

COOKING AND REHEATING**COOKING Critical Limits**

PRODUCTS				CRITICAL LIMITS		
• Poultry • Wild Game Animals (live-caught or field dressed) • <u>STUFFED</u> fish, meat (including, but not limited to, pork), poultry, ratites, or pasta containing fish, meat, poultry, or ratites • <u>STUFFING</u> containing fish, meat, poultry, or ratites				165°F instantaneous 7-log reduction of <i>Salmonella</i> (or 7D kill)		
Microwave Cooking – for raw animal foods • Covered, rotated, or stirred throughout or midway through the cooking process and held covered for 2 minutes				165°F with 2-minute post-cooking hold (7D kills of <i>Salmonella</i>)		
• <u>COMMINUTED</u> fish, ground beef, or other meats • <u>RAW SHELL EGGS</u> – not prepared for immediate service (combined or hot held). (Also see highly susceptible populations) • Ratites • Mechanically tenderized and injected meats				155°F for 17 seconds OR 158°F for <1 second OR 150°F for 1 minute OR 145°F for 3 minutes (5D kill of <i>Salmonella</i>)		
• Raw shell egg prepared for immediate service • Commercially raised game animals • Other raw animals not otherwise specified in this table				145°F for 15 seconds (3D kill of <i>Salmonella</i>)		
<u>WHOLE MUSCLE, INTACT BEEF STEAK</u> that has been properly labeled as such may be served undercooked as ready-to-eat if not serving a highly susceptible population				Surface temperature ≥145°F and cooked color change on all external surfaces		
<u>PLANT FOOD FOR HOT HOLDING</u> : plant foods requiring time/temperature control for safety that will be hot held				135°F – cooked to the hot holding temperature		
WHOLE ROASTS OF BEEF, CORNED BEEF, PORK, OR CURED PORK						
Critical Limits				Oven Parameters Based on Oven Type and Roast Weight		
Temperature	Time in Minutes	Temperature	Time in Seconds	Oven Type	Roast Weight <10 lbs. (4.5 kg)	Roast Weight ≥10lbs. (4.5 kg)
130°F	112	147°F	134	Still Dry	≥350°F	≥250°F
131°F	89	149°F	85			
133°F	56	151°F	54	Convection	≥325°F	≥250°F
135°F	36	153°F	34			
136°F	28	155°F	22	High Humidity ¹	≥250°F	≥250°F
138°F	18	157°F	14			
140°F	12	158°F	0			
142°F	8			1. Relative humidity >90% for ≥ 1 hour as measured in the cooking chamber or oven vent, or in a moisture-impermeable bag that provides 100% humidity.		
144°F	5					
145°F	4					
COMMERCIALLY PACKAGED FOOD						
• Manufactured food with cooking instructions: Cooked according to those instructions in READY-TO-EAT FOODS or offered in unPACKAGED form for human consumption. • Manufactured food with information that it has not been processed to control pathogens: Critical limit appropriate for the product when used in READY-TO-EAT FOODS or offered for human consumption.						

COOKING AND REHEATING**A. COOKING Critical Limits (continued)**

COOKING RAW ANIMAL FOODS USING A NON-CONTINUOUS COOKING PROCESS	
- Procedures must have prior approval from the regulatory authority before process is implemented. - Written procedure must be available on-site and: - Describes the process and critical limits for critical control points identifies below. - Describes monitoring, corrective actions, and recordkeeping procedure. - Include a system for clearly marking undercooked animal food. - Address separation of partially cooked animal foods from ready-to-eat foods. - Initial heating process is completed with 60 minutes. - Immediately after heating, product is cooled to: - Within 2 hours from 135°F to 70°F; and - Within a total of 6 hours from 135°F to 41°F or less. - After cooling, held cold at 41°F or less OR frozen. - For non-continuous cooking: Prior to Service or Sale- cooked to proper temperatures as per 3.401.11 (A-C) (in the Food Code section 3-401.14(D)	

B. REHEATING Critical Limits

REHEATING COOKED TIME/TEMPERATURE CONRRLO FOR SAFETY FOODS FOR HOT HOLDING	
Process/Product	Critical Limit
Reheating for hot holding	165°F for 15 seconds – process not to exceed 2 hours
Reheating in a microwave oven	165°F for 15 seconds - rotated or stirred - covered - allowed to stand for 2 minutes after reheating
Commercially processed ready-to-eat foods	135°F – process not to exceed 2 hours
Remaining unsliced portions of cooked roasts	Using oven parameters and minimum time and temperatures conditions previously presented in the chart for cooking roasts.
Preparation for immediate service	Food cooked, refrigerated, and then prepared for immediate service in response to an individual customer request may be served at any temperature.

Some Questions for Assessing Active Managerial Control of COOKING Processes

- Are specific procedures in place for cooking foods?
 - Are the cooking procedures product-specific (roasts, hamburgers, etc.)?
 - Are any cooking procedures based on equipment temperature for a set amount of time?
 - Is slow cook process used for any of the food products (like roasts)?
 - Does the facility receive steaks from whole muscle intact beef? Is there labeling to document this?
 - Does the staff know the correct cooking temperatures?
- Are raw animal foods cooked to customer order (i.e., rare, medium-rare, medium, or well-done)? If yes, what food items?
- If raw animal foods are intentionally undercooked or served raw, does the establishment have a proper consumer advisory?
- Are there any meats that are partially cooked and cooled in preparation for large volume preparation later?
- How are cooking temperatures monitored?
- What type of equipment is used to measure the final internal product cooking temperatures?
- What actions do employees take when food does not reach the proper temperature?
- Are cooking logs maintained (although not required per the Food Code)?

Some Questions for Assessing Active Managerial Control of REHEATING Processes

- What happens to leftover food?
- Do you cook food well in advance of mealtimes?
- Do you reheat for hot holding any products that have been previously cooked at the food processing/manufacturer level?
- How are food products reheated? Range top/steamer/microwave/steam kettle/oven or another device?
- How are reheating temperatures monitored?
- What actions are taken if reheating temperatures are not attained within the required amount of time?
- Are reheating logs maintained (although not required per the Food Code)?

Tips for Assessing Active Managerial Control of COOKING and REHEATING Processes

- Enlist the help of cooperative food employees to notify you of foods that have finished cooking. This allows you to continue with the inspection in other areas of the operation yet continue to verify that proper cooking/reheating temperatures are being met.
- Observe whether or not food employees are equipped with appropriate temperature measuring devices and are using them to check final cooking/reheating temperatures.
- Ask food employees if they know the required critical limits for cooking and reheating.
- Compare your calibrated temperature measuring devices with those used by the food establishment.
- Ask food employees to demonstrate proper calibration of temperature measuring devices.
- Determine if there are any specific procedures established by the operation for cooking or reheating foods. If not, how are employees taught how to conduct the cooking/reheating process? What training did they receive?
- For high volume cooking equipment such as grills, conveyor systems, clam shells, and broilers, ask employees how they know that a product has achieved the final cook/reheat temperatures if they are not checked with a thermometer. For example, has the establishment conducted time/temperature assessments that ensure that products are cooked or reheated properly using a validated process specific to the equipment being used?
- Ask food employees what action is taken when they discover cooking/reheating temperatures are not being achieved. There should be a short-term corrective action that focuses on the continued cooking/reheating of the product until it attains the proper temperature (Food Code critical limit). In addition, there should be a long-term corrective action that assesses whether the facility's procedures are appropriate, the equipment is working properly, employees are properly trained, and other underlying root causes are addressed.
- Determine if the establishment maintains any documentation of cooking/reheating temperatures taken during the course of the day.
- Determine whether raw or undercooked animal foods are served including raw or undercooked animal foods used as ingredients in custards, sauces, or dressings. If so, determine if the establishment has an acceptable consumer advisory with disclosure and reminder.

