PROCEDURAL STEP 4

Implement Control Measures in Prerequisite Programs or at CCPs in Your HACCP Plans and Establish Critical Limits

The objective of procedural step 4 is to implement control measures in your food safety management system to prevent, eliminate, or reduce hazards to acceptable levels. Once control measures have been identified in Procedural Step 3 – Hazard Analysis, you should determine how you will achieve active managerial control. Control may be achieved at Critical Control Points (CCPs) in your HACCP plans or through prerequisite programs. By definition, a CCP is an operational step at which control can be applied and is essential to prevent or eliminate a hazard or reduce it to an acceptable level. If an operational step is the last step at which control can be applied to prevent or eliminate a hazard or reduce it to an acceptable level, then you should consider controlling it as a CCP. If a step later in the process will control the hazards of concern, that step, rather than the one in question, will most likely be a CCP. Depending on your operation, control measures may be effectively implemented in your prerequisite programs

For instance, you may decide that cold holding during storage is best controlled through prerequisite programs rather than through your HACCP plans. It is important to consider the flow of food as you make this determination. The *Food Code* provides specific measurable criteria referred to as critical limits designed to prevent, eliminate, or reduce hazards in foods. The critical limits are based on the best available science and pertain to control measures applied within operational steps. Common examples might be time/temperature standards and no bare hand contact with ready-to-eat food. You should make sure that you have established the appropriate critical limits to control the identified hazards. It is recommended that you refer to the most recent version of the *Food Code* or your state, local, or tribal regulations for help with determining the appropriate critical limits for the identified control measures.

COMMON OPERATIONAL STEPS USED IN RETAIL AND FOOD SERVICE

The following information about the common operational steps conducted at retail is provided to assist in your decision-making as you move through the procedural steps presented in this document. Common operational steps conducted at retail include, but are not limited to, receiving, storing, preparing, cooking, cooling, reheating, hot and cold holding, assembly/set-up/packing, serving, and selling.

RECEIVING

Receiving is an important operational step to food safety. At receiving, your main concern is contamination from pathogens and the formation of harmful toxins.

Two recommended control measures of importance during this operational step include:

- Receiving the food at proper temperatures and getting perishable food into cold storage quickly

- Obtaining food, ingredients, and packaging materials from approved sources (suppliers who are regulated and inspected by appropriate regulatory authorities)

Ready-to-eat, potentially hazardous food is a special concern at receiving. Because this food will not be cooked before service, pathogenic bacterial growth could be considered a significant hazard during this step for refrigerated, ready-to-eat foods.

Having prerequisite programs in place to control product temperature is generally adequate to control the hazards present at receiving of most of these products. Besides checking the product temperature, you should check the appearance, odor, color, and condition of the packaging.

Seafood, whether ready-to-eat or not, requires special attention during receiving. Federal regulations require processors of seafood and seafood products for interstate distribution to have a HACCP plan. These processors are the only approved sources for seafood sold in interstate commerce; therefore, you may ask your interstate seafood supplier for documentation that the firm has a HACCP plan in place. Processors of seafood and seafood products that are sold or distributed only within a state may or may not be required to have a HACCP plan, depending on the state, local, or tribal regulations.

In order to destroy parasites in certain species of fish intended for raw consumption, either you or the seafood processor should freeze the fish at a given time and temperature. You should ask to see specifications on these species of fish to be sure that they have been frozen to destroy the parasites.

Molluscan shellfish (oysters, clams, mussels, and scallops) that are received raw in the shell or shucked should be purchased from suppliers who are listed on the FDA Interstate Certified Shellfish Shippers' List or on a list maintained by your state shellfish control authority. Shellfish received in the shell should bear a tag (or a label for shucked shellfish) that states the date and location of harvest, in addition to other specific information. Finfish harvested from certain areas may naturally contain a toxin called ciguatera. Other finfish may develop a toxin after harvest if strict temperature control is not maintained. This toxin is called scombrotoxin (histamine). For finfish, temperature control and approved sources are important at receiving because cooking will not eliminate these toxins. For more information on toxins and parasites in fish, you may refer to the FDA Food Code.

