SECTION D
Conducting Risk-based Inspections

A. PURPOSES AND SCOPE:

(1) The ultimate responsibility for food safety at the food service establishment lies with the food service permit holder, the Certified Food Safety Manager (CFSM) and or the Person in Charge (PIC) and their ability to develop and maintain effective food safety management systems. The goal of Section D is to provide the Environmental Health Specialist, also known here after as EHS, with a practical, HACCP-based approach to evaluate the food service establishment through his assessment of active managerial control of foodborne illness risk factors within the establishment. Since food safety management systems are designed by food service operators to best meet their own needs, the EHS will need to use a risk-based methodology during his or her inspections to uncover the systems being used and to evaluate their effectiveness.

(2) Regardless of the resource limitations that the EHS may have, he or she can still use the principles of HACCP to guide their inspections. Many of them already have the technical food safety knowledge needed to effectively use a HACCP approach.

(3) 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:

(a) Food from Unsafe Sources
(b) Inadequate Cooking
(c) Improper Holding Temperature
(d) Contaminated Equipment
(e) Poor Personal Hygiene

B. RISK-BASED ROUTINE INSPECTIONS:

(1) 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.

(2) Environmental Health 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.

(3) 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.

(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.

(5) 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. Routine inspections and follow-up activities must be proactive by using an inspection process designed to evaluate the implementation of the Chapter's interventions and the degree of active managerial control that foodservice operators have over foodborne illness risk factors. The five interventions within the Chapter below were new interventions introduced with the 1993 FDA Model 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:

(a) Demonstration of Knowledge
(b) Implementation of Employee Health Policies
(c) Hands as a Vehicle of Contamination
(d) Time/Temperature Relationships
(e) Consumer Advisory.

(6) When the Georgia Food Service Rules and Regulations Chapter 290-5-14 hereafter called, the Chapter, interventions are not being implemented or if behaviors, activities, or procedures likely to cause foodborne illness are observed, EHS 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.

(7) 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.

(8) The inspection process is also an opportunity to educate the operator on the public health reasons supporting the Chapter 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.

(9) 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.

C. WHAT IS NEEDED TO PROPERLY CONDUCT A RISK-BASED INSPECTION:

(1) Schedule Inspections Based on Risk:

(a) Studies have shown that the types of food served, the food preparation processes used, the volume of food, and the populations served all have a bearing on the occurrence of foodborne illness risk factors in foodservice establishments. Rule 290-5-14-.10 subsection (2)(a) of the Chapter requires that food service establishments be grouped into three categories based on potential and inherent food safety risks. In addition, Rule 290-5-14-.10 subsection (2)(b) requires that Health Authorities 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.

(b) Table 1 of this Section 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 local Health Authority will need to group all food service establishments within their jurisdiction according to risk categories according to the Chapter Rule 290-5-14-.10 subsection (2)(a). It is recommended that each local Health Authority reassess each establishment's assigned risk categorization at a rate of not less than once per year.

Table 1. Risk Categorization of Food Establishments

RISK CATEGORY	DESCRIPTION	FREQUENCY #/YR
1 (NO COOK STEP)	Examples include mobile food service units serving hot dogs, most concessionaires and coffee shops. Establishments that serve or sell only pre-packaged, non-potentially hazardous foods (non time/temperature control for safety (TCS) foods). Establishments that prepare only non-potentially hazardous foods (non-TCS 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 do not intake raw ingredients of animal origin and cook them for food safety. Establishments that do not prepare or serve any food items that require a consumer disclosure and reminder. Establishments that do not have processing steps that require a variance and/or HACCP plan.	1
2 (COOK STEP)	Examples may include schools, and fast food service operations. Limited menu. Most products are prepared/cooked and served immediately. May have an extensive menu and with handling of raw ingredients. May conduct complex preparation of potentially hazardous foods (TCS foods) requiring cooking, cooling, and reheating for hot holding such as a full service restaurant. Variety of processes require hot and cold holding of potentially hazardous food (TCS food).	2
3 (REQUIRED HACCP PLAN)	Establishments that conduct specialized processes, e.g., smoking and curing; reduced oxygen packaging for extended shelf life, requiring a variance and an approved HACCP plan. An example may be a full service restaurant that serves sushi rice. 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).	3
Note: Frequency of Inspection will also be based on Establishment grading as per the Chapter in Rule 290-5-14-.10 (2)(b)		

(c) Regardless of the risk category initially assigned to food establishments, the following factors may be used by local Health Authorities to justify an increase in inspection frequency:

