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by State law would not be allowed to feed residents (note that RNs, LPNs or CNAs **are** permitted to feed residents), and there were no resident negative outcomes.

- o Paid feeding assistants are assisting eligible residents; however supervising nurses are not nearby or *immediately available to promptly respond to an emergency*, but there have been no negative resident outcomes.

Level 1 - Severity 1 does not apply for this regulatory requirement.

F812

(F371)

§483.60(i) Food safety requirements.

The facility must –

§483.60(i)(1) - Procure food from sources approved or considered satisfactory by federal, state or local authorities.

- (i) *This may include food items obtained directly from local producers, subject to applicable State and local laws or regulations.*
- (ii) *This provision does not prohibit or prevent facilities from using produce grown in facility gardens, subject to compliance with applicable safe growing and food-handling practices.*
- (iii) *This provision does not preclude residents from consuming foods not procured by the facility.*

§483.60(i)(2) - Store, prepare, distribute and serve food in accordance with professional standards for food service safety.

INTENT §483.60(i)(1)-(2) - To ensure that the facility:

- Obtains food for resident consumption from sources approved or considered satisfactory by Federal, State or local authorities;
- Follows proper sanitation and food handling practices to prevent the outbreak of foodborne illness. Safe food handling for the prevention of foodborne illnesses begins when food is received from the vendor and continues throughout the facility's food handling processes; and,
- Ensures food safety is maintained when implementing various culture change initiatives such as when serving buffet style from a portable steam table, or during a potluck.

OVERVIEW §483.60(i)

Nursing home residents risk serious complications from foodborne illness as a result of their compromised health status. Unsafe food handling practices represent a potential source of pathogen exposure for residents. Sanitary conditions must be present in health care food service settings to promote safe food handling. CMS recognizes the U.S. Food and Drug Administration's (FDA) Food Code and the Centers for Disease Control and Prevention's (CDC) food safety guidance as national standards to procure, store, prepare, distribute and serve food in long term care facilities in a safe and sanitary manner.

Effective food safety systems involve identifying hazards at specific points during food handling and preparation, and identifying how the hazards can be prevented, reduced or

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eliminated. It is important to focus attention on the risks that are associated with foodborne illness by identifying critical control points (CCPs) in the food preparation processes that, if not controlled, might result in food safety hazards. Some operational steps that are critical to control in facilities to prevent or eliminate food safety hazards are thawing, cooking, cooling, holding, reheating of foods, and employee hygienic practices.

Web sites for additional information regarding safe food handling to minimize the potential for foodborne illness include:

- National Food Safety Information Network's Gateway to Government Food Safety Information at <http://www.FoodSafety.gov>;
- United States Food & Drug Administration Food Code Web site at <http://www.fda.gov/Food/GuidanceRegulation/RetailFoodProtection/FoodCode/>

DEFINITIONS §483.60(i)-(2)

The following definitions are provided to clarify terms related to professional standards for food service safety, sanitary conditions and the prevention of foodborne illness. Foodborne illness refers to illness caused by the ingestion of contaminated food or beverages.

"Critical Control Point" *means a specific point, procedure, or step in food preparation and serving process at which control can be exercised to reduce, eliminate, or prevent the possibility of a food safety hazard.*

"Cross-contamination" *means the transfer of harmful substances or disease-causing microorganisms to food by hands, food contact surfaces, sponges, cloth towels, or utensils which are not cleaned after touching raw food, and then touch ready-to-eat foods. Cross-contamination can also occur when raw food touches or drips onto cooked or ready-to-eat foods.³⁸*

"Danger Zone" *means temperatures above 41 degrees Fahrenheit (F) and below 135 degrees F that allow the rapid growth of pathogenic microorganisms that can cause foodborne illness. Potentially Hazardous Foods (PHF) or Time/Temperature Control for Safety (TCS) Foods held in the danger zone for more than 4 hours (if being prepared from ingredients at ambient temperature) or 6 hours (if cooked and cooled) may cause a foodborne illness outbreak if consumed.*

"Dry Storage" *means storing/maintaining dry foods (canned goods, flour, sugar, etc.) and supplies (disposable dishware, napkins, and kitchen cleaning supplies).*

"Food Contamination" *means the unintended presence of potentially harmful substances, including, but not limited to microorganisms, chemicals, or physical objects in food.³⁹*

"Food Preparation" *means the series of operational processes involved in preparing foods for serving, such as: washing, thawing, mixing ingredients, cutting, slicing, diluting concentrates, cooking, pureeing, blending, cooling, and reheating.*

³⁸ Partnership for Food Safety Education. (n.d.). Retrieved from <http://www.fightbac.org>.

³⁹ Partnership for Food Safety Education. (n.d.). Retrieved from <http://www.fightbac.org>.

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“Food Service/Distribution” *means* the processes involved in getting food to the resident. This may include holding foods hot on the steam table or under refrigeration for cold temperature control, dispensing food portions for individual residents, family style and dining room service, or delivering trays to residents’ rooms or units, etc.

“Potentially Hazardous Food (PHF)” or “Time/Temperature Control for Safety (TCS) Food” *means* food that requires time/temperature control for safety to limit the growth of pathogens (*i.e.*, bacterial or viral organisms capable of causing a disease or toxin formation).