STORAGE
When food is in refrigerated storage, your food safety management system should focus on:

- Maintaining temperature control to limit the growth of pathogenic bacteria that may be present in a ready-to-eat product

- Storing food so that cross-contamination of ready-to-eat food with raw animal foods is prevented

When determining the storage temperature and monitoring frequency of products in cold storage, you may decide to set the temperature lower than what is required by your local regulations. By setting the temperature lower than what is required by your regulations, small upward deviations in temperature that you detect through frequent monitoring can be quickly corrected before bacteria begin to grow. For example, if you are storing potentially hazardous, ready-to-eat foods under refrigeration, you may decide to set a critical limit for the refrigeration units to operate at 38 ºF. This provides a safety cushion that allows you the opportunity to see a trend toward exceeding 41 ºF and to intervene with appropriate corrective actions before bacteria begin to grow to dangerous levels.

Monitoring procedures for ready-to-eat food ideally include internal product temperature checks. You should assess whether it is realistic and practical for you to do this depending on the volume of food you are storing. You may choose to base your monitoring system on the air temperature of the refrigerated equipment as a prerequisite program.

How often you should monitor the air temperature depends on:

- Whether the air temperature of the refrigerator accurately reflects the internal product temperature – (Remember, your food safety refrigeration temperature must be based on the internal product temperature of the food stored within a refrigeration unit, not the ambient air temperature)

- The capacity and use of your refrigeration equipment

- The volume and type of food products stored in your cold storage units

- The prerequisite programs that support monitoring this process

- Shift changes, volume of business, and other operational considerations

Special consideration should be given to the storage of scombroid toxin-forming fish due to the potential formation of histamine. To control histamine formation in scombroid toxin-forming fish, the critical limit temperature of 41 ºF should be managed either through your HACCP plan as a CCP or through your prerequisite programs. Also, your HACCP plan or prerequisite programs should ensure that reduced oxygen packaged smoked fish is maintained at 38 ºF to prevent the outgrowth of *Clostridium botulinum* Type E. Separating raw foods from ready-to-eat products in your operation's refrigeration and storage facilities can control the potential for cross-contamination. When determining how you will arrange foods in your storage units to prevent cross-contamination, you should consider the flow of food. For example, if chicken and beef are stored side-by-side on a shelf, consider whether or not employee practices will allow the raw chicken to drip onto the beef. Also, you should consider storing ready-to-eat, potentially hazardous food away from the door, in the coolest part of the walk-in cooler. These products will not undergo any further kill step; thus, preventing the growth of spore-forming bacteria is especially important for these products.

PREPARATION

Of all the operational steps, preparation has the greatest variety of activities that should be controlled, monitored, and in some cases, documented. It is impossible to include in this Manual a summary that covers the diversity of menus, employee skills, and facility designs that impact the preparation of food. The preparation step may involve several processes, including thawing, mixing together ingredients, cutting, chopping, slicing, or breading. At the preparation step, prerequisite programs can be developed to control some hazards and assist in the implementation of a food safety management system that minimizes:

- bacterial growth

- contamination from employees and equipment

- Small batch preparation is an important tool for controlling bacterial growth because limiting the amount of food prepared minimizes the time the food is kept at a temperature that allows for growth. Pre-planning the volume of food and the time needed for preparation minimizes the time food is in the temperature danger zone at this operational step.

- When thawing frozen foods, maintaining proper product temperature and managing time are the primary controls for minimizing bacterial growth. Procedures should be in place to minimize the potential for microbial, chemical, and physical contamination during thawing.

- Use of pre-chilled ingredients to prepare a cold product such as tuna salad may assist you in maintaining temperature control for this process.

- Front-line employees will most likely have the greatest need to work with the food. A well-designed and managed personal hygiene program that has been communicated to all employees will minimize the potential for bacterial, parasitic, and viral contamination.

