper and draw one slip at random. The number appearing on that strip of paper represents the first establishment to be drawn. If a ledger or list is being used for sampling and the number drawn is 7, then the seventh entry in the ledger or list would be the first establishment in the sample. The second establishment would be the 27th entry, the third would be the 47th entry and so forth, until the sample of 40 is drawn.

ALTERNATE SAMPLE LIST

Deletion of an establishment from the sample of files to be reviewed will be limited to those establishments which have not been in business long enough to have at least three regularly scheduled inspections or those files where no risk factor or *Food Code* intervention violation is documented on the 'start-point inspection.'

When an establishment file is eliminated from the initial random draw, a new establishment file will be drawn from a pre-determined alternate sample list. Alternate files will be drawn in the same manner as the original sample and at the same time as the original sample selection. It is suggested that the number of alternate files selected be at least 30 percent of the original sample size. If a large number of files selected in the initial draw do not have risk factor or *Food Code* intervention violations on the 'start-point inspection,' then a larger alternate sample will be needed.

The sample list of alternate files shall be kept separate from the original sample list. When an original selected file cannot be rated because it has not been in business long enough to have received at least three routine inspections or because it has no risk factor/intervention violation on the start-point inspection, a substitute file from the pre-selected alternate list will be reviewed. Substitute files from the alternate list will be chosen in the order in which the files were drawn.

If a random number generator or a table of random numbers is used for the initial sample selection, then this same method should be used to select the appropriate number of files for the alternate sample list. Again, this is the easiest and preferred method of sample selection.

If method 1 is used for the random selection, the alternate sample files will be the last files drawn. For example, if the sample size required is 20, then 26 files will be selected, and the last 6 files drawn will be designated as alternative files.

If method 2 is used for the random selection, a separate drawing of the alternate files will be made using an interval determined as follows: the number of establishments in the inventory, minus the number of files drawn for the original sample, divided by the number of alternate files needed. Using our example from method 2 above:

$$800 \text{ (inventory)} - 40 \text{ (files drawn in the original sample)} / 12 \text{ (30\% of the original sample)} = 63$$

To establish a starting point for the new interval of 63, write the numbers 1 – 63 inclusively on separate slips of paper and draw one at random. The number drawn will be the first file selected for the alternate sample and every 63rd file afterward until 12 files are drawn.

REVIEWING AND RATING THE FILES

Step 1. Identify the items on the local inspection report that correspond to each of the risk factors and interventions on the worksheet. Record the local item numbers on the “reference key” line of the worksheet. If there is no corresponding local requirement for a particular *FDA Code* risk factor or intervention, record “NA” for not applicable. You may find the Standard No. 1, Appendix A Worksheets, helpful in making this comparison. Note that the program is not penalized under Standard No. 6 for sections of the *Food Code* that have not been adopted.

Step 2. Open the first establishment inspection file that was randomly selected in Step 1 above. Identify the third oldest routine inspection report in the file, starting at the current date and working back chronologically. This inspection will be the “start-point inspection” for the review of this file. Using the reference key line on the worksheet, determine which risk factors and interventions were out of compliance at the time of this ‘start-point inspection.’ Place a check under each item that is out of compliance on the horizontal status line. If there is no risk factor/intervention that was out of compliance on the third oldest inspection in the file, you may move to the fourth oldest inspection in the file and use it for the ‘start-point inspection’ if it contains a risk factor/intervention that was out of compliance. If there is no risk factor/intervention that was out of compliance on the third or fourth oldest inspection, eliminate this file from the review and select a substitute file from the alternate list. ***[NOTE: Be sure to indicate the date of the start-point inspection on the Appendix F worksheet for each reviewed file. This will aid the reviewer during a validation audit.]***

Step 3. Review all of the documentation in the establishment file from the start-point inspection forward to the current date and determine whether follow-up action was taken and documented for each of the out-of-compliance risk factors and interventions that were out of compliance on the start-point inspection. Determine whether there was at least one type of follow-up activity for each item that was marked out of compliance. Place “Yes” in the appropriate line and column to indicate that follow-up action was documented in the establishment file. Make a notation below each “Yes” to indicate the type of action taken such as “RH” for Reheat, “WL” for warning letter or “RCP” for risk control plan. If there is no documentation in the establishment file to indicate that follow-up action was taken for each

specific risk factor or intervention that was out of compliance, the presumption is that follow up did not occur. Indicate by “yes” or “no” in the last column whether follow-up actions complied with the jurisdiction's written step-by-step procedure for compliance and enforcement.

In order for an individual establishment file to pass, each column marked with a violation at the start-point inspection must have a subsequent “yes” answer to indicate that at least one type of follow-up action was taken. Actions must have complied with the jurisdiction's written step-by-step procedure for compliance and enforcement. A single start-point violation without a final resolution, either correction or a compliance/enforcement activity causes the file to fail. Circle the appropriate “pass” or “fail” notation at the bottom of the work sheet.

Repeat Steps 2 and 3 with each of the randomly selected establishment files. When all of the files have been reviewed, total the number of files that passed and divide by the total number of files that met the sample selection criteria that were reviewed. To meet Standard No. 6, eighty percent (80%) of the files must pass.

See the example following and blank Worksheet.

DRAFT Voluntary National Retail Food Regulatory Program Standards –December 2007

EXAMPLE:

Sample Work Sheet -Compliance and Enforcement

File No: 1

Risk Factors and Food Code Interventions											
Establishment Name Seafood Palace	Unsafe Source	Inadequate Cooking	Improper holding Temperatures Hot & Cold	Time/Temperature Parameters not met. (Time as a control, date marking, rapid cooling)	Bare hand contact with ready-to-eat PHF	Poor Personal Hygiene	Contaminated Food Contact Surfaces & Equipment	Consumer Advisory (when required)	Demonstration of Knowledge by PIC	Employee Health Control system or policy implemented.	Was the Written Procedure Followed?
Permit Number 339											
Inspection Date (start point) 3 May 2000											
Reference Key to local inspection items	1	2,34,5	6,7	8,11	13	14	15	NA	NA	16	Circle One
Start Point Inspection Violations		X		X	X	X					YES or NO
Was on site corrective action taken ?		Yes RH		YES EM	Yes Glove						
Was follow up corrective action taken?				Yes RCP		Yes TR					
Was enforcement action taken?		Yes WL									
Each column in which a violation is noted must receive a yes response to one of the three questions in order for the file to pass. Additionally, written procedures must have been followed.											Circle One <u>PASS/FAIL</u>

In this example, the file passes because each of the violations noted on the start point inspection, dated 3 May 2000, has documented follow-up action in the file. The "NA" under Consumer Advisory indicates that the jurisdiction does not have a requirement for this intervention. The "yes" in the last column indicates that the compliance and enforcement procedure of the jurisdiction was followed.

*Define the acronyms and notations used to reflect follow-up action. **RH**= Reheat to safe temperature, **RCP**= risk control plan successfully completed, **WL**= warning letter sent, **EM** =embargo, **TR** = training required

Work Sheet - Compliance and Enforcement

File No. _____

Risk Factors and Food Code Interventions											
Establishment Name	Unsafe Source	Inadequate Cooking	Improper holding Temperatures Hot & Cold	Time/Temperature Parameters not met. (Time as a control, date marking, rapid cooling)	Bare hand contact with ready-to-eat PHF	Poor Personal Hygiene	Contaminated Food Contact Surfaces & Equipment	Consumer Advisory (when required)	Demonstration of Knowledge by PIC	Employee Health Control system or policy implemented.	Was the Written Procedure Followed?
Permit Number											
Inspection Date (Start Point)											
Reference Key to local inspection items											CIRCLE ONE
Start Point Inspection Violations											YES
Was on-site corrective action taken?											or
Was follow up corrective action taken?											NO
Was enforcement action taken?											
Each column in which a violation is noted must receive a yes response to one of the three questions in order for the file to pass. Additionally, written procedures must have been followed.											Circle One PASS/FAIL

*Define the acronyms and notations used to reflect follow up action.

Appendix G - Supplement to Standard No. 7 - Industry and Community Relations

It is necessary to maintain records of the Industry and Consumer Interaction forums and of the Educational Outreach activities over the last 24-month period. The following chart is used to document that status. Meeting minutes, agendas, by-laws, charters, membership criteria and lists, frequency of meetings, roles, performed actions and documentation of food safety educational efforts are to be maintained by the regulatory authority.

