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Conducting Risk-based Inspections

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1. PURPOSE AND SCOPE

This Annex provides regulatory program managers and front-line inspection staff with guidance on planning, scheduling, conducting, and evaluating risk-based inspections. The *FDA's Voluntary National Retail Food Regulatory Program Standards* (Program Standards)

(<http://www.fda.gov/Food/FoodSafety/RetailFoodProtection/ProgramStandards/default.htm>) provide additional recommendations to assist regulatory program managers in the planning and development of a risk-based inspection program.

The primary focus of this Annex is to provide inspectors with methods for conducting risk-based inspections. Various strategies that can be used by regulatory professionals to assist operators in achieving active managerial control of foodborne illness risk factors are also included in this Annex.

As presented in Annex 4, the Centers for Disease Control and Prevention (CDC) Surveillance Report for 1993-1997, "Surveillance for Foodborne Disease Outbreaks – United States" (<http://www.cdc.gov/mmwr/preview/mmwrhtml/ss4901a1.htm>) identifies the most frequently reported contributing factors to foodborne illness. Five of these broad categories of contributing factors directly relate to food safety concerns within retail and food service establishments and are collectively termed by the FDA as "foodborne illness risk factors." These five broad categories are:

- Food from Unsafe Sources
- Inadequate Cooking
- Improper Holding Temperatures
- Contaminated Equipment
- Poor Personal Hygiene.

The FDA manual, *Managing Food Safety: A Regulator's Manual for Applying HACCP Principles to Risk-based Retail and Food Service Inspections and Evaluating Voluntary Food Safety Management Systems* (FDA's Regulator's Manual) (<http://www.fda.gov/Food/FoodSafety/RetailFoodProtection/ManagingFoodSafetyHACCPPrinciples/Regulators/default.htm>), provides additional information on conducting risk-based inspections. Annex 4 of the Food Code provides additional information on Hazard Analysis and Critical Control Point (HACCP) principles and the process approach to HACCP. It should be reviewed in conjunction with the material found in this Annex to better prepare for performing risk-based inspections.

The "Retail Food Program Resource Guide," a CD-ROM containing pertinent FDA documents referenced in this Annex, is available for use by federal, state, local, and tribal regulatory agencies. It is produced by and available through FDA Regional Retail Food Specialists or the FDA Division of Federal-State Relations (HFC-150); U.S. Food and Drug Administration; 5600 Fishers Lane, Room 12-07; Rockville, Maryland 20857; PHONE (301) 827-6906; (FAX) (301) 443-2143.

2. RISK-BASED ROUTINE INSPECTIONS

Inspections have been a part of food safety regulatory activities since the earliest days of public health. The term "routine inspection" has been used to describe periodic inspections conducted as part of an on-going regulatory scheme.

Program managers should strive to have adequate staffing and resources to allow all inspectors ample time to thoroughly evaluate establishments and ask as many questions as needed to fully understand establishments' operations. For most jurisdictions, however, inspectors continue to have limited time in which to complete inspections. This does not negate the need to thoroughly identify and assess the control of foodborne illness risk factors during each inspection.

It is a false assumption that inspectors cannot conduct risk-based inspections in a limited timeframe. Even with limited time, inspectors can focus their inspections on assessing the degree of active managerial control an operator has over the foodborne illness risk factors. By focusing inspections on the control of foodborne illness risk factors, inspectors can be assured that they are making a great impact on reducing foodborne illness.

As described in Annex 4, active managerial control means the purposeful incorporation of specific actions or procedures by industry management into the operation of their

businesses to attain control over foodborne illness risk factors. It embodies a preventive rather than reactive approach to food safety through a continuous system of monitoring and verification.

Developing and implementing food safety management systems to prevent, eliminate, or reduce the occurrence of foodborne illness risk factors is recommended to achieve active managerial control. Regulatory inspections and follow-up activities must be proactive by using an inspection process designed to evaluate the implementation of Food Code interventions and the degree of active managerial control that retail and foodservice operators have over foodborne illness risk factors. The five Food Code interventions below were new interventions introduced with the 1993 Food Code and they are just as important today as they were in 1993. They encompass a wide-range of control measures specifically designed to protect consumer health:

- Demonstration of Knowledge
- Implementation of Employee Health Policies
- Hands as a Vehicle of Contamination
- Time/Temperature Relationships
- Consumer Advisory.

When Food Code interventions are not being implemented or if behaviors, activities, or procedures likely to cause foodborne illness are observed, inspectors should verify that the operator takes immediate corrective action so that consumers do not become sick or injured. Observations made on the day of the inspection, as well as information gained about the behaviors, activities, and procedures that occur at other times, allow inspectors to assess the strengths and weaknesses of the food safety management system that is in place.

An operator should be made aware of the inspectional findings both during, and at the conclusion of, the inspection and strategies for achieving compliance in the future should be discussed. Corrective actions taken during the inspection and repeat violations should be noted on the inspection report. Repeat violations should trigger further compliance and enforcement actions.

The inspection process is also an opportunity to educate the operator on the public health reasons supporting the Code requirements. If operators are afforded the chance to ask questions about general food safety matters, they may clearly understand the public health significance of non-compliance.

Lastly, if the operator demonstrates a history of violations related to foodborne illness risk factors, the inspection process can be used to assist the operator with implementing long-term control systems to prevent those risk factors from occurring in the future.

3. WHAT IS NEEDED TO PROPERLY CONDUCT A RISK-BASED INSPECTION?

A. Schedule Inspections Based on Risk

Studies have shown that the types of food served, the food preparation processes used, the volume of food, and the population served all have a bearing on the occurrence of foodborne illness risk factors in retail and foodservice establishments. Standard 3 of the Program Standards requires that regulatory jurisdictions develop and use a process that groups food establishments into at least three categories based on potential and inherent food safety risks. In addition, Standard 3 requires that regulatory jurisdictions assign inspection frequency based on the risk categories to focus program resources on food operations with the greatest food safety risk. With limited resources, creating a variable inspection frequency for each category will allow inspection staff to effectively spend more time in high risk establishments that pose the greatest potential risk of causing foodborne illness.

Table 1 of this Annex provides an example of risk categories and assignment of inspection frequency based on risk. In this example, the type of food served, food preparation processes conducted, and history of compliance related to foodborne illness risk factors are used as the basis of categorizing risk. Each jurisdiction is encouraged to develop risk categories tailored to their specific program needs and resources and to reassess the risk categories on an annual basis.

Regardless of the risk category initially assigned to food establishments, regulatory jurisdictions sometimes consider whether the establishment has implemented a voluntary food safety management system like HACCP, to justify a decrease in inspection frequency. Likewise, the following factors are among many that regulatory jurisdictions sometimes use to justify an increase in inspection frequency:

- History of non-compliance with provisions related to foodborne illness risk factors or critical items
- Specialized processes conducted
- Food preparation a day in advance of service
- Large number of people served
- History of foodborne illness and/or complaints
- Highly susceptible population served.

Annex 5, Table 1. Risk Categorization of Food Establishments

RISK CATEGORY	DESCRIPTION	FREQUENCY #/YR
1	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.	1
2	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.	2
3	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.	3
4	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.	4

B. Have the Proper Equipment

In order to conduct risk-based inspections, each inspector must be provided with the proper equipment to assess the control of foodborne illness risk factors within food establishments. See Program Standard 8 at <http://www.fda.gov/Food/FoodSafety/RetailFoodProtection/ProgramStandards/ucm125049.htm> for recommendations of equipment needed by inspectors. At a minimum, each inspector should be provided with the following essential equipment:

- Thermocouple with the appropriate probes for the food being tested
- Alcohol swabs or other suitable equipment for sanitizing probe thermometers
- Chemical test kits for different chemical sanitizer types
- Heat-sensitive tape or maximum registering thermometer
- Flashlight
- Head cover, such as baseball cap, hair net, or equivalent.