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

(2) Have the Proper Equipment:

(a) 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. At a minimum, each EHS should be provided with the following essential equipment:

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

(b) Other equipment may be provided to EHS on an "as needed" basis. While it is desirable for each inspector to have the following equipment, depending on the resources available to the Health Authority, this equipment may be shared in a central office as appropriate:

1. Pressure gauge for determining in-line pressure of hot water at injection point of warewashing machine (15-25 psi)
2. Light meter
3. Measuring device for measuring distances
4. Time/temperature data logger
5. pH meter
6. Water activity meter
7. Camera
8. Computers with or without an electronic inspection system
9. Black light

10. Foodborne illness investigation kits
11. Sample collection kits
12. Cell phones.

(3) Provide Adequate Training: EHS staff shall have the knowledge, skills, and ability to adequately perform their required duties. EHS 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

(a) Classroom Training:

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

   a. Basic knowledge of Chapter 290-5-14
   b. Public health principles
   c. Communication skills
   d. Epidemiology
   e. Microbiology
   f. HACCP.

2. FDA's ORA-U (http://www.fda.gov/ora/training/) provides basic curriculum components free of charge to Health Authorities via the Internet. It allows EHS to access training as needed. Online learning allows the local Health Authority to cost-effectively disseminate the most current technical and regulatory information on an as-needed basis.

(b) Field Training and Experience:

1. The second phase of training will move the new EHS into the field with a training officer, the District Standard. 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 Chapter interventions, and completing the inspection form. If an electronic database is used by the local Health Authority, training in its use should be included in this phase.

2. The evaluation of food safety management systems based on HACCP principles is to be part of the field training experience. The trainee and the trainer will review establishment menus, operations, recipes, and standard operating procedures. EHS must 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 will also include a familiarization with the compliance and enforcement protocol in the Chapter including recommendation of voluntary strategies, such as risk-control plans, to prevent risk factor occurrence.

(c) Standardization: The third part of staff training will include standardization. This process improves uniformity in the application and interpretation of applicable regulations, inspection methodology, and report writing. Standardization of County EHS will be as per Chapter in Rule 290-5-14-.09 and as prescribed within the Georgia Standardization Procedure – ***see Part I Section B Subsection I entitled, "Certification and Standardization of Environmental Health Personnel" and Part II Section L – "Georgia Standardization Procedure"***.

(d) Continuing Education: The training process for EHS should be continuous. The final phase of training will include a mechanism to ensure that learning is ongoing and staff is kept abreast of food safety issues and the latest science. ***See Part I Section B Subsection I entitled, "Certification and Standardization of Environmental Health Personnel"***.

(4) Ensure Adequate Program Resources:

(a) The local Health Authority is encouraged to maintain adequate funding, staff, and equipment necessary to support a risk-based food safety program designed to reduce the occurrence of foodborne illness risk factors. Local Health Authorities should do everything they can to secure funding and resources to support their food safety program.

(b) The food safety program budget should provide the necessary resources to develop and maintain a food safety program that has a staffing level of one full-time equivalent (FTE) devoted to the food service program 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.

(5) Focus the Inspection:

(a) Conducting a risk-based inspection requires EHS 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 the Chapter interventions also be verified during each inspection. EHS 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 employee's questions to supplement actual observations.

(b) Food service establishment operators must implement "control measures" to ensure food safety. Control measures are actions or activities that are used to prevent, eliminate, or reduce food safety hazards. EHS 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 EHS to understand that the food preparation processes and all the associated control measures initiated by a food service operator represent a food safety management system. It will be necessary for EHS to ask questions in order to gain information about the system already in place. Once the degree of active managerial control is determined, EHS will be able to assist operators with strengthening their existing food safety management systems.

(6) Lead by Example:

(a) Nonverbal communication is just as important as verbal communication in relaying important food safety principles to food service establishment operators. By setting the example during inspections, EHS 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 EHS set the example during inspections:

1. 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
2. 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
3. Being careful not to touch ready-to-eat (RTE) food with their bare hands
4. Washing and sanitizing their thermocouple probe at the start of the inspection and between foods
5. Using a proper hair restraint and practicing good personal hygiene

6. Being careful not to contaminate clean and sanitized food contact-surfaces with unclean hands or their inspection equipment.