Industry and Consumer Interaction Forums

Forum Title	Regulatory Participants By Organization	Industry Participants by Organization	Consumer Participants by Organization	Meeting Dates	Summary of Activities Related to Control of Risk Factors

Educational Outreach

Dates	Summary of Activities

OTHER OUTREACH ACTIVITIES

Please list any additional outreach activities of note below.

Dates	Summary of Activities

Appendix H - Supplement to Standard No. 8- Program Support and Resources

Program Support and Resources Worksheet

Do you have sufficient funds, staff, equipment, and resources necessary to meet the following Standards? Answer 'yes' or 'no' in each block. A 'no' answer requires an explanation. Use additional pages as needed. Disclosure and analysis only is required for Standards 1 through 7 and 9. Standard 8 requires a positive response to the three identified items. ****The row at the bottom for "other shared resources" provides a place for you to identify needs that may not be easily attached to a specific Standard (i.e. copy machines, data lines, etc.)

Standard #	Funding	Staffing	Equipment	Other resources needed
1				
2				
3				
4				
5				
6				
7				
8		*	**	***
9				
****Other shared resources				

Do you meet the full-time equivalent (FTE) staff to inspection ratio as required in Standard 8? **Do your inspectors have the equipment provided and available as required in Standard 8? *Does your department have the equipment and supplies necessary to maintain the records and reports system that supports the program as required in Standard 8?*

The requirements of Standard 8 are met. _____ Yes _____ No

Signature: _____ Title: _____ Date: _____

DEPARTMENT OF HEALTH AND HUMAN SERVICES FOOD AND DRUG ADMINISTRATION FDA National Registry Report	FORM APPROVED: OMB NUMBER: EXPIRATION DATE:
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Jurisdiction Reporting	Address	City	State	Zip
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To: FDA Regional Retail Food Specialist	Date
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Enrollment Only: <input type="checkbox"/>	Self Assessment: <input type="checkbox"/>	Verification Audit: <input type="checkbox"/>	Baseline Survey: <input type="checkbox"/>
Standard #	Standard Met (✓ all that apply & add the date met)	Verification Audit Confirmed	Original: <input type="checkbox"/> Update: <input type="checkbox"/>
	Date: (required)	Date: (required)	Date:
1.	<input type="checkbox"/>	<input type="checkbox"/>	Date:
2.	<input type="checkbox"/>	<input type="checkbox"/>	
3.	<input type="checkbox"/>	<input type="checkbox"/>	
4.	<input type="checkbox"/>	<input type="checkbox"/>	
5.	<input type="checkbox"/>	<input type="checkbox"/>	
6.	<input type="checkbox"/>	<input type="checkbox"/>	Survey Audit Confirmed: <input type="checkbox"/>
7.	<input type="checkbox"/>	<input type="checkbox"/>	Date:
8.	<input type="checkbox"/>	<input type="checkbox"/>	
9.	<input type="checkbox"/>	<input type="checkbox"/>	
Risk Reduction Confirmed			Yes: <input type="checkbox"/> No: <input type="checkbox"/>

Self Assessment Completed by:			
Name (printed)	Signature	Title	Agency

Verification Audit Completed by:			
Name (printed)	Signature	Title	Agency

Baseline Survey Completed by:			
Name (printed)	Signature	Title	Agency

Baseline Survey-Update Completed by:			
Name (printed)	Signature	Title	Agency

Action Plan Completed by:			
Name	Signature	Title	Agency

Public reporting burden for this collection of information is estimated to average 92 hours per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to: Food and Drug Administration, Office of Food Safety, Retail Food and Cooperative Programs Coordination Staff (HFS – 320), CFSAN, 5100 Paint Branch Parkway, College Park, Maryland 20740. An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number.

Signed Affidavit of Permission to Publish in National Registry transmitted with this report? Yes: <input type="checkbox"/> No: <input type="checkbox"/>

Program Manager Name: (print)	Signature of Program Manager:	Date
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RELEASE RECORD AND AGREEMENT - PERMISSION TO PUBLISH IN NATIONAL REGISTRY

I, the undersigned, am enrolling _____ as participant in the Draft Voluntary National Retail Food Regulatory Program Standards.

I, the undersigned, confirm, that a *Self-Assessment* of the _____ Retail Food Program, has been completed in accordance with the *U.S. Food and Drug Administration (FDA) Draft Voluntary National Retail Food Regulatory Program Standards* on _____ (date).

I, the undersigned, confirm that _____ (Name of Jurisdiction) has completed a baseline survey on the occurrence of foodborne illness risk factors.

I, the undersigned, confirm, that I have:

- Requested _____ (Auditor) perform a *Verification Audit* of the above-named Retail Food Program *Self-assessment*.
- Reviewed and agree with the findings of the *Verification Audit* report dated _____.
- Requested that the *Auditor* forward the *Verification Audit* report, dated _____, to the FDA.

On behalf of the state or local regulatory agency, permission is hereby granted to publish the following in the FDA National Registry of Retail Food Protection Programs via the Internet:

- Enrollment information
- Self-assessment findings
- Baseline survey completion date and trend, if applicable
- Verification audit findings

Public reporting burden for this collection of information is estimated to average less than 1 hour per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to: Food and Drug Administration, Food and Drug Administration, Office of Food Safety, Retail Food and Cooperative Programs Coordination Staff (HFS – 320), CFSSAN, 5100 Paint Branch Parkway, College Park, Maryland 20740. An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number.

Signed: _____ Title: _____

Jurisdiction: _____ Date: _____

**Appendix J - Supplement to Standard No. 9 – Program Assessment
Retail Food Program Database of Foodborne Illness Risk Factors
Baseline Data Collection Form**

Date: _____
 Time In: _____ Time Out: _____ Inspector: _____
 Data Collected During: _____
 Establishment: _____ Manager: _____
 Physical Address: _____
 City: _____ Industry Segment: _____
 State: _____ Zip: _____ County: _____ Facility Type: _____

Certified Food Protection Manager: **YES NO**

_____ 41°F (5°C) or _____ 45°F (7°C) or _____ 41°F (5°C) + 45°F (7°C) is the cold holding requirement for this jurisdiction.

STATUS OF OBSERVATIONS:

- IN** = Item found in compliance (**IN** Compliance marking must be based on actual observations)
- OUT** = Item found out of compliance (**OUT** of Compliance marking must be based on actual observations)
- NO** = Not observable (**NO** marking is made when the data item is part of the establishment's operation or procedures, OR is seasonal and is not occurring at the time of the inspection)
- NA** = Not applicable (**NA** marking is made when the data item is NOT part of the establishment's operation or procedures)

CDC RISK FACTORS

****CDC RISK FACTOR - FOODS FROM UNSAFE SOURCE****

FOOD SOURCE

STATUS 1. Approved Source

- IN OUT** A. All food from Regulated Food Processing Plants/ No home prepared/canned foods
- IN OUT NA** B. All Shellfish from NSSP listed sources. No recreationally caught shellfish received or sold
- IN OUT NA NO** C. Game, wild mushrooms harvested with approval of Regulatory Authority

STATUS 2. Receiving / Sound Condition

- IN OUT** A. Food received at proper temperatures/ protected from contamination during transportation and receiving/food is safe, unadulterated

- IN OUT NA NO** A. Shellstock tags/labels retained for 90 days from the date the container is emptied
IN OUT NA NO B. As required, written documentation of parasite destruction maintained for 90 days for Fish products
IN OUT NA C. CCP monitoring records maintained in accordance with HACCP plan when required
-
-
-

****CDC RISK FACTOR-INADEQUATE COOK****

PATHOGEN DESTRUCTION

STATUS 4. Proper Cooking Temperature Per Potentially Hazardous Food (PHF)

(NOTE: Cooking temperatures must be taken to make a determination of compliance or non-compliance. Do not rely upon discussions with managers or cooks to make a determination of compliance or non-compliance. If one food item is found out of temperature, that PHF category must be marked as OUT of compliance.)