Other equipment may be provided to inspectors on an “as needed” basis. While it is desirable for each inspector to have the following equipment, depending on the resources available to the agency, this equipment may be shared in a central office as appropriate:

- Pressure gauge for determining in-line pressure of hot water at injection point of warewashing machine (5-30 psi)
- Light meter
- Measuring device for measuring distances
- Time/temperature data logger
- pH meter
- Water activity meter
- Camera
- Computers with or without an electronic inspection system
- Black light
- Foodborne illness investigation kits
- Sample collection kits
- Cell phones.

C. Provide Adequate Training

Standard 2 of the Program Standards explains that regulatory staff shall have the knowledge, skills, and ability to adequately perform their required duties. Inspectors need the proper training before they can be expected to conduct risk-based inspections. Training includes a combination of classroom training, in-field training, standardization, and continuing education. For specific training recommendations refer to Program Standard 2 at

<http://www.fda.gov/Food/FoodSafety/RetailFoodProtection/ProgramStandards/ucm125038.htm> and its accompanying Appendix B at

<http://www.fda.gov/Food/FoodSafety/RetailFoodProtection/ProgramStandards/ucm125236.htm>

(1) Classroom Training

The first phase of staff training should provide an orientation to the program with a review of program history, structure, and relationships to other food-related programs. Specific emphasis should be on the program's goals and objectives. The basic training curriculum should include the following components:

- Prevailing statutes, regulations, or ordinances
- Public health principles
- Communication skills
- Epidemiology
- Microbiology
- HACCP.

FDA's ORA-U

(<http://www.fda.gov/Training/ForStateLocalTribalRegulators/ucm121831.htm>)

provides basic curriculum components free of charge to regulators via the internet. This allows state, local, and tribal health departments to conserve their time and funding resources instead of developing their own training courses. It also allows inspectors to access training as needed. Distance learning allows government agencies and industries to cost-effectively disseminate the most current technical and regulatory information on an as-needed basis.

(2) Field Training and Experience

The second phase of training should move the new inspector into the field with a training officer. On-site training should focus on specific inspection tasks such as interviewing, making observations, measuring conditions such as temperatures and sanitizer strength, assessing the control operators have over the foodborne illness risk factors, ensuring implementation of Food Code interventions, and completing the inspection form. If an electronic database is used by the agency, training in its use should be included in this phase.

The evaluation of food safety management systems based on HACCP principles should be part of the field training experience. The trainee and the trainer should review establishment menus, operations, recipes, and standard operating procedures. Inspectors should be able to demonstrate proficiency in gathering information about the food preparation processes, including accurate charting of the food flows and determination of the Critical Control Points (CCPs) and critical limits in an operation. This part of the training should also include a familiarization with the compliance and enforcement protocol in place in the jurisdiction including recommendation of voluntary strategies to prevent risk factor occurrence.

(3) Standardization

The third part of staff training should include standardization. This process improves uniformity in the application and interpretation of applicable regulations, inspection methodology, and report writing. The Program Standards recommend that staff conducting inspections undergo a standardization process similar to the one described in the *FDA Procedures for Standardization and Certification of Retail Food Inspection/ Training Officers*

(<http://www.fda.gov/Food/FoodSafety/RetailFoodProtection/InspectionsQualityAssurance/Standardization/default.htm>). Standardization should be completed after the trainee completes classroom and field training.

(4) Continuing Education

The training process for inspection staff should be continuous. The final phase of training should include a mechanism to ensure that learning is ongoing and staff is kept abreast of food safety issues and the latest science.

D. Ensure Adequate Program Resources

As indicated in Standard 8 of the Program Standards, regulatory agencies should have adequate funding, staff, and equipment necessary to support a risk-based retail food safety program designed to reduce the occurrence of foodborne illness risk factors. Program management should do everything they can to secure funding and resources to support regulatory food programs.

Standard 8 of the Program Standards also states that the program budget should provide the necessary resources to develop and maintain a retail food safety program that has 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.

4. RISK-BASED INSPECTION METHODOLOGY

A. Focus the Inspection

Conducting a risk-based inspection requires inspectors to focus their efforts on evaluating the degree of active managerial control that operators have over foodborne illness risk factors. In addition, it is essential that the implementation of Food Code interventions also be verified during each inspection. Inspectors need to spend the majority of their time observing the behaviors, practices, and procedures that are likely to lead to out-of-control foodborne illness risk factors and asking management and food employees questions to supplement actual observations.

Retail and food service operators implement “control measures” to ensure food safety. Control measures are actions or activities that are used to prevent, eliminate, or reduce food safety hazards. Inspectors need to determine the control measures that should be implemented to prevent the occurrence of foodborne illness risk factors in each food preparation process. In order to determine the foodborne illness risk factors common to each operation, it is important for inspectors to understand that the food preparation processes and all the associated control measures initiated by a retail or food service operator represent a food safety management system. It will be necessary for inspectors to ask questions in order to gain information about the system already in place. Once the degree of active managerial control is determined, inspectors will be able to assist operators with strengthening their existing food safety management systems.

B. Lead by Example

Nonverbal communication is just as important as verbal communication in relaying important food safety principles to retail and food service operators. By setting the example during inspections, inspectors not only demonstrate competency, but they also relay important food safety information to the person in charge and food employees. The following are ways that inspectors set the example during inspections:

- Washing their hands when entering the food preparation area at the beginning of the inspection and after engaging in any activities that might contaminate their hands
- Not working when they are suffering from symptoms such as diarrhea, fever, vomiting, or jaundice or if they are diagnosed with a disease transmittable by food
- Being careful not to touch ready-to-eat (RTE) food with their bare hands
- Washing and sanitizing their thermocouple probe at the start of the inspection and between foods
- Using a proper hair restraint and practicing good personal hygiene
- Being careful not to contaminate clean and sanitized food contact-surfaces with unclean hands or their inspection equipment.

C. Conduct Inspections at Variable Times

Inspectors should enter the food establishment during hours of operation or at other reasonable times. Inspectors should show identification and provide the permit holder or person in charge with a verbal or written notice of the purpose of the inspection. Procedures outlined in the Food Code and in the jurisdiction’s procedures should be followed if access to conduct an inspection is denied. Refusal should be documented on the inspection report and an administrative or judicial inspection order obtained.

In planning for inspections, inspectors should consider the importance of timing. Several operational steps at retail such as receiving, preparation, and cooling can be

evaluated only during limited time periods. In order to properly evaluate critical processes that occur outside of the normal 8 a.m. to 5 p.m. working hours, an inspector should be allowed the flexibility to conduct inspections early in the morning, late in the evening, and even on weekends.

D. Establish Inspection Priorities and Use Inspection Time Wisely

With the limited time allotted for inspections, inspectors must develop clear priorities to make the most efficient use of their time in each food establishment. Although basic sanitation issues generally do not change during the course of an inspection, critical behaviors, practices, and procedures leading to foodborne illness risk factors may be only observable during limited time periods of the preparation or cooling process. For this reason, assessment of the active managerial control of foodborne illness risk factors should generally be performed before reviewing basic sanitation issues.

To effectively set priorities, the following four activities should be completed early in the inspection:

- (1) Establish an open dialogue with the person in charge
- (2) Review previous inspection records
- (3) Conduct a menu or food list review
- (4) Conduct a quick walk-through.

(1) Establish an Open Dialogue with the Person in Charge

The tone of the inspection is often set during the first few minutes of the inspection. A professional but personable approach is the balance which should be maintained. Genuine interest in the food establishment and the staff translates into good relations which may be helpful in conveying the goal of promoting public health. Having an open dialogue with the person in charge during all phases of the inspection gives inspectors an opportunity to learn important information about the existing food safety management system.

It is important to know both the strengths and weaknesses of the existing food safety management system early in the inspection in order to focus the inspection on weak areas. Questions about practices and procedures related to foodborne illness risk factors and Food Code interventions such as the establishment's employee health policy and consumer advisory notice should be asked during all phases of the inspection. It is important to ask enough questions to fully understand the system being utilized in the food establishment. This is especially true when evaluating whether the employees are adhering to the established no bare hand contact and handwashing policies. Asking the person in charge questions about important activities such as receiving, cooling, and preparation is also important in relaying the importance of out-of-control foodborne illness risk factors.