(7) Conduct Inspections at Variable Times:

(a) EHS should enter the food service establishment during hours of operation or at other reasonable times. They should show identification and provide the permit holder or person in charge with a verbal or written notice of the purpose of the inspection. Requirements outlined in Rule 290-5-14-.10 subsection (2) (d) of the Chapter should be followed if access to conduct an inspection is denied. Refusal should be documented on the inspection report and an inspection warrant should be obtained as per the Chapter in Rule290-5-14-.10 subsection (2)(d) 1. Legal council representing the local Health Authority should always be consulted during this process.

(b) In planning for inspections, EHS should consider the importance of timing. Several operational steps at the food service establishment 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, EHS should be allowed the flexibility to conduct inspections early in the morning and late in the evening.

(8) Establish Inspection Priorities and Use Inspection Time Wisely:

(a) With the limited time allotted for inspections, EHS 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.

(b) 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:

a. The tone of the inspection is often set during the first few minutes of the inspection. A professional but personable approach is the balance that should be maintained. Genuine interest in the food establishment and the staff translates into good relations that 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 EHS an

opportunity to learn important information about the existing food safety management system. However, there may be times when misunderstanding of the applicability of a particular rule of the Chapter may occur where an interpretation may be sought by either the food service operator or the Environmentalist. See Part-I, Section A of this Manual for processes by which the food service operator may seek clarification of the applicability of a Rule or a violation of the Chapter noted by the Environmentalist during an inspection. In addition, Part-I Section A of this Manual provides the process by which an interpretation of a Rule and Regulation of the Chapter may be sought by both the food service operator and the Environmentalist.

b. 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 the Chapter 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 hand washing 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.

c. The person in charge should be encouraged to accompany EHS 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 Chapter interventions is more apparent if they are pointed out during the inspection rather than waiting until the end. Violations shall be marked on the inspection form even if immediate corrective actions are taken. Corrective actions taken will also be recorded on the inspection form. EHS 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.

d. 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, EHS should ask in the

beginning of the inspection if any foods are currently being cooled or reheated.

It is important for EHS 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:

   a. In order to detect trends of out-of-control foodborne illness risk factors, it is important for EHS 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 EHS 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 Section.

   b. Knowledge of what has been corrected from the last inspection also gives EHS an opportunity to provide positive feedback to the operator and allows inspectors to track corrected violations in accordance with the Chapter.

3. Conduct a Menu/Food List Review:

   a. Menus, including all written and verbal lists of foods prepared and offered in a food service 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.

   b. A review of the menu/food list allows inspectors to begin to group food items into one of three broad process categories. 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:

(I). High-risk foods or high-risk food preparation processes

(II). Operational steps requiring further inquiry such as receiving, preparation, cooking, and cooling.

c. 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 EHS 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.

d. Several operational steps like receiving, preparation, cooking, and cooling may not be inspected as vigorously in 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 EHS asks enough questions to obtain information about the operational steps that they cannot directly observe during the current inspection.

4. Conduct a Quick Walk-through:

a. As EHS 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 walkthrough is especially important to observe several activities that might otherwise go unnoticed or unobserved until later in the inspection, including:

1. Receiving:
2. Food preparation and handling
3. Cooking
4. Cooling

5. Reheating.

b. Speaking directly to the food service employees doing specific tasks is also an excellent way to assess the effectiveness of the person in charge performing his or her duty of food safety training. Should an employee be found not washing equipment and utensil properly, the EHS may question the employee's knowledge of the warewashing sink's proper set up and use. Further, noting that receiving or food preparation is occurring at the beginning of the inspection allows EHS an opportunity to take advantage of viewing "real-life" production processes and will help them to obtain a clear picture of the establishment's true practices. Receiving and food preparation only occur during limited times, so EHS may want to stop and observe these operational steps while they are happening.

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

(9) Determine Process Flows:

(a) 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.

(b) Most food items produced in a 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 EHS to be knowledgeable regarding how food is prepared in the operation. Knowing how products are prepared in an establishment allows EHS to focus their inspections on the critical procedures and steps in the preparation of those products.

(10) Determine Foodborne Illness Risk Factors In Process Flows: EHS 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, EHS should independently evaluate each operation and food preparation process conducted.

(11) Assess Active Managerial Control of Foodborne Illness Risk Factors and Implementation of the Chapter's Interventions:

(a) 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.

(b) 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.

(c) 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 Chapter interventions. Assessment of active managerial control involves more than determining compliance with the Chapter provisions. In assessing whether the operator has active managerial control, EHS 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, EHS 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, the EHS

observes that control measures are not being implemented appropriately to control risk factor occurrence, immediate corrective action must be taken.