- IN OUT NA NO** A. Raw shell eggs broken for immediate service cooked to 145°F (63°C) for 15 seconds. Raw shell eggs broken but not prepared for immediate service cooked to 155°F (68°C) for 15 seconds
IN OUT NA NO B. Comminuted Fish, Meats, Game animals cooked to 155°F (68°C) for 15 seconds
IN OUT NA NO C. Roasts, including formed roasts, are cooked to 130°F (54°C) for 112 minutes or as Chart specified and according to oven parameters per Chart ***(NOTE: This data item includes beef roasts, corned beef roasts, pork roasts, and cured pork roasts such as ham).***
IN OUT NA NO D. Poultry; stuffed fish, stuffed meat, stuffed pasta, stuffed poultry, stuffed ratites, or stuffing containing fish, meat, poultry or ratites cooked to 165°F (74°C) for 15 seconds
IN OUT NA NO E. Wild game animals cooked to 165°F (74°C) for 15 seconds
IN OUT NA NO F. Raw animal foods cooked in microwave are rotated, stirred, covered, and heated to 165°F (74°C). Food is allowed to stand covered for 2 minutes after cooking
IN OUT NA NO G. Pork, ratites, injected meats are cooked to 155°F (68°C) for 15 seconds. Specify product and temperature in the space below. ***(NOTE: Pork observed cooked between 145° F (63°C) and 155°F (68°C), would be marked OUT here, but marked IN under Supplemental Item 17 A. Please make notes in the comment section.)***
IN OUT NA NO H. All other PHF cooked to 145°F (63°C) for 15 seconds
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STATUS 5. Rapid Reheating For Hot Holding

- IN OUT NA NO** A. PHF that is cooked and cooled on premises is rapidly reheated to 165°F (74°C) for 15 seconds for hot holding
- IN OUT NA NO** B. Food reheated in a microwave is heated to 165°F (74°C) or higher
- IN OUT NA NO** C. Commercially processed ready to eat food, reheated to 140°F (60°C.) or above **for hot holding**
- IN OUT NA NO** D. Remaining unsliced portions of roasts are reheated for hot holding using minimum oven parameters
-
-
-

****CDC RISK FACTOR - IMPROPER HOLD****

LIMITATION OF GROWTH OF ORGANISMS OF PUBLIC HEALTH CONCERN

STATUS 6. Proper Cooling Procedure

(NOTE: Record any temperature above 41°F (5°C) on blank lines. Production documents as well as statements from managers, person- in-charge (PIC), and employees, regarding the time the cooling process was initiated, may be used to supplement actual observations.)

- IN OUT NA NO** A. Cooked PHF is cooled from 140°F (60°C) to 70°F (21°C) within 2 hours **and** from 140°F (60°C) to 41°F (5°C) or below within 6 hours
- IN OUT NA NO** B. PHF (prepared from ingredients at ambient temperature) is cooled to 41°F (5°C) or below within 4 hours
- IN OUT NA NO** C. Foods received at a temperature according to Law are cooled to 41°F (5°C) within 4 hours
-
-
-

STATUS 7. Cold Hold (41°F (5°C))

*(NOTE: For the purposes of this Baseline, 41° F (5°C) or below will be used as the criteria for assessing all PHF that are maintained/held cold.) If one product is found out of temperature the item is marked **OUT** of compliance.)*

- IN OUT** A. PHF is maintained at 41°F (5°C) or below, except during preparation, cooking, cooling or when time is used as a public health control. **(Record products and temperatures in the space below.)**
-
-
-

STATUS 8. Hot Hold (140° F (60°C))

IN OUT NA NO A. PHF is maintained at 140°F (60°C) or above, except during preparation, cooking, or cooling or when time is used as a public health control. **(NOTE: Products held between 135°F (57°C) and 140°F (60°C) should be marked OUT in 8A, but IN under supplemental item number 18A. Record actual product and measured temperatures in the space below.)**

IN OUT NA NO B. Roasts are held at a temperature of 130°F (54°C) or above

STATUS 9. Time

IN OUT NA NO A. Ready-to-eat PHF held for more than 24 hours is date marked as required (prepared on-site)

IN OUT NA NO B. Discard RTE PHF and/or opened commercial container exceeding 7 days at ≤ 41°F (5°C) or 4 days at ≤ 45°F (7°C)

IN OUT NA NO C. Opened Commercial container of prepared ready-to-eat PHF is date marked as required

IN OUT NA NO D. When time only is used as a public health control, food is cooked and served within 4 hours as required

****CDC RISK FACTOR-CONTAMINATED EQUIPMENT****

PROTECTION FROM CONTAMINATION

STATUS 10. Separation / Segregation / Protection

IN OUT NA NO A. Food is protected from cross contamination by separating raw animal foods from raw ready-to-eat food and by separating raw animal foods from cooked ready-to-eat food

IN OUT NA NO B. Raw animal foods are separated from each other during storage, preparation, holding, and display

IN OUT C. Food is protected from environmental contamination – critical items

IN OUT NA NO D. After being served or sold to a consumer, food is not re-served

STATUS 11. Food-Contact Surfaces

(NOTE: This item will require some judgment to be used when marking this item IN or OUT of compliance. This item should be marked OUT of compliance if observations are made that supports a pattern of non-compliance with this item. One dirty utensil, food contact surface or one sanitizer container without sanitizer would not necessarily support an OUT of compliance mark. You must provide notes concerning an OUT of compliance mark on this item.)

IN OUT A. Food-contact surfaces and utensils are clean to sight and touch and sanitized before use

****CDC RISK FACTOR-POOR PERSONAL HYGIENE****

PERSONNEL

STATUS 12. Proper, Adequate Handwashing

IN OUT NO A. Hands are clean and properly washed when and as required

STATUS 13. Good Hygienic Practices

IN OUT NO A. Food Employees eat, drink, and use tobacco only in designated areas / do not use a utensil more than once to taste food that is sold or served / do not handle or care for animals present. Food employees experiencing persistent sneezing, coughing, or runny nose do not work with exposed food, clean equipment, utensils, linens, unwrapped single-service or single-use articles

STATUS 14. Prevention of Contamination From Hands

IN OUT NA NO A. Employees do not contact exposed, ready-to-eat food with their bare hands. *(NOTE: In determining the status of this data item, an assessment of alternative methods when otherwise approved is to be made to determine implementation in accordance with the guidelines contained in Annex 3, 2001 Food Code, page 289.)*

STATUS 15. Handwash Facilities

- IN OUT** A. Handwash facilities conveniently located and accessible for employees
IN OUT B. Handwash facilities supplied with hand cleanser / sanitary towels / hand drying devices
-
-
-

****CDC RISK FACTOR - OTHER****

FOREIGN SUBSTANCES

STATUS 16. Chemicals

- IN OUT NA** A. If used, only approved food or color additives. Sulfites are not applied to fresh fruits and vegetables intended for raw consumption
IN OUT B. Poisonous or toxic materials, chemicals, lubricants, pesticides, medicines, first aid supplies, and other personal care items are properly identified, stored and used
IN OUT NA C. Poisonous or toxic materials held for retail sale are properly stored
-
-
-

SUPPLEMENTAL ITEMS

(NOTE: The following items will be included as part of FDA’s 2003 Baseline. These are additional items to the original 42 data items (contained in Section 1 – 16) that were assessed as part of the original baseline.)

STATUS 17. Proper Cooking Temperature (Supplement to Item 4G)

- IN OUT NA NO** A. Pork is cooked to 145°F (63°C) or above for 15 seconds. **(NOTE: Final cooking temperatures of Pork Roasts are recorded under data item 4C.)**
IN OUT NA NO B. Ratites and injected meats are cooked to 155°F (68°C) for 15 seconds
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-
-

STATUS 18. Hot Hold (135°F (57°C)) – (Supplement to Item 8A)

- IN OUT NA NO** A. PHF is maintained at 135°F (57° C) or above, except during preparation, cooking, or Cooling or when time is used as a public health control. **(NOTE: Products held between 135°F (57°C) and 140°F (60°C) should be marked OUT in 8A. Record actual product and measured temperatures.)**
-
-
-

STATUS 19. Employee Health Policy

IN OUT A. Facility has a **written policy** that is consistent with 2-201 of the Food Code for excluding and restricting employees on the basis of their health and activities as they relate to diseases that are transmissible through food. **Written policy** includes a statement regarding employee responsibility to notify management of symptoms and illnesses identified in the Food Code

STATUS 20. Treating Juice

IN OUT NA NO A. When packaged in a food establishment, juice is treated under a HACCP Plan to reduce pathogens or be labeled as specified in the Food Code

STATUS 21. Cooling – Raw Shell Eggs

IN OUT NA NO A. After receiving, raw shell eggs are immediately placed under refrigeration that maintains ambient air temperature of 45°F (7°C) or less

STATUS 22. Cold Holding – Raw Shell Eggs

IN OUT NA NO A. After receipt, raw shell eggs are stored in refrigerated equipment that maintains ambient air temperature of 45°F (7°C) or less

STATUS 23. Food & food preparation for highly susceptible populations

(NOTE: These items pertain specifically to those facilities that serve Highly Susceptible Populations as defined in the Food Code. Establishments would include such facility types as Hospitals, Nursing Homes and Elementary Schools.)