The person in charge should be encouraged to accompany inspectors during the inspection. This may ultimately save time since violations can be pointed out and corrected as they are observed. In addition, the importance of violations related to foodborne illness risk factors and Food Code interventions is more apparent if they are pointed out during the inspection rather than waiting until the end. Violations should be marked on the inspection form even if immediate corrective actions are taken. Corrective actions taken should also be recorded on the inspection form. Inspectors can also use this time to share knowledge about critical processes. By communicating the public health rationale behind the regulations, inspectors will leave the person in charge with a clear understanding for why active managerial control of foodborne illness risk factors must be a top priority in the day-to-day operation of the business.

Early in the inspection, inspectors should inquire about activities that are presently occurring. Processes that occur over time like cooling and reheating also need to be assessed over time; thus, inspectors should ask in the beginning of the inspection if any foods are currently being cooled or reheated.

It is important for inspectors to allow the operator a chance to discuss issues related to food safety. One-way communication in which inspectors do all the talking is not conducive to a risk-based philosophy. An effective risk-based inspection is dependent on inspectors' ability to maintain two-way communication in order to properly assess behaviors, processes, and procedures that occur in the food establishment.

(2) Review Previous Inspection Reports

In order to detect trends of out-of-control foodborne illness risk factors, it is important for inspectors to review past inspection reports before conducting an inspection. This can be done in the office or on-site in the food establishment. This activity is especially important in jurisdictions where inspectors rotate from one inspection to the next. If the same foodborne illness risk factor is out-of-control during more than one inspection, it is strongly recommended that the operator develop an intervention strategy to prevent its recurrence. Intervention strategies are discussed later in this Annex.

Knowledge of what has been corrected from the last inspection also gives inspectors an opportunity to provide positive feedback to the operator and allows inspectors to track corrected violations in accordance with their jurisdiction's policies and procedures.

(3) Conduct a Menu/Food List Review

Menus, including all written and verbal lists of foods prepared and offered in a food establishment, can be reviewed in a fairly simple manner. The review can either be done simultaneously with a quick walk-through of the operation or at the beginning of the inspection as a discussion with management. The menu/food list also does not need to be reviewed during every inspection. If a review was done during a recent inspection, inspectors should inquire about new items, seasonal items, substitutions, or changes in preparation since the last menu review was conducted.

A review of the menu/food list allows inspectors to begin to group food items into one of three broad process categories (discussed in Annex 4 of the Food Code and later in this Annex). Mentally grouping products by process assists inspectors in focusing the inspection on the control measures critical to each process. Conducting a review of the menu/food list also allows inspectors to establish inspection priorities by identifying:

- High-risk foods or high-risk food preparation processes
- Operational steps requiring further inquiry such as receiving, preparation, cooking, and cooling.

By identifying high-risk foods or high-risk food preparation processes, inspectors can focus the inspection on those foods or processes that are more likely to cause foodborne illness if uncontrolled. The menu/food list review might be the only time inspectors are made aware of specialized processes such as formulating a food so that it is not potentially hazardous (time/temperature control for safety) food or high-risk seasonal menu items such as “raw oysters on the half shell.” Foods such as shellstock and certain fish for raw consumption require documentation that should be reviewed during the inspection. If Caesar salad or hollandaise sauce is served, further inquiry is needed regarding the preparation of these items since they are sometimes prepared with raw or undercooked eggs.

Several operational steps like receiving, preparation, cooking, and cooling may not be inspected as vigorously in retail and food service inspections due, in part, to the hours of the day in which these steps occur. If a food establishment is inspected in the afternoon hours, for example, receiving and food preparation might have already occurred. In order to evaluate the establishment’s active managerial control of foodborne illness risk factors, it is imperative that inspectors ask enough questions to obtain information about the operational steps that they cannot directly observe during the current inspection.

(4) Conduct a Quick Walk-through

As inspectors discuss the menu or food list and establishes open communication with the person in charge, it is suggested that they conduct a quick walk-through of the food establishment to observe what is going on at that time. Conducting a quick walk-through is especially important to observe several activities that might otherwise go unnoticed or unobserved until later in the inspection, including:

- Receiving
- Food preparation and handling
- Cooking
- Cooling
- Reheating.

Speaking directly to the food service employees preparing the food is also an excellent way to assess the effectiveness of the establishment's food safety training and standard operating procedures for critical processes such as cooling. Noting that receiving or food preparation is occurring at the beginning of the inspection allows inspectors an opportunity to take advantage of viewing "real-life" production processes and will help inspectors to obtain a clear picture of the establishment's true practices. Receiving and food preparation only occur during limited times, so inspectors may want to stop and observe these operational steps while they are happening.

Early in the inspection, temperatures of potentially hazardous foods (time/temperature control for safety (TCS) foods) should be taken. For example, if inspecting in the morning, inspectors should check the temperatures of last night's stored leftovers. If inspecting in the afternoon, inspectors should check the temperatures of foods prepared that morning that are now cooling. Also, inspectors should ask whether any foods are currently being cooked or reheated.

E. Determine Process Flows

Many retail and food service establishments have implemented effective food safety management systems by establishing controls for the food preparation methods and processes common to their operation. Control of food preparation processes rather than individual food items is often called the "process approach" to HACCP. The process approach using the principles of HACCP can best be described as dividing the many food items in an operation into food preparation processes then analyzing the foodborne illness risk factors associated with each process. By placing managerial controls on specific operational steps in the flow of food, foodborne illness can be prevented.

As presented in Annex 4 of the Food Code, most food items produced in a retail or food service establishment can be categorized into one of three preparation processes based on the number of times the food passes through the temperature danger zone between 41° F and 135° F. In conducting risk-based inspections, it is necessary for an inspector to be knowledgeable regarding how food is prepared in the operation. Knowing how products are prepared in an establishment allows inspectors to focus their inspections on the critical procedures and steps in the preparation of those products.

F. Determine Foodborne Illness Risk Factors In Process Flows

Annex 4 of the Food Code details the essential control measures specific to each food preparation process, in addition to essential facility-wide control measures. Inspectors should generally focus their inspections on verifying that operators have implemented control measures to control for foodborne illness risk factors common to the processes conducted in each operation. There may be other foodborne illness risk factors unique to specific operations; thus, inspectors should independently evaluate each operation and food preparation process conducted.

G. Assess Active Managerial Control of Foodborne Illness Risk Factors and Implementation of Food Code Interventions

Although some food establishments have formal HACCP plans, many do not. Even without a HACCP system, every food establishment needs to have active managerial control of foodborne illness risk factors. This may be achieved through several means, such as training programs, manager oversight, or standard operating procedures. For example, some food establishments incorporate control measures into individual recipes, production schedules, or employee job descriptions to achieve active managerial control.

While a person in charge may require the maintenance of in-house written records by employees to ensure that monitoring is being performed using the correct method and at the proper frequency, foodborne illness risk factors may be managed without the use of formal record keeping. Monitoring, whether through direct observations or by taking appropriate measurements, is by far the most important step in ensuring food safety. If an operator is effectively monitoring all critical activities in the food establishment and taking corrective actions when needed, safe food will result. With a few exceptions, maintaining formal records at retail is not required; therefore, records may not be in place for use during the inspection. As a result, it will be necessary to use direct observations and interviewing to determine whether a food establishment is adequately monitoring foodborne illness risk factors in their existing food safety management system.

This section provides a comprehensive discussion of how to assess the active managerial control of each of the foodborne illness risk factors and the implementation of each of the Food Code interventions. Assessment of active managerial control involves more than determining compliance with Food Code provisions. In assessing whether the operator has active managerial control, inspectors should observe whether the operator has established the appropriate control measures and critical limits and whether appropriate monitoring and corrective action procedures are in place and followed. In addition, inspectors should assess whether managers and employees are knowledgeable of food safety principles and critical practices and procedures necessary to prevent foodborne illness. If during the inspection inspectors observe that control measures are not being implemented appropriately to control risk factor occurrence, immediate corrective action must be taken.

