



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

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Chapter 1 - Introduction

PURPOSE AND SCOPE

There is no doubt that you, the state, local, or tribal health inspector, play a significant role in reducing foodborne illness in your jurisdiction, yet your job can be overwhelming at times due to diminishing resources, increasing workload with limited staff, and growing liability. Many of you are continually forced to reassess your priorities due to increased media attention on food safety, threats from emerging pathogens, and food security, while being challenged to do more with less while maintaining your professional integrity.

Although the majority of these challenges are beyond your control, the allocation of your inspectional time is one element that you can change and continue to use to your advantage. You may undoubtedly become frustrated when you find the same violation at the same establishment, inspection after inspection. You may be able to change this pattern by focusing your inspection on the violations most likely to cause foodborne illness and by assisting retail and food service operators in the development or enhancement of food safety management systems to reduce the recurrence of these violations.



This Manual provides you with a manageable scheme for prioritizing your inspections using a risk-based approach. The traditional regulatory inspection places emphasis on assessing compliance with all applicable regulations. The same emphasis may be placed on structural violations of the code as those violations likely to lead to foodborne illness. Although this type of inspection has done a great deal to improve basic sanitation and to upgrade food facilities in the United States, it emphasizes reactive rather than preventive measures. The traditional regulatory inspection only seeks to obtain correction of food safety concerns that already exist, rather than to prevent future violations from occurring.



Each individual in the food chain from farmer to processor to retailer to consumer has some responsibility for food safety. The ultimate responsibility for food safety at the retail level lies not with the regulatory authority but with retail and food service operators and their ability to develop and maintain effective food safety management systems. Nevertheless, you can help industry with this responsibility by utilizing a risk-based inspection approach to identify



strengths and weaknesses in their systems and suggesting possible solutions for improvement during inspections.

This Manual was written to provide a "roadmap" for evaluating retail and food service establishments based on the application of HACCP principles. The acronym "HACCP" stands for "Hazard Analysis and Critical Control Point." It is a preventive approach implemented by industry to control food safety hazards. Using HACCP principles during inspections will help to assist you in evaluating the effectiveness of food safety management systems implemented by industry.

The voluntary strategies presented in this Manual also foster food safety partnerships between you and your retail or food service operators, which will facilitate your active role in improving their existing food safety management systems. Please note that this Manual is not a comprehensive resource for learning about HACCP principles; therefore, you should have a basic understanding of the principles of HACCP before using this Manual. Annex 1 lists several resources that are available to you should you require a more comprehensive explanation of HACCP.

Many regulatory jurisdictions are already conducting risk-based inspections using HACCP principles and other innovative approaches. This Manual is based on experience gained from many of these approaches and is provided to you, the regulatory food safety professional, to help you enhance the effectiveness of your inspections by incorporating a risk-based approach.

BACKGROUND

What are Foodborne Illness Risk Factors?

In an ideal world, determining the effectiveness of a retail and food service regulatory program would be based on the occurrence of foodborne illness within that jurisdiction. The occurrence of foodborne illness is, however, underreported, making it an unreliable program measurement. As an alternative, the occurrence of foodborne illness risk factors can be used to gauge program effectiveness.

The Centers for Disease Control and Prevention (CDC) Surveillance Report for 1993-1997, "Surveillance for Foodborne-Disease Outbreaks – United States," identifies the most significant 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."

The foodborne illness risk factors are:

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

Until recently, there were no standardized, systematically-compiled statistics for the incidence of occurrence of foodborne illness risk factors in retail or food service facilities. As a result, implementation of food safety management systems designed to improve conditions leading to out-of-control risk factors was difficult.

In 2000, FDA completed a project designed to fill this information void and published its results in the *Report of the FDA Retail Food Program Database of Foodborne Illness Risk Factors*. The report, commonly referred to as the “FDA Baseline Report,” is provided to regulators and industry with the expectation that it will be used to focus greater attention and increased resources on the control of risk factors. A copy of the report is available from FDA through the following website:
<http://www.cfsan.fda.gov/~dms/retrsk.html>.

The measurable trends identified in CDC’s 1993 - 1997 Surveillance Report and in FDA’s Baseline Report indicate that routine regulatory inspections should place an increased focus on assessing an establishment’s active managerial control over the five CDC-identified risk factors.

What is Meant by Active Managerial Control?

The term “active managerial control” is used extensively throughout this Manual to describe industry’s responsibility for developing and implementing food safety management systems to reduce the occurrence of foodborne illness risk factors. Although the term may be new to some, the basic management principles are probably already being used in the day-to-day operations of most of the establishments you regulate.

Active managerial control means the purposeful incorporation of specific actions or procedures by industry management into the operation of their business 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.

There are many tools that can be used by industry to provide active managerial control of risk factors. Elements of an effective food safety management system may include the following:



- Certified food protection managers who have shown a proficiency of required information by passing a test that is part of an accredited program
- Standard operating procedures (SOPs) for performing critical operational steps in a food preparation process such as cooling
- Recipe cards that contain the specific steps for preparing a food item and the food safety critical limits such as final cooking temperatures that need to be monitored and verified
- Purchase specifications
- Equipment and facility design and maintenance
- Monitoring procedures
- Record keeping
- Employee health policy for restricting or excluding ill employees
- Manager and employee training
- On-going quality control and assurance
- Specific goal-oriented plans, like Risk Control Plans (RCPs), that outline procedures for controlling specific foodborne illness risk factors

How are HACCP Principles Being Used in Retail and Food Service?

For several decades, food safety professionals have recognized the importance of HACCP principles for controlling risk factors that directly contribute to foodborne illness. Within the retail and food service industries, the implementation of these science-based food safety management principles varies.