IN OUT NA NO A. Prepackaged juice/beverage containing juice with a warning label (21 CFR, Section 101.17(g)) not served

IN OUT NA NO B. Pasteurized eggs or egg products substituted for raw shell eggs in preparation of foods that are not cooked to minimum required temperatures, (specified in Section 4.0 of this Baseline Form), unless cooked to order & immediately served; broken immediately before baking and thoroughly cooked; or included as an ingredient for a recipe supported by a HACCP plan that controls Salmonella Enteritidis

IN OUT NA NO C. Raw or partially cooked animal food and raw seed sprouts not served

SHEET-MARKING INSTRUCTIONS
Retail Food Program Database of Foodborne Illness Risk Factors
Data Collection Form

Date: _____
Time In: _____ Time Out: _____ Inspector: _____
Data Collected During: _____
Establishment: _____ Manager: _____
Physical Address: _____
City _____ Industry Segment: _____
State: _____ Zip: _____ County: _____ Facility Type: _____

Certified Food Protection Manager: **YES** **NO**

YES marking indicates that there is a food protection manager present at the time of inspection who has been certified through a CFP recognized program.

NO marking indicates that there are **NO** certified food protection managers in the establishment at the time of inspection **OR** certification has been obtained through a program **NOT** recognized by the Conference for Food Protection.

_____ 41°F (5°C) or _____ 45°F (7°C) or _____ 41°F (5°C) + 45°F (7°C) is the cold holding requirement for this jurisdiction.

STATUS OF OBSERVATIONS:

- IN** = Item found in compliance (**IN** Compliance marking must be based on actual observations)
- OUT** = Item found out of compliance (**OUT** of Compliance marking must be based on actual observations)
- NO** = Not observable (**NO** marking is made when the data item is part of the establishment's operation or procedures, **OR** is seasonal and is not occurring at the time of the inspection)
- NA** = Not applicable (**NA** marking is made when the data item is **NOT** part of the establishment's operation or procedures)

CDC RISK FACTORS

CDC RISK FACTOR - FOODS FROM UNSAFE SOURCE

FOOD SOURCE

STATUS **1. Approved Source**

_____ **A. All food from Regulated Food Processing Plants/ No home prepared/canned foods**

IN / OUT This item should be marked either IN or OUT. If it is marked OUT of compliance make notes as to why it is OUT of compliance.

_____ **B. All Shellfish from NSSP listed sources. No recreationally caught shellfish received or sold**

IN / OUT This item may be marked either **IN** or **OUT**. If it is marked **OUT** of compliance make notes as to why it is **OUT** of compliance.

NA This item is marked **NA** if no shellfish are sold at the establishment.

_____ **C. Game, wild mushrooms harvested with approval of Regulatory Authority**

IN / OUT This item may be marked either **IN** or **OUT**. If it is marked **OUT** of compliance make notes as to why it is **OUT** of compliance.

NA This item is marked **NA** if no game or wild mushrooms are sold at the establishment.

NO This item is marked **NO** if no game or wild mushrooms are in the facility at the time. Mark **NO** if game/ wild mushrooms are a seasonal or an occasional menu item but are not being used at the time of inspection.

STATUS **2. Receiving / Sound Condition**

_____ **A. Food received at proper temperatures/ protected from contamination during transportation and receiving/food is safe, unadulterated.**

IN / OUT This item may be marked **IN** or **OUT** of compliance on any one of the listed items. If the food is safe and unadulterated, but you are not able to check any temperatures of food during receiving or are not able to determine the condition of foods transported, mark the item **IN** compliance with an explanation on the lines below as to what the **IN** represents. If one or all the listed items are **OUT** of compliance, make appropriate notes as to why the item is marked out of compliance.

STATUS **3. Records**

_____ **A. Shellstock tags/labels retained for 90 days from the date the container is emptied.**

IN / OUT This item may be marked **IN** or **OUT** of compliance with notes made concerning the reason it is marked **OUT** of compliance.

NA This item is marked **NA** if shell stock is not used in the establishment.

NO This item is marked **NO** when shellstock is a seasonal or occasional item and has not been sold or used within the establishment within the past 90 days or you were unable to determine from invoices or purchases records whether shellstock was used or sold within the past 90 days.

- _____ **B. As required, written documentation of parasite destruction maintained for 90 days for fish products.**
- IN / OUT** This item may be marked **IN** or **OUT** of compliance with notes made concerning the reason if it is marked **OUT** of compliance.
- NA** This item is marked **NA** if these types of fish products are not used in the establishment.
- NO** This item may be marked **NO** if fish products of this type are a seasonal or occasional item and no fish products of this type are in the facility during visit and you are unable to determine compliance through purchase records, on-site documentation or invoices.

- _____ **C. CCP monitoring records maintained in accordance with HACCP plan when required.**
- IN / OUT** This item may be marked **IN** or **OUT** of compliance with notes made concerning the reason if it is marked **OUT** of compliance.
- NA** This item is marked **NA** if these types of records are not required for the operation of the establishment.

****CDC RISK FACTOR – INADEQUATE COOK****

PATHOGEN DESTRUCTION

- STATUS** **4. Proper Cooking Temperature Per Potentially Hazardous Food (PHF)**
- (NOTE: Cooking temperatures must be taken to make a determination of compliance or non-compliance. Do not rely upon discussions with managers or cooks to make a determination of compliance or non-compliance. If one food item is found out of temperature, that PHF category must be marked as OUT of compliance.)*
- _____ **A. Raw shell eggs broken for immediate service cooked to 145°F (63°C) for 15 seconds. Raw shell eggs broken but not prepared for immediate service cooked to 155°F (68°C) for 15 seconds.**
- IN / OUT** This item may be marked **IN** or **OUT** of compliance, with notes made concerning the reason if it is marked **OUT** of compliance.
- NA** This item is marked **NA** when raw shell eggs are not used in the establishment, including raw shell eggs not used in recipes.
- NO** This item is marked **NO** if raw shell eggs are used in the establishment, but you are unable to determine the cooking temperature.

B. Comminuted Fish, Meats, Game Animals (commercially raised) cooked to 155°F (68°C) for 15 seconds

IN / OUT This item may be marked **IN** or **OUT** of compliance for one or all of the types of meat, with notes made concerning the reason if it is marked **OUT** of compliance.

NA This item is marked **NA** if no comminuted meats are used in the establishment.

NO This item is marked **NO** if one or more types of meat are used, but you are unable to determine the cooking temperature for any of them.

C. Roasts, including formed roasts, are cooked to 130°F (54°C) for 112 minutes or as chart specified and according to oven parameters per chart. (NOTE: This data item includes beef roasts, corned beef roasts, pork roasts, and cured pork roasts such as ham).

IN / OUT This item may be marked **IN** or **OUT** of compliance for one or all of the types of meat, with notes made concerning the reason if it is marked **OUT** of compliance.

NA This item is marked **NA** when roasts or formed roasts are not cooked in the establishment

NO This item is marked **NO** if one or more of these meat items are used, but you are unable to determine the cooking temperature for any of them.

D. Poultry; stuffed fish, stuffed meat, stuffed pasta, stuffed poultry, stuffed ratites, or stuffing containing these items cooked to 165°F (74°C) for 15 seconds

IN / OUT This item may be marked **IN** or **OUT** of compliance for one or all of the types of stuffed items or stuffing containing these items with notes made concerning the reason it is **OUT** of compliance.

NA This item is marked **NA** if none of the types of stuffed items or stuffing containing these items are used in the establishment.

NO This item is marked **NO** if one or more of these food items are used, but you are unable to determine the cooking temperature for any of them.

E. Wild game animals cooked to 165°F (74°C) for 15 seconds

IN / OUT This item may be marked **IN** or **OUT** of compliance with notes made concerning the reason it is **OUT** of compliance.

NA This item is marked **NA** if no wild game animals are used in the establishment.

NO This item is marked **NO** if wild game animals are used, but you are unable to determine the cooking temperature for any of them.

F. Raw animal foods cooked in microwave are rotated, stirred, covered, and heated to 165°F (74° C). Food is allowed to stand covered for 2 minutes after cooking.

IN / OUT This item may be marked **IN** or **OUT** of compliance with notes made concerning the reason if it is marked **OUT** of compliance.