IMPROPER HOLDING/TIME & TEMPERATURE CONTROL

SUMMARY: IMPROPER HOLDING/TIME & TEMPERATURE CONTROL AREAS

- A. Assessing Active Managerial Control of Cooling Processes
- B. Assessing Active Managerial Control of Cold Holding and Date Marking
- C. Assessing Active Managerial Control of Hot Holding
- D. Assessing Active Managerial Control of Time Used as a Microbial Growth Barrier

A. COOLING Critical Limits

COOLING TIME/TEMPERATURE CONTROL FOR SAFETY (TCS) FOODS	
Process/Product	Critical Limit
Cooling of properly cooked TCS foods	- Within 2 hours from 135°F to 70°F AND - Within a total of 6 hours from 135°F to 41°F or less
Cooling of TCS foods from ambient temperature ingredients	Cooled to 41°F within 4 hours
Cooling of TCS foods received in compliance with laws that allow temperatures $\geq 41^\circ\text{F}$ during shipment	- Cooled to 41°F within 4 hours - Exception – Raw shell eggs must immediately be placed in refrigeration maintaining an air temperature of 45°F or less

Some Questions for Assessing Active Managerial Control of COOLING Processes

- What TCS Foods are cooked and then cooled?
- What TCS Foods are prepared from ambient room temperature ingredients?
- What does the operation do with leftovers, particularly at the end of the business day?
- Does the operation cook food well in advance of mealtimes?
- What is the density of foods that are cooled?
 - Thin liquids (broth-based soups)
 - Thick liquids (gravies; sauces)
 - Semi-Solids (Casseroles; Stuffed Pastas)
 - Solids (Roasts; Cuts of Meats)
- What cooling methods are used for TCS Foods?
 - Shallow pans under refrigeration
 - Breaking down the product to smaller portions
 - Blast chiller/rapid cooling equipment
 - Ice Water Bath/Ice Wands
 - Type of container to facilitate heat transfer (stainless steel vs. plastic)
 - Ice as an ingredient
- How are cooling temperatures monitored?
- How do employees ensure that the cooling time frames are met?
- What corrective actions do they take if the time frames are not met?
- Are cooling records maintained (though not required per the Food Code)?

Tips for Assessing Active Managerial Control of COOLING Processes

- Vary the time of day the inspection is conducted to ensure cooling is observed. 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 you to verify cooling of products that may have been prepared that morning or are still in the process of cooling.
- Become familiar with an establishment's food production schedule.
- Determine if food products are being cooled very early in the inspection.
- Discuss the cooling process with the food employee who worked with the product prior to cooling. Accurate time-temperature assessments related to when the cooling process was initiated are essential to determining the effectiveness of the cooling procedure being used.
- Ask food employees and managers about the cooling procedures used, even if cooling is not taking place during the inspection.
- Take temperatures of foods being cooled at the beginning of the inspection and again towards the end of the inspection. An evaluation of the two temperatures in conjunction with the elapsed time between the two readings will give an indication of the cooling rate. A single temperature check of cooling foods does not always provide enough information to assess the procedure.
- Take temperature measurements in the geometric center of the product, then at various points around the perimeter of the product. Ask additional questions to determine the time parameters involved. Temperature differences in a container of food may provide evidence that the product is in the process of cooling (e.g., cooler temperatures around the outer edges versus warmer temperatures in the middle).
- Ask questions of food employees about the cooling method used. Do they know that the method used cools foods to the proper temperature within the required time frame? Validating that the cooling procedure works is an important component of active managerial control, especially for facilities that intend to cool leftovers at the close of business and will not have staff available to monitor actual temperatures as the food proceeds through the cooling process.
- If an establishment has confirmed (or validated) that a cooling procedure works, they may have implemented a monitoring system that primarily focuses on the proper implementation of the cooling methods. Visual checks may be conducted of the depth of foods in containers, number of filled bags placed in cooling tanks, amount of ice added to recipes, etc. This information is important for assessing the level of active managerial control and determining whether an establishment follows its own procedures.
- Determine if ingredients used to make menu items are pre-chilled before preparation. After preparation, assess whether these products are placed in large containers to cool or stacked in a manner that will not facilitate cooling. Foods that are prepared from ambient air temperature ingredients (even pre-chilled ingredients), such as tuna salads, meat sandwiches, cole slaw, all varieties of salad, etc., are often overlooked as ones that require proper cooling. During batch preparation, the temperature of the ingredients of these products cause rise significantly.
- Assess each cooling method used to determine if sufficient controls are in place. This is because an establishment may need to implement a variety of cooling methods to address the different variety of foods required to be cooled. In most cases, however, one cooling method will work for all types of foods (thin liquids, thick liquids, semi-solids, solid).
- A thorough assessment of cooling requires an evaluation of all the information gained from food employees and management, in combination with temperature measurements taken.

B. COLD HOLDING and DATE MARKING Critical Limits

COLD HOLDING OF TIME/TEMPERATURE CONTROL FOR SAFETY (TCS) FOODS	
Process/Product	Critical Limit
Cold holding of TCS foods	41°F or less.
Raw unpasteurized shell eggs	Stored in refrigerated equipment maintaining 45°F or less.

DATE MARKING FOR READY-TO-EAT (RTE), TIME TEMPERATURE CONTROL FOR SAFETY (TCS) FOODS	
Process/Product	Critical Limit
- Refrigerated RTE, TCS Foods: - Prepared in the establishment - Opened package from a commercial processing plant - Held for more than 24 hours	7 days at 41°F or less. - Marked to indicate the date or day the food must be consumed on the premises, sold, or discarded. - Day of “preparation” or “opening is counted as “Day 1”. - Date mark not to exceed manufacturer’s use by date.
RTE, TCS Foods Subsequently Frozen:	Marked at the time of freezing as to the days already held at refrigeration and upon removing from the freezer, the new “date” is 7 days minus the time held before freezing.

**Some Questions for Assessing Active Managerial Control of
COLD HOLDING and DATE MARKING Processes**

- How do they monitor their refrigeration units to ensure they are maintaining proper temperature?
- Are there any refrigeration/cold food storage units located outside of the kitchen area (salad bars, food transportation units, etc.)?
- Does the establishment use methods, other than storing under refrigeration, to maintain foods cold (e.g. storage in ice)?
- What kind of monitoring procedures do they implement for ensuring food is at the proper cold holding temperature?
- What type of equipment is used to check the food product temperatures? How often is this done? How do they know their temperature measuring devices are accurate?
- Do they keep temperature logs? Do they record the temperature of the refrigeration units, product temperatures, or both? (not required per the Food Code)
- How do employees know what food is to be used first (first in, first out)?
- What is their date marking procedure for ready-to-eat, TCS Food?