Many multi-unit corporations and institutions, as well as independent operators, have developed effective food safety management systems that incorporate the seven principles of HACCP. The FDA document, *"Managing Food Safety: A Manual for the Voluntary Implementation of HACCP Principles for Operators of Food Service and Retail Establishments,"* is designed to aid industry in establishing effective, voluntary food safety management systems based on the principles of HACCP. The manual is available from FDA through the following website:
<http://www.cfsan.fda.gov/~dms/hret2toc.html>.

The products made in retail and food service operations are as varied as the methods and processes used to make them. The resources available to retail and food service operators to help them with identifying and controlling the risk factors particular to their operations also vary. Due to this diversity, implementation of "textbook HACCP" is impractical in most retail and food service operations.

Like many other quality assurance programs, the principles of HACCP provide a common-sense approach to identifying and controlling "problems." Consequently, many food safety management systems at the retail level incorporate some, if not all, of the principles of HACCP. Given the diversity of retail and food service operations, however, it is important for you to recognize that there is more than one "correct" application of HACCP principles. Regulatory inspection programs must be flexible

enough to operate in a complementary and effective manner in this dynamic retail environment.

The DRAFT FDA *Voluntary National Retail Food Regulatory Program Standards* establish a framework that regulatory agencies can use to –

- Design and manage a comprehensive, risk-based retail food safety program
- Provide direction and focus on the causative factors of foodborne illness based on HACCP principles
- Reinforce sanitation, operational, and environmental prerequisite programs

The complete set of *Program Standards* is available from FDA through the following website: <http://www.cfsan.fda.gov/~dms/ret-toc.html>.

SUMMARY

The ultimate responsibility for food safety at the retail level lies with retail and food service operators and their ability to develop and maintain effective food safety management systems. The goal of this Manual is to provide you with a practical, HACCP-based approach to evaluate industry's active managerial control of foodborne illness risk factors. It is essential that regulatory program managers design an inspection program based on HACCP principles that guides and supports their field staff in assisting operators with incorporating these principles into their routine activities. Since food safety management systems are designed by retail and food service operators to best meet their own needs, you will need to use a risk-based methodology during your inspections to uncover the systems being used and to evaluate their effectiveness.

Chapter 2 – Conducting Risk-based Inspections

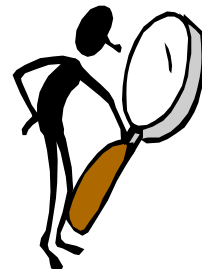
Regardless of the resource limitations you may have, you can still use the principles of HACCP to guide your inspections. Many of you already have the technical food safety knowledge needed to effectively use a HACCP approach.

For the purposes of this discussion, “hazards” are defined as the specific biological, chemical, or physical properties or agents that, if uncontrolled, may lead to illness or injury. Risk factors are the poor conditions, procedures, or practices that result in out-of-control food safety hazards. As stated in Chapter 1, risk factors include –

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

THE FOCUS OF RISK-BASED INSPECTIONS

Conducting a risk-based inspection requires you to focus on evaluating the degree of active managerial control that an operator has over risk factors. In order for you to properly assess active managerial control, you will need to spend the majority of your time observing the practices and procedures that are likely to lead to out-of-control risk factors and asking food workers questions to assess the operation.



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. You will need to determine the control measures that should be implemented to prevent the occurrence of risk factors in each food preparation process. In order to determine the risk factors common to each operation, it is important for you 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 you to ask questions in order to gain information about the system already in place. Once you have done this, you will be able to determine the degree of active managerial control present in the facility and will be able to assist the operator in strengthening the system.

SETTING THE EXAMPLE

In focusing your inspection, it is important for you to realize that your nonverbal communication is just as important as your verbal communication in relaying important food safety messages to retail and food service operators. You set the example for them to follow during all phases of your inspection. The following are ways that you set the example:

- Washing your hands when entering the food preparation area at the beginning of the inspection and after engaging in any activities that might contaminate your hands
- Not working when you are suffering from symptoms such as diarrhea, fever, vomiting, or jaundice or if you are diagnosed with a disease transmittable by food
- Being careful not to touch ready-to-eat (RTE) food with your bare hands
- Washing and sanitizing your thermocouple probe at the start of the inspection and between taking temperatures of 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 your inspection equipment



As an experienced food safety professional, you already demonstrate these personal practices in each of your inspections. You will need the additional support of your program management, however, in providing you with state-of-the-art equipment needed to perform a risk-based inspection. Utilizing the proper equipment demonstrates competency and preparedness to the operator and may convince the operator to also use the appropriate equipment. For instance, when you check the temperature of thin hamburgers using a needle probe thermocouple, you demonstrate to the operator the proper method for taking temperatures of thin products. At a minimum, you should have the following equipment to conduct a risk-based inspection:

- Thermocouple with the appropriate probes for the foods being tested
- Alcohol swabs or other suitable equipment for sanitizing probe thermometers
- Sanitization test kits
- Heat sensitive tape or maximum registering thermometer
- Flashlight

ESTABLISHING INSPECTION PRIORITIES

In planning for inspections you should consider the importance of timing. Several operational steps at retail such as receiving, preparation, and cooling can only be evaluated during limited time periods. Times may need to be varied from inspection to inspection to ensure that all critical processes are evaluated.

With the limited time allotted for inspections, you must develop clear priorities to make the most efficient use of your time in each facility. Although basic sanitation issues generally do not change during the course of a routine inspection, critical practices and procedures leading to risk factors may only be observable during limited time intervals. For this reason, assessment of the active managerial control of risk factors should generally be performed before reviewing basic sanitation issues.