(12) Demonstration of Knowledge:

(a) It is the responsibility of the person in charge to ensure compliance with Chapter 290-5-14. Knowledge and application of the Chapter's 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.

(b) 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:

1. A valid food protection manager certificate
2. No critical violations during the current inspection
3. Correct responses to food safety related questions as presented in Rule 290-5-14-.03 subsection (1) (c) of the Chapter

(13) Assessing Safe Sources and Receiving Temperatures:

(a) 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. EHS 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, EHS should:

1. Verify internal product temperatures
2. Examine package integrity upon delivery
3. Look for signs of temperature abuse (e.g., large ice crystals in the packages of frozen products)
4. Examine delivery truck and products for potential for cross-contamination
5. 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
6. 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.

(b) When evaluating approved sources for shellfish, such as clams, oysters, and mussels, EHS should ask whether shellfish are served at any time during the

year. If so, they 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 (http://www.cfsan.fda.gov/~ear/shellfis.html). EHS 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.

(c) With regard to fish, EHS 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 the EHS's arrival, temperatures should be taken, especially if there are finfish such as tuna, mahi-mahi, bluefish, mackerel, and snapper. These fish are subject to scombrotoxin formation if time/temperature abused. EHS should verify freshness by conducting an organoleptic inspection of the gills, eyes, and bodies of the fish.

(d) EHS 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, they should verify that the freezing records are maintained for at least 90 days beyond the date of sale or service.

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

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

(g) During the inspection, EHS 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, they 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 EHS should inquire as to the source of these products.

(h) Food from unapproved, unsafe, or otherwise unverifiable sources should be discarded or put on hold until appropriate documentation is provided. In addition, EHS 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.

(14) Assessing Contaminated Equipment and Potential for Cross-Contamination:

(a) 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.

(b) As EHS walk through the food establishment, they should examine food storage areas for proper storage, separation, segregation, and protection from contamination. They 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.

(c) 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.

(d) Following the flow of food as it is prepared in the food establishment may alert EHS to opportunities for cross-contamination. When contamination has occurred between raw and ready-to-eat food, they 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.

(e) EHS 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 Chapter 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.

(f) 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 re-sanitized.

(g) 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 hand washing 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 re-sanitize the equipment.

(h) EHS should observe hand washing operations. If hand washing 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. They 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, they should verify that the placement of sinks and food preparation areas do not facilitate opportunities for cross-contamination from one to the other.

(i) With regard to the cleaning and sanitization of food-contact surfaces, EHS 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 Chapter. Questions should be asked to assess how utensils and cookware are washed, rinsed, and sanitized in the food service establishment. When assessing the warewashing procedure and equipment, they should pay particular attention to cooking and baking equipment that is too large to fit in the warewashing-machine or sinks. It is good ideas 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.

(15) Assessing Cooking Temperatures:

(a) If an opportunity exists, food cooking temperatures and times must be verified by EHS during each inspection. Every effort should be made to assess the cooking temperatures of a variety of products served in the food establishment.

(b) 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.

(c) Critical limits for cooking potentially hazardous foods (TCS foods) in the Chapter 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.

(d) 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 parts of a product are the points of measurement of product temperature particularly when measuring critical limits for cooking.

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

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

(g) Food establishments should routinely monitor cooking temperatures. EHS 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.

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

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

(16) Assessing Holding Time and Temperatures and Date Marking:

(a) Available hot and cold holding temperatures, as well as cooling time and temperatures, of potentially hazardous foods (TCS foods) must 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 or satellite kitchens. As a rule, every effort should be made to assess every hot and cold holding unit in the food service establishment during a risk-based inspection

(b) Use of an infrared thermometer for verifying holding temperatures is not consistent with the Chapter requirements since verifying only the surface temperature of the food may not alert EHS 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, EHS should not stir a food before taking its temperature since it is important to know the temperature of the food before it is agitated.

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

(d) 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 marking violations. 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.