It is suggested that your program include instructions to your employees as to when and how to wash their hands. It is also very important to identify and restrict or exclude ill employees from working with food, especially if they have diarrhea, vomiting, fever, or jaundice. Special consideration should be given to eliminating bare hand contact in the preparation of ready-to-eat

foods. How will you accomplish controlling the hazards presented by hand contact with ready-to-eat foods? Does the time of day, frequency, or duration of the preparation step allow for easy monitoring? You should review your operation to determine whether this operational step will be controlled as a CCP in your HACCP plans or as a prerequisite program. Procedures should be in place to prevent cross-contamination from utensils and equipment. Designated areas or procedures that separate the preparation of raw foods from ready-to-eat foods minimize the potential for bacterial contamination. Proper cleaning and sanitizing of food-contact surfaces is recommended in this operational step.

COOKING

This operational step only applies to foods listed in Processes #2 and #3. Cooking foods of animal origin is the most effective operational step for reducing or eliminating biological contamination. Cooking to proper temperatures for a specified time will kill most harmful bacteria and parasites. Therefore, frequent monitoring of cooking temperatures is highly recommended. You should determine the best system to use for ensuring that the proper cooking temperature and time are reached. Checking the internal product temperature is the desirable monitoring method. However, when large volumes of food are cooked, a temperature check of each individual item may not be practical. For instance, a quick service operation may cook several hundred hamburgers during lunch. Since checking the temperature of each hamburger will probably not be reasonable for you to do, you should routinely verify that the specific process and cooking equipment are capable of attaining a final internal product temperature at all locations in or on the cooking equipment. Once a specific process has been shown to work for you, the frequency of record keeping (to be discussed in Procedural Step 7) may be reduced. In these instances, a record keeping system should be established to provide scheduled product temperature checks to ensure that the process is working. Special consideration should be given to time and temperature when cooking raw animal foods**.** In developing your HACCP plans or prerequisite programs, it is important to understand that the critical limits are product-specific during the cooking step. For example, the safe cooking temperature/time for poultry is 165 ºF for 15 seconds, while 155 ºF for 15 seconds is the safe cooking temperature for ground beef. To ensure adequate destruction of pathogens by heat, the cooking operational step should be managed either as a CCP in your HACCP plans or as a prerequisite program and be based upon the same level of safety established by the critical limits in the *Food Code*. Consult the latest edition of the *Food Code* available on the FDA/CFSAN - website (http://www.cfsan.fda.gov/~dms/foodcode.html) or your local or state regulations for further guidance.

COOLING

One of the most labor-intensive operational steps is rapidly cooling foods to control bacterial growth. Improper cooling of potentially hazardous foods has been consistently identified as one of the factors contributing to foodborne illness. Foods that have been cooked and held at improper temperatures provide an excellent environment for the growth of spore-forming bacteria. Recontamination of a cooked food item by poor employee practices or cross-contamination from other food products, utensils, and equipment is also a concern at this operational step. Improperly cooling food can begin a snowball effect that cannot be reversed. Even with proper reheating, toxins released by toxin-producing bacteria after cooking and improper cooling may not be destroyed to levels safe enough for human consumption. Special consideration should be given to large food items such as roasts, turkeys, thick soups, stews, chili, and large containers of rice or refried beans. These foods take a long time to cool because of their mass and volume. If the hot food container is tightly covered, the cooling rate will be further slowed. By reducing the volume of the food in an individual container and leaving an opening for heat to escape by keeping the cover loose, the rate of cooling can be dramatically increased. Commercial refrigeration equipment is designed to hold cold food at the proper temperature, not cool large masses of food. Some alternatives for cooling foods include:

- Using rapid chill refrigeration equipment designed to cool the food to acceptable temperatures quickly by using increased compressor capacity and high rates of air circulation.

- Avoiding the need to cool large masses by preparing smaller batches closer to periods of service.

- Stirring hot food while the food container is in an ice water bath

- In soups or stews, redesigning your recipe so that you cook a concentrated base and add enough cold water or ice to make up the volume that you need.

- Pre-chilling ingredients used to make products such as chicken and tuna salad

Whichever cooling method you choose, you should verify that the process works. A record keeping system should be established to provide scheduled product temperature checks to ensure the process is working. If a specific process has been shown to work for you, the frequency of record keeping may be re-evaluated. To control biological hazards, it is recommended that the cooling operational step be managed either as a CCP in your HACCP plans or as a prerequisite program and be based upon the same level of safety established by the critical limits in the *Food Code*.