By setting priorities early in the inspection, observations attributed to out-of-control risk factors can be distinguished from those related to general sanitation and maintenance. You can set priorities by completing four activities early in your inspection:

- Establishing an open dialogue with the person in charge
- Reviewing previous inspection records
- Conducting a menu or food list review
- Conducting a quick walk-through

Establishing an Open Dialogue with the Person In Charge



Having an open dialogue with the person in charge during all phases of your inspection gives you 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 your inspection so that you can focus your inspection on weak areas. For instance, through your questioning, you learn that the facility cooks chicken that is used in several end products such as soups and salads. You also learn that the facility checks the temperature of the chicken to make sure that it is cooked, but you quickly realize that no further monitoring is conducted when the chicken is cooling. Knowing this, you begin your inspection by checking cooling.

Even if you are unable to have a discussion with the person in charge at the beginning of the inspection, questions about practices and procedures related to risk factors and *Food Code* interventions, like the facility's employee health policy and consumer advisory, can certainly be asked as you conduct your inspection. It is important to ask enough questions to fully understand the system being utilized in the 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 relating the seriousness of out-of-control risk factors. If the person in charge has the time, have him or her accompany you as you conduct your inspection. This will ultimately save you time because you can point out violations as they are observed. These violations should still be marked on your inspection form, but you can obtain immediate corrective action to abate the problem before someone gets sick. You can also use this time to share your knowledge about critical processes. By communicating the public health rationale behind your regulations, you will leave the person in charge with a clear understanding for why active managerial control of risk factors must be a top priority in the day-to-day operation of the business.



Reviewing Previous Inspection Reports

In order to detect trends of out-of-control risk factors, it is important for you to review past inspection reports prior to conducting your inspection. This can be done in your office or on-site at the facility. This activity is especially important in jurisdictions where health inspectors rotate from one inspection to the next. If the same 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 (see Chapter 3). Knowledge of what has been corrected from the last inspection also gives you the opportunity to provide some positive feedback to the operator and allows you to track corrected violations in accordance with your jurisdiction's policy.



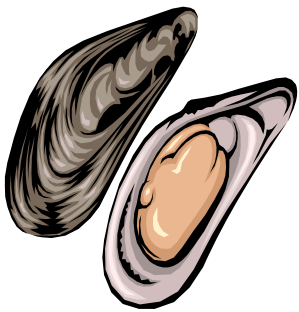
Conducting a Menu/Food List Review

The menu, whether written as in the case of restaurants, or a list of foods prepared and sold found in retail food stores, can be reviewed in a fairly simple manner. The review can either be done simultaneously with a quick walk-through of the operation (discussed later) or as a discussion with management at the beginning of the inspection. The menu/food list also does not need to be reviewed during every inspection. If a review was done during a recent inspection, you can simply ask the person in charge if there have been any changes since the last inspection. A review of the menu/food list allows you to begin to group food items into one of three broad process categories (discussed later) that will allow you to focus your inspection

on risk factors associated with each process. Conducting a review of the menu/food list also allows you to establish inspection priorities by identifying –

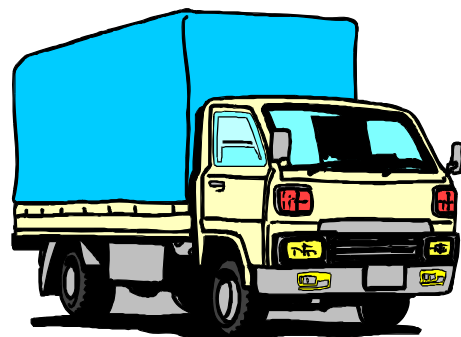
- High-risk foods or high-risk food preparation processes
- Operational steps requiring further inquiry such as receiving, preparation, cooking, and cooling

By identifying high-risk foods or high-risk food preparation processes, you can focus your inspection on those foods or processes that will most likely cause foodborne illness if uncontrolled. High-risk foods include products like raw chicken that naturally carry a high pathogenic load. If such products are used in a facility, practices related to cross-contamination and cooking should be a priority during the inspection. If there are foods that go through the temperature danger zone several times, cooling and holding practices should be reviewed. If the establishment is primarily a “Cook and Serve” operation, then time can best be spent on observing cooking practices.



The menu/food list review might be the only time you are made aware of specialized processes such as formulating a food so that it is not potentially hazardous or high-risk seasonal menu items such as raw oysters. Foods such as shellstock and certain fish for raw consumption require documentation that should be reviewed during the inspection. You may discover items on the menu such as Caesar salad or hollandaise sauce. Further inquiry is needed regarding the preparation of these items since they are sometimes prepared with raw 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 facility is inspected in the afternoon hours, for example, receiving and food preparation might have already occurred. You should ask questions to obtain information about the operational steps that you cannot directly observe in order to evaluate the establishment’s active managerial control.



Conducting a Quick Walk-through

As you discuss the menu or food list with the person in charge, it is suggested that you conduct a quick walk-through of the facility 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 until later in the inspection:

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

Noting that receiving or food preparation is occurring at the beginning of the inspection allows you to take advantage of “real-life” production processes and will help you to obtain a clear picture of the establishment's true practices. Receiving and food preparation only occur during limited times, so you may want to stop and observe these operational steps while they are happening.

For example, during the initial walk-through with the person in charge, you may see that salad is being prepared. In response, you might want to take some time to observe the preparation practices. This also offers you an excellent opportunity to interact with the food employees to observe if the food is being properly handled using utensils and to find out how the ingredients were received and stored prior to preparation. 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 (SOPs) for critical processes such as cooling.