(e) Corrective actions for foods found in violation should be required based on the Rule 290-5-14-.10 subsection (3) of the Chapter (i.e., the Chapter) and the guidance provided within this Manual. If foods are to be discarded, forms such as, "Withhold from Sale Order" may need to be completed as per

Rule 290-5-14-.10 subsection (3) of the Chapter. 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 EHS with enough information to make the appropriate recommendation for on-site correction:

1. Are there any written procedures in place for using time alone as a public health control and, if so, are they being followed properly?
2. What are the ingredients of the food and how was it made?
3. Is it likely that the food contains *Clostridium perfringens*, *Clostridium botulinum*, or *Bacillus cereus* as hazards?
4. Has there been an opportunity for post-cook contamination with raw animal foods or contaminated equipment?
5. If there has been an opportunity for post-cook contamination, can the hazards of concern be eliminated by reheating?
6. Are the food employees practicing good personal hygiene including frequent and effective hand washing?
7. Was the food reheated or cooked to the proper temperature before being allowed out of temperature control?
8. What is the current temperature of the food when taken with a probe thermometer?
9. 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?
10. Is it likely that food has cooled to its current temperature after being out of temperature control for the alleged time?
11. Will the food be saved as leftovers?
12. How long before the food will be served?
13. 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?

(f) 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.

(g) 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. EHS must verify that the written procedures are on-site and followed in accordance with the Chapter.

(h) 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. EHS must ask questions to ascertain whether the system in place to control for *L. monocytogenes* meets the intent of Rule 290-5-14-.04 subsection (6) (g) in the Chapter. Food that should be date marked and is not must be discarded.

(17) Assessing Reheating for Hot Holding:

(a) 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 preopening preparation or other preparation periods, EHS 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.

(b) 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.

(18) Assessing Cooling:

(a) 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 a EHS 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 EHS become as familiar as possible with each operation and schedule their inspections accordingly.

(b) Due to the time parameters involved in cooling, EHS should always inquire at the beginning of the inspection whether there are any products currently being cooled. This allows EHS 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.

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

(d) 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.

(e) 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.

(f) The following guidance may be used for determining the appropriate corrective action for improper cooling:

1. Cooked hot food may be reheated to 165 ºF for 15 seconds and the cooling process started again using a different cooling method if the food is:

    a. Above 70 ºF and two hours or less into the cooling process.

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

    a. Above 70 ºF and more than two hours into the cooling process; or

    b. Above 41 ºF and more than six hours into the cooling process.

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

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

(a) 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:

1. Employee health policy
2. Proper hand washing
3. No bare hand contact with ready-to-eat foods.

(b) 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 Rule 290-5-14-.03 subsection (4) of the Chapter. 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.

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

1. What kind of policy do you have in place for handling sick employees?
2. Is there a written policy? (Note: a written policy is not required in the Chapter, but having a written policy may give an indication of the formality of the policy being discussed.)
3. Describe how managers and food employees are made knowledgeable about their duties and responsibilities under the employee health policy.
4. 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?
5. What are food employees instructed to do when they are sick?
6. What conditions or symptoms are reported?
7. What may some indicators be of someone who is working while ill?
8. When are employees restricted from working with exposed food or food-contact surfaces? When are they excluded from working in the food establishment?

9. For employees that are sick and cannot come to work, what policy is in place for allowing them to return and for notifying the local Health Authority?

(d) 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 hand washing. EHS 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.

(e) If ready-to-eat food is touched with bare hands, EHS 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:

1. Does the facility have an employee health policy to identify, restrict, and exclude ill employees?
2. Did the employees working with the food in question effectively wash their hands and is hand washing facilities adequate?
3. Is there an approved, alternate procedure to no bare hand contact (i.e., variance with an approved HACCP plan) in place and was it followed before the bare hand contact?
4. Has there been an opportunity for the employee's hands to become contaminated?

(f) EHS should examine the location of hand washing sinks in relation to where food is being prepared. A basic distance measurement is referenced within ***Part-I Section F - Handwashing located within the "Food Service Establishment Manual for Design, Installation and Construction"*** as a guideline when considering the location and number of hand washing 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 is an adequate number of hand washing sinks or whether the hand washing sinks are conveniently located.

(g) 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 hand washing sink using the referenced distance measurement in the plan review manual, if a prep table the length of

the line is placed between the line and the hand washing sink, the hand washing sink may not be conveniently located. Likewise, one hand washing 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.

(20) Assessing Compliance with Approved Procedures: When conducting certain specialized processes, the Chapter requires variances and HACCP plans. This is because such processes carry a considerable risk if not conducted under strict controls. For food service 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.

(21) Assessing Special Requirements Related to Highly Susceptible Populations (HSP):

(a) Food establishments that serve highly susceptible populations (HSP) must adhere to additional requirements as specified under Rule 290-5-14-.04 subsection (9) of the Chapter. 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 Rules of the Chapter.

(b) 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 EHS 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.

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

(a) 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.