NA This item is marked **NA** if raw animal foods are not cooked in a microwave.

NO This item is marked **NO** if raw animal foods are cooked in a microwave but you are unable to determine the cooking temperatures during your inspection.

G. Pork, Ratites and injected meats are cooked to 155°F (68° C) for 15 seconds.

IN / OUT This item may be marked **IN** or **OUT** of compliance for one or all of the foods listed, with notes made concerning the reason it is marked **OUT** of compliance. *(NOTE: Pork observed cooked between 145°F (63°C) and 155°F (68°C) , would be marked **OUT** here, but marked **IN** under supplemental item number 17. Please Make notes in the comment section.)*

NA This item is marked **NA** if **NONE** of the listed foods are cooked in the establishment

NO This item is marked **NO** if one or more of the listed foods are cooked in the establishment, but you are unable to determine the cooking temperature during your visit.

H. All other PHF cooked to 145°F (63°C) for 15 seconds.

IN / OUT This item may be marked **IN** or **OUT** of compliance with notes made concerning the reason if it is marked **OUT** of compliance.

NA This item is marked **NA** if no other PHF foods are cooked in the establishment

NO This item is marked **NO** if one or more of the food types for this category are cooked in the establishment, but you are unable to determine the cooking temperature during your visit.

STATUS **5. Rapid Reheating For Hot Holding**

A. PHF that is cooked and cooled on premises is rapidly reheated to 165°F (74°C) for 15 seconds for hot holding

IN / OUT This item may be marked **IN** or **OUT** of compliance, with notes made concerning the reason if it is marked **OUT** of compliance.

NA This item is marked **NA** if foods are not held over for a second service.

NO This item is marked **NO** if foods are held over for a second service, but you are unable to check the reheating procedure. Do not depend solely on discussions with management or cooks to make a determination on this item.

- _____ **B. Food reheated in a microwave is heated to 165°F (74° C) or higher.**
- IN / OUT** This item may be marked **IN** or **OUT** of compliance, with notes made concerning the reason if it is marked **OUT** of compliance.
- NA** This item is marked **NA** if foods are not reheated in a microwave in the establishment.
- NO** This item is marked **NO** if foods are reheated in a microwave but you were unable to make a determination of compliance.

- _____ **C. Commercially processed ready to eat food reheated to 140°F (60°C) or above for hot holding.**
- IN / OUT** This item may be marked **IN** or **OUT** of compliance, with notes made concerning the reason if it is marked **OUT** of compliance.
- NA** This item is marked **NA** if commercially processed ready to eat foods are not reheated in the establishment.
- NO** This item is marked **NO** if commercially processed ready to eat foods are reheated in the establishment but you were unable to make a determination of compliance.

- _____ **D. Remaining unsliced portions of roasts are reheated for hot holding using minimum oven parameters.**
- IN / OUT** This item may be marked **IN** or **OUT** of compliance, with notes made concerning the reason if it is marked **OUT** of compliance.
- NA** This item is marked **NA** if remaining unsliced portions of beef roasts are not used or reheated in the establishment.
- NO** This item is marked **NO** if remaining unsliced portions of beef roasts are reheated in the establishment, but you were unable to make a determination of compliance.

****CDC RISK FACTOR - IMPROPER HOLD****

LIMITATION OF GROWTH OF ORGANISMS OF PUBLIC HEALTH CONCERN

(NOTE: Record any temp above 41 °F (5 °C) on blank lines. Production documents as well as statements from managers, person-in-charge (PIC), and employees regarding the time the cooling process was initiated may be used to supplement actual observations.)

STATUS 6. Proper Cooling Procedure

_____ **A. Cooked PHF is cooled from 140°F (60°C) to 70°F (21°C) within 2 hours and from 140° F (60°C) to 41°F (5°C) or below within 6 hours.**

IN / OUT This item may be marked **IN** or **OUT** of compliance, with notes made concerning the reason if it is marked **OUT** of compliance.

NA This item is marked **NA** if the establishment is a cook-serve establishment type or does not cool or reheat food.

NO This item is marked **NO** if the establishment does cool PHF for a second service, but you were unable to make a determination of compliance.

_____ **B. PHF is cooled to 41°F (5°C) or below within 4 hours (prepared from ingredients at ambient temperature)**

IN / OUT This item may be marked **IN** or **OUT** of compliance, with notes made concerning the reason if it is marked **OUT** of compliance.

NA This item is marked **NA** if the establishment has no PHF that are prepared from ingredients at ambient temperature.

NO This item is marked **NO** if these types of foods are prepared, but you were unable to make a determination of compliance.

_____ **C. Foods received at a temperature according to Law are cooled to 41°F (5°C) within 4 hours.**

IN / OUT This item may be marked **IN** or **OUT** of compliance, with notes made concerning the reason if it is marked **OUT** of compliance.

NA This item is marked **NA** if the establishment does not receive raw shell eggs, shellstock, milk or other products that have a transport temperature above 41°F (5°C).

NO This item is marked **NO** if the establishment does receive raw shell eggs, shellstock, milk or other products that have a transport temperature above 41°F (5°C), but you were unable to determine if these products were cooled down as described above.

STATUS 7. Cold Hold

*(NOTE: For the purposes of this Baseline, 41° F (5°C) or below will be used as the criteria for assessing all PHF that are maintained/held cold.) If one product is found out of temperature the item is marked **OUT** of compliance.)*

_____ **A. PHF is maintained at 41°F (5°C) or below, except during preparation, cooking, cooling or when time is used as a public health control.**

IN / OUT This item may be marked **IN** or **OUT** of compliance, with notes made concerning the reason if it is marked **OUT** of compliance.

STATUS 8. Hot Hold

*(NOTE: If one product is found out of temperature the item is marked **OUT** of compliance. Record all temperatures taken.)*

_____ **A. PHF is maintained at 140°F (60°C) or above, except during preparation, cooking, or cooling or when time is used as a public health control.**

*(NOTE: Products held between 135°F (57°C) and 140°F (60° C) should be marked **OUT** in 8.A. but **IN** under supplemental item number 18A. Record actual product and measured temperatures taken.)*

IN / OUT This item may be marked **IN** or **OUT** of compliance, with notes made concerning the reason if it is marked **OUT** of compliance.

NA This item is marked **NA** if there is no PHF hot holding in the establishment.

NO This item is marked **NO** only in rare instances when you are unable to determine compliance. Inspections should be conducted during a time when hot holding temperatures can be taken.

_____ **B. Roasts are held at a temperature of 130°F (54°C) or above**

IN / OUT This item may be marked **IN** or **OUT** of compliance with notes made concerning the reason if it is marked **OUT** of compliance.

NA This item is marked **NA** if roast is not a menu item.

NO This item is marked **NO** only when you are unable to determine compliance. Inspections should be conducted during a time when hot holding temperatures can be taken.

STATUS 9. Time

_____ **A. Ready-to- eat PHF held for more than 24 hours is date marked as required (prepared on site)**

IN / OUT This item may be marked **IN** or **OUT** of compliance, with notes made concerning the reason if it is marked **OUT** of compliance.

NA This item is marked **NA** if there are no RTE PHF held for more than 24 hours

NO This item is marked **NO** when RTE PHF are held for more than 24 hours and you are unable to determine compliance. Do not depend solely on information from managers or cooks.

_____ **B. Discard RTE PHF and/or opened commercial container exceeding 7 days at < 41°F (5°C) or 4 days at < 45°F (7°C).**

IN / OUT This item may be marked **IN** or **OUT** of compliance, with notes made concerning the reason if it is marked **OUT** of compliance.

NA This item is marked **NA**, such as when there is no RTE PHF prepared-on-premises, or opened commercial container held for more than 24 hours.

NO This item is marked **NO** if no date marking is done in the establishment and you are unable to determine compliance based on other information provided by PIC, manager or employees.

_____ **C. Opened commercial container of prepared ready-to-eat PHF is date marked as required.**

IN / OUT This item may be marked **IN** or **OUT** of compliance, with notes made concerning the reason if it is marked **OUT** of compliance.

NA This item is marked **NA** if there are no commercially prepared RTE PHF held.

NO This item is marked **NO** when commercially prepared RTE PHF are date marked and you are unable to determine compliance. Do not depend solely on information from managers or cooks.

_____ **D. When time only is used as a public health control, food is cooked and served within 4 hours as required.**

IN / OUT This item may be marked **IN** or **OUT** of compliance with notes made concerning the reason if it is marked **OUT** of compliance.