Early in the inspection, it is also ideal to check the temperatures of potentially hazardous foods in the cooling process from the morning preparation if the inspection is in the afternoon or last night's meal service if the inspection is occurring in the morning. Also, you might want to ask whether any food is currently being cooked or reheated. The observations you make, along with the feedback you get from questioning the person in charge or the food service employees, will help you evaluate whether foods appear to have been properly processed.

EVALUATING EXISTING FOOD SAFETY MANAGEMENT SYSTEMS

Although some establishments have formal HACCP plans in place, many do not. Even without a HACCP system, every establishment needs to have active managerial control of risk factors. This may be achieved through several means, such as training programs, manager oversight, or standard operating procedures. For example, some

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, 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 to ensuring food safety. If an operator is effectively monitoring all critical activities in the 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 your inspection. As a result, it will be necessary to use direct observations and interviewing to determine whether an establishment is adequately monitoring risk factors in their existing food safety management system.

Every establishment has some type of set pattern of procedures even if it is simply described as “the way we do things.” A small, independent operation may not have written procedures, yet it may have adequate procedures that are routinely followed. Good communication is required to discover these types of informal management systems.

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 three food preparation processes then analyzing the risk factors associated with each process. By placing managerial controls on specific operational steps in the flow of food, foodborne illness can be prevented.

DETERMINING PROCESS FLOWS

The flow of food in a retail or food service establishment is the path that food follows from receiving through service or sale to the consumer. Several activities or stages make up the flow of food and are called operational steps. Examples of operational steps include receiving, storing, preparing, cooking, cooling, reheating, holding, assembling, packaging, and serving. Keep in mind that the terminology used for operational steps may differ between food service and retail food store operations. 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 to 135 °F:

- **Process 1: Food Preparation with No Cook Step**

Example flow: Receive - Store - Prepare – Hold – Serve

(other food flows are included in this process, but there is no cook step to destroy pathogens while in the retail or food service facility)

- **Process 2: Preparation for Same Day Service**

Example flow: Receive - Store - Prepare - Cook – Hold – Serve

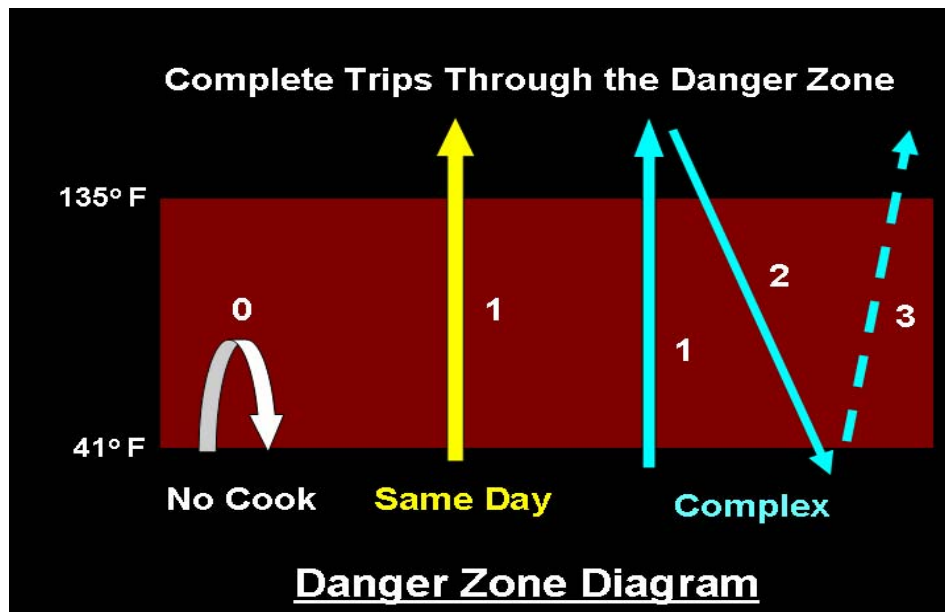
(other food flows are included in this process, but there is only one trip through the temperature danger zone)

- **Process 3: Complex Food Preparation**

Example flow: Receive - Store - Prepare - Cook - Cool - Reheat - Hot Hold - Serve

(other food flows are included in this process, but there are always two or more complete trips through the temperature danger zone)

A summary of the three food preparation processes in terms of number of times through the temperature danger zone can be depicted in a Danger Zone diagram. Note that while foods produced using process 1 may *enter* the danger zone, they are neither cooked to destroy pathogens, nor are they hot held. Foods which go through the danger zone only once are classified as Same Day Service, while foods that go through more than once are Complex.



The three food preparation processes conducted in retail and food service establishments are not intended to be all-inclusive. For instance, quick service facilities may have “cook and serve” processes specific to their operation. These processes are likely to be different from the “Same Day Service” preparation processes in full service restaurants since many of their foods are generally cooked and hot held before service.

In addition, in retail food stores, operational steps such as packaging and assembly may be included in all of the food preparation processes prior to being sold to the consumer.

It is also very common for a retail or food service operator to have a single item like a chicken salad sandwich that is created using several components that may be produced using more than one kind of food preparation process. It is important for you to remember that even though variations of the three food preparation process flows are common, the control measures – actions or activities that can be used to prevent, eliminate, or reduce food safety hazards – to be implemented in each process will generally be the same based on the number of times the food goes through the temperature danger zone.

THE HAZARD ANALYSIS

In the “process approach” to HACCP, conducting a hazard analysis on individual food items is time and labor intensive and is generally unnecessary. Identifying and controlling the hazards in each food preparation process listed above achieves the same control of risk factors as preparing a HACCP plan for each individual product.