“Storage” refers to the retention of food (before and after preparation) and associated dry goods.

GUIDANCE §483.60(i)(1)-(2)

If there is reason to believe that a potential food borne illness/outbreak has occurred at the facility, surveyors should not attempt to investigate on their own but should consult with their State or local Department of Public Health that handles these types of investigations, i.e., Food & Drug or Infection Control departments. In addition States or local public health agencies may have requirements for reporting a potential food borne illness/outbreak, facilities must follow these requirements as appropriate.

Much of this guidance is referenced from the 2013 Recommendations of the United States Public Health Service Food and Drug Administration Food Code. While we do not expect surveyors to determine compliance with this Food Code we are providing a link for reference and information only.

<https://www.fda.gov/downloads/Food/GuidanceRegulation/RetailFoodProtection/FoodCode/UCM374510.pdf>

Food contaminants fall into 3 general categories:

1. Biological Contamination - are pathogenic bacteria, viruses, toxins, and spores that contaminate food. The two most common types of disease producing organisms are bacteria and viruses. Parasites may also contaminate food, but are less common.

Factors which may influence the growth of bacteria *may include but are not limited to:*

- Hazardous nature of the food. Although almost any food can be contaminated, certain foods are considered more hazardous than others and are called “potentially hazardous foods (PHF) or Time/Temperature Controlled for Safety (TCS)” food. Examples of PHF/TCS foods include ground beef, poultry, chicken, seafood (fish or shellfish), cut melon, unpasteurized eggs, milk, yogurt and cottage cheese;
- Acidity (pH) of the food. More acidic food (i.e., pH < 5), such as pineapple, vinegar, and lemon juice, tends to inhibit bacterial growth;
- Water percentage of the food. Foods that have a high level of water (e.g., fruits and vegetables) encourage bacterial growth; and
- Time and temperature control of the food. Time in conjunction with temperature controls is critical. The longer food remains in the danger zone, the greater the risks for growth of harmful pathogens. Bacteria multiply rapidly in a moist environment in the danger zone. Freezing does not kill bacteria. Rapid death of most bacteria occurs at 165 degrees F or above.

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NOTE: Some foods may be considered a TCS food needing time/temperature control for safety to limit pathogenic microorganism growth or toxin formation. Examples include foods held for later service (e.g., cooked rice, beans, grilled sautéed onions, or baked potatoes).

2. Chemical Contamination - The most common chemicals that can be found in a food system are cleaning agents (such as glass cleaners, soaps, and oven cleaners) and insecticides. Chemicals used by the facility staff, in the course of their duties, may contaminate food (e.g., if a spray cleaner is used on a worktable surface while food is being prepared it becomes exposed to a chemical). An inadequately identified chemical may be mistaken for an ingredient used in food preparation. For example, incorrectly stored (e.g., dishwashing liquid stored in a syrup bottle) or unlabeled (e.g., white granulated cleaner that looks like salt) cleaning products may be inadvertently added to food and cause illness. Chemical products *and* supplies, must be *clearly marked as such and* stored separately from food items.

3. Physical Contamination - Physical contaminants are foreign objects that may inadvertently enter the food. Examples include, but are not limited to, staples, fingernails, jewelry, hair, glass, metal shavings from can openers, and pieces or fragments of bones from fish or chicken for example.

Potential Factors Implicated in Foodborne Illnesses - Many influences may contribute to foodborne outbreaks, such as:

- **Poor Personal Hygiene** - Employees, residents, family or visitor's health and hygiene are significant factors in preventing foodborne illness. "Infectious" individuals (persons capable of transmitting an infection or communicable disease) are a source of contaminants such as Norovirus, Influenza, etc. Proper hand washing techniques and exclusion of infectious individuals from handling food are critical for prevention of foodborne illness.
- **Inadequate Cooking and Improper Holding Temperatures** - Poorly cooked food or food that is not held at appropriate temperatures may promote the growth of pathogens that cause foodborne illness.
- **Contaminated Equipment** - Equipment can become contaminated in various ways including, but not limited to:
 - Poor personal hygiene;
 - Improper sanitation; and
 - Contact with raw food (e.g., poultry, eggs, seafood, and meat).
- **Unsafe Food Sources** - If surveyors have concerns or questions regarding the origin or processing of meat or other food products served to the facility residents, the surveyor should request that the facility provide documents which indicate the food product is from an approved or satisfactory source, as required by §483.60(i)(1) (F812).

NOTE: The food procurement requirements for facilities are not intended to restrict resident choice. All residents have the right to accept food brought to them by family or visitor(s).

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Strategies for Control of Potential Foodborne Illness - The table below illustrates the more commonly identified ingestible food items and sources of contamination which have been associated with food borne illness and possible strategies to prevent illness.