**Tips for Assessing Active Managerial Control of
COLD HOLDING and DATE MARKING Processes**

- Check cold holding temperatures with a thermocouple, thermistor, or other appropriate temperature measuring device. This includes the temperature of TCS food during transport (receiving trucks, cold holding carts being used to transport food to patient room in a hospital, satellite kitchens, or off-site catering events).
- DO NOT USE an infrared thermometer for verifying cold holding temperatures.
- Relying on surface temperatures may mask potential problems related to improper internal product temperatures and will not provide enough information to make an accurate assessment of cold holding procedures. In addition, inspectors should not stir cold soups and the like since it is important to know the temperature before the food is agitated.
- Open top refrigerated display cases and sandwich prep units may present significant cold holding challenges. When located across from cooking equipment or hot holding devices, these units may have a difficult time maintaining product temperatures. For refrigerated display cases, packaged food products may be stored directly on top of refrigerated air vents or placed in the case in a manner that blocks the flow of refrigerated air. Determine the system the establishment has in place for monitoring these units to ensure product temperatures are maintained at 41°F or less. An alarm system (commonly used by large grocery store chains) may not be sufficient alone in ensuring product temperatures are maintained at 41°F or less.
- Cold holding temperature control does not stop once the product leaves the kitchen. How does the facility ensure cold holding temperatures are maintained for products sent to satellite schools, patient rooms, or other food distribution points that may be off-site? Who is responsible for monitoring the temperature once it leaves the kitchen area? Is it the kitchen foodservice personnel or is it the nursing staff in hospital facilities? Are satellite school facilities responsible for checking temperatures when the food arrives? How is this done and reported back to the main commissary kitchen?
- Date marking systems may use calendar dates, days of the week, color-coded marks, or another type of system. When the person in charge explains the system, is it clear to you what is expected, and does it meet the Food Code requirements? Can food employees explain the system and is their version consistent with management's expectation?
- How does the manager/food employees handle situations when they discover prepared food that has been stored in the walk-in cooler or other refrigeration unit without date marking or that has expired dates?

C. HOT HOLDING Critical Limits

HOT HOLDING OF TIME/TEMPERATURE CONTROL FOR SAFETY (TCS) FOODS	
Process/Product	Critical Limit
Hot holding of TCS foods (<i>except roasts</i>)	135°F or above (per manufacturer's instructions)
Hot holding of roasts cooked or reheated to required time-temperatures	130°F or above (per manufacturer's instructions)

Some Questions for Assessing Active Managerial Control of HOT HOLDING Processes

- How are cooked foods held until service?
- How is the temperature of hot foods controlled? Steam table, stove/oven, hot box?
- Are there any hot food storage units located outside of the kitchen area (hot food bars, food transportation units, etc.)?
- What kind of monitoring procedures do they implement for ensuring food is at the proper hot holding temperature?
- What type of equipment is used to check the food product temperatures? How often is this done? How do they know their temperature measuring devices are accurate?
- Do they keep temperature logs? Do they record the temperature of the hot holding units, product temperatures, or both?
- What corrective actions are taken when food is found out of temperature?

Tips for Assessing Active Managerial Control of HOT HOLDING Processes

- Check hot holding temperatures with a thermocouple, thermistor, or other appropriate temperature measuring device. This includes the temperature of TCS food during transport (hot holding carts being used to transport food to patient room in a hospital, satellite kitchens, or off-site catering events).
- DO NOT USE an infrared thermometer for verifying hot holding temperatures. Relying on surface temperatures may mask potential problems related to improper internal product temperatures and will not provide enough information to make an accurate assessment of cold holding procedures. In addition, inspectors should not stir a food before taking its temperature since it is important to know the temperature before the food is agitated.
- The geometric center of a product is usually the point of measurement; however, evaporative cooling may mean that the top layer of food is cooler than the product in the center of the container which may be nearer the heat source. Thus, additional measurements taken at points farthest from the heat source, e.g., near the product surface for food held on a steam table, may be warranted. In large holding units and on steam tables, it is necessary to take the temperatures of foods in various locations to ensure the equipment is working properly.
- If deviations are noted in hot holding temperatures, it is important to take extra steps to find out whether the problem is the result of equipment failure or a breakdown in a preceding process such as cooking or reheating.

D. TIME USED AS A MICROBIAL GROWTH BARRIER Critical Limits

TIME USED AS A MICROBIAL GROWTH BARRIER FOR TCS FOODS	
• Written procedure must be available on-site and: ○ Identifies the foods to be held using time only as a public health control. ○ Describes the procedures for implementing time without temperature as a public health control (procedures, training, monitoring, documentation)	
• Time without temperature control is used as the public health control up to a MAXIMUM OF <u>4 HOURS</u> ○ Food must have an initial temperature of: ▪ 41°F or less when removed from cold holding temperature control, OR ▪ 135°F or above when removed from hot holding temperature control. ▪ TCS Food marked or identified with a maximum 4-hour period when removed from temperature control. ▪ After 4 hours any remaining food product is discarded. ▪ Unmarked containers or packages or containers marked that exceed a 4-hour limit are to be discarded.	
• Time without temperature control is used as the public health control up to a MAXIMUM OF <u>6 HOURS</u> ○ Food must have an initial temperature of: ▪ 41°F or less when removed from cold holding temperature control. ▪ Food temperature may not exceed 70°F during the 6-hour period. ▪ The food shall be monitored to ensure the warmest portion of the food does not exceed 70°F during the 6-hour holding period. ▪ TCS Food marked to indicate time when the food is removed from 41°F or less cold holding temperature control. ▪ TCS Food marked or identified with a maximum 6-hour period when removed from temperature control. ▪ TCS Food is discarded if the temperature of the food exceeds 70°F OR ▪ After 6 hours any remaining food product is discarded. ▪ Unmarked containers or packages or containers marked that exceed a 6-hour limit are to be discarded.	

Some Questions for Assessing Active Managerial Control of TIME AS A MICROBIAL GROWTH BARRIER

- How long is TCS Food being held out of temperature before or after cooking?
- How do you monitor how long products are out of temperature control?
- Do you have specific food products for which you use time instead of temperature as a food safety control?
- What type of system do you have in place to monitor the time?
- Who is responsible for ensuring that time frames for holding products out of temperature control are not exceeded?
- What happens to food that exceeds the time frames for holding?
- For the products that you hold using time rather than temperature, what action do you take after 2 hours if it appears that all the products will not be sold or served within the 4- or 6-hour time frames?