(b) EHS 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, they 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.

(23) Assessing Compliance with Consumer Advisory:

(a) EHS 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. They should review the menu or food list to verify that a consumer advisory with a disclosure and reminder is present as specified under Rule 290-5-14-.04 subsection (7)(e) of the Chapter.

(b) In addition to reviewing the menu or food list, EHS 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.

(24) Evaluating Basic Sanitation and Facilities (Good Retail Practices):

(a) 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 service 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:

1. Protect products from contamination by biological, chemical, and physical food safety hazards
2. Control bacterial growth that can result from temperature abuse during storage

3. Maintain equipment, especially equipment used to maintain product temperatures.

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

1. Pest control
2. Food protection (non-critical)
3. Equipment maintenance
4. Water
5. Plumbing
6. Toilet facilities
7. Sewage
8. Garbage and refuse disposal
9. Physical facilities.

E. ACHIEVING ON-SITE AND LONG-TERM COMPLIANCE:

(1). Developing an Effective Compliance and Enforcement Protocol:

(a) Compliance and enforcement are essential elements of the Chapter and encompass all voluntary and regulatory enforcement actions taken to achieve compliance with it. Rule 290-5-14-.10 establishes a compliance and enforcement protocol that will result in credible follow-up for each violation noted during an inspection, especially violations related to foodborne illness risk factors and Chapter interventions. Lack of follow-up on the part of the County Health Authority signals to the operator that the critical violations noted were not important.

(b) The resolution of out-of-compliance foodborne illness risk factors and the Chapter's interventions must be documented in each food establishment record. The desired outcome of the Chapter is an effective compliance and enforcement program that is implemented consistently to achieve compliance with its Rules and Regulation requirements.

(c) It is essential that local Health Authorities 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 local Health Authority as prescribed within Rule 290-5-14-.10 of the Chapter. Involuntary enforcement actions include, but are not limited to, such activities as warning letters, re-inspections, citations, administrative fines, hearings, permit suspensions, and permit revocation - ***see Rule 290-5-14-.10 subsection (1) (b), (c), (d) and (e) and subsection (2) (i), (j), (m), (n),(o) and (p)***.

(d) Food establishment with a history of noncompliance or with the number of foodborne illness risk factors and interventions violated at a level as indicated within Rule 290-5-14-.10 of the Chapter thereby warranting enforcement action, signals the need for either a strong enforcement response or an alternate approach to compliance to protect public health. Such compliance can be achieved through active managerial control, behavioral change by using tools such as Risk Control Plans.

(e) 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 this manual as "intervention strategies." Intervention strategies can be divided into two groups:

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

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

(2) <u>On-site Correction</u>:

(a) 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.

(b) **It is essential to consumer protection and to the Health Authority's 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 the management of the food service establishment. 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.

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

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

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

(e) 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 EHS may need to conduct a hazard analysis of the food in order to determine the appropriate course of action to take.

(3) Intervention Strategies for Achieving Long-term Compliance:

(a) 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 Chapter 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.

(b) 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.

(c) The operator may best achieve long-term compliance through voluntary actions. 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.

(c) Change Equipment and Layout:

1. Critical limits are difficult to achieve when equipment does not work properly. In addition, this is why maintenance and replacement of equipment is important as well. 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. This is why good plan and specification review is important in the construction, renovation and remodeling food service establishments. For example:

   a. 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.
   b. Splash from a nearby hand washing sink is seen on a prep table. A splashguard is installed to prevent cross contamination from the hand washing sink to the prep table.

(4) Establish Buyer Specifications: Written specifications for the goods and services purchased by a food establishment prevent many problems. For example:

(a) 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 service establishment. Buyer specifications are established to place the responsibility for freezing the fish on the supplier.

(b) 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.

(5) 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:

(a) 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.

(b) Pasteurized eggs are substituted in recipes that call for raw or undercooked eggs to reduce the risk of foodborne illness.

(c) 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.

(d) 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.

(6) 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 Chapter 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.

(7) Develop and Implement Standard Operating Procedures (SOPs):

(a) 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:

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

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

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

(8) Develop and Implement Risk Control Plans (RCPs):

(a) A Risk Control Plan (RCP) is a concisely written management plan developed by the retail or food service operator with input from the EHS that describes a management system for controlling specific out-of-control risk factors. A (RCP) is intended to be a voluntary strategy that the EHS and the PIC jointly develop to promote long-term compliance for *specific* out-of-control 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. By implementing basic control systems over a period of time (e.g., 60 – 90 days), it is likely that the new controls will become "habits" that continue.