Source of Contamination	Primary Agents of Concern	Primary Control Strategies
A. Hazards that are likely to occur - strategies that must be in place to prevent foodborne illness.		
Eggs - unpasteurized or raw	<ul style="list-style-type: none"> • Salmonella 	<ul style="list-style-type: none"> • PHF/TCS • Cook until all parts of the egg are completely firm • Prevention of cross-contamination to foods
Poultry, raw	<ul style="list-style-type: none"> • Campylobacter • Salmonella 	<ul style="list-style-type: none"> • PHF/TCS • Cook to proper temperature • Prevention of cross-contamination to <i>other</i> foods
	<ul style="list-style-type: none"> • Clostridium perfringens 	<ul style="list-style-type: none"> • PHF/TCS • Cook to proper temperature
Meat, raw	<ul style="list-style-type: none"> • E. coli O157:H7 • Salmonella • Campylobacter 	<ul style="list-style-type: none"> • PHF/TCS • Cook to proper temperature • Prevention of cross-contamination to foods
	<ul style="list-style-type: none"> • Clostridium perfringens 	<ul style="list-style-type: none"> • PHF/TCS • Cook to proper temperature
Infectious food workers	<ul style="list-style-type: none"> • Norovirus • Hepatitis A virus • Shigella • Salmonella 	<ul style="list-style-type: none"> • Exclusion of infectious food workers • Proper hand-washing procedures • <u>Avoid bare-hand contact with any foods</u>
	<ul style="list-style-type: none"> • Staphylococcus aureus 	<ul style="list-style-type: none"> • Proper hand-washing procedures • Avoid bare-hand contact with foods
B. Hazards that may occur as a result of food products being adulterated, and for which good food handling practices are needed to minimize the potential for foodborne illness transmission. <i>The US Food & Drug Administration (FDA considers food adulteration as the act of intentionally debasing the quality of food offered for sale either by the admixture or substitution of inferior substances or by the removal of some valuable ingredient.</i>		
Fruits and vegetables, fresh	<ul style="list-style-type: none"> • E. coli O157:H7 • Salmonella • Norovirus • Hepatitis A virus • Shigella 	<ul style="list-style-type: none"> • Wash by facility staff prior to use • Keep cut and raw fruits and vegetables refrigerated
Ready-to-eat meat and poultry products	<ul style="list-style-type: none"> • Listeria monocytogenes 	<ul style="list-style-type: none"> • Proper refrigeration during storage
Pasteurized dairy products	<ul style="list-style-type: none"> • Listeria monocytogenes 	<ul style="list-style-type: none"> • Proper refrigeration during storage
Ice	<ul style="list-style-type: none"> • Norovirus 	<ul style="list-style-type: none"> • Cleaning and sanitizing the internal components of the ice machine and utensils according to manufacturers' guidelines

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Employee Health - Employees who handle food must be free of communicable diseases and infected skin lesions. (See the requirement at 42 CFR §483.80(a)(2)(v), F880, *Infection Control*, requiring a facility to have an infection prevention and control program that specifies policies for, among other things, the circumstances under which a facility must prohibit an employee from direct contact with residents or their food).

Hand Washing, Gloves, and Antimicrobial Gel - Employees should never use bare hand contact with any foods ready to eat or otherwise. Since the skin carries microorganisms, it is critical that staff involved in food preparation and services consistently utilize good hygienic practices and techniques. Staff should have access to proper hand washing facilities with available soap (regular or anti-microbial), hot water, and disposable towels and/or heat/air drying methods. Antimicrobial gel (hand hygiene agent that does not require water) cannot be used in place of proper hand washing techniques in a food service setting.

The appropriate use of *items* such as gloves, tongs, deli paper, and spatulas is essential in minimizing the risk of foodborne illness. Gloved hands are considered a food contact surface that can get contaminated or soiled. Disposable gloves are a single use item and should be discarded between and after each use.

The use of disposable gloves is not a substitute for proper hand washing. *Hands must be washed before putting on gloves and after removing gloves. Failure to change gloves and wash hands between tasks, such as medical treatments or contact with residents, between handling raw meats and ready to eat foods or between handling soiled and clean dishes, can contribute to cross-contamination.*

Hair Restraints/Jewelry/Nail Polish - Dietary staff must wear hair restraints (e.g., hairnet, hat, and/or beard restraint) to prevent hair from contacting food. Staff should maintain nails that are clean and neat, and wearing intact disposable gloves in good condition that are changed appropriately to reduce the spread of infection. Since jewelry can harbor microorganisms, it is recommended that staff keep jewelry to a minimum and cover hand or wrist jewelry with gloves when handling food.

Food Receiving and Storage - When food, food products or beverages are delivered to the nursing home, facility staff must inspect these items for safe transport and quality upon receipt and ensure their proper storage, keeping track of when to discard perishable foods and covering, labeling, and dating all PHF/TCS foods stored in the refrigerator or freezer as indicated.

When food is brought into the facility from an off-site kitchen (any kitchen that is not proximate to the facility), this kitchen must be approved and inspected by the appropriate Federal, State, or local authorities. *This does not include food brought to residents from their family or visitors. Obtain a copy of the last approved inspection of the off-site kitchen to verify it has been approved and inspected by the appropriate Federal, State or local authorities. Do not visit the off-site kitchen. Continue to inspect the facility for safe food handling, storage, and food quality after receiving the food delivery.*

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Food handling risks associated with food stored on the units may include but are not limited to:

- Food left on trays or countertops beyond safe time and/or temperature requirements;
- Food left in refrigerators beyond safe "use by" dates (including, but not limited to foods that have been opened but were not labeled, etc.);
- Food stored in a manner (open containers, without covers, spillage from one food item onto another, etc.) that allows cross-contamination; and
- Failure to maintain refrigerated food temperatures at safe levels;

Personal Refrigerators – The specific food storage requirements at F812 are for the nursing home food storage and do not apply to residents' personal refrigerators. However, the nursing home must ensure, under Life Safety Code regulations, that the resident room has an adequate electrical system, such as proper outlets, to allow the connection of a refrigerator without overloading the electrical system. Please see F813 related to nursing facility requirements to have a policy regarding personal food items.