(1) Demonstration of Knowledge

It is the responsibility of the person in charge to ensure compliance with the Code. Knowledge and application of Food Code provisions are vital to preventing foodborne illness and injury. Data collected by FDA suggest that having a certified food manager on-site has a positive effect on the occurrence of certain foodborne illness risk factors in the industry.

In order to assess whether the person in charge demonstrates knowledge, inspectors should verify that the person in charge has one or more of the following:

- A valid food protection manager certificate
- No priority item violations during the current inspection
- Correct responses to food safety related questions as presented in ¶ 2-102.11(C) of the Food Code.

(2) Assessing Safe Sources and Receiving Temperatures

The time and day of the inspection is important when assessing whether foods are received from safe sources and in sound condition. Foods may be received in the food establishment on set days. Inspectors should ask questions to ascertain the day or days that deliveries are received and also the receiving procedures in place by the food establishment. Inspections can be scheduled at times when it is known that products will be received by the food establishment. If food is being delivered during the inspection, inspectors should:

- Verify internal product temperatures
- Examine package integrity upon delivery
- Look for signs of temperature abuse (e.g., large ice crystals in the packages of frozen products)
- Examine delivery truck and products for potential for cross-contamination
- Observe the food establishment's behaviors and practices as they relate to the establishment's control of contamination and holding and cooling temperatures of received products
- Review receiving logs and other documents, product labels, and food products to ensure that foods are received from regulated food processing plants (no foods prepared at home) and at the proper temperature.

When evaluating approved sources for shellfish, such as clams, oysters, and mussels, inspectors should ask whether shellfish are served at any time during the year. If so, inspectors should review the tags or labels to verify that the supplier of the shellfish is certified and on the most current Interstate Certified Shellfish Shippers List [found at \(http://www.fda.gov/Food/FoodSafety/Product-SpecificInformation/Seafood/FederalStatePrograms/InterstateShellfishShippersList/default.htm\)](http://www.fda.gov/Food/FoodSafety/Product-SpecificInformation/Seafood/FederalStatePrograms/InterstateShellfishShippersList/default.htm). Inspectors should note whether all required information is provided on the tags or label (harvester's certification number, harvest waters and date, type and quantity of shellfish and similar information for each dealer that handles the shellfish after the harvester). Shellstock tags should also be retained for 90 days in chronological order.

With regard to fish, inspectors should verify that fish are commercially caught and harvested and received from reputable vendors. If fish are being delivered during the inspection or if they were received just before inspectors' arrival, temperatures should be taken, especially if there are finfish such as tuna, mahi-mahi, bluefish, mackerel, and snapper. These fish are subject to scombrototoxin formation if time/temperature abused.

Inspectors should verify freshness by conducting an organoleptic inspection of the gills, eyes, and bodies of the fish.

Inspector should verify that fish, except for certain species of tuna, intended for raw or undercooked consumption have been frozen for the required time and temperature parameters to destroy parasites by either reviewing freezing records or verifying that a letter of guarantee from the purveyor is kept on file. If freezing is conducted on-site, inspectors should verify that the freezing records are maintained for at least 90 days beyond the date of sale or service.

With regard to the service of game or wild mushrooms, inspectors should ask if these products are served at any time during the year. If so, inspectors should verify that they are from an approved source by reviewing invoices.

With regard to juice and milk products, inspectors should verify that fluid milk and milk products are pasteurized and received at the proper temperature. For packaged juice, inspectors should verify that the juice was pasteurized or otherwise treated to achieve a 5-log reduction of the most resistant microorganism.

During the inspection, inspectors should inquire as to the source of foods that have been removed from their original containers. If at any time during the inspection there is any doubt as to the source of certain products, inspectors should ask for invoices or receipts to demonstrate their source. Certain products, such as flat breads, waffles, pies, and cakes may require special cooking equipment to prepare. If suitable equipment is not on-site to prepare such products and the products are not stored in original containers, then inspectors should inquire as to the source of these products.

Food from unapproved, unsafe, or otherwise unverifiable sources should be discarded or put on hold or under embargo until appropriate documentation is provided. In addition, inspectors should ensure that management and employees are aware of the risk of serving or selling food from unapproved sources. Fish that are intended to be consumed raw or undercooked and for which no freezing certification or equipment is found on-site, can be used in menu items that will be fully cooked. If cooking is not an option due to the menu items served, the fish should be discarded.

(3) Assessing Contaminated Equipment and Potential for Cross-Contamination

This risk factor involves the proper storage and use of food products and equipment to prevent cross-contamination. The cleaning, sanitization, and storage of food-contact surfaces of equipment and utensils in a manner to prevent transmission of foodborne pathogens or contamination is also included in this risk factor.

As inspectors walk through the food establishment, they should examine food storage areas for proper storage, separation, segregation, and protection from contamination. Inspectors should look to see that raw animal foods and ready-to-eat foods are

separated during receiving, storage, and preparation. For example, cooked shrimp should not be returned to the same container that previously held uncooked product. Cutting boards should be washed, rinsed, and sanitized between trimming uncooked chicken and cooked steak.

In addition, raw animal foods should be separated by cooking temperatures such that foods requiring a higher cooking temperature, like chicken, should be stored below or away from foods requiring a lower temperature, like pork and beef. If potentially hazardous foods (TCS foods) are not being cooled, they should be covered or packaged while in cold storage.

Following the flow of food as it is prepared in the food establishment may alert inspectors to opportunities for cross-contamination. When contamination has occurred between raw and ready-to-eat food, inspectors should assess whether the food can be reconditioned. In some cases, depending on the affected food, it may be possible to reheat the food to eliminate any hazards. If the food cannot be reconditioned, then the food should be discarded.

Inspectors should verify that exposed food such as chips, bread, and dipping sauces are not re-served to the consumer. Consumer self-service operations are addressed in the Code with regard to the types of food offered for consumer self-service, the protection of food on display, and the required monitoring by employees of such operations.

A visual check of the food-contact surfaces of equipment and utensils should be made to verify that the utensils are maintained clean and sanitized using the approved manner and frequency. Utensils that are observed to have debris, grease, or other visible contamination should be rewashed and resanitized.

Observations should be made to determine whether practices are in place to eliminate the potential for contamination of utensils, equipment, and single-service items by environmental contaminants, employees, and consumers. When clean equipment and utensils are stored where they are subject to environmental contamination such as near handwashing sinks or prep sinks, inspectors should have the operator rearrange the equipment in a manner to prevent cross-contamination. Depending on the circumstances, the operator may need to rewash and resanitize the equipment.

Inspectors should observe handwashing operations. If handwashing sinks and fixtures are located where splash may contaminate food contact surfaces or food, then splash guards should be installed or food-contact surfaces should be relocated to prevent cross-contamination.

Inspectors should pay particular attention to prep sinks, especially those that are currently in use at the time of the inspection. Built-up grime is a visible sign that the sink is not being washed, rinsed, and sanitized appropriately before use. If there are designated vegetable or meat sinks, inspectors should verify that the placement of sinks

and food preparation areas do not facilitate opportunities for cross-contamination from one to the other.

With regard to the cleaning and sanitization of food-contact surfaces, inspectors should verify the compliance of any warewashing operations by ensuring that cleaning and sanitizing procedures for all food-contact surfaces conform to the requirements in the Food Code. Questions should be asked to assess how utensils and cookware are washed, rinsed, and sanitized in the food establishment. When assessing the warewashing procedure and equipment, inspectors should pay particular attention to cooking and baking equipment that is too large to fit in the dishmachine or sinks. It is a good idea to have the person responsible for dishwashing demonstrate the procedure that is followed in the food establishment by setting up the sinks and watching the dishwashing procedure.

(4) Assessing Cooking Temperatures

Food cooking temperatures and times should be verified by inspectors during each inspection. Every effort should be made to assess the cooking temperatures of a variety of products served in the food establishment.

To assess cooking, inspections must occur at times when food is being cooked. It is also important to conduct inspections during busy times, such as lunch and dinner, as there may be a tendency for the operator to rush the cooking of foods during these times.