Tips for Assessing Active Managerial Control of TIME AS A MICROBIAL GROWTH BARRIER

- Each temperature scenario for using time only as a microbial growth barrier incurs different risks in regard to the type of foodborne pathogens able to grow and the rate of growth likely to occur. For both cooling and warming conditions, growth depends on the amount of time the food spends in an optimum growth temperature range and its equilibration with its surroundings.
- Several factors influence the rate of temperature changes in a food such as the type of food, thickness of food, and the temperature differential between the food and its surroundings. When evaluating the safety of a 4-hour limit for food with no temperature control, products and environmental parameters must be selected for a worst-case scenario for pathogen growth and possible toxin production.
- Consider the type of operation that is using time as a microbial growth barrier. Are the establishment's written procedures easy to implement? Monitoring the time period for the food may be a greater challenge if the product is displayed in an area of the store that is located outside of the food preparation area such as rotisserie chicken displayed in the aisle section outside the deli area in a retail food store.
- Determining how the operation maintains clear marking of the 4-hour period of time may be difficult if multiple batches are made during the course of the day and are stored, commingled, in a display case. In this scenario, each individual product would have to be clearly marked or a system that provides distinct separation of lots would have to be established within a display or holding case.
- Having written procedures and appropriate product marking will only be effective if the individuals responsible for the procedure are properly implementing them. The individuals responsible for monitoring (and when appropriate, discarding the product) must be clearly identified.
- Holding cold food without temperature control has some additional consideration. An assessment of the products' start temperature must be made to ensure it was maintained at 41°F or below prior to being removed from temperature control.
- Determine where these products are stored prior to using time as a public health control and evaluate the product temperature within these refrigeration units. The type of refrigeration unit and its capacity should also be considered when assessing these products.
- Holding cold food without temperature control must include a system for assuring the product temperature never exceeds 70°F. The ideal scenario would be to have a product temperature measuring device constantly recording or displaying the warmest part of the food. In many cases, an establishment may want to use alternative monitoring such as the ambient air temperature of a refrigeration unit. What steps have they taken to validate that this type of procedure is effective, and how do they verify that the system is implemented at all times?
- Keep in mind that using time as a microbial growth barrier is an intentional use of time rather than temperature to control growth of pathogens. Corrective action of a cold holding problem may use the same principles as when time alone is used but it is different in that when time is used, the establishment needs to have a distinct system in place. The assessment should not only be on the written procedures in place, but the rotation of the product. Does the facility add product to a container under time control in busy periods or does the system incorporate procedures for completely changing out the containers? Are foods intended to be held cold without temperature control, stored, or commingled with foods intended to be temperature-controlled?

ASSESSING ACTIVE MANAGERIAL CONTROL FOR RISK FACTOR AREAS

PERSONAL HYGIENE

**Reference for Active Managerial Control for this risk factor is contained in the FDA Employee Health and Personal Hygiene Handbook.*

Active Managerial Control for the Personal Hygiene risk factor must include all three of the elements identified A-C below. Concurrent use of each of these three control measures will help prevent the transmission of viruses, bacteria, and protozoan oocysts from food employees to customers through contaminated food.

- A. Restricting or excluding ill food employees from working with food.
- B. Using proper handwashing procedures.
- C. Eliminating bare hand contact with foods that are ready-to-eat.

A. EMPLOYEE HEALTH Critical Limits

- Restricting or excluding ill food employees from working with food.
 - These 6 pathogens must be addressed in an establishment's employee health program. These pathogens have a low infectious dose, contaminate the gastrointestinal system after ingestion, and are shed in feces.
 - Norovirus
 - *Salmonella* Typhi (typhoid-like fever)
 - *E. coli* O157:H7, Enterohemorrhagic or Shiga toxin-producing *E. Coli*
 - *Shigella* spp.
 - Hepatitis A virus
 - *Salmonella* (nontyphoidal)
 - These symptoms of foodborne illness must be addressed in an establishment's employee health program.
 - Vomiting
 - Diarrhea
 - Jaundice (yellow skin or eyes)
 - Sore throat with fever.
 - Infected cuts and burns with pus on hands and wrists. Employees may still be allowed to work with food if they follow the following practices:
 - On hand or wrist, you need an impermeable cover, such as a finger cot, and a single use glove over that protective covering.
 - On arms, must be protected by an impermeable cover.
 - Any other body part needs to be covered by a dry, durable, tight-fitting bandage.
 - The manager or Person-in-Charge (PIC) is to make certain that food employees are trained on the subject of the:
 - Cause of foodborne illness.
 - Relationship between the food employee's job task, personal hygiene, and foodborne illness
 - Requirement for reporting.
 - Specific symptoms, diagnoses, and exposures that must be reported to the Person-in-Charge.
 - Management should explain to food employees the importance of reporting specific symptoms and any diagnoses or exposures to foodborne illness. Things to be reported to management include:
 - Vomiting, diarrhea, jaundice, sore throat with fever, or any exposed boil or open, infected wounds or cuts on hands or arms
 - An illness diagnosed by a health practitioner that was caused by: *Salmonella* Typhi; *Shigella* spp.; Norovirus; Hepatitis A; or *E. coli* O157:H7 or other Enterohemorrhagic or Shiga toxin producing *E. coli*.
 - Past illness with typhoid-like fever within the past 3 months unless treated with antibiotics.
 - Exposure to typhoid-like fever, shigellosis, Norovirus, Hepatitis A virus, *E. coli* O157:H7 or other Enterohemorrhagic or Shiga toxin-producing *E. coli*, by eating or serving food that was implicated in a foodborne illness outbreak or if residing with a diagnosed individual.
- Exclusion and restriction policies must adhere to those provided in the decision tree tables contained in the FDA Employee Health and Personal Hygiene Handbook.

Some Questions for Assessing Active Managerial Control of EMPLOYEE HEALTH

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

Tips for Assessing Active Managerial Control of EMPLOYEE HEALTH

- In general, most individuals do not like discussing subjects related to illnesses such as diarrhea and vomiting. It will be important to put the Person-in-Charge at ease. Explaining that the Centers for Disease Control and Prevention (CDC) has identified that employees coming to work when ill is a primary contributor of foodborne illness will provide rationale to establish a common ground for communication. Including a discussion of the difficult economy and the pressure on employees to work in order to have income often helps operators relate to the business side of the issue.
- Establishing a dialogue with the operator requires more than asking questions. In fact, an operator may feel they are being interrogated if too many questions are asked in succession. Be cognizant of the types of questions you are asking the operator. Not all the questions included in the previous Employee Health questions section need to be asked to assess the extent of an operation's employee health program or policies.
- Though it is important to look for visible signs of illnesses of wound infections at any time during the inspection, asking questions regarding an operation's employee health policy may be better addressed later in the inspection rather than the beginning. Often times this is a gap area for an operator because they haven't really thought about it in the past and regulatory agencies did not make it a priority during their inspections. Stressing a gap area in an establishment's food safety management system early on in the inspection may make the operator defensive and guarded.
- Employee Health can be a complex and intimidating subject for most operators who are first and foremost businesspeople. Do not be mistaken, it is a subject they care about and know it is important to prevent ill employees from working to protect their customers and business. Much of the information pertaining to employee health will not be retained by the operator if it is based merely on an open discussion at the end of the inspection. It is important to leave a simple reference sheet or other written materials that will assist them in developing a sound employee health program. Two useful tools in this

endeavor are the FDA Employee Health and Personal Hygiene Handbook or CD. These tools contain comprehensive Standard Operating Procedures and include forms for documenting food employees training and responsibilities pertaining to foodborne illnesses and their symptoms.