(b) A (RCP) should stress simple control measures that can be integrated into the daily routine. It should be brief, no more than one or two pages for a single risk factor, and address the following points in very specific terms:

1. What is the risk factor to be controlled?
2. How is the risk factor controlled?
3. Who is responsible for the control?
4. What monitoring and record keeping is required?
5. Who is responsible for monitoring and completing records?
6. What corrective actions should be taken when deviations are noted?
7. How long is the plan to continue?
8. How are the results of the (RCP) communicated to you?

(c) 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 their facility and operation. Since the (RCP) is tailored to meet the needs of the establishment, the operator takes complete ownership of the plan and is ultimately responsible for its development and implementation. Your role as the health inspector is 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 their 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 your interest in seeing their plan succeed. This also gives you an opportunity to answer any questions and offer feedback to make the (RCP) more useful. See the following example of a risk control plan:

Example - Risk Control Plan (Part A)

Example Risk Control Plan for Turkey Vegetable Soup					
Establishment Name: ABC	**Establishment**			**Type of Facility: Full Service**	
Physical Address: 123 Any	**Street**			**Person in**	**Charge: John Doe**
City: Any City	**State: Any State**		**Zip:**	**00000**	**County: Any County**
Inspection Time In: 9:00 a.m.	**Inspection Time Out: 12:30 p.m.**	**Date: July 12, 2001**	**Inspector's Name: Jane Doe**		
Agency: Your jurisdiction					

Specific observation noted during inspection:

Temperature of turkey vegetable soup in walk-in cooler was 65 °F after cooling in the walk-in all night (12 hours).

Applicable code violation(s):

290-5-14-.04(5)(d) - Soup not cooled from 135 °F - 41 °F in 6 hours or less

Risk factor to be controlled:

Improper Holding Temperatures (Cooling)

What must be done to achieve compliance in the future:

Cool from 135 to 41 °F within 6 hours provided that food is cooled from 135 to 70 °F in < 2 hours.

Example - Risk Control Plan (Part B)

How will active managerial control be achieved:

(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)

Conduct a Trial Run to Determine if Cooling Procedure Works:

The head chef will portion soup at a temperature of 135 °F in cleaned and sanitized 3-inch metal pans, and place them uncovered in the coolest, protected area of the walk-in cooler. He will record the time on the "Time-Temperature Log." Two hours later, the temperature of the soup will be checked and recorded. If the temperature of the soup is not 70 °F or less, the soup will be reheated to 165°F, and the trial run will be restarted in an ice bath. When the temperature is 70°F or less within 2 hours, the time and temperature will be recorded, and cooling will continue. Four hours later, the temperature of the soup will again be checked and recorded. If the soup is 41 °F or less, the cooling procedure will be established. If the soup is not 41 °F or less, it will be discarded and other cooling options will be used (see below).

Procedure:

When there is less than one gallon of soup left over at the end of the day, the head chef will log the volume and disposition of the soup. When the volume is greater than one gallon, the established procedure will be followed. The head chef will complete the Temperature Log daily for 30 days. The general manager will review the log weekly for completeness and adherence to the procedure.
Other options that may be suggested to the operator include: purchasing a data logger to record cooling overnight; discarding any leftover soup at the end of the day; using chill sticks/ice paddles; using a ice bath to cool leftovers prior to storage; and purchasing a blast chiller).

How will the results of implementing the RCP be communicated back to the inspector:

The log will be available for review by the county health authority upon request.

As the person in charge of the _____ located at _____,
I have voluntarily developed this risk control plan, in consultation with
_____ and understand the provisions of this plan.

_____ _____
(County Health Authority) (Date)

F. INSPECTION FORM AND SCORING:

(1) The Inspection Form:

(a) The Georgia Department of Community Health (DCH) current approved Food Service Establishment Inspection Report Form and Food Service Inspection Report Addendum Form(s), as referenced within Rule 290-5-14-.10 subsection (2)(f) 1. of the Chapter, are the official documents utilized by the Health Authority for documentation of compliance of the food establishment with its 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. Likewise, through public display, the food service inspection report form will serve to make the dining public aware of the compliance status of the food service establishment. In this way, the dining public can make a well informed decision concerning their health.

(b) The food service inspection report addendum form 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.