Critical limits for cooking potentially hazardous foods (TCS foods) in the Food Code include specifications that all parts of the food be heated to a certain temperature. For large roasts, temperature measurement should take into account post-cooking heat rise which allows the temperature to reach equilibrium throughout the food. The critical limit of time at the terminal temperature must also be measured during inspections. For example, a roast beef cooked at 54°C (130°F) is required to be held at this temperature for 112 minutes to ensure destruction of pathogens. Cooking times and temperatures should be noted on the inspection report.

The correct temperature measuring device and technique are essential in accurately determining the temperatures of potentially hazardous foods (TCS foods). The geometric center or thickest part of a product are the points of measurement of product temperature particularly when measuring critical limits for cooking.

Inspectors should take internal temperatures of products using a thermocouple or thermistor with a probe suitable for the product thickness. A thin diameter probe should be used for temperature measurements of hamburger patties and fish filets. Alternately, although less desirable, an inspector may use a suitable, calibrated bimetal stem thermometer for checking cooking temperatures of thick foods. Infrared thermometers are inappropriate for measuring internal cooking temperatures.

In order to better assess cooking during all phases of the inspection, inspectors could enlist the help of cooperative food employees to notify them of foods that have finished cooking. This allows inspectors to continue with the inspection in other areas of the operation yet continue to verify that proper cooking temperatures are being met.

Food establishments should routinely monitor cooking temperatures. Inspections should verify that monitoring is occurring by involving the person in charge in these activities during the regulatory inspection. The presence of required thermometers and their proper use should be assessed.

Comparisons should be made between inspectors' calibrated temperature measuring device and those used by the food establishment. Notation of deviations should be made on the inspection report. Inspectors should ask food establishment personnel to demonstrate proper calibration of their temperature measuring devices.

If required cooking temperatures are not met, inspectors should have the operator continue cooking the food until the proper temperature is reached. Additionally, inspectors should explain the public health significance of inadequate cooking to management and food employees.

(5) Assessing Holding Time and Temperatures and Date Marking

Hot and cold holding temperatures, as well as cooling time and temperatures, of potentially hazardous foods (TCS foods) should be thoroughly checked with a thermocouple, thermistor, or other appropriate temperature measuring device during each inspection. This includes the temperature of potentially hazardous food (TCS food) during transport, e.g., hot holding carts being used to transport food to patient rooms in a hospital, satellite kitchens, or off-site catering events. As a rule, every effort should be made to assess every hot and cold holding unit in the food establishment during a risk-based inspection

Use of an infrared thermometer for verifying holding temperatures is not consistent with Food Code requirements since verifying only the surface temperature of the food may not alert inspectors to problems that exist under the food's surface. Such problems could stem from improper cooling, in the case of cold-held foods, or improper reheating, in the case of hot-held foods. In addition, inspectors should not stir a food before taking its temperature since it is important to know the temperature of the food before it is agitated.

The geometric center of a product is usually the point of measurement of product temperature particularly when measuring the critical limit for cold holding.

The hot holding critical limit may need additional measurements taken at points farthest from the heat source, e.g., near the product surface for food held on a steam table. Temperatures monitored between packages of food, such as cartons of milk or packages of meat, may indicate the need for further examination. However, the

temperature of a potentially hazardous food (TCS food) itself, rather than the temperature between packages, is necessary for regulatory citations. In large holding units and on steam tables, it is necessary to take the temperatures of foods in various locations to ensure that the equipment is working properly. If deviations are noted in the product temperatures, it is important to take extra steps to find out whether the problem is the result of equipment failure or whether a breakdown in a process such as cooling or reheating is the reason for the problem.

Corrective actions for foods found in violation should be required based on the jurisdiction's regulatory food code. If foods are to be discarded, forms such as those used for stop sale or embargo may need to be completed and signed by the person in charge in accordance with the jurisdiction's regulatory food code. In order to properly evaluate the degree of time and temperature abuse and the proper disposition of the affected food, several issues must be considered. Answers to these questions, in combination with observations made during the inspection, should provide inspectors with enough information to make the appropriate recommendation for on-site correction:

- Are there any written procedures in place for using time alone as a public health control and, if so, are they being followed properly?
- What are the ingredients of the food and how was it made?
- Is it likely that the food contains *Clostridium perfringens*, *Clostridium botulinum*, or *Bacillus cereus* as hazards?
- Has there been an opportunity for post-cook contamination with raw animal foods or contaminated equipment?
- If there has been an opportunity for post-cook contamination, can the hazards of concern be eliminated by reheating?
- Are the food employees practicing good personal hygiene including frequent and effective handwashing?
- Was the food reheated or cooked to the proper temperature before being allowed out of temperature control?
- What is the current temperature of the food when taken with a probe thermometer?
- How long has the food been out of temperature control (ask both the manager and food employees)? Are the answers of the food employees and the manager consistent with one another?
- Is it likely that food has cooled to its current temperature after being out of temperature control for the alleged time?
- Will the food be saved as leftovers?
- How long before the food will be served?
- Given what is known about the food, the food's temperature, the handling of the food, and the alleged time out of temperature, is it reasonably likely that the food already contains hazards that cannot be destroyed by reheating?

Even if food can be reconditioned by reheating, steps should be taken by the person in charge to ensure compliance in the future. Examples include repairing malfunctioning or inoperative equipment or implementing a risk control plan (RCP) to modify

preparation procedures or to institute a procedure for monitoring holding temperatures of food.

If using time only or time-temperature combinations in lieu of temperature for controlling the growth and toxin-formation of pathogenic bacteria, strict controls must be in place and followed. Inspectors should verify that the written procedures are on-site and followed in accordance with the Food Code.

Date marking is the mechanism by which active managerial control of time-temperature combinations can prevent the growth of *Listeria monocytogenes* in potentially hazardous (TCS), ready-to-eat foods during cold storage. With exceptions, all ready-to-eat, potentially hazardous foods (TCS foods) prepared on-site and held for more than 24 hours should be date marked to indicate the day or date by which the foods need to be served or discarded. Inspectors should ask questions to ascertain whether the system in place to control for *L. monocytogenes* meets the intent of the Food Code. Food that should be date marked and is not should be discarded.

(6) Assessing Reheating for Hot Holding

In order to assess a food establishment's control of reheating for hot holding, the time of day that the inspection occurs is a key factor. Every effort should be made to schedule an inspection during pre-opening preparation. If inspections are conducted during pre-opening preparation or other preparation periods, inspectors should ask questions regarding the history of hot-held foods. Foods in compliance for minimum hot holding temperatures may have in fact been improperly reheated before being placed into hot holding units or steam tables.

If items are found "reheating" on the steam table, further inquiry is needed to assess whether the equipment in question is capable of reheating the food to the proper temperature within the maximum time limit. Corrective action for foods found out of compliance for reheating for hot holding would depend on how long the food had been out of temperature and other factors. In most cases, however, the food may be rapidly reheated and hot held.

(7) Assessing Cooling

Improper cooling remains a major contributor to bacterial foodborne illness. Cooling temperatures and times need to be closely evaluated during every inspection. In order to assess whether a food establishment has control over cooling, the time of day that the inspection occurs is critical. Early morning inspections allow an opportunity to verify that leftovers from the night before were cooled properly or cooled using a proper cooling method. Alternatively, afternoon inspections may allow an inspector to verify cooling of products that may have been prepared that morning. Because many food establishments prepare bulk products only on certain days of the week, it is essential that inspectors become as familiar as possible with each operation and schedule their inspections accordingly.

Due to the time parameters involved in cooling, inspectors should always inquire at the beginning of the inspection whether there are any products currently being cooled. This allows inspectors an opportunity to take initial temperatures of the products and still have time to re-check temperatures later in the inspection in order to verify that critical limits are being met.

Problems with cooling can often be discovered through inquiry alone. Even when no cooling is taking place, inspectors should ask the food employees and managers questions about the cooling procedures in place.

When examining cold holding units, bulk containers and buckets, tightly packed pans, shrouded rolling racks, or closed rolling cabinets should warrant further temperature and time investigation. Bulk containers and buckets should be opened since they are commonly reused for food storage and cooling.