B. HANDWASHING Critical Limits

- Using proper handwashing procedures
 - When food employees should wash their hands:
 - Immediately after engaging activities that contaminate hands.
 - When entering a food preparation area.
 - Before putting on clean, single-use gloves for working with food and between glove changes.
 - Before engaging in food preparation.
 - Before handling clean equipment and serving utensils.
 - When changing tasks and switching between handling raw foods and working with ready-to-eat foods.
 - After handling soiled dishes, equipment, or utensils.
 - After touching bare human body parts, for example, parts other than clean hands and clean, exposed portions of arms.
 - After using the toilet.
 - After coughing, sneezing, blowing your nose, using tobacco, eating, or drinking.
 - After caring for or handling service animals or aquatic animals such as molluscan shellfish or crustacean in display tanks.
 - Handwashing procedure:
 - Clean hands and exposed portions of arms, including surrogate prosthetic devices for hands and arms, for at least 20 seconds using the following procedure:
 1. Rinse under clean, warm running water.
 2. Apply soap and rub all surfaces of the hands and fingers together vigorously with friction for at least 10 to 15 seconds, giving particular attention to the area under the fingernails, between the fingers/fingertips, and surfaces of the hands, arms, and surrogate prosthetic devices.
 3. Rinse thoroughly with clean, warm running water.
 4. Thoroughly dry the hands and exposed portions of arms with single-use paper toweling, a heated air hand-drying device, or a clean, unused towel system that supplies the user with a clean towel.
 - May avoid recontamination of hands and arms using a clean barrier, such as a paper towel, when turning off hand sink faucets or touching the handle of a restroom door.

Some Questions for Assessing Active Managerial Control of HANDWASHING

- How do employees know when to wash their hands and what method to use?
- What type of system do you have in place to ensure employees wash their hands when you expect them to do so?
- Who is responsible for checking to see that employees practice good handwashing procedures?
- What action is taken when an employee is observed not washing their hands when you expect them to do so?
- What type of system do you have in place to ensure that hand sinks are continually stocked with hand soap and paper towels (or hand drying devices)?
- Do you use any techniques or methods to encourage employees to wash their hands?
- Do you maintain any type of documentation that attempts to monitor employees' handwashing within the kitchen area?

Tips for Assessing Active Managerial Control of HANDWASHING

- Conducting an assessment of proper and adequate handwashing procedures in an establishment requires patience. A snapshot observation of poor employee practice may not provide enough information to gain an understanding of the root cause of the problem. The lack of handwashing and improper handwashing methods are not always directly attributed to an employee failing to follow good practices. Observations of the entire food preparation procedure can uncover environmental antecedents to poor handwashing such as: the volume of foods being prepared, activity level in the establishment, location of handwashing facilities and an employee's ability to reach them, and lack of training or monitoring by food service management. In order to change employee behavior, it is essential to identify the root cause of the problem.
- It is important to know what the management's handwashing policy is. Not only can an assessment be made as to whether the establishment's policy adequately addresses all aspects of proper handwashing, but it can provide an indication as to whether the employees are following the procedure as described by management. This can provide an indication as to the level of awareness and training employees are receiving regarding the importance of handwashing.
- Having the foodservice manager or person-in-charge with you during the assessment of handwashing can help establish a common understanding of the root causes that might be contributing to poor practices. Management can observe first-hand the employee practices that have the potential to put their business at risk. The person-in-charge will begin to recognize that they need to reinforce the importance of proper handwashing procedures on a continual basis and have a method for providing feedback to all employees on how well they are doing.
- Having the person-in-charge/manager with you during the inspection provides an opportunity to assess what corrective actions are in place to address poor handwashing practices. If management observes poor handwashing, do they implement the type of corrective action they have described? If not, why not?

C. NO BARE HAND CONTACT WITH READY-TO-EAT FOODS Critical Limits

- No bare hand contact with foods that are ready-to-eat.
 - Bare hand contact with a ready-to-eat food such as sandwiches and salads can result in contamination of food and contribute to foodborne illness outbreaks. Food employees should always use suitable utensils such as spatulas, tongs, single-use gloves, or dispensing equipment when handling ready-to-eat foods.
 - Single-use gloves used along with handwashing can be an effective barrier to decrease the transfer of microorganisms from the hand to the food. Gloves are not total barriers to microbial transmission and will not be an effective barrier alone for food workers without education on proper glove use and handwashing requirements. Procedures for the use of single-use gloves include:
 - Always wash hands before donning gloves.
 - Change disposable gloves between handling raw products and ready-to-eat products.
 - Do not wash or reuse disposable gloves.
 - Discard torn or damaged disposable gloves.
 - Cover an infected lesion with pus (e.g. cut, burn, or boil) with a waterproof covering and disposable glove.
 - Wear disposable gloves over artificial nails, nail polish, or uncleanable orthopedic support devices.
 - The Food Code only allows bare hand contact with ready-to-eat food when the regulatory authority has granted prior approval for alternative procedure. The alternative procedure must address the management of food employees and related food handling activities to prevent food contamination, including the enforcement of thorough handwashing practices after toilet use.
 - The Food Code 3-301.11(D) allows bare hand contact with ready-to-eat foods that are being added as an ingredient to a food that:
 - contains a raw animal food and is to be cooked in the establishment to required minimum temperatures, OR
 - does not contain raw animal food but is to be cooked in the food establishment to heat all parts of the food to 165°F.

Some Questions for Assessing Active Managerial Control of
NO BARE HAND CONTACT WITH READY-TO-EAT FOODS

- Where do you prepare your salads?
- At what times of day do you prepare salads, sliced fruits, or prepare cold-cut lunch meat sandwiches?
- Who is responsible for expediting the bread rolls and salads to the customer? Where does this process take place?
- What procedures are employees expected to follow when working with ready-to-eat foods?
- Can you describe the system you have in place to ensure employees that work with ready-to-eat foods follow your operational procedures?
- What action would be taken if you observed one of your food employees handling ready-to-eat foods with their bare hands?
- Do you slice, wash, or prepare any ready-to-eat foods that will be subsequently added as an ingredient to a food product that will be cooked?
- Do you conduct any ready-to-eat food processes for which an alternative procedure is in place to no bare hand contact? Is this alternative procedure in written form? Can you describe the alternative procedure? Have you submitted it to the health department for review?
- How do you know which foods can be touched with bare hands?

**Tips for Assessing Active Managerial Control of
NO BARE HAND CONTACT WITH READY-TO-EAT FOODS**

- In order to conduct an assessment of No Bare Hand Contact it is important to have knowledge of the menu items that are intended to be served as ready-to-eat foods. Salads, cold lunch meat sandwiches, fruit bowls, or salads containing fruit usually have a designated preparation area within the kitchen. Identifying the location where ready-to-eat foods are prepared will provide an opportunity to observe food preparation procedures. Much like handwashing, it is important to observe the entire procedure/process in order to identify potential root causes for the occurrence of bare hand contact with ready-to-eat foods.
- It is also important to know what methods management has established in their procedures to ensure no bare hand contact with ready-to-eat foods. In many foodservice operations, multiple methods such as the use of single-use gloves, utensils, paper wraps, etc. are employed to prevent bare hand contact with ready to-eat foods. Often, these are task specific. Some operations may provide options for the employee (single-use gloves or utensils). Understanding the expected methods to prevent bare hand contact with ready-to-eat foods will provide a foundation for assessing how well employees have been trained and give an indication as to whether a system is in place to ensure operational procedures are being followed.
- An assessment of no bare hand contact with ready-to-eat should also include observations of foodservice personnel that may not be assigned to the kitchen area. In many operations, wait staff have responsibilities for dispensing bread, desserts, salads, and other ready-to-eat foods. The other side of the cook/make line, where food orders are picked up by wait staff, should be a focus point for observing procedures designed to prevent no bare hand contact with ready-to-eat foods. Industry refers to this part of the operation as the Expo Area (expediting the orders to the customer). In addition, fruits such as limes and lemons intended for drinks are sometimes sliced in the bar area. Active managerial control of no bare hand contact with ready-to-eat foods needs to extend to these external kitchen areas as well.
- Keep in mind that no bare hand contact with ready to eat foods is only one component of active managerial control of poor personal hygiene. An assessment of handwashing and employee health must always be conducted in conjunction with no barehand contact.