Example: An establishment has dozens of food items (including baked chicken and meatloaf) in the “Preparation for Same Day Service” category. Each of the food items may have unique hazards (See Annex 3), but regardless of their individual hazards, control via proper cooking and holding will generally ensure the safety of all of the foods in this category. An illustration of this concept follows:

- Even though they have unique hazards, baked chicken and meatloaf are items frequently grouped in the “Same Day Service” category (Process 2).
- *Salmonella* and *Campylobacter*, as well as spore-formers, such as *Bacillus cereus* and *Clostridium perfringens*, are significant biological hazards in chicken.
- Significant biological hazards in meatloaf include *Salmonella*, *E. coli* O157:H7, *Bacillus cereus*, and *Clostridium perfringens*.
- Despite their different hazards, the control measure used to kill pathogens in both these products is cooking to the proper temperature.
- Additionally, if the products are held after cooking, then proper hot holding or time control is also necessary to prevent the outgrowth of spore-formers that are not destroyed by cooking.

As with product-specific HACCP, critical limits for cooking remain specific to each food item in the process. In the scenario described above, the cooking step for chicken requires a final internal temperature of 165 °F for 15 seconds to control the pathogen load for *Salmonella*. Meatloaf, on the other hand, is a ground beef product and requires

a final internal temperature of 155 °F for 15 seconds to control the pathogen load for both *Salmonella* and *E. coli* O157:H7. Note that there are some operational steps, such as refrigerated storage or hot holding, that have critical limits that apply to all foods.

The following table further illustrates this concept. Note that the only unique control measure applies to the critical limit of the cooking step for each of the products. Other food safety hazards and control measures may exist that are not depicted here:

Process 2: Preparation for Same Day Service		
Example Products	Baked Meatloaf	Baked Chicken
Example Biological Hazards	<i>Salmonella</i>	<i>Salmonella</i>
	<i>E. coli</i> O157:H7	<i>Campylobacter</i>
	<i>Clostridium perfringens</i>	<i>Clostridium perfringens</i>
	<i>Bacillus cereus</i>	<i>Bacillus cereus</i>
	Various fecal-oral route pathogens	Various fecal-oral route pathogens
Example Control Measures (there may be others)	Refrigeration 41 °F or below	Refrigeration 41 °F or below
	Cooking at 155 °F for 15 seconds	Cooking at 165 °F for 15 seconds
	Hot Holding at 135 °F or above OR Time Control for 4 hours or less	Hot Holding at 135 °F or above OR Time Control for 4 hours or less
	No bare hand contact with RTE food, proper handwashing, exclusion/restriction of ill employees	No bare hand contact with RTE food, proper handwashing, exclusion/restriction of ill employees

DETERMINING RISK FACTORS IN PROCESS FLOWS

Several of the most common risk factors associated with each food preparation process are discussed below. Remember that while you should generally focus your inspection on these risk factors, there may be other risk factors unique to an operation or process that are not listed here. You should evaluate each operation and food preparation process independently.

Facility-wide Considerations

In order to have active managerial control over personal hygiene and cross-contamination, an operator must implement control measures in all phases of the operation. The following control measures should be evaluated during your inspection regardless of the food preparation process used –

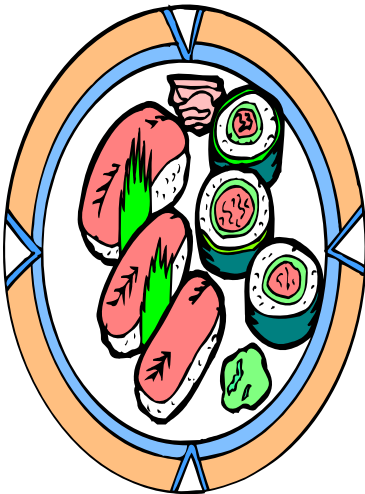
- **No bare hand contact with RTE foods (or use of an approved, alternative procedure)** to help prevent the transfer of viruses, bacteria, or parasites from hands
- **Proper handwashing** to help prevent the transfer of viruses, bacteria, or parasites from hands to food
- **Restriction or exclusion of ill employees** to help prevent the transfer of viruses, bacteria, or parasites from hands to food
- **Prevention of cross-contamination** of RTE food or clean and sanitized food contact surfaces with soiled cutting boards, utensils, aprons, etc. or raw animal foods



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Food Preparation Process 1 – Food Preparation with No Cook Step

Example Flow: RECEIVE – STORE – PREPARE – HOLD – SERVE



Several food flows are represented by this particular process. Many of these food flows are common to both retail food stores and food service facilities, while others only apply to retail operations. Raw, ready-to-eat food, such as sashimi, raw oysters, and salads, are grouped in this category. Components of these foods are received raw and will not be cooked prior to consumption. Foods cooked at the processing level but that undergo no further cooking at the retail level before being consumed are also represented in this category. Examples of these kinds of foods are deli meats, cheeses, and other pasteurized products. In addition, foods that are received and sold raw but are to be cooked by the consumer after purchase, i.e. hamburger meat, chicken, and steaks, are also included in this category.

All the foods in this category lack a kill (cook) step *while at the retail or food service establishment*. In other words, there is no complete trip made through the danger zone for the purpose of destroying pathogens. During your inspection, you can ensure that the food received in the facility is as safe as possible by checking that the food is

received in good condition and from approved sources. Without a kill step to destroy pathogens, the primary responsibility of the operator will be to prevent further contamination by ensuring that employees follow good hygienic practices. In addition, cross contamination must be prevented by properly storing your products away from raw animal foods and soiled equipment and utensils. Foodborne illness may result from ready-to-eat food being held at unsafe temperatures for long periods of time due to the outgrowth of bacteria.