- **Dry Food Storage** - Dry storage may be in a room or area designated for the storage of dry goods, such as single service items, canned goods, and packaged or containerized bulk food that is not PHF/TCS. The focus of protection for dry storage is to keep non-refrigerated foods, disposable dishware, and napkins in a clean, dry area, which is free from contaminants. Controlling temperature, humidity, and rodent and insect infestation helps prevent deterioration or contamination of the food. Dry foods and goods should be handled and stored *in a manner that* maintains the integrity of the packaging until they are ready to use. It is recommended that foods stored in bins (e.g., flour or sugar) be removed from their original packaging. Food and food products should always be kept off the floor and clear of ceiling sprinklers, sewer/waste disposal pipes, and vents to maintain food quality and prevent contamination. Desirable practices include managing the receipt and storage of dry food, removing foods not safe for consumption, keeping dry food products in closed containers, and rotating supplies.
- **Refrigerated Storage** - PHF/TCS foods must be maintained at or below 41 degrees F, unless otherwise specified by law. Frozen foods must be maintained at a temperature to keep the food frozen solid. Refrigeration prevents food from becoming a hazard by significantly slowing the growth of most microorganisms. Inadequate temperature control during refrigeration can promote bacterial growth. Adequate circulation of air around refrigerated products is essential to maintain appropriate food temperatures. Foods in a walk-in unit should be stored off the floor. Practices to maintain safe refrigerated storage include:
 - Monitoring food temperatures and functioning of the refrigeration equipment daily and at routine intervals during all hours of operation;
 - Placing hot food in containers (e.g., shallow pans) that permit the food to cool rapidly;
 - Separating raw foods (e.g., beef, fish, lamb, pork, and poultry) from each other and storing raw meats on shelves below fruits, vegetables or other ready-to-eat foods so that meat juices do not drip onto these foods; and
 - Labeling, dating, and monitoring refrigerated food, including, but not limited to leftovers, so it is used by its use-by date, or frozen (where applicable) or discarded.

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Safe Food Preparation - Many steps in safe food preparation must be controlled and monitored to prevent foodborne illness. Identification of potential hazards in the food preparation process and adhering to critical control points can reduce the risk of food contamination and thereby *minimize the risk of foodborne illness. When verifying food temperatures, staff should use a thermometer which is both clean, sanitized, and calibrated to ensure accuracy.*

- **Cross-Contamination** - Cross-contamination can occur when harmful substances, *i.e., chemical or disease-causing microorganisms* are transferred to food by hands (*including gloved hands*), food contact surfaces, sponges, cloth towels, or utensils that are not adequately cleaned. Cross-contamination can also occur when raw food touches or drips onto cooked or ready-to-eat foods.

Examples of ways to reduce cross-contamination include, but are not limited to:

- Store raw meat (e.g., beef, pork, lamb, poultry, and seafood) separately and in drip-proof containers and in a manner that prevents cross-contamination of other food in the refrigerator;
- Between uses, store towels/cloths used for wiping surfaces during the kitchen's daily operation in containers filled with sanitizing solution at the appropriate concentration per manufacturer's specifications. *Assure that these sanitizing solutions are safe and do not have a risk of chemical contamination when preparing foods.* Periodically testing the sanitizing solution helps assure that it maintains the correct concentration.
- Clean and sanitize work surfaces, including cutting boards and food-contact equipment (e.g., food processors, blenders, preparation tables, knife blades, can openers, and slicers), between uses *and consistent with applicable code.*
- **Thawing** - Thawing *some* foods at room temperature *may not be acceptable* because *it may be within the danger zone for rapid bacterial proliferation.* Recommended methods to safely thaw frozen foods include:
 - Thawing in the refrigerator, in a drip-proof container, and in a manner that prevents cross-contamination;
 - Completely submerging the item under cold water (at a temperature of 70 degrees F or below) that is running fast enough to agitate and float off loose ice particles;
 - Thawing the item in a microwave oven, then cooking and serving it immediately afterward; or
 - Thawing as part of a continuous cooking process.
- **Final Cooking Temperatures** - *Temperatures are critical in preventing foodborne illness.* Cooking food to the temperature and for the time specified below will either kill dangerous organisms or inactivate them sufficiently so that there is little risk to the resident if the food is eaten promptly after cooking.