(c) Section K within Part-II of this Manual provides copies of the current (DCH) approved Food Service Establishment Inspection Report Form and the Food Service Inspection Report Addendum Form(s) to be completed during construction/pre-operational, initial, routine, follow-up, and informal follow-up inspections as required by the Chapter.

(2) Debiting Methodology:

(a) If a violation exists during an inspection, ***it shall 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. A slight violation, such as one dirty utensil among hundreds of clean utensils, does not indicate that the food establishment is significantly deviating from the Chapter requirements; therefore, discretion in marking is required.

(b) It is very important to investigate the root causes of violations and mark them appropriately. Without taking this extra step, EHS 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, EHS must identify the causes.

(3) Grading, Posting of Inspection Report Forms and Enforcement:

(a) The inspection grading will be as referenced within Rule 290-5-14-.10 subsection (2) (h), (l), (m) and (n) of the Chapter. The overall Score/Grade along with the frequency of occurrence of Risk Factors/ Public Health Interventions (RF/PHI) and Good Retail Practices (GRP) being out of control or repeated will serve as the basis for triggering follow-up inspections or other forms of enforcement action such as voluntary or in-voluntary closure of the establishment. In addition, scoring and posting the food service inspection report form will provide a mechanism for consumers to make informed choices regarding their health.

(b) Posting of the Food Service Establishment Inspection Report Form and the Food Service Inspection Report Addendum Form(s) will be as per Rule 290-5-14-.10 subsection (2) (g), (n), and (o) of the Chapter.

(c) Enforcement of the Chapter will be as per Rule 290-5-14-.10 Compliance Procedures. Amended.

(4) Closing Conference:

(a) 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 must be recorded on the inspection report and in the closing conference - ***see Rule 290-5-14-.10 subsection (2) (f)***.

(b) 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 Chapter interventions is far more important than corrections of non-critical items.

Example Immediate Corrective Actions and Intervention Strategies for Achieving Long-Term Compliance of Out-of-Control Procedures

Out-of-Control Procedure	Associated Hazards	Immediate Correction Action(s)	Intervention Strategies for Achieving Long-term Compliance
Bare Hand Contact with RTE Food	Bacteria, Parasites, and Viruses via Fecal-oral Route	Conduct Hazard Analysis.	RCP, Train Employees, SOP/HACCP Development
Cold Holding	Vegetative Bacteria, Toxin-forming and Spore-forming Bacteria, Scrombrotoxin (Finfish)	Conduct Hazard Analysis.	RCP, Change Equipment, Train Employees, Develop SOP/HACCP/Recipe
Contaminated Equipment	Bacteria, Parasites, and Viruses	Clean and Sanitize Equipment; Discard or Reheat RTE Food.	Train Employees, Change Equipment or Layout, Develop SOP
Cooking	Vegetative Bacteria, Parasites, and Possibly Viruses	Continue Cooking to Proper Temperature.	RCP, Change Equipment, Train Employees, Develop SOP/HACCP/Recipe
Cooling	Toxin-forming and Spore-forming Bacteria	Conduct Hazard Analysis.	RCP, Change Equipment, Train Employees, Develop SOP/HACCP/Recipe
Cross-Contamination of RTE Foods with Raw Animal Foods	Bacteria, Parasites, and Possibly Viruses	Discard or Reheat RTE Food.	RCP, Change Equipment Layout, Train Employees, Develop SOP/HACCP/Recipe
Food Source/ Sound Condition	Bacteria/Parasites/ Viruses/Scombrotoxin/ Ciguatera Toxin	Reject or Discard.	Change Buyer Specifications, Train Employees
Freezing to Control Parasites	Parasites	Freeze Immediately; Discard; or Cook.	RCP, Change Buyer Specifications, Develop SOP/HACCP/Recipe, Change Equipment, Train Employees
Handwashing	Bacteria, Viruses, and Parasites	Wash Hands Immediately; Conduct Hazard Analysis.	RCP, Change Equipment Layout, Train Employees, Develop SOP/HACCP
Hot Holding	Toxin-forming and Spore-forming Bacteria	Conduct Hazard Analysis.	RCP, Change Equipment, Train Employees, Develop SOP/HACCP/Recipe
Receiving Temperatures	Scombrotoxin, Bacteria	Reject or Discard.	Change Buyer Specifications, Train Employees, Develop SOP/HACCP/Recipe
Reheating for Hot Holding	Vegetative Bacteria; Toxin-forming and Spore-forming Bacteria	Conduct Hazard Analysis.	RCP, Change Equipment, Train Employees, Develop SOP/HACCP/Recipe