ASSESSING ACTIVE MANAGERIAL CONTROL FOR RISK FACTOR AREAS

PREVENTION OF CONTAMINATION/CONTAMINATED EQUIPMENT

SUMMARY: PREVENTION OF CONTAMINATION AREAS

- A. Assessing Active Managerial Control of Separation of Raw Animal Foods from Ready-to-Eat Foods
- B. Separation of Raw Animal Foods of Different Species

SUMMARY: CONTAMINATED EQUIPMENT AREAS

- C. Assessing Active Managerial Control of Cleaning Frequency
- D. Assessing Active Managerial Control of Cleaning and Sanitation of Food Contact Surfaces

A. SEPARATION OF RAW ANIMAL FOODS FROM READY-TO-EAT FOODS Critical Limits

- Preventing Cross contamination
 - Food shall be protection from cross contamination by separating raw animal foods during storage, preparation, holding, and display from:
 - Ready-to-eat foods including other raw animal food such as fish for sushi or molluscan shellfish or other raw ready-to-eat food such as fruits and vegetables.
 - Cooked ready-to-eat food.
 - **NOTE:** Frozen commercially processed and packaged raw animal food may be stored or displayed with or above frozen, commercially processed and packaged, ready-to-eat food.
 - Packaging raw animal foods with ready-to-eat foods, when they are going to be used as ingredients intended for future preparation/cooking, is allowed.

B. SEPARATION OF RAW ANIMAL FOODS OF DIFFERENT SPECIES Critical Limits

- Preventing Cross contamination
 - Foods shall be protection from cross contamination by separating types of raw animal foods from each other such as beef, fish, lamb, pork, and during storage, preparation, holding, and display by:
 - Using separate equipment for each type, or
 - Arranging each type of food in equipment so that cross-contamination of one type with another is prevented, and
 - Preparing each type of food at different times or separate areas.
 - Not storing and displaying comminuted or otherwise non-intact meats above whole-muscle intact cuts of meat unless they are packages in a manner that precludes the potential for cross contamination.

**Some Questions for Assessing Active Managerial Control for
PREVENTING CONTAMINATION OF FOODS**

- Describe your system for storing raw animal foods in the walk-in cooler?
- Where are ready-to-eat foods that require refrigeration stored before service?
- How do food employees know which food products go on what shelves in the walk-in cooler?
- What steps do you use to prevent cross-contamination in the food preparation area?
- How do you verify that foods are being stored, prepared, held, and displayed to prevent cross-contamination? How often is this verification done?

**Tips for Assessing Active Managerial Control for
PREVENTING CONTAMINATION OF FOODS**

- Ask questions about the locations for the preparation of ready-to-eat foods and raw foods of animal origin. Gaining an understanding of the flow of food as it is prepared in the food establishment may uncover potential opportunities for cross contamination. Most establishments have a system or production schedule for preparing different products during the course of the day.
- One of the preparation focus points should be the food preparation sink. Most foodservice operations have only one designated food preparation sink that is often used to wash ready-to-eat vegetables/fruits AND thaw raw animal food items such as fish or other seafood items. What system does the facility have in place to prevent cross-contamination for the multiple varieties of foods that are processed using the food preparation sink?
- High volume areas like grill lines sometimes require food employees to work with both ready-to-eat and raw animal foods. What system or procedures does the operation have in place to prevent cross-contamination from utensils such as tongs and spatulas? How are work responsibilities delegated between employees? Has the management of the operation given any thought to segregating out work responsibilities based on preventing cross-contamination? (Example: one employee only works with ready-to-eat foods and another with raw animal food products)
- Observing the entire preparation procedure can provide a more complete picture of the establishment's active managerial control for preventing cross contamination. What happens to the containers and utensils that have been used to transport and dispense raw animal food products to preparation areas? Are the same utensils or containers used to remove and store the cooked product?
- Observe whether practices are in place to eliminate the potential for contamination of food, utensils, equipment, or single-service items from environmental contamination. For example, handwashing sinks and fixtures may be located where splash may contaminate food contact surfaces or food. Splash guards may need to be installed or food contact surface relocated to prevent contamination.
- Raw animal foods stored on shelves in refrigeration units should be separated by cooking temperatures such that food requiring a higher cooking temperature like chicken is stored below or away from foods requiring a lower cooking temperature like pork and beef. If foods are not being cooled, they should be covered or packaged while in storage.

C. CLEANING & SANITIZING OF FOOD CONTACT SURFACES Critical Limits

- Cleaning and Sanitizing Frequency
 - Food contact surfaces and utensils shall be cleaned and sanitized each time:
 - There is a change from working with raw animal foods to ready-to-eat foods.
 - Between uses with raw fruits and vegetables and with time-temperature control for safety foods.
 - Before using or storing food temperature measuring devices.
 - Contamination may have occurred, such as dropping a utensil on the floor.
 - Before each use of raw animal food (except in contact with a succession of different meat and poultry each requiring a higher cooking temperature, such as raw hamburger followed by raw chicken. 4-602.11(B) does not include fish, due to allergen cross contact concern).
 - Cleaning frequency based on ambient temperature of the refrigerated room or areas:

Preparation Room Temperature	Cleaning Frequency	Refrigerated room temperatures and cleaning frequency to be documented.
41°F or less	24 hours	
> 41°F to 45°F	20 hours	
> 45°F to 50°F	16 hours	
> 50°F to 55°F	10 hours	
> 55°F unrefrigerated rooms	4 hours	

- Cleaning frequency time-temperature control for safety foods – food contact surfaces:
 - In storage, containers of time-temperature control for safety foods (maintained at proper refrigeration temperatures and date marked) are cleaned when emptied.
 - Containers in serving situations such as salad bars that maintained and refilled with time-temperature control for safety foods, are cleaned at least every 24 hours.
 - In-use utensils intermittently stored in a container of hot water at $\geq 135^{\circ}\text{F}$ are cleaned every 24 hours or more frequently to preclude accumulation of soil residues.
- Cleaning frequency non-time temperature control for safety foods – food contact surfaces:
 - Utensils and equipment – at any time when contamination may have occurred.
 - At least every 24 hours for iced tea dispensers and consumer self service utensils.
 - Before restocking consumer self-service equipment and utensils.
 - In or enclosed components of equipment such as ice bins, ice makers, beverage nozzles and syrup dispensing lines/tubes, cooking oil storage tanks and distribution lines, coffee bean grinders, and water vending equipment; as specified by the manufacturer or as necessary to preclude accumulation of soil residues.