Monitoring the food's internal temperature is important and will help ensure n
microorganisms can no longer survive and food is safe for consumption. Foods should
reach the following internal temperatures in these situations:

 - Poultry and stuffed foods, *i.e., turkeys, pork chops, chickens, etc.* - 165 degrees F;
 - Ground meat (e.g., ground beef, ground pork), ground fish, and eggs held for service - at least 155 degrees F;
 - Fish and other *non-ground* meats - 145 degrees F;
 - *If the facility is using unpasteurized eggs these eggs must be cooked until all parts of the egg are completely firm, regardless of a resident's request for such things as*

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“sunny side up”. To accommodate residents choice for items such as “sunny side up” the facility must use pasteurized eggs only;

- When cooking raw foods in the microwave, *they* should be rotated and stirred during the cooking process so that all parts are heated to a temperature of at least 165 degrees F, and allowed to stand covered for at least 2 minutes after cooking to obtain temperature equilibrium.

NOTE: Fresh, frozen, or canned fruits and vegetables that are cooked do not require the same level of microorganism destruction as raw *meats*/foods. Cooking to a hot holding temperature (135 degrees F) prevents the growth of pathogenic bacteria that may be present in or on these foods.

- **Reheating Foods** - Reheated cooked foods present a risk because they have passed through the danger zone multiple times during cooking, cooling, and reheating. The PHF/TCS food that is cooked and cooled must be reheated so that all parts of the food reach an internal temperature of 165 degrees F for at least 15 seconds before holding for hot service. Ready-to-eat foods that require heating before consumption are best taken directly from a sealed container (secured against the entry of microorganisms) or an intact package from an approved food processing source and heated to at least 135 degrees F for holding for hot service. Although proper reheating will kill most organisms of concern, some toxins, such as that produced by *Staphylococcus aureus*, cannot be inactivated by reheating food.

NOTE: Using a steam table to reheat food is unacceptable since it does not bring the food to the proper temperature within acceptable timeframes.

- **Cooling** - Improper cooling is a major factor in causing foodborne illness. Taking too long to chill PHF/TCS foods has been consistently identified as one factor contributing to foodborne illness. Foods that have been cooked and held at improper temperatures promote the growth of disease-causing microorganisms that may have survived the cooking process (e.g., spore-formers). Cooled food items can be re-contaminated by unsanitary handling practices or cross-contaminated from other food products, utensils, and equipment.

Large or dense food items, such as roasts, turkeys, soups, stews, legumes, and chili may require interventions (e.g., placing foods in shallow pans, cutting roasts into smaller portions, utilizing ice water baths, and stirring periodically) in order to be chilled safely within an allowed time period. These foods take a long time to cool because of their volume and density. If the hot food container is tightly covered, the cooling rate may be slowed further, leading to longer cooling times during which the food remains in the danger zone.

Cooked potentially hazardous foods that are subject to time and temperature control for safety are best cooled rapidly within 2 hours, from 135 to 70 degrees F, and within 4 more hours to the temperature of approximately 41 degrees F. The total time for cooling from 135 to 41 degrees F should not exceed 6 hours.

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- **Modified Consistency** - Residents who require a modified consistency diet may be at risk for developing foodborne illness because of the increased number of food handling steps required when preparing pureed and other modified consistency foods. When hot pureed, ground, or diced food drop into the danger zone (below 135 degrees F), the mechanically altered food must be reheated to 165 degrees F for 15 seconds *if holding for hot service*.
- **Eggs** –
 - Pooled eggs are raw eggs that have been cracked and combined together. The facility should crack only enough eggs for immediate service in response to a resident's requests or as an ingredient immediately before baking.
 - Unpasteurized Eggs- Salmonella infections may be prevented by substituting unpasteurized eggs with pasteurized eggs in the preparation of foods that will not be thoroughly cooked, such as, but not limited to, Caesar dressing, Hollandaise or Béarnaise sauce, egg fortified beverages, ice cream, and French toast.
 - Raw eggs with damaged shells are also unsafe because of the potential for contamination.

Food Service and Distribution - Various systems are available for serving and distributing food items to residents. These include but are not limited to tray lines, portable steam tables transported to a unit or dining area, open shelved food transport carts with covered trays, or enclosed carts that have hot and cold compartments. Some systems incorporate a heating element (pellet) under each plate of hot food. The purpose of these systems is to provide safe holding and transport of the food to the resident's location. Food safety requires consistent temperature control from the tray line to transport and distribution to prevent contamination (e.g., covering food items). The length of time needed to transport trays is more critical when the food is simply covered and transported in open or closed carts without a heated and cooled environment.

- **Tray line and Alternative Meal Preparation and Service Area** - The tray line may include, but is not limited to the steam table where hot prepared foods are held and served, and the chilled area where cold foods are held and served. A resident's meal tray may consist of a combination of foods that require different temperatures. Food preparation or service area problems/risks to avoid include, but are not limited to:
 - Holding foods in danger zone temperatures which are between 41 degrees F and 135 degrees F;
 - Using the steam table to heat food;
 - Serving meals on soiled dishware and with soiled utensils; and
 - Handling food with bare hands or improperly handling equipment and utensils.

While PHF/TCS foods are on the tray line, the temperature of the foods should be periodically monitored throughout the meal service to ensure proper hot or cold holding temperatures are maintained. If time is being used in place of temperature as a means of ensuring food safety, the facility must have a system in place to track the amount of time a PHF/TCS is held out of temperature control and dispose of it accordingly.