In addition to the facility-wide considerations, an inspection involving this food preparation process should focus on ensuring that the facility has active managerial control over the following:

- **Cold holding or using time alone** to inhibit bacterial growth and toxin production
- **Food source** (especially for shellfish due to concerns with viruses, natural toxins, and *Vibrio* and for certain marine finfish intended for raw consumption due to concerns with ciguatera toxin) (See Annex 3)
- **Receiving temperatures** (especially certain species of marine finfish due to concerns with scombrototoxin)
- **Date marking** of RTE PHF held for more than 24 hours to control the growth of *Listeria monocytogenes*
- **Freezing** certain species of fish intended for raw consumption due to parasite concerns (See Annex 3)
- **Cooling from ambient temperature** prevent the outgrowth of spore-forming or toxin-forming bacteria



Food Preparation Process 2 – Preparation for Same Day Service

Example Flow: RECEIVE – STORE – PREPARE – COOK – HOLD – SERVE

In this food preparation process, food passes through the danger zone only once in the retail or food service facility before it is served or sold to the consumer. Food is usually cooked and held hot until served, i.e. fried chicken, but can also be cooked and served immediately. In addition to the facility-wide considerations, an inspection involving this food preparation process should focus on ensuring that the facility has active managerial control over the following:



- **cooking** to destroy bacteria and parasites; and
- **hot holding or using time alone** to prevent the outgrowth of spore-forming bacteria.

Food source and receiving temperatures/cold holding prior to cooking are also important if dealing with certain marine finfish due to

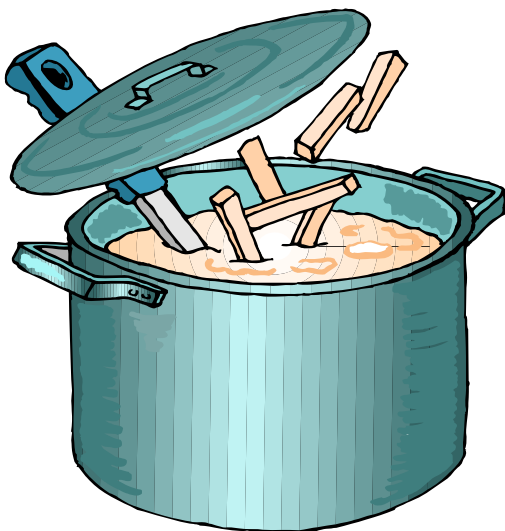
concerns with ciguatera toxin and scombrototoxin. Consult Annex 3 for other special considerations related to seafood.

Food Preparation Process 3 – Complex Food Preparation

Example Flow: RECEIVE – STORE – PREPARE – COOK – COOL – REHEAT – HOT HOLD – SERVE

Foods prepared in large volumes or in advance for next day service usually follow an extended process flow. These foods will pass through the temperature danger zone more than one time; thus, the potential for the growth of spore-forming or toxigenic bacteria is greater in this process. Failure to adequately control food product temperatures is one of the most frequently encountered risk factors contributing to foodborne illness. In addition, foods in this category have the potential to be recontaminated with *Listeria monocytogenes*, which could grow during refrigerated storage. The key to managing the operational steps within this food preparation process is to minimize the time foods are at unsafe temperatures.

In addition to the facility-wide considerations, an inspection involving this food preparation process should focus on ensuring that the facility has active managerial control over the following:



- **cooking** to destroy bacteria and parasites;
- **cooling** to prevent the outgrowth of spore-forming or toxin-forming bacteria;
- **hot and cold holding or using time alone** to inhibit bacterial growth and toxin formation
- **date marking** of RTE PHF held for more than 24 hours to control the growth of *Listeria monocytogenes*
- **reheating** for hot holding, if applicable.

Food source and receiving temperatures/cold holding prior to cooking are also important if dealing with certain marine finfish due to concerns with ciguatera toxin and scombrototoxin. Consult Annex 3 for other special considerations related to seafood.

ASSESSING ACTIVE MANAGERIAL CONTROL OF RISK FACTORS

The *Food Code* provides specific measurable criteria, often referred to as critical limits, designed to prevent, eliminate, or reduce hazards in foods. These critical limits are based on the best available science and pertain to control measures applied at operational steps. Common examples include time/temperature standards and no bare hand contact with RTE food.

At a minimum, an operator's food safety management system should be based on achieving the same level of safety established by the critical limits in the *Food Code*. When determining the degree of active managerial control an operator has over risk factors, you should observe whether the operator has established the appropriate control measures and critical limits and whether appropriate monitoring procedures are in place.

A sample list of questions to assist you in assessing an operator's active managerial control of risk factors at operational steps throughout the flow of food is in Annex 4 of this Manual. This list can be used in conjunction with any inspection form or simply as a tool to help you organize your inspection. In addition, Annex 4 of the 2001 FDA *Food Code* (or Annex 5 in the 2005 FDA *Food Code*) contains additional information on assessing the active managerial control of foodborne illness risk factors.

EVALUATING BASIC SANITATION AND FACILITIES

Systems to control basic operational and sanitation conditions within a facility, often referred to as Good Retail Practices (GRPs), Prerequisite Programs, or Standard Operating Procedures (SOPs), are the foundation of a successful food safety management system. With this in mind, consider how the establishment actively monitors these activities. Just as monitoring is required by the establishment to ensure that risk factors are controlled, monitoring of basic sanitation conditions in the facility allows the operator an excellent opportunity to detect weaknesses and initiate actions for improvement. Although the main focus of an inspection should be on evaluating the active managerial control of risk factors, overall sanitation should not be overlooked.