NA This item is marked **NA** if time is not used as a public health control.

NO This item is marked **NO** when time is used for a public health control and you are unable to determine compliance. Do not depend solely on information from managers or cooks.

****CDC RISK FACTOR-CONTAMINATED EQUIPMENT****

PROTECTION FROM CONTAMINATION

STATUS	10. Separation / Segregation / Protection
_____	<u>A. Food is protected from cross-contamination by separating raw animal foods from raw ready-to-eat food and by separating raw animal foods from cooked ready-to-eat food.</u>
IN / OUT	This item may be marked IN or OUT of compliance, with notes made concerning the reason if it is marked OUT of compliance.
NA	This item is marked NA , such as when there is a vegetarian menu or only commercially pre-cooked animal foods are used.
NO	This item is marked NO when raw animal foods are used or served seasonally and you are unable to determine compliance.
_____	<u>B. Raw animal foods are separated from each other during storage, preparation, holding, and display.</u>
IN / OUT	This item may be marked IN or OUT of compliance, with notes made concerning the reason if it is marked OUT of compliance.
NA	This item is marked NA when there are NO raw animal foods used or only one raw animal species is used
NO	This item is marked NO when raw animal foods are used or served seasonally and you are unable to determine compliance.
_____	<u>C. Food is protected from environmental contamination – critical items.</u>
IN / OUT	This item may be marked IN or OUT of compliance, with notes made concerning the reason if it is marked OUT of compliance.
_____	<u>D. After being served or sold to a consumer, food is not re-served.</u>
IN / OUT	This item may be marked IN or OUT of compliance, with notes made concerning the reason if it is marked OUT of compliance. <i>(NOTE: Actual observation of the disposition of unwrapped/unprotected, served food being returned to the kitchen must be made.)</i>
NA	This item may be marked NA for retail operations for which there is no opportunity for re-service of foods, such as carry-out service only in restaurants or meat, produce and seafood depts. within retail food stores.
NO	This item may be marked NO if you are not able to observe the disposition of unwrapped/unprotected foods after they have been served to the public and returned to the kitchen or food preparation area.

STATUS 11. Food Contact Surfaces

(NOTE: This item will require some judgment to be used when marking this item IN or OUT of compliance. This item should be marked OUT of compliance if observations are made that supports a pattern of non-compliance with this item. One dirty utensil, food contact surface or one sanitizer container without sanitizer would not necessarily support an OUT of compliance mark. You must provide notes concerning an OUT of compliance mark on this item.)

_____ **A. Food contact surfaces and utensils are clean to sight and touch and sanitized before use**

IN / OUT This item may be marked **IN** or **OUT** of compliance with notes made concerning the reason if it is marked **OUT** of compliance.

****CDC RISK FACTOR-POOR PERSONAL HYGIENE****

PERSONNEL

STATUS 12. Proper, Adequate Handwashing

(NOTE: Maximum effort must be made to observe all sections of PERSONNEL.)

_____ **A. Hands are clean and properly washed when and as required.**

IN / OUT This item may be marked **IN** or **OUT** of compliance, with notes made concerning the reason if it is marked **OUT** of compliance. This item must be marked **OUT** of compliance if one person is observed with dirty hands or hands that have not been properly washed as required.

NO This item may be marked **NO** for retail operations-only in the case where no food workers are present to observe, such as a retail food store produce section where the display aisle has been fully stocked prior to the inspection.

STATUS 13. Good Hygienic Practices

_____ **A. Food Employees eat, drink, and use tobacco only in designated areas / do not use a utensil more than once to taste food that is sold or served / do not handle or care for animals present. Food employees experiencing persistent sneezing, coughing, or runny nose do not work with exposed food, clean equipment, utensils, linens, unwrapped single-service or single-use articles**

IN / OUT This item may be marked **IN** or **OUT** of compliance, with notes made concerning the reason if it is marked **OUT** of compliance. This item must be marked **OUT** of compliance if one person is observed to be out of compliance with this item.

NO This item may be marked **NO** for retail operations only in the case where no food workers are present.

STATUS 14. Prevention of Contamination From Hands

_____ **A. Employees do not contact exposed, ready-to-eat food with their bare hands.**

IN / OUT This item may be marked **IN** or **OUT** of compliance, with notes made concerning the reason if it is marked **OUT** of compliance. This item must be marked **OUT** of compliance if one person is observed to be out of compliance with this item. *(NOTE: In determining the status of this data item, an assessment of alternative methods when otherwise approved is to be made to determine implementation in accordance with the guidelines contained in Annex 3, 2001 Food Code, page 289.)*

NA This item may be marked **NA** for facilities that do not prepare ready-to-eat foods, such as retail meat or seafood department.

NO This item may be marked **NO** for retail operations that prepare ready-to-eat foods only in the case where no food workers are present.

STATUS 15. Handwash Facilities

_____ **A. Handwash facilities conveniently located and accessible for employees.**

IN / OUT This item may be marked **IN** or **OUT** of compliance, with notes made concerning the reason if marked **OUT** of compliance.

_____ **B. Handwash facilities supplied with hand cleanser / sanitary towels / hand drying devices**

IN / OUT This item may be marked **IN** or **OUT** of compliance, with notes made concerning the reason if it is marked **OUT** of compliance.

****CDC RISK FACTOR - OTHER****

FOREIGN SUBSTANCES

STATUS 16. CHEMICAL

_____ **A. If used, only approved food or color additives. Sulfites are not applied to fresh fruits and vegetables intended for raw consumption.**

IN This item is marked **IN** compliance if no unapproved additives are on site; or if sulfites are on the premises, but they are used properly.

OUT This item is marked **OUT** of compliance if unapproved additives are found on premises or approved additives are improperly used, i.e. on fresh fruits & vegetables.

NA This item is marked **NA** if the food establishment does not use any additives.

_____ **B. Poisonous or toxic materials, chemicals, lubricants, pesticides, medicines, first aid supplies, and other personal care items properly identified, stored and used.**

IN / OUT This item may be marked **IN** or **OUT** of compliance, with notes made concerning the reason if marked **OUT** of compliance. It may be marked **OUT** of compliance for improper storage or use of any one of the listed items.

_____ **C. Poisonous or toxic materials held for retail sale are properly stored.**

IN / OUT This item may be marked **IN** or **OUT** of compliance, with notes made concerning the reason if it is marked **OUT** of compliance. It may be marked **OUT** of compliance for improper storage or use of any one of the items.

NA This item may be marked **NA** if the establishment does not hold 'poisonous or toxic materials for retail sale'.

SUPPLEMENTAL ITEMS

(NOTE: The following items will be included as part of FDA's 2003 Baseline. These are additional items to the original 42 data items (contained in Section 1 – 16) that were assessed as part of the original baseline.)

STATUS **17. Proper Cooking Temperature (Supplement to Item 4G)**

_____ **A. Pork is cooked to 145°F (63°C) or above for 15 seconds.** *(NOTE: Final cooking temperatures of Pork Roasts are recorded under data item 4C.)*

IN / OUT This item may be marked **IN** or **OUT** of compliance for pork, with notes made concerning the reason it is marked **OUT** of compliance. Please make note of actual temperature in the comment section.

NA This item may be marked **NA** if pork is not cooked in the establishment

NO This item may be marked **NO** if pork is cooked in the establishment, but you are unable to determine the cooking temperature during your visit.

_____ **B. Ratites and injected meats are cooked to 155°F (68°C) or above for 15 seconds.**

IN / OUT This item may be marked **IN** or **OUT** of compliance for ratites or injected meats, with notes made concerning the reason it is marked **OUT** of compliance. Make notes of actual temperatures in the comments section.

NA This item may be marked **NA** if no ratites or injected meats are prepared in the establishment.

NO This item may be marked **NO** if ratites or injected meats are cooked in the establishment, but you are unable to determine the cooking temperature during your visit.

STATUS **18. Hot Hold (135°F (57°C)) – (Supplement to Item 8A.)**

_____ **A. PHF is maintained at 135°F (57°C) or above, except during preparation, cooking, or cooling or when time is used as a public health control.**

(NOTE: Products held between 135°F (57°C) and 140°F (60°C) should be marked OUT in 8A. Record actual product and measured temperatures.)

IN / OUT This item may be marked **IN** or **OUT** of compliance, with notes made concerning the reason if it is marked **OUT** of compliance.

NA This item may only be marked **NA** if there is no PHF hot holding in the establishment.