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- **Food Distribution** - Dining locations include any area where one or more residents eat their meals. These can be located adjacent to the kitchen or a distance from the kitchen, such as residents' rooms and dining rooms in nursing units on other floors or wings of the building. Potential food handling problems/risks associated with food distribution include:
 - Staff distributing trays without first properly washing their hands; and
 - Serving food to residents after collecting soiled plates and food waste, without proper hand washing.

Snacks - Snacks refer to foods served between meals or at bed time. Temperature control and freedom from contamination are also important when ready-to-eat or prepared food items for snacks are sent to the unit and are held for delivery, stored at the nursing station in a unit refrigerator or unit cupboards, or stored in personal refrigerators in resident rooms.

Special Events - Facility-sponsored special events, such as cookouts and picnics where food may not be prepared in the facility's kitchen and is served outdoors or in other locations, require the same food safety considerations.

Potluck Events – Are generally events where families, volunteers or other non-facility staff may organize to provide enjoyment to nursing home residents and support a person-centered, homelike environment. These are different from a facility's special event.

Regarding food brought into a nursing home prepared by others, please remember the nursing home is responsible for:

- Storing visitor food in such a way to clearly distinguish it from food used by or prepared by the facility.
- Ensuring safe food handling once the food is brought to the facility, including safe reheating and hot/cold holding, and handling of leftovers.
- Preventing contamination of nursing home food, if nursing home equipment and facilities are used to prepare or reheat visitor food.
- ✓ • Clearly identifying what food has been brought in by visitors for residents and guests when served.

Should a foodborne illness occur as a result of a potluck held at the facility, the nursing home could be held responsible. For example, the facility could be held responsible if the facility failed to ensure the food was protected from contamination while being stored in the refrigerator and became contaminated from raw meat juices or failed to ensure staff involved in food service used appropriate hand hygiene and a foodborne illness resulted.

Nursing Home Gardens – Nursing homes that have their own gardens such as, vegetable, fruit or herbs may be compliant with the food procurement requirements as long as the facility has and follows policies and procedures for maintaining and harvesting the gardens, including ensuring manufacturer's instructions are followed if any pesticide(s), fertilizer, or other topical or root-based plant preparations are applied.

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NOTE: Facilities must be in compliance with any State or local requirements that may exist pertaining to food grown on facility grounds for resident consumption.

Transported Foods - If residents take prepared foods with them out of the facility (e.g., bag lunches for residents attending dialysis, clinics, sporting events, or day treatment programs), the foods must be handled and prepared for them with the same safe and sanitary approaches used during primary food preparation in the facility. Appropriate food transport equipment or another approach to maintaining safe temperatures for food at special events can help minimize the risk of foodborne illness.

Ice - Appropriate ice and water handling practices prevent contamination and the potential for waterborne illness. Ice must be made from potable water. Ice that is used to cool food items (e.g., ice in a pan used to cool milk cartons) is not to be used for consumption. Keeping the ice machine clean and sanitary will help prevent contamination of the ice. Contamination risks associated with ice and water handling practices may include, but are not limited to:

- Staff, residents, visitors, etc., who fail to wash their hands adequately and *use the scoop in an ice machine*, or handle ice with their bare hands, are not following appropriate infection control practices when dispensing ice; and
- Unclean equipment, including the internal components of ice machines that are not drained, cleaned, and sanitized as needed and according to manufacturer's specifications.
- *Ice chests or coolers used to store and transport ice should be cleaned regularly, especially prior to use and when contaminated or visibly soiled.*

Refrigeration - The facility's refrigerators and/or freezers must be in good working condition to keep foods at or below 41 degrees F and the freezer must keep frozen foods frozen solid. The following are methods to determine the proper working order of the refrigerators and freezers:

- Document the temperature of external and internal refrigerator gauges as well as the temperature inside the refrigerator. Measure whether the temperature of a PHF/TCS food is 41 degrees or less;
- To make sure the cooling process is effective, measure the temperature of a PHF/TCS that has a prolonged cooling time (e.g., one in a large, deep, tightly covered container). Determine if it is in the danger zone;
- Check for situations where potential for cross-contamination is high (e.g., raw meat stored over ready-to-eat items);
- Check the firmness of frozen food and inspect the wrapper to determine if it is intact enough to protect the food; and
- Interview food service personnel regarding the operation of the refrigerator and the freezer.

Temperature control and freedom from contamination is also important when food or snacks are sent to a unit and held at the nursing station in a unit refrigerator or unit cupboards, *or stored in personal refrigerators in resident rooms*. Food handling risks associated with food stored on the units may include but are not limited to:

- Food left on trays or countertops beyond safe time and/or temperature requirements;
- Food left in refrigerators beyond safe "use by" dates (including, but not limited to foods that have been opened but were not labeled, etc.);

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- Food stored in a manner (open containers, without covers, spillage from one food item onto another, etc.) that allows cross-contamination; and
- Failure to maintain refrigerated food temperatures at safe levels;

Personal Refrigerators – The specific food storage requirements at F812 are for the nursing home food storage and do not apply to residents' personal refrigerators. However, the nursing home must ensure, under Life Safety Code regulations, that the resident room has an adequate electrical system, such as proper outlets, to allow the connection of a refrigerator without overloading the electrical system. Please see F813 related to nursing facility requirements to have a policy regarding personal food items.