D. CLEANING AND SANITIZING OF FOOD CONTACT SURFACES Critical Limits

- Cleaning and Sanitizing Procedures/Critical
 - Sanitation: Concentration, pH, Temperature, Hardness, and Contact Time

Minimum Concentration (ppm or mg/L)	pH ≤ 10.0 and Minimum Temperature	pH ≤ 8.0 and Minimum Temperature	Contact Time
Chlorine 25	120°F	120°F	≥ 10 seconds
Chlorine 50	100°F	75°F	≥ 7 seconds
Chlorine 100	55°F	55°F	≥ 10 seconds
Iodine ≥ 12.5 to 25	pH ≤ 5.0 or per label, 75°F		≥ 30 seconds
Quaternary Ammonium (per label)	Water hardness ≤ 500 ppm or mg/L or per label; 75°F		
Hot Water Sanitize 3 compartment sink with integral heating device	≥ 171°F immersed in rack or basket		

NOTE: All chemical sanitizers shall be listed in 21 CFR 178.1010 Sanitizing Solutions and used in accordance with EPA-approved manufacturer's label use instructions.

- Warewashing: Mechanical and Manual

WAREWASHING MECHANICAL & MANUAL		Minimum Wash Temperature	Minimum Sanitizing Temperature
SPRAY TYPE WAREWASHERS Single Tank, Hot Water Sanitize	Stationary rack, single temperature	165°F	165°F
	Stationary rack dual temperature	150°F	180°F
	Conveyor, multi temperature	160°F	
Multi-Tank, Hot Water Sanitize	Conveyor, multi temperature	150°F	Sanitization levels as stated in the above table or per labeled manufacturer's instructions on the container.
Chemical Sanitize	Any warewashing machine	120°F	
3 Compartment Sink	Cleaning agent labeling may permit lower washing temperatures	110°F	

**Some Questions for Assessing Active Managerial Control for
CLEANING AND SANITIZING FOOD CONTACT SURFACES**

- Can you demonstrate how the 3-compartment sink is set up when equipment and utensils are soiled and need to be cleaned?
- How do you know that the sanitizer concentration is correct?
- What procedures do you have in place to ensure that the dish machine is operating properly?
- Describe the method you use to clean the meat slicer?
- Who is responsible for cleaning the food preparation sink? What procedure is used?
- How does an employee know that the food preparation sink was previously cleaned and sanitized before they use it to prepare food?
- Do you have a cleaning schedule for food equipment that cannot be sent thorough the dish machine or cleaned in the three-compartment sink?

**Tips for Assessing Active Managerial Control for
CLEANING AND SANITIZING FOOD CONTACT SURFACES**

- Special attention needs to be given to the cleaning and sanitizing procedure for workstations where both raw animal food products and ready-to-eat foods are processed during the course of the day. Is there a planned system or schedule for what types of foods are prepared during the course of the day? For example, are ready-to-eat food processed before raw animal foods OR is preparation done on an as-needed basis. While this assessment is important for all operations, it is especially critical for smaller establishments that may have limited space for food preparation.
- In addition to the schedule and flow of food preparation, it is important to obtain an understanding of who is responsible for ensuring that a food preparation surface has been cleaned and sanitized. Is it the responsibility of the person who completed preparing food on the work surface/sink or is it the responsibility of the person who will be using the surface to clean and sanitize it before placing food on a worktable or in a preparation sink? Understanding these types of systems will provide insights as to how well the cleaning and sanitizing procedure is monitored throughout the facility.
- An assessment of wiping cloths used for food contact surfaces requires more than just checking the sanitizer concentration of the solution in the wiping cloth buckets. Observe how, when, and on what surfaces food employees use the wiping cloth. Is it being used to clean surfaces that have accumulated heavy amounts of organic material or may have been used to process raw animal foods? Keep in mind that sanitizers will only be effective if the surface has been cleaned /rinsed first. High volume work areas like grill lines may create challenges for employees to effectively clean and sanitize food contact surfaces.
- It is often difficult to observe how an establishment cleans and sanitizes food contact surfaces and equipment that will not be processed through the three compartment sink or a mechanical dish machine. Meat slicers, cooking kettles, broasters, blenders, and large mixing bowls are just a few examples of the types of equipment that will have to be cleaned and sanitized in place. During the inspection, some time should be allocated to obtaining information from front line employees as to the procedure and frequency for cleaning and sanitizing these large pieces of equipment. It is best to have the person responsible for cleaning and sanitizing the food contact surface/equipment explain and/or demonstrate the procedure.

ASSESSING ACTIVE MANAGERIAL CONTROL FOR RISK FACTOR AREAS**APPROVED SOURCE****SUMMARY: APPROVED SOURCE AREAS**

- A. Assessing Active Managerial Control of Approved Sources and Receiving
- B. Assessing Active Managerial Control for Parasite Destruction
- C. Assessing Active Managerial Control for Molluscan Shellfish

A. APPROVED SOURCES AND RECEIVING Critical Limits

- Assessing Active Managerial Control of Food Deliveries
 - Delivery vehicle clean, free from insects / vermin; no evidence of cross contamination.
 - Time-Temperature Control for safety foods delivered under refrigeration are 41°F or below (unless specified in Law).
 - Frozen foods do not show evidence of thawing or freezing.
 - Evaluations indicate no signs of spoilage; off odors; discoloration; thawing of frozen foods; ice crystals; etc.
 - Product packaging is not damaged exposing food to contamination.
 - Cans do not bulge, leak, or have creased seams.
 - All products are within their “use-by” dates.

B. PARASITE DESTRUCTION Critical Limits

- Assessing Active Managerial Control of Parasite Destruction
 - Before service or sale in ready-to-eat form, raw, raw-marinated, partially cooked, or marinated-partially cooked FISH shall be:
 - Frozen and stored at a temperature of -4°F or below for a minimum of 168 hours (7 days) in a freezer.
 - Frozen at -31°F or below until solid and stored at -31°F or below for a minimum of 15 hours.
 - Frozen at -31°F or below until solid and stored at -4°F for a minimum of 24 hours.
 - The above freezing requirement for parasite destruction do not apply to:
 - Molluscan Shellfish
 - Tuna of species *Thunnus alalunga*, *Thunnus albacares* (Yellowfin tuna), *Thunnus atlanticus*, *Thunnus maccoyii* (Bluefin tuna, Souther), *thunnus obesus* (Bigeye tuna), or *Thunnus thynnus* (Bluefin tuna, Northern)
 - Aquaculture fish, such as salmon, that:
 - If raised in open water, are raised in net-pens.
 - Are raised in land-based operations such as ponds or tanks, and are fed formulated feed, such as pellets, that contain no live parasites infective to the aquaculture fish.
 - Fish eggs that have been removed from the skin and rinsed.
 - Freezing records, creation, and retention.
 - Freezing temperature and time shall be recorded and the records retained for 90 days beyond the time of service or sale of the fish, OR
 - A written agreement or statement from the supplier stipulating fish are frozen to the required temperature and time, retained for 90 days beyond the time of service or sale of the fish, OR
 - A written agreement or statement from supplier or aquaculturist stipulating that the fish were raised and fed feed with no live parasites infective to aquaculture fish is to be retained for 90 calendar days beyond the time of service and sale of the fish.