NO This item should be marked **NO** only in rare instances, when you are unable to determine compliance. Inspections should be conducted during a time when hot holding temperatures can be taken.

STATUS **19. Employee Health Policy**

_____ **A. Facility has a written policy that is consistent with 2-201 of the Food Code for excluding and restricting employees on the basis of their health and activities as they relate to diseases that are transmissible through food. Written policy includes a statement regarding employee responsibility to notify management of symptoms and illnesses identified in the Food Code.**

IN / OUT This item must be marked **IN** or **OUT** of compliance, with notes made concerning the reason if it is marked **OUT** of compliance. *(NOTE: In order to mark this item IN the establishment must have a WRITTEN employee health policy.)*

STATUS **20. Treating Juice**

_____ **A. When packaged in a food establishment, juice is treated under a HACCP Plan to reduce pathogens or be labeled as specified in the Food Code.**

IN / OUT This item may be marked **IN** or **OUT** of compliance, with notes made concerning the reason it is marked **OUT** of compliance.

NA This item is marked **NA** when juice is not packaged in the food establishment.

STATUS **21. Cooling – Raw Shell Eggs**

_____ **A. After receiving, raw shell eggs are immediately placed under refrigeration that maintains ambient air temperature of 45°F (7°C) or less.**

IN / OUT This item may be marked **IN** or **OUT** only if you are there to observe receipt of raw shell eggs and their disposition.

NA This item is marked **NA** when the establishment does not receive raw shell eggs.

NO This item is marked **NO** only when raw shell eggs are received but you are not there to observe their actual receipt and immediate disposition OR raw shell eggs are only a seasonal item,

STATUS **22. Cold Holding – Raw Shell Eggs**

_____ **A. After receipt, raw shell eggs are stored in refrigerated equipment that maintains ambient air temperature of 45°F (7°C) or less.**

IN / OUT This item may be marked **IN** or **OUT** of compliance, with notes made concerning the reason it is marked **OUT** of compliance.

NA This item is marked **NA** when the establishment does NOT receive raw shell eggs.

NO This item is marked **NO** when raw shell eggs are received but there were no raw shell eggs on the premises at this time and you were unable to determine compliance. Additionally **NO** is marked when raw shell eggs are a seasonal or a limited use item within the establishment and none are on the premises at the time of your inspection.

STATUS **23. Food & Food Preparation for Highly Susceptible Populations**

(NOTE: These items pertain specifically to those facilities that serve Highly Susceptible Populations as defined in the Food Code. Establishments would include such facility types as Hospitals, Nursing Homes and Elementary Schools.)

_____ **A. Prepackaged juice/beverage containing juice with a warning label (21 CFR, Section 101.17(g)) not served.**

IN / OUT This item may be marked **IN** or **OUT** of compliance, with notes made concerning the reason if marked **OUT** of compliance.

NA This item is marked **NA** if no highly susceptible population is served or if the facility does not serve any juice.

NO This item is marked **NO** if juice is served to a highly susceptible population, but no juice or packages containing juice are present within the establishment to verify compliance.

B. Pasteurized eggs or egg products substituted for raw shell eggs in preparation of foods that are not cooked to minimum required temperatures. (specified in Section 4.0 of this Baseline Form), unless cooked to order & immediately served; broken immediately before baking and thoroughly cooked; or included as an ingredient for a recipe supported by a HACCP plan that controls Salmonella Enteritidis.

- IN / OUT** This item may be marked **IN** or **OUT** of compliance, with notes made concerning the reason if marked **OUT** of compliance.
- NA** This item is marked **NA** if no highly susceptible population is served or if eggs are not served
- NO** This item is marked **NO** if eggs are used in the preparation of foods in an establishment that serves a highly susceptible population and the preparation of eggs is not observed and no eggs or pasteurized egg /pasteurized egg products are in the establishment

C. Raw or partially cooked animal food and raw seed sprouts not served.

- IN / OUT** This item may be marked **IN** or **OUT** of compliance, with notes made concerning the reason if marked **OUT** of compliance.
- NA** This item is marked **NA** if raw or partially cooked animal food or raw seed sprouts are not prepared for service within an establishment that services a highly susceptible population.

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CDC Risk Factor FOODS FROM UNSAFE SOURCES Food Source	CDC Risk Factor INADEQUATE COOK Pathogen Destruction
<p>1. Approved Source</p> <p align="center"><u>Data Item - 1A</u></p> <p>3-201.11* Compliance with Food Law 3-201.12* Food in A Hermetically Sealed Container. 3-201.13* Fluid Milk and Milk Products</p> <p align="center"><u>Data Item – 1B</u></p> <p>3-201.14* Fish 3-201.15* Molluscan Shellfish 3-202.18* Shellstock Identification</p> <p align="center"><u>Data Item – 1C</u></p> <p>3-201.16* Wild Mushrooms 3-201.17* Game Animals</p>	<p>4. Proper Cooking Temperature per PHF</p> <p align="center"><u>Data Item – 4A</u></p> <p>3-401.11(A)(1)(a)* Raw Animal Foods 3-401.11(A)(2)* Raw Animal Foods</p> <p align="center"><u>Data Item – 4B</u></p> <p>3-401.11(A)(2)* Raw Animal Foods</p> <p align="center"><u>Data Item – 4C</u></p> <p>3-401.11(B)(1)(2)* Raw Animal Foods</p> <p align="center"><u>Data Item – 4D</u></p> <p>3-401.11(A)(3)* Raw Animal Foods</p> <p align="center"><u>Data Item – 4E</u></p> <p>3-401.11(A)(3)* Raw Animal Foods</p> <p align="center"><u>Data Item – 4F</u></p> <p>3-401.12* Microwave Cooking</p> <p align="center"><u>Data Item – 4G</u></p> <p>3-401.11(A)(2)* Raw Animal Foods</p> <p align="center"><u>Data Item – 4H</u></p> <p>3-401.11(A)(1)(b)* Raw Animal Foods</p>
<p>2. Receiving/Sound Condition</p> <p align="center"><u>Data Item – 2A</u></p> <p>3-202.11* Temperature 3-202.15* Package Integrity 3-101.11* Safe, Unadulterated, and Honestly Presented</p>	<p>5. Rapid Reheating for Hot Holding</p> <p align="center"><u>Data Item 5A</u></p> <p>3-403.11(A)* Reheating for Hot Holding</p> <p align="center"><u>Data Item 5B</u></p> <p>3-403.11(B)* Reheating for Hot Holding - Microwave</p> <p align="center"><u>Data Item 5C</u></p> <p>3-403.11(C)* Reheating for Hot Holding – Commercially Processed RTE Food</p> <p align="center"><u>Data Item 5D</u></p> <p>3-403.11(E)* Reheating for Hot Holding – Remaining sliced portions roasts Of beef</p>
<p>3. Records</p> <p align="center"><u>Data Item – 3A</u></p> <p>3-202.18* Shellfish Identification 3-203.12* Shellfish Maintaining Identification</p> <p align="center"><u>Data Item – 3B</u></p> <p>3.402.11* Parasite Destruction 3.402.12* Records, Creation and Retention</p> <p align="center"><u>Data Item – 3C</u></p> <p>3-502.12* Reduced Oxygen Packaging, Criteria 8-103.12* Conformance with Approved Procedures</p>	