Equipment and Utensil Cleaning and Sanitization - A potential cause of foodborne outbreaks is improper cleaning (washing and sanitizing) of equipment and protecting equipment from contamination via splash, dust, grease, etc.

Machine Washing and Sanitizing - Dishwashing machines use either heat or chemical sanitization methods. *Manufacturer's instructions must always be followed.* The following are *general recommendations* according to the U.S. Department of Health and Human Services, Public Health Services, Food and Drug Administration Food Code for each method.

High Temperature Dishwasher (heat sanitization):

- Wash - 150-165 degrees F;
 - Final Rinse - 180 degrees F;
- (160 degrees F at the rack level/dish surface reflects 180 degrees F at the manifold, which is the area just before the final rinse nozzle where the temperature of the dish machine is measured); or 165 degrees F for a stationary rack, single temperature machine.

Low Temperature Dishwasher (chemical sanitization):

- Wash - 120 degrees F; and
- Final Rinse - 50 ppm (parts per million) hypochlorite (chlorine) on dish surface in final rinse.

The chemical solution must be maintained at the correct concentration, based on periodic testing, at least once per shift, and for the effective contact time according to manufacturer's guidelines.

Manual Washing and Sanitizing - A 3-step process is used to manually wash, rinse, and sanitize dishware correctly. The first step is thorough washing using hot water and detergent after food particles have been scraped off. The second is rinsing with hot water to remove all soap residues. The third step is sanitizing with either hot water or a chemical solution maintained at the correct concentration, based on periodic testing, *at least when initially filled and as needed, such as with extended use,* and for the effective contact time according to manufacturer's guidelines. *Facilities must have appropriate and adequate testing equipment, such as test strips and thermometers, to ensure adequate washing and sufficient concentration of sanitizing solution is present to effectively clean and sanitize dishware and kitchen equipment.*

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After washing and rinsing, dishes and utensils are sanitized by immersion in either:

- Hot water (at least 171 degrees F) for 30 seconds; or
- A chemical sanitizing solution used according to manufacturer's instructions. Chemical sanitization requires greater controls than hot water sanitization. Manufacturer's instructions must **always** be followed.

A high concentration of sanitation solutions may be potentially hazardous (see manufacturer's instructions) and may be a chemical contaminant of food. Improper test strips yield inaccurate results when testing for chemical sanitation.

Drying food preparation equipment and utensils with a towel or cloth may increase risks for cross contamination.

Cleaning Fixed Equipment - When cleaning fixed equipment (e.g., mixers, slicers, and other equipment that cannot readily be immersed in water), the removable parts must be washed and sanitized and non-removable parts cleaned with detergent and hot water, rinsed, air-dried and sprayed with a sanitizing solution (at the effective concentration). Finally, the equipment is reassembled and any food contact surfaces that may have been contaminated during the process are re-sanitized (according to the manufacturer's instructions). Service area wiping cloths are cleaned and dried or placed in a chemical sanitizing solution of appropriate concentration.

PROCEDURES §483.60(i)(1)-(2)

Through observation, interviews, and record review, determine:

- *If the facility obtained food safe for consumption from approved sources; If the facility stores, prepares, distributes, and serves food in a sanitary manner to prevent foodborne illness;*
- *If the facility has systems (e.g., policies, procedures, training, and monitoring) in place to prevent the spread of foodborne illness and minimize food storage, preparation and handling practices that could cause food contamination and could compromise food safety; and*
- *If the facility utilizes safe food handling from the time the food is received from the vendor and throughout the food handling processes in the facility.*

Adhere to sanitary requirements (e.g., proper washing hands when entering the kitchen and between tasks, use of hair restraints) when assessing the kitchen and meal service throughout the survey process.

Observations - *Complete the initial brief kitchen tour upon arrival at the facility, with observations focused on practices that might indicate potential for foodborne illness. Make additional observations throughout the survey process during times when food is being stored, prepared, cooked, plated, transported, and distributed to determine if safe food handling practices are being followed. Corroborate observations through interview, record review, and other appropriate documentation.*

Food Procurement Procedures: *Determine whether food meets safe and sanitary conditions related to when, where, and how the food was received for residents' consumption. If a concern*

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is identified, check invoices from food vendors when necessary to verify the source of food acquisition and the date of delivery.

Storage of Food

- *Observe for food storage practices that may place the food, including ice, at risk for biological, chemical, or physical contamination.*
- *Check dry storage areas for canned goods that have a compromised seal (e.g., punctures);*
- *Check all facility refrigerators, including those on resident units, to ensure foods are held at appropriate temperatures and PHF/TCS foods for labeling and dates (e.g., use by dates);*
- *Check freezers to ensure foods are frozen solid;*
- *Look for evidence of pests, rodents and droppings and other sources of contamination in food storage areas; and*
- *Check resident rooms for safe food storage practices.*