C. SHELLSTOCK Critical Limits

- Assessing Active Managerial Control of Molluscan Shellfish
 - Molluscan Shellfish obtained from source identified on the Interstate Certified Shellfish Shippers List (ICSSL) which can be found at: [Interstate Certified Shellfish Shippers List | FDA](#)
 - Molluscan Shellfish shall be obtained in container bearing legible source identification tags or labels:
 - Harvester's tag or label
 - The harvester's identification number is assigned by the shellfish control authority.
 - The date of harvesting.
 - Most precise identification of harvest location including the abbreviation of the name of the state or country in which the shellfish are harvested.
 - Type and quantity of shellfish.
 - Statement in bold, capitalized type: **THIS TAG IS REQUIRED TO BE ATTACHED UNTIL CONTAINER IS EMPTIED OR RETAGGED AND THEREAFTER KEPT ON FILE FOR 90 DAYS.**
 - Dealer's tag or label
 - Dealer's name and address, and the certification number assigned by the shellfish control authority.
 - The original shipper's certification number including the abbreviation of the name of the state or country in which the shellfish are harvested.
 - The same information as specified for the harvester's tag or label (above).
 - Statement in bold, capitalized type: **THIS TAG IS REQUIRED TO BE ATTACHED UNTIL CONTAINER IS EMPTIED AND THEREAFTER KEPT ON FILE FOR 90 DAYS.**
 - Shellfish tag maintenance:
 - Remain attached to the container in which the shellstock are received until the container is empty.
 - The date when the last shellstock from the container is sold or served must be recorded on the tag or label.
 - Tags are to be retained in chronological order for 90 days from the date recorded on the tag or label (the date when the last shellstock from the container is sold or served).
 - National Shellfish Sanitation Program also requires the following label in tags:
 - **RETAILER INFORM YOUR CUSTOMERS. Thoroughly cooking foods of animal origin such as beef, eggs, fish, lamb, poultry, or shellfish reduce the risk of foodborne illness. Individuals with certain health conditions may be at higher risk if these foods are consumed raw or undercooked. Consult your physician or public health official for further information.**
<http://www.issc.org>
 - Shucked Shellfish
 - Shipped in nonreturnable containers.
 - May be removed from original containers for displaying/dispensing if the labeling information is retained and correlated to the date when, or dates during which, the shellfish are sold or served.
 - Labeled with name, address, and certification number of the shucker-packer or repacker; and
 - "sell by" date for < ½ gallon, or
 - "Date shucked" for ≥ ½ gallon.

**Some Questions for Assessing Active Managerial Control for
APPROVED SOURCES AND RECEIVING**

- How do you verify that the food you receive is from an approved source?
- Do you have purchase specifications for specific food items?
- Do you have any food products that require the supplier to sign a certificate of conformance with your operation?
- What method do you use to verify the source of your shellfish?
- How frequently do you have food delivered to your facility?
- Have you established specific times of the days when food is to be delivered to your facility or do you work within the parameters of the supplier's schedule?
- Who is responsible for checking food delivered to the facility?
- What do you check when food is delivered to your establishment?
- How do you know if the food is at the proper temperature when it is received?
- Do you maintain any receiving logs?
- What system do you have in place to ensure that the fish you serve raw or undercooked has been frozen to destroy parasites?

**Tips for Assessing Active Managerial Control for
APPROVED SOURCES AND RECEIVING**

- The time and day of the inspection is important when assessing whether food is received from safe sources and in sound condition. Food may be received in the food establishment on set days. Ask questions to ascertain the day or days that deliveries are received and also the receiving procedures in place by the food establishment. Schedule inspections at times when it is known that the product will be received by the food establishment.
- If food is being delivered during the inspection, you should:
 - Verify internal product temperatures.
 - Examine package integrity upon delivery.
 - Look for signs of temperature abuse (e.g., large ice crystals in the packages of frozen products)
 - Examine the delivery truck and products for potential for cross contamination.
 - Observe the food employees' behaviors and practices as they relate to the establishment's control of contamination and holding and cooling temperatures of received products
 - Review receiving logs and other documents, product labels, and food products to ensure that foods are received from regulated food processing plants (no foods prepared at home) and at the proper temperature.
- When evaluating approved sources for shellfish, such as clams, oysters, and mussels, you should ask whether shellfish are served at any time during the year. If so, review the tags or labels to verify that the supplier of the shellfish is certified and on the most current Interstate Certified Shellfish Shippers List found at:
 - [Interstate Certified Shellfish Shippers List | FDA](#)
- Note whether all required information is provided on the tags or labeled and that these records have been retained for 90 days and stored in chronological order.

- Verify that fish are commercially caught and harvested from reputable vendors. If fish are being delivered during the inspection or if they were received just before your arrival, temperatures should be taken, especially if there are finfish such as tuna, mahimahi, bluefish, mackerel, and snapper. These fish are subject to scombrototoxin formation if time/temperature abused. Verify freshness by checking the gills, eyes, and bodies of the fish for any discoloration or off odors.
- With exceptions, fish intended for raw or undercooked consumption should be assessed to ensure they have been frozen for the required time and temperature to destroy parasites. This can be verified by either reviewing freezing records or verifying that a letter of guarantee from the supplier/distributor is kept on file. If freezing is conducted on-site, verify that the freezing records are maintained for at least 90 days beyond the date of sale or service.

Suggested Immediate Corrective Actions and Intervention Strategies for ACHIEVING LONG-TERM COMPLIANCE OF OUT-OF-CONTROL PROCEDURES

Out-of-Control Procedure	Associated Hazards	Immediate Corrective 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. See Participant Guide for additional guidance.	RCP, Train Employees, SOP/HACCP Development
Cold Holding	Vegetative Bacteria, Toxin-forming and Spore-forming Bacteria, Scombrototoxin (Finfish)	Conduct Hazard Analysis. See Participant Guide for additional guidance.	Change Equipment, RCP, 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.	Change Equipment, RCP, Train Employees, Develop SOP/HACCP/Recipe
Cooling	Toxin-forming and Sporeforming Bacteria	Conduct Hazard Analysis. See Participant Guide for additional guidance.	Change Equipment, RCP, 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.	Change Equipment Layout, RCP, Train Employees, Develop SOP/HACCP/Recipe
Food Source/Source Condition	Bacteria/Parasites/ Viruses/Scombrototoxin/ Ciguatera Toxin	Reject or Discard.	Change Buyer Specifications, Train Employees
Freezing to Control Parasites	Parasites	Freeze Immediately; Discard; or Cook.	Change Buyer Specifications, RCP, Develop SOP/HACCP/Recipe, Change Equipment, Train Employees
Handwashing	Bacteria, Viruses, and Parasites	Wash Hands Immediately; Conduct Hazard Analysis. See participant manual for additional guidance.	Change Equipment Layout, Train Employees, RCP, Develop SOP/HACCP
Hot Holding	Toxin-forming and Sporeforming Bacteria	Conduct Hazard Analysis. See participant manual for additional guidance.	Change Equipment, RCP, Train Employees, Develop SOP/HACCP/Recipe
Receiving Temperatures	Scombrototoxin, 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. See participant manual for additional guidance.	Change Equipment, RCP, Train Employees, Develop SOP/HACCP/Recipe