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

Examples of concerns addressed by the programs above include the following:

- Receiving temperatures
- Pest control
- Toxic chemical storage and labeling
- Food protection (non-critical)
- Equipment cleaning and maintenance
- Water
- Plumbing
- Toilet facilities
- Sewage
- Garbage and refuse disposal
- Physical facilities

SUMMARY

Although retail and food service operators have the responsibility for establishing food safety management systems, you, the regulator, have a vital, multi-faceted role in consumer protection. Your primary responsibility is to ensure the operator has effective control of risk factors. Once you have conducted a menu review and established a dialogue with the person in charge and food service workers, you will have enough information to mentally place menu items into one of the three process flows. Your inspection can then focus on assessing the operator's active managerial control of risk factors associated with each process.

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

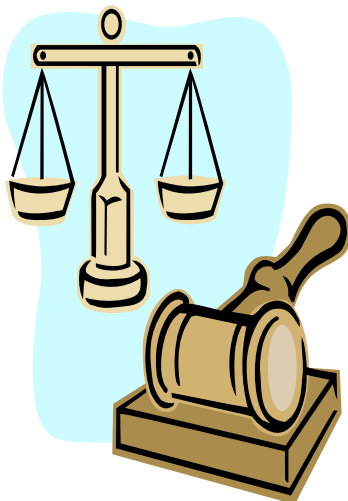
Chapter 3 - Intervention Strategies

This Chapter will introduce you to intervention strategies designed to immediately correct out-of-control risk factors and to prevent their recurrence. Your program manager can incorporate any of these strategies into your jurisdiction's compliance and enforcement protocol. You can use several of these strategies as suggestions to industry for achieving immediate and long-term active managerial control of risk factors.

THE ROLE OF INTERVENTION STRATEGIES IN COMPLIANCE AND ENFORCEMENT

Compliance and enforcement are essential elements of a regulatory program and involve all voluntary and involuntary corrections made by the operator. Voluntary corrections by the operator are referred to in this 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 risk factors can be tailored to each operation's resources and needs. This will require you to work with the operator to identify weaknesses in their existing food safety management system and consulting with them to strengthen any weak areas noted. Intervention strategies can also be adopted as part of a progressive compliance and enforcement program. Many jurisdictions around the country have successfully used the intervention strategy concept as a "first step" in their compliance and enforcement protocol. If the operator is willing to work with you to gain ownership of food safety, a long-term behavior change will more likely result. This may help reduce the amount of enforcement proceedings that occur as a result of involuntary compliance.

Involuntary compliance results from the following enforcement activities:

- Warning letters
- Re-inspections
- Citations
- Administrative fines and hearings
- Permit suspensions

Although these enforcement activities are a necessary function in your regulatory work, obtaining voluntary corrections by the operator has proven to be more effective in achieving long-term compliance.

ON-SITE CORRECTION

On-site corrections are intended to achieve immediate corrective action of out-of-control 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. For example –



- Undercooking hamburger meat presents an immediate danger to the consumer that can be corrected on-site by additional cooking.
- Preparing lettuce on the same work surface previously used to cut raw chicken without having washed, rinsed, and sanitized the surface presents an immediate danger to the consumer that can be corrected on-site by discarding the contaminated lettuce.

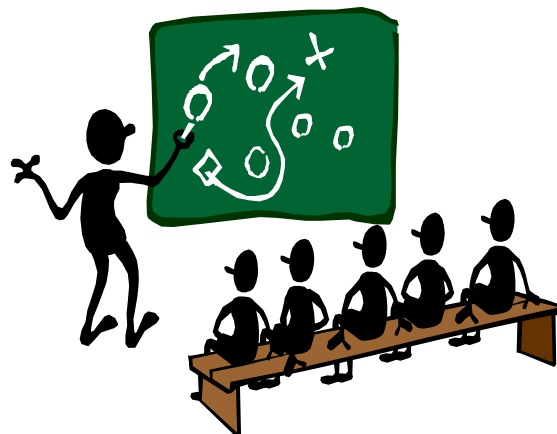
Annex 6 provides a full list of suggested on-site corrections for out-of-control procedures found during your inspections.

It is essential to consumer protection and to regulatory credibility for on-site correction to be obtained for any out-of-control risk factors. 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. If the operation is briefly stopped to address the out-of-control risk factor, the operator may be more responsive to addressing the practices resulting in the out-of-control risk factor in the future. A more favorable impact on future behavior may result that might not have been achieved through discussion alone.

When recommending on-site correction, effective communication regarding out-of-control risk factors is essential and can often be accomplished by –

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

Although the person in charge is ultimately responsible for the conditions in the facility and should therefore be informed of all out-of-control risk factors, timely training of the food service workers can in many cases have a great impact on future behavior. A translator and/or special training material may be necessary when language or education barriers exist. Remember that while it is important for both the person in charge and food service workers to know why they are having to make a correction, the long-term effectiveness of making the correction may be lost if you are too technical or scientific in your rationale.



During the discussion of inspection findings with the person in charge, you should keep the discussion focused on correction of violations that present an immediate danger to the consumer. **Discussion of lesser code violations should be deferred until out-of-control risk factors are discussed and on-site correction is obtained.** It is important to point out to the operator that while most basic sanitation problems do not pose a significant threat to the public, foodborne illness caused by out-of-control risk factors often results in significant losses to consumers and the operator. Negligence for not having a strong food safety management system in place to control risk factors can result in financial ruin for even the largest of retail operations.

DETERMINING THE APPROPRIATE ON-SITE CORRECTION

To assist you in determining the appropriate on-site correction, you should reference your existing regulatory policies and procedures. In the event that your jurisdiction does not have such policies and procedures, your experience and professional judgment will help you to offer the operator practical solutions for bringing the risk factors under control.