REHEATING

This operational step applies only to those foods that you listed in Process #3. If food is held at improper temperatures for enough time, pathogens have the opportunity to multiply to dangerous numbers. Proper reheating provides an important control for eliminating some of these organisms. Remember that although proper reheating will kill most organisms of concern, it will not eliminate toxins such as those produced by *Staphylococcus aureus* and *Bacillus cereus* or foodborne viruses. Special consideration should be given to the time and temperature in the reheating of cooked foods. To control biological hazards, it is recommended that reheating be managed either as a CCP in your HACCP plans or as a prerequisite program and be based upon the same level of safety established by the critical limits in the *Food Code*.

HOLDING (HOT, COLD, OR TIME)

All three processes may involve the holding of foods, i.e. hot and cold holding or use of time alone as public health control. When there is a cooking step to eliminate bacteria, all but the spore-forming bacteria should be destroyed. If cooked food is not held at the proper temperature or, absent temperature control, for the appropriate time, the rapid growth of these spore-forming bacteria is a major concern. When food is held, cooled, and reheated in a food establishment there is an increased risk from contamination caused by personnel, equipment, procedures, or other factors. Harmful bacteria that are introduced into a product that is not held at proper temperature have the opportunity to multiply to large numbers in a short period of time. Once again, management of personal hygiene and the prevention of cross-contamination impact the safety of the food at this operational step. Keeping food products at 135 ºF or above during hot holding and keeping food products at or below 41 ºF is effective in preventing microbial growth**.** As an alternative to temperature control, the *Food Code* details actions when time alone is used as a control, including a comprehensive monitoring and food marking system to ensure food safety. How often you monitor the temperature of foods during hot holding determines what type of corrective action you are able to take when 135 ºF is not met. If the critical limit is not met, your options for corrective action may include evaluating the time the food is out of temperature to determine the likelihood of hazards, and based on that evaluation, reheating or discarding the food. Your frequency of monitoring during this operational step may mean the difference between reheating the food to 165 ºF or discarding it. When determining the monitoring frequency of cold product temperatures, it is recommended that the interval between temperature checks is established to ensure that hazards are being controlled and time is allowed for an appropriate corrective action. For example, if you are holding potentially hazardous ready-to-eat

foods under refrigeration, such as potato salad at a salad bar, you may decide to set a critical limit at 41 ºF or below. You may also want to set a target, or operating limit, less than 41 ºF in order to provide a safety cushion that allows you the opportunity to see a trend toward exceeding 41 ºF and to intervene with appropriate corrective actions. To control biological hazards, it is recommended that hot or cold holding or use of time alone as a public health control be managed either as a CCP in your HACCP plans or as a prerequisite program and be based upon the same level of safety established by the critical limits in the *Food Code*.

SET UP, ASSEMBLY, AND PACKING

Set up, assembly, and packing are operational steps used by some retail food establishments, including caterers [e.g., restaurant-caterers, interstate conveyance caterers, commissaries, grocery stores (for display cases), schools, nursing homes, hospitals, or food delivery services]. Set up, assembly, and packing may involve wrapping food items, assembling these items onto trays, and packing them into a transportation carrier or display case. An example would be an airline flight kitchen where food entrees are wrapped, assembled, and placed into portable food carts that are taken to a final holding cooler. Hospital kitchens would be another example where patient trays are assembled and placed into carriers for transportation to nursing stations. Food may be placed in bulk containers for transportation to another site where it is served. Your food safety management system should address the potential for bacterial contamination and growth, bare hand contact with ready-to-eat foods, and proper handwashing.

SERVING/SELLING

This is the final operational step before the food reaches the customer. When employees work with food and food-contact surfaces, they can easily spread bacteria parasites, and viruses. Managing personal hygiene is important to controlling these hazards**.** It is recommended that a management program for employee personal hygiene be implemented that addresses the following:

- Procedures for proper handwashing
- The appropriate use of gloves and dispensing utensils
- Control of bare hand contact with ready-to-eat foods
- Exclusion and restriction of ill employees

Specific procedures are recommended for customer self-service displays such as salad bars and buffet lines to protect food from contamination. Special consideration should be given to preventing cross-contamination from soiled utensils and equipment and minimizing contamination from the customer.