The geometric center of a product is often chosen as the point of measurement of product temperature particularly when measuring the critical limits for cooling. For foods that are being cooled, temperature profiles throughout the product may show proper temperatures at outer edges and hot spots at the core of the product. Inspectors can verify cooling by first taking a temperature measurement in the geometric center of the product, then at various points around the perimeter of the product. Warmer temperatures in the center of the product, in combination with cooler temperatures around the perimeter, indicate that a product is cooling. Additional questions should be asked to ascertain the cooling time parameters of the food in question. Information gained from food employees and management, in combination with temperature measurements taken, should form the basis for assessing compliance of cooling during an inspection.

The following guidance may be used for determining the appropriate corrective action for improper cooling. Cooked hot food may be reheated to 165 °F for 15 seconds and the cooling process started again using a different cooling method if the food is:

- Above 70 °F and two hours or less into the cooling process; and
- Above 41 °F and six hours or less into the cooling process.

Cooked hot food should be discarded immediately if the food is:

- Above 70 °F and more than two hours into the cooling process; or
- Above 41 °F and more than six hours into the cooling process.

A different, more accelerated, cooling method may be used for prepared ready-to-eat foods if the food is above 41 °F and less than four hours into the cooling process; however, such foods should be discarded if the food is above 41 °F and more than four hours into the cooling process.

(8) Assessing Personal Hygiene, Hands As a Vehicle of Contamination, and Proper Implementation of Employee Health Policies

Special attention should be given to the potential for hands as a vehicle of contamination. An effective management system for prevention of hand contamination involves three elements:

- Employee health policy
- Proper handwashing
- No bare hand contact with ready-to-eat foods.

There are a wide range of communicable diseases and infections that can be transmitted by an infected food employee. Proper management of the risks associated with ill food employees begins with employing healthy people and implementing a policy that excludes or restricts ill employees as specified in Chapter 2 of the Food Code. Employees must be aware of the symptoms, illnesses, or conditions that must be reported to the person in charge. In addition, the person in charge must be knowledgeable regarding the appropriate action to take should certain symptoms, illnesses, or conditions be reported.

With regard to the employee health policy, inspectors should ask a series of open-ended questions to ascertain whether the employee health policy in place complies with the Food Code. The following are example questions that may be asked:

- What kind of policy do you have in place for handling sick employees?
- Is there a written policy? (Note: a written policy is not required in the Food Code, but having a written policy may give an indication of the formality of the policy being discussed.)
- Describe how managers and food employees are made knowledgeable about their duties and responsibilities under the employee health policy.
- Are food employees asked if they are experiencing certain symptoms or illnesses upon conditional offer of employment? If so, what symptoms or illnesses are food employees asked about? Is there a written record of this inquiry?
- What are food employees instructed to do when they are sick?
- What conditions or symptoms are reported?
- What may some indicators be of someone who is working while ill?
- When are employees restricted from working with exposed food or food-contact surfaces? When are they excluded from working in the food establishment?
- For employees that are sick and cannot come to work, what policy is in place for allowing them to return and for notifying the regulatory authority?

Special attention should be given to the potential for hands as a vehicle of contamination. Ensuring that hands are washed using the proper procedure and at the appropriate times must be a top priority during every inspection. Data show that viruses

can be tenacious even in the presence of good handwashing. Inspectors should observe employee use of utensils and gloves during the preparation and service of ready-to-eat foods and ingredients, such as salads and sandwiches.

If ready-to-eat food is touched with bare hands, inspectors will need to address several questions in order to make the appropriate on-site correction recommendation. The answers to the following questions should provide enough information to determine the likelihood of occurrence of hazards transmitted by bare hands and should be the basis for making a recommendation for on-site correction:

- Does the facility have an employee health policy to identify, restrict, and exclude ill employees?
- Did the employees working with the food in question effectively wash their hands and are handwashing facilities adequate?
- Is there an approved, alternate procedure to no bare hand contact in place and was it followed before the bare hand contact?
- Has there been an opportunity for the employee's hands to become contaminated?

Inspectors should examine the location of handwashing sinks in relation to where food is being prepared. Many jurisdictions use a basic distance measurement as a guideline when considering the location and number of handwashing sinks required in a food establishment during the plan review process. While this information can be used to assist with the review process, it should not be used as the sole basis for determining whether there are an adequate number of handwashing sinks or whether the handwashing sinks are conveniently located.

Special emphasis should be placed on spacing in and around fixed equipment, the expected staffing, and the flow of food throughout a food establishment. For instance, a kitchen may be 30 feet in length and 12 feet wide. Although the size of the kitchen may dictate only one handwashing sink using a basic distance measurement, if a prep table the length of the line is placed between the line and the handwashing sink, the handwashing sink may not be conveniently located. Likewise, one handwashing sink located at the end of cook line is useless to employees working at the other end if there is limited space for employees to go around one another during busy periods.

(9) Assessing Compliance with Approved Procedures

When conducting certain specialized processes, variances and HACCP plans are required by the Code. This is because such processes carry a considerable risk if not conducted under strict controls. For food establishments conducting specialized processes, each inspection should involve a review of the written variance, if applicable,

and the implementation of the HACCP plan to ensure that food safety hazards are being consistently controlled.

(10) Assessing Special Requirements Related to Highly Susceptible Populations (HSP)

Food establishments that serve highly susceptible populations (HSP) must adhere to additional requirements as specified under Part 3-8 of the Code. Every effort should be made to inspect such facilities during preparation, service, or other applicable times to assess these additional requirements as well as those in other sections of the Food Code.

Because those persons who are very young, elderly, or who live in a facility that provides custodial care are extremely vulnerable to foodborne illness because of age or health status, it is important that risk factors be controlled on-site in a timely manner. Inspections of HSP facilities should be conducted by inspectors knowledgeable in the control of foodborne illness risk factors who take extra care to assure that the most vulnerable segment of the population are not at risk.

(11) Assessing Labeling, Storage, and Use of Poisonous and Toxic Chemicals

During each inspection, the proper labeling, storage, and use of poisonous and toxic chemicals should be verified. Containers of poisonous or toxic materials and personal care items shall bear a legible manufacturer's label. Working containers used for storing poisonous or toxic materials such as cleaners and sanitizers taken from bulk supplies should be clearly and individually identified with the common name of the material. Only chemicals that are necessary to the operation and maintenance of a food establishment, such as for the cleaning and sanitizing of equipment and utensils and the control of insects and rodents, should be in the food establishment. Medicines necessary for the health of employees may be allowed in a food establishment, but they should be labeled and stored to prevent contamination of food and food-contact surfaces.

Inspectors should verify that solutions containing poisonous and toxic chemicals, like mop water, are discarded in an appropriate service sink to prevent contamination of food and food-contact surfaces. In addition, inspectors should check delivery trucks to verify that food is protected from chemical contamination during shipment. Any food that has been cross-contaminated with poisonous or toxic chemicals should be discarded or rejected immediately.

(12) Assessing Compliance with Consumer Advisory

Inspectors should ascertain whether animal foods such as beef, eggs, fish, lamb, milk, pork, poultry, or shellfish are served or sold raw, undercooked, or without otherwise being processed to eliminate pathogens, either in ready-to-eat form or as an ingredient

in another ready-to-eat food. Inspectors should review the menu or food list to verify that a consumer advisory with a disclosure and reminder is present as specified under § 3-603.11 of the Food Code.

In addition to reviewing the menu or food list, inspectors should ask whether raw or undercooked foods are served or sold routinely or seasonally. It is useful to know foods that are often served in this manner such as oysters-on-the half shell, hollandaise sauce, béarnaise sauce, eggnog, salad dressings, hamburgers to order, or sunny-side-up eggs.

H. Evaluating Basic Sanitation and Facilities (Good Retail Practices)

An important part of a risk-based, routine inspection is to review how the food establishment actively monitors the active managerial control of foodborne illness risk factors and interventions; however, overall sanitation should not be overlooked. Systems to control basic operational and sanitation conditions within a food establishment, referred to as Good Retail Practices (GRPs), are the foundation of a successful food safety management system. GRPs found to be out-of-compliance may give rise to conditions that may lead to foodborne illness, e.g., sewage backing up in the kitchen. Just as monitoring is required by the food establishment to ensure that foodborne illness risk factors are controlled and interventions are in place, monitoring of basic sanitation conditions in the food establishment allows the operator an excellent opportunity to detect weaknesses and initiate actions for improvement. Basic operational and sanitation programs must be in place to:

- Protect products from contamination by biological, chemical, and physical food safety hazards
- Control bacterial growth that can result from temperature abuse during storage
- Maintain equipment, especially equipment used to maintain product temperatures.