In most cases, selecting the most appropriate on-site correction when out-of-control risk factors are observed will be straightforward. For instance, if hamburgers are inadequately cooked, the on-site correction is to continue cooking until the appropriate cooking temperature is reached.

Determining the most appropriate on-site correction of out-of-control procedures such as inadequate hot and cold holding can be very complicated. Since determining on-site correction depends on a number of factors, you may need to conduct a hazard analysis of the food in order to determine the appropriate course of action to take. Annex 6 of this Manual lists the out-of-control procedures that may require a hazard analysis in order to determine the appropriate on-site correction. More information on conducting a hazard analysis is found in Annex 3.

Limitations of Reheating as an On-site Correction

One on-site correction used in the field is reheating. A common misconception is that reheating is a “magic step” for eliminating hazards resulting from improper holding or cooling. If a ready-to-eat, potentially hazardous food is improperly held or cooled, the potential for spore- or toxin-forming bacteria growth increases. Whether to recommend that the food be reheated or discarded depends on a number of factors including, but not limited to –

- the hazards of significance
- the nature of the food
- its intended use
- other important considerations discussed later in this section including the degree of time and temperature abuse



Although reheating can eliminate vegetative bacterial cells resulting from post-cook contamination (i.e. *Salmonella*) or from improper holding or cooling (i.e. *Clostridium perfringens*), it has limitations that must be considered.

Some bacteria form spores that survive cooking. These spores can germinate and grow if food is improperly held after cooking. Bacterial spores are likely to be present in most foods. When a food is expected to contain spores of toxigenic bacteria such as *Clostridium botulinum* or *Bacillus cereus*, reheating may be ineffective. The emetic toxin of *B. cereus*, which has been largely associated with outbreaks in starchy foods, is very stable to heat. While the toxin of *C. botulinum* may be destroyed with extended reheating, the critical limit for reheating in the *Food Code* (165 °F for 15 seconds) will not be effective in ensuring the food’s safety.

Staphylococcus aureus does not produce spores, only a heat-stable toxin when present in large numbers. Time- or temperature-abused, RTE, PHFs that are touched by bare hands or otherwise contaminated with the organism are at risk.

Neither cooking nor reheating destroys chemical hazards such as ciguatera toxin or scombrototoxin in fish; therefore, fish that are subject to these hazards and are received from unapproved sources or at improper temperatures should be rejected.

Viruses are somewhat resistant to heat and given their low infectious dose may not be reduced to safe levels using the reheating parameters in the *Food Code*. Therefore, if ready-to-eat food is touched with bare hands, you will need to address several questions in order to make the appropriate on-site correction recommendation, including:



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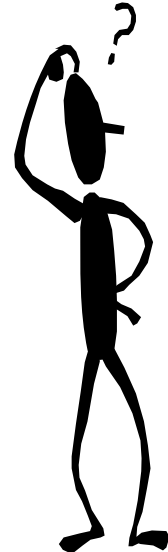
- Does the facility have an employee health policy to identify, restrict, and exclude ill employees?
- Did the employees working with the food in question effectively wash their hands and are handwashing facilities adequate?
- Is there an approved, alternate procedure to no bare hand contact in place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

Use these questions as the framework for making a recommendation for on-site correction that is based on current science and your extensive knowledge of the operation. Once you have answered these questions, you should have enough information to determine the likelihood of occurrence of hazards transmitted by bare hands. Remember that viruses may not be destroyed to safe levels by reheating, so if you determine in your assessment that there is a high risk of viral contamination, then discarding the affected food may be the most appropriate recommendation for on-site correction.

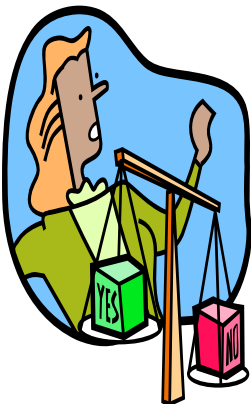
When bare hand contact with ready-to-eat food is not observed or when bare hand contact is observed but the risk of viral contamination is low, additional analysis is needed before recommending reheating as an on-site correction for food found out of temperature. In order to properly evaluate the degree of time and temperature abuse and the proper disposition of the affected ready-to-eat food, the following questions should be considered:

- 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 *C. perfringens*, *C. botulinum*, or *B. cereus* as hazards (see Annex 3)?
- 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 workers practicing good personal hygiene including frequent and effective handwashing?
- Was the food reheated or cooked to the proper temperature before being placed 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 when asked how long the food has been out of temperature control?
- 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 you know 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?



The answers to these questions, in combination with observations you make during your inspection, should provide you with enough information to make the appropriate recommendation for on-site correction. If you are still unable to determine the most appropriate disposition of the food after you have conducted your assessment, you may want to consult your supervisor.



As you can see, there is no “catch-all” rule for determining the appropriate on-site correction. Due to the economic hardship that may be involved, it is important for you to base your recommendations on sound science. It is crucial that you have a significant, working knowledge of food microbiology. Your final decision should be based on the best scientific analysis and professional judgment after considering all the information that you have at hand. In some cases, you may even need to consult with other food safety professionals to determine if a food is safe to eat or whether a correction is needed.

LONG-TERM COMPLIANCE

While on-site correction of out-of-control risk factors is essential to consumer protection, achieving long-term compliance is equally important. Overcoming several misconceptions about long term compliance will help you 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 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 or duration of the inspection. Another misconception is that training alone will result in risk factors being controlled. While training may help, there is no guarantee that knowledge acquired will equate to knowledge applied in the workplace. Another assumption is that enforcement actions such as citations or administrative hearings or on-site corrections 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 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 system components may be used alone or in combination by the operator to provide voluntary active managerial control of risk factors:

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.