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CDC Risk Factor IMPROPER HOLD Limitation of Growth of Organisms of Public Health Concern	CDC Risk Factor IMPROPER HOLD Limitation of Growth of Organisms of Public Health Concern
<p>6. Proper Cooling Procedure</p> <p align="center"><u>Data Item 6A</u></p> <p>3-501.14(A)* Cooling – Cooked PHF</p> <p align="center"><u>Data Item 6B</u></p> <p>3-501.14(B)* Cooling – PHF prepared from ingredients at ambient temperature</p> <p align="center"><u>Data Item 6C</u></p> <p>3-501.14(C)* Cooling – PHF receipt of foods allowed at >41° F (5° C) during shipment</p>	<p>9. Time</p> <p align="center"><u>Data Item 9A</u></p> <p>3-501.17(A)(1)(2)* Ready-to-Eat, PHF, Date Marking – On-premises Preparation</p> <p><i>(Food is to be date marked at the time of preparation with the “consume by” date. This consume by date should include the day if preparation and is:</i></p> <p><i>(1) ≤ 7 calendar days at 41° F (5° C) or less; or</i></p> <p><i>(2) ≤ 4 calendar days at 45° F (7° C))</i></p> <p align="center"><u>Data Item 9B</u></p> <p>3-501.18* Ready-to-Eat, PHF, Disposition</p> <p><i>(Food shall be discarded if not consumed within ≤ 7 calendar days at 41° F (5° C) or less; or ≤ 4 calendar days at 45° F (7° C))</i></p> <p align="center"><u>Data Item 9C</u></p> <p>3-501.17(C)* Ready-to-Eat, PHF, Date Marking – commercially processed food</p> <p><i>(Commercially processed food containers shall be clearly marked, at the time originally opened in a food establishment, with the consume by date which is, including the day the original container is opened:</i></p> <p><i>(1) ≤ 7 calendar days at 41° F (5° C) or less; or</i></p> <p><i>(2) ≤ 4 calendar days at 45° F (7° C))</i></p> <p align="center"><u>Data Item 9D</u></p> <p>3-501.19* Time as a Public Health Control</p>
<p>7. Cold Hold (41° F (5° C))</p> <p align="center"><u>Data Item 7A</u></p> <p>3-501.16(B)* PHF, Hot and Cold Holding</p> <p><i>(For the purposes of this Baseline, 41° F (5° C) or below will be used as the criteria for assessing all PHF that are maintained/held cold.)</i></p>	
<p>8. Hot Hold (140° F (60° C))</p> <p align="center"><u>Data Item 8A</u></p> <p>3-501.16(A)* PHF, Hot and Cold Holding</p> <p align="center"><u>Data Item 8B</u></p> <p>3-501.16(A)* PHF, Hot and Cold Holding</p>	

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CDC Risk Factor CONTAMINATED EQUIPMENT Protection from Contamination	CDC Risk Factor POOR PERSONAL HYGIENE Personnel
<p>10. Separation / Segregation /Protection</p> <p align="center"><u>Data Item 10A</u></p> <p>3-302.11(A)(1)* Packaged and Unpackaged Food – Separation, Packaging, and Segregation <i>(Separate raw animal foods from raw RTE and cooked RTE foods)</i></p> <p align="center"><u>Data Item 10B</u></p> <p>3-302.11(A)(2)* Packaged and Unpackaged Food – Separation, Packaging, and Segregation <i>(Separate raw animal foods by using separate equipment, special arrangement of food in equipment to avoid cross contamination of one type with another, or by preparing different types of food at different time or in separate areas)</i></p> <p align="center"><u>Data Item 10C</u></p> <p>3-302.11(A)(4-6)* Packaged and Unpackaged Food – Separation, Packaging, and Segregation</p> <p>3-304.11(B)* Food Contact with Equipment and Utensils</p> <p align="center"><u>Data Item 10D</u></p> <p>3-306.14(A)(B)* Returned Food, Reservice or Sale</p>	<p>12. Proper, Adequate Handwashing</p> <p align="center"><u>Data Item 12A</u></p> <p>2-301.11* Clean Condition 2-301.12* Cleaning Procedure 2-301.14* When to Wash 2-301.15* Where to Wash</p> <hr/> <p>13. Good Hygiene Practices</p> <p align="center"><u>Data Item 13A</u></p> <p>2-401.11* Eating, Drinking, or Using Tobacco 2-401.12* Discharges from the Eyes, Nose and Mouth 2-403.11* Handling Prohibition – Animals 3-301.12* Preventing Contamination when Tasting</p> <hr/> <p>14. Prevention of Contamination from Hands</p> <p align="center"><u>Data Item 14A</u></p> <p>3-301.11* Preventing Contamination from Hands</p>
<p>11. Food Contact Surfaces</p> <p align="center"><u>Data Item 11A</u></p> <p>4-601.11(A) & (B)* Equipment, Food Contact Surfaces and Utensils</p> <p>4-602.11* Equipment Food-Contact Surfaces and Utensils - Frequency</p> <p>4-701.10* Sanitization of Equipment and Utensils – Food Contact Surfaces and Utensils</p> <p>4-702.11* Sanitization of Equipment and Utensils – Before Use After Cleaning</p>	<p>15. Handwash Facilities</p> <p align="center"><u>Data Item 15A</u></p> <p>5-203.11* Handwashing Lavatory-Numbers and Capacity 5-204.11* Handwashing Lavatory-Location and Placement 5-205.11* Using a Handwashing Lavatory-Operation and Maintenance</p> <p align="center"><u>Data Item 15B</u></p> <p>6-301.11 Handwashing Cleanser, Availability 6-301.12 Hand Drying Provision</p>

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CDC Risk Factor OTHER Foreign Substance	CDC Risk Factor SUPPLEMENTAL ITEMS
<p>16. Chemical</p> <p align="center"><u>Data Item 16A</u></p> <p>3-202.12* Additives 3-302.14* Protection from Unapproved Additives <i>(NOTE: Regarding SULFITES – Refers to any sulfites added in the food establishment, not to foods processed by a commercial processor or that come into the food establishment already on foods)</i></p> <p align="center"><u>Data Item 16B</u></p> <p>7-101.11* Identifying Information, Prominence-Original Containers 7-102.11* Common Name-Working Containers</p> <p><i>Operational Suppliers and Applications</i> 7-201.11* Separation-Storage 7-202.11* Restriction-Presence and Use 7-202.12* Conditions of Use 7-203.11* Poisonous or Toxic Material Containers – Prohibitions 7-204.11* Sanitizers, Criteria-Chemicals 7-204.12* Chemicals for Washing Fruits and Vegetables 7-204.13* Boiler Water Additives, Criteria 7-204.14* Drying Agents, Criteria 7-205.11* Incidental Food Contact, Criteria-Lubricants 7-206.11* Restricted Use Pesticides, Criteria 7-206.12* Rodent Bait Stations 7-206.13* Tracking Powders, Pest Control and Monitoring 7-207.11* Restriction and Storage-Medicines 7-207.12* Refrigerated Medicines, Storage 7-208.11* Storage-First Aid Supplies 7-209.11* Storage-Other Personal Care Items</p> <p align="center"><u>Data Item 16C</u></p> <p><i>Stock and Retail Sale of Poisonous or Toxic Material</i></p> <p>7.301.11* Separation-Storage and Display <i>(Separation is to be by spacing or partitioning)</i></p>	<p>17. Proper Cooking Temperature (supplement to 4G – 2001 Food Code)</p> <p align="center"><u>Data Item 17A</u></p> <p>3-401.11(A)(1)* Raw Animal Foods (pork)</p> <p align="center"><u>Data Item 17B</u></p> <p>3-401.11(A)(2)* Raw Animal Foods (ratites and injected meats)</p> <hr/> <p>18. Hot Hold (135° F) (supplement to 8A – 2005 Food Code(proposed))</p> <p align="center"><u>Data Item 18A</u></p> <p>3-501.16(A)(1)* PHF, Hot and Cold Hold</p> <hr/> <p>19. Employee Health Policy</p> <p align="center"><u>Data Item 19A</u></p> <p>2-201.11 Responsibility of Person in Charge 2-201.12* Exclusions and Restrictions 2-201.13 Removal of Exclusions and Restrictions 2.201.14* Responsibility of a Food Employee or an Applicant to Report to the Person in Charge 2-201.15* Reporting by the Person in Charge</p> <hr/> <p>20. Treating Juice – 2001 Food Code</p> <p align="center"><u>Data Item 20A</u></p> <p>3-202.110 Juice Treated 3-404.11 Treating Juice</p> <hr/> <p>21. Cooling Raw Shell Eggs – 2001 Food Code</p> <p align="center"><u>Data Item 21A</u></p> <p>3-501.14(D)* Cooling</p> <hr/> <p>22. Cold Holding – Raw Shell Eggs – 2001 Food Code</p> <p align="center"><u>Data Item 22A</u></p> <p>3-501.16(B) Hot and Cold Holding</p>

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CDC Risk Factor Supplemental Items	
<p>23. Food & Food Preparation for Highly Susceptible Populations – 2001 <i>Food Code</i></p> <p align="center"><u>Data Item 23A</u> 3-801.11(A)(2)* Prohibited Foods</p> <p align="center"><u>Data Item 23B</u> 3-801.11(B)* Prohibited Foods 3-801.11(E)* Prohibited Foods</p> <p align="center"><u>Data Item 23C</u> 3-801.11(D)* Prohibited Foods</p>	

LEGEND

<p>C = Celsius F = Fahrenheit RTE = Ready-to-Eat PHF = Potentially Hazardous Food R.A. = Regulatory Authority</p>