Examples of concerns addressed by the basic operation and sanitation programs mentioned above include the following:

- Pest control
- Food protection (CORE ITEM)
- Equipment maintenance
- Water
- Plumbing
- Toilet facilities
- Sewage
- Garbage and refuse disposal
- Physical facilities.

5. ACHIEVING ON-SITE AND LONG-TERM COMPLIANCE

A. Developing an Effective Compliance and Enforcement Protocol

Compliance and enforcement are essential elements of a regulatory program and encompass all voluntary and regulatory enforcement actions taken to achieve compliance with regulations. Standards 3 and 6 of the Program Standards explain the need of regulatory jurisdictions to establish a compliance and enforcement protocol that results in credible follow-up for each violation noted during an inspection, especially violations related to foodborne illness risk factors and Food Code interventions. Lack of follow-up on the part of the regulatory agency signals to the operator that the priority item and priority foundation item violations noted were not important.

The resolution of out-of-compliance foodborne illness risk factors and Food Code interventions must be documented in each food establishment record. The desired outcome of Standard 6 is an effective compliance and enforcement program that is implemented consistently to achieve compliance with regulatory requirements.

Compliance and enforcement options may vary depending on state and local law. It is essential that regulatory jurisdictions develop a written compliance and enforcement protocol that details the order in which both voluntary corrections may be taken on the part of the operator and involuntary enforcement actions are to be taken on the part of the regulatory authority. Involuntary enforcement actions include, but are not limited to, such activities as warning letters, re-inspections, citations, administrative fines, permit suspensions, and hearings.

Food establishment with a history of noncompliance at a level predetermined by the jurisdiction or with the number of foodborne illness risk factors and interventions violated warranting a regulatory action, signals the need either a strong regulatory response or an alternate approach to compliance to protect public health, e.g., active managerial control, behavioral change.

Voluntary corrections taken on the part of the operator include, but are not limited to, such activities as on-site corrections at the time of inspection, voluntary destruction, risk control plans, and remedial training. Obtaining voluntary corrections by the operator can be very effective in achieving long-term compliance. Voluntary corrections by the operator are referred to in FDA's Regulator's Manual as "intervention strategies." Intervention strategies can be divided into two groups:

- Those designed to achieve immediate on-site correction
- Those designed to achieve long-term compliance.

Successful intervention strategies for out-of-control foodborne illness risk factors can be tailored to each operation's resources and needs. This will require inspectors to work

with the operator to identify weaknesses in the existing food safety management system and consulting with the operator to strengthen any weak areas noted.

B. On-site Correction

On-site corrections are intended to achieve immediate corrective action of out-of-control foodborne illness risk factors posing an immediate, serious danger to the consumer during the inspection. Usually these violations are "operational" rather than structural and can be addressed by management at the time of the inspection.

It is essential to consumer protection and to regulatory credibility for on-site correction to be obtained for any out-of-control foodborne illness risk factors before completing the inspection and leaving the food establishment. Obtaining on-site correction conveys the seriousness of the violation to management. Failure to require on-site correction when an out-of-control risk factor has been identified implies that the risk factor has little importance to food safety.

When recommending on-site correction, effective communication regarding out-of-control foodborne illness risk factors is essential and can be accomplished best by:

- Discussing food safety concerns in words that can be easily understood by the person in charge and employees
- Conveying the seriousness of the out-of-control foodborne illness risk factors in terms of increased risk of illness or injury.

During the discussion of inspection findings with the person in charge, inspectors should keep the discussion focused on correction of violations that present an immediate danger to the consumer. Discussion of less serious code violations should be deferred until out-of-control foodborne illness risk factors are discussed and on-site correction is obtained.

In most cases, selecting the most appropriate on-site correction when out-of-control foodborne illness risk factors are observed will be straightforward; however, in instances such as improper cooling, the appropriate corrective action may be more complicated. Since determining on-site correction depends on a number of factors, an inspector may need to conduct a hazard analysis of the food in order to determine the appropriate course of action to take.

C. Intervention Strategies for Achieving Long-term Compliance

While on-site correction of out-of-control foodborne illness risk factors is essential to consumer protection, achieving long-term compliance and behavior change is equally important. Overcoming several misconceptions about long-term compliance will help in achieving a desirable change of behavior. For example, in jurisdictions using a 44-item inspection report in which only observed violations are marked, it is often taken for

granted that if there are no violations marked, the foodborne illness risk factors are being controlled. This is not necessarily true since the observation of code violations is subject to many variables such as the time of day, day of the week, or duration of the inspection. An inspection system that records only observed violations rather than the actual status of all foodborne illness risk factors, such as whether the risk factor was in compliance, not observed, or not applicable to the operation, may be unable to detect some foodborne illness risk factors that are continually or cyclically out of control.

Another misconception is that training alone will result in foodborne illness risk factors being controlled. While training may help, there is no guarantee that knowledge acquired will equate to knowledge applied in the workplace. In order for knowledge to translate into changed behavior, it must be reinforced and the behavior must be repeated for a period of time sufficient for the behavior to become an ingrained pattern. Another assumption is that regulatory enforcement actions such as citations or administrative hearings or on-site corrections alone will automatically result in future management control. Unfortunately, there is no assurance that any of these actions will result in the long-term control of foodborne illness risk factors.

Long-term compliance may best be achieved through voluntary actions by the operator. If an operator supports the concept that a food safety management system is needed, there is a better chance that long-term compliance will be achieved. The following are ways operators can better ensure long-term active managerial control of foodborne illness risk factors.

(1) Change Equipment and Layout

Critical limits are difficult to achieve when equipment does not work properly. Proper calibration of equipment is vital to achieving food safety. When calibration is unsuccessful or is not feasible, equipment should be replaced. In addition to equipment malfunctioning, poor equipment layout can present opportunities for cross contamination and must be considered. For example:

- Hamburgers with uniform thickness and weight are not all reaching a safe cooking temperature in a given time. Upon examination, it is determined that the grill is distributing heat unevenly. A new element is installed to correct the problem.
- Splash from a nearby handwashing sink is seen on a prep table. A splash guard is installed to prevent cross contamination from the handwashing sink to the prep table.

(2) Establish Buyer Specifications

Written specifications for the goods and services purchased by a food establishment prevent many problems. For example:

- Fish posing a parasite hazard and intended for raw consumption have not been frozen for the specified time and temperature and no freezing equipment is on-site at the food establishment. Buyer specifications are established to place the responsibility for freezing the fish on the supplier.
- Lobster tails, hamburgers, or other products cooked with a set time parameter on a conveyor are not reaching the proper temperature in the specified time because they are larger than the size for which the conveyor is calibrated. Buyer specifications are established to restrict the size of products received from the supplier.

(3) Develop and Implement Recipe/Process Instructions

Simple control measures integrated into recipes and processes can improve management control over foodborne illness risk factors. For example:

- Process instructions that specify using color-coded cutting boards for separating raw animal foods from ready-to-eat products are developed to control the potential for cross contamination.
- Pasteurized eggs are substituted in recipes that call for raw or undercooked eggs to reduce the risk of foodborne illness.
- Commercially precooked chicken is used in recipes calling for cooked chicken such as chicken salad to reduce the risk of contaminating food-contact surfaces and ready-to-eat food with raw chicken.
- Pasta is chilled in an ice bath immediately after cooking and before apportioning into single servings. This is specified in the procedures for cooking spaghetti.

(4) Establish First-In-First-Out (FIFO) Procedures

Product rotation is important for both quality and safety reasons. “First-In-First-Out” (FIFO) means that the first batch of product prepared and placed in storage should be the first one sold or used. Date marking foods as required by the Food Code facilitates the use of a FIFO procedure in refrigerated, ready-to-eat, potentially hazardous foods (TCS foods). The FIFO concept limits the potential for pathogen growth, encourages product rotation, and documents compliance with time/temperature requirements.

(5) Develop and Implement Standard Operating Procedures (SOPs)

Following standardized, written procedures for performing various tasks ensures that quality, efficiency, and safety criteria are met each time the task is performed. Although every operation is unique, the following list contains some common management areas that can be controlled with SOPs:

- Personnel (disease control, cleanliness, training)
- Facility maintenance
- Sanitary conditions (general cleaning schedule, chemical storage, pest control, sanitization of food-contact surfaces)
- Sanitary facilities (approved water supply and testing, if applicable, scheduled in-house inspection of plumbing, sewage disposal, handwashing and toilet facilities, trash removal)
- Equipment and utensil maintenance.

SOPs can also be developed to detail procedures for controlling foodborne illness risk factors:

- Procedures are implemented for measuring temperatures at a given frequency and for taking appropriate corrective actions to prevent hazards associated inadequate cooking.
- Adequate handwashing is achieved by following written procedures that dictate frequency, proper technique, and monitoring.

(6) Develop and Implement Risk Control Plans (RCPs)

An RCP is a concisely written management plan developed by the retail or food service operator with input from inspectors that describes a management system for controlling specific out-of-control foodborne illness risk factors. An RCP is intended to be a voluntary strategy that inspectors and the person in charge jointly develop to promote long-term compliance for *specific* out-of-control foodborne illness risk factors. For example, if food is improperly cooled in the establishment, a system of monitoring and record keeping outlined in an RCP can ensure that new procedures are established to adequately cool the food in the future. An RCP should require that the basic control systems in the plan be implemented for a designated period of time (e.g., 60 – 90 days) and allow inspector oversight. The longer the plan is implemented, the more likely it is that the new controls will become "habits" that continue to be used in the food establishment after inspector oversight ends.

An RCP should stress simple control measures that can be integrated into the daily routine. It should be brief, no more than one page for each risk factor, and address the following points in very specific terms:

- What is the risk factor to be controlled?
- How is the risk factor controlled?
- Who is responsible for the control?
- What monitoring and record keeping is required?
- Who is responsible for monitoring and completing records?
- What corrective actions should be taken when deviations are noted?

- How long is the plan to continue?
- How are the results of the RCP communicated to inspectors?

By implementing an RCP, the retail or food service operator will have the opportunity to determine the appropriate corrective action for the identified problem and design an implementation strategy to best suit the establishment and operation. Since the RCP is tailored to meet the needs of the food establishment, the operator takes complete ownership of the plan and is ultimately responsible for its development and implementation. The role of inspectors are to consult with the operator by suggesting ways that the risk factor(s) might be controlled.

By creating an RCP, the operator realizes that a problem exists in the established food safety management system and commits to a specific correction plan rather than merely acknowledging a single violation. Follow up by telephone or in person indicates to the operator that inspectors are interested in seeing the plan succeed. This also gives inspectors an opportunity to answer any questions and offer feedback to the operator to make the RCP more useful. An example of an RCP, along with a blank template that can be used by regulatory jurisdictions, is found in FDA's Regulator's Manual: <http://www.fda.gov/Food/FoodSafety/RetailFoodProtection/ManagingFoodSafetyHACCPPrinciples/Regulators/default.htm>.

(7) Develop and Implement Comprehensive Voluntary Food Safety Management Systems based on HACCP Principles

The *Food Code* only requires HACCP plans for a few specialized processes; however, the development of voluntary HACCP plans is always encouraged. FDA Operator's Manual, "*Managing Food Safety: A Manual for the Voluntary Use of HACCP Principles for Operators of Food Service and Retail Establishments*" is written to aid food establishment managers in the development of food safety management systems based on HACCP principles. A retail or food service operator, in consultation with an appropriate regulatory authority or other food safety professional, can use this document to establish an effective food safety management system to control for all foodborne illness risk factors. This document is available from FDA through the following website:

<http://www.fda.gov/Food/FoodSafety/RetailFoodProtection/ManagingFoodSafetyHACCPPrinciples/Operators/default.htm>.

6. INSPECTION FORM AND SCORING

A. The Inspection Form

The inspection form is the official document utilized by a regulatory agency for documentation of compliance of the food establishment with regulatory requirements. The goal of the inspection form is to clearly, concisely, and fairly present the compliance status of the food establishment and to convey compliance information to the permit holder or person in charge at the conclusion of the inspection.

The inspection report should be kept in the food establishment's files for subsequent compliance actions and review before the next inspection. Individual inspection reports are to be made available for public review in accordance with Freedom of Information criteria.

Annex 7 of the Food Code provides an inspection form that may be completed for routine, follow-up, and compliance inspections. This inspection form meets requirements established in Standards 3 and 6 of the Program Standards.

B. Debiting Methodology

If a violation exists during an inspection, it should always be marked on the inspection report, even if corrected on site. Violations existing at the time of the inspection probably would have persisted if it were not for the inspection. Slight violations, such as one dirty utensil among hundreds of clean utensils, does not indicate that the food establishment is significantly deviating from the Code requirements; therefore, discretion in marking is required.

It is very important to investigate the root causes of violations and mark them appropriately. Without taking this extra step, inspectors will merely point out violations and will not identify weaknesses in the management system in place. If long-term control of the behaviors or practices leading to the violations is expected, inspectors must identify the causes.

C. Scoring

Regulatory agencies may use scoring methods to rate food establishments. Depending on the system used, establishment scoring may provide an indication of how well a food establishment is complying with the food safety rules of the regulatory agency.

Some agencies use a system of compliance tools as provided in Chapter 8 and Annex 1 of the Food Code to protect public health. The inspection score may serve as the basis for triggering follow-up inspections or other forms of regulatory sanctions when they fall too far from the accepted levels. In addition, scoring may provide a mechanism for consumers to make informed choices regarding where they want to eat.

Use of scoring systems also has negative consequences. For example, it is possible for a food establishment to receive a high numerical or letter score while exhibiting some very serious deficiencies. In recognition of this drawback, some jurisdictions forego scoring systems in favor of demerits or debit systems without assigning a final score. This focuses attention on the items needing correction. Compliance and enforcement decisions can still be based on the increasing levels of identified deficiencies. Whatever method or system of establishment rating is used, policies regarding follow-up and enforcement actions should be established in writing, linked to the rating system, and administered consistently.

7. CLOSING CONFERENCE

The closing conference should include a detailed discussion of the food establishment's plans for correcting violations found during the inspection. The evidence collected or observed during the inspection and the alternatives available for compliance should be emphasized. On-site corrections made during the inspection should be acknowledged on the inspection report and in the closing conference.

The compliance plan should address changes in procedures that will prevent the recurrence of noted violations. The food establishment's compliance plans should be formally documented on the inspection report form. Follow-up letters may be necessary to elicit fulfillment of these agreements. It is important to stress to the operator that long-term correction of violations related to foodborne illness risk factors and Food Code interventions is far more important than corrections of core items.

8. SUMMARY

Although a retail and food service operator has the responsibility for establishing a food safety management system for controlling foodborne illness risk factors, inspectors have a vital, multi-faceted role in consumer protection. It is essential that inspectors are provided with the proper training, equipment, time, and resources to adequately perform their jobs.

The primary role of inspectors is to ensure that the operator has effective control of foodborne illness risk factors. Once inspectors have established a dialogue with the person in charge and employees, conducted a menu/food list review, and established a dialogue with the person in charge, inspectors will have enough information to mentally place menu items into one of the three process flows. The inspection can then focus on assessing the operator's active managerial control of foodborne illness risk factors associated with each process.

Once out-of-control foodborne illness risk factors are identified, the role of inspectors shifts to assisting the operator with strengthening the existing food safety management system through intervention strategies designed to achieve immediate and long-term compliance. With inspector's assistance, a retail and food service operator can achieve long-term behavioral change resulting in a reduction in risk factor occurrence and an increase in public health protection.