Food Preparation Procedures

- *Observe staff food handling practices, such as proper hand washing, the appropriate use of utensils, gloves, and hairnets;*
- *Observe food handling practices that have potential for cross-contamination (e.g., use of food contact surfaces and equipment to prepare various uncooked and ready-to-eat foods);*
- *Have staff demonstrate the calibration technique to ensure the temperature readings on the thermometers are reliable;*
- *Determine if the dietary staff are ensuring PHF/TCS foods are at approved cold holding, hot holding, and final cook temperatures;*
- *Determine if the dietary staff follow approved cooling and reheating procedures for PHF/TCS foods;*
- *Observe staff preparing modified consistency (e.g., pureed, mechanical soft) PHF/TCS foods to determine whether food safety was compromised;*
- *If the staff is preparing resident requests for undercooked eggs (i.e. sunny side up, soft scrambled, soft boiled), determine if pasteurized shell eggs or liquid pasteurized eggs were used to prevent foodborne illness; and*
- *During meal service, observe whether the staff measure the temperature of all hot and cold menu items.*

Service after Meal Times

- *Observe whether facility personnel are operating the dish washing machine according to the manufacturer's specifications.*
- *Check whether the facility has the appropriate equipment and supplies to verify the safe operation of the dish washing machine and the washing of pots and pans.*
- *Check the sanitizing method used (high temperature or chemical) in dishwashing and for storing sanitizing cloths is adequate for sanitizing of dishware, utensils, pots/pans, and equipment.*

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- *Observe stored dishes, utensils, pots/pans, and equipment for evidence of soiling. These items should be stored in a clean dry location and not exposed to splash, dust or other contamination; and*
- *Evaluate whether proper hand washing is occurring between handling soiled and clean dishes to prevent cross-contamination of the clean dishes.*

Interviews - *During the course of the survey, interview the staff who performs the task about the procedures they follow to procure, store, prepare, distribute, and serve food to residents. In addition to food safety practices, determine:*

- *What is the facility's practice for dealing with employees who come to work with symptoms of contagious illness (e.g., coughing, sneezing, diarrhea, vomiting) or open wounds;*
- *Whether the facility has, and follows, a cleaning schedule for the kitchen and food service equipment; and*
- *If there is a problem with equipment, how staff informs maintenance and follows up to see if the problem is corrected.*

Record Review - *In order to investigate identified food safety concerns, review supporting data, as necessary, including but not limited to:*

- *Any facility documentation, such as dietary policies and procedures, related to compliance with food sanitation and safety, including but not limited to policies addressing facility food service, potluck events, food from visitors, facility gardens;*
- *Determine if the food service employees have received training related to such compliance;*
- *Monitoring records, such as temperature logs from the tray line, refrigerators, and freezers, and dishwasher temperature and sanitizing records;*
- *Maintenance records, such as work orders and manufacturer's specifications, related to equipment used to store, prepare, and serve food.*

Review of Facility Practices - *Review of facility practices may include, but is not limited to, review of policies and procedures for sufficient staffing, staff training, and following manufacturer's recommendations as indicated. In order to establish if the facility has a process in place to prevent the spread of foodborne illness, interview the staff to determine how they:*

- *Monitor whether the facility appropriately procures, stores, prepares, distributes, and serves food;*
- *Identify and analyze pertinent issues and underlying causes of a food safety concern;*
- *Implement interventions that are pertinent and timely in relation to the urgency and severity of a concern; and*
- *Monitor the implementation of interventions and determine if additional modification is needed.*

DEFICIENCY CATEGORIZATION

- **Examples of Level 4, immediate jeopardy to resident health and safety, include, but are not limited to:**
 - *A 10-quart covered stock pot with 8 quarts of cooked beans was in the refrigerator. The internal temperature of the beans at the time of survey was measured at 68*

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degrees F. The cook stated these beans had been cooked the day before and were going to be served at the next meal, unaware they had been improperly cooled. Improperly cooled beans are at risk for growing toxin producing bacteria that are not destroyed in the reheating process.

- A roast (raw meat) thawing on a plate in the refrigerator had bloody juices overflowing and dripping onto uncovered salad greens on the shelf below. The contaminated salad greens were used to make salad for the noon meal;
- The facility had a recent outbreak of Norovirus after the facility allowed a food worker who was experiencing vomiting and diarrhea to continue preparing food.

- ***An example of Level 3, Actual harm (physical or psychological) that is not immediate jeopardy, includes, but is not limited to:***
 - *The facility failed to properly cool leftover turkey. The turkey was served to the residents, which resulted in an outbreak of foodborne illness, which, based on the facility population, did not result in or have the potential for causing serious harm to any resident.*

- ***Examples of Level 2 - No actual harm with a potential for more than minimal harm (physical or psychological) that is not immediate jeopardy, include but are not limited to:***
 - Food service workers sliced roast pork on the meat slicer. The meat slicer was not washed, rinsed, and sanitized after use;
 - During the initial tour of the kitchen, two food service workers were observed on the loading dock. One was smoking and the other employee was emptying trash. Upon returning to the kitchen, they proceeded to prepare food without washing their hands;
 - Upon inquiry by the surveyor, the food service workers tested the sanitizer of the dish machine, the chemical rinse of the pot-and-pan sink, and a stationary bucket used for wiping cloths. The facility used chlorine as the sanitizer. The sanitizer tested less than 50 ppm in all three locations. Staff interviewed stated they were unaware of the amount of sanitizer to use and the manufacturer's recommendations to maintain the appropriate ppm of available sanitizer.

Level 1 - Severity 1 does not apply for this regulatory requirement.

POTENTIAL TAGS FOR ADDITIONAL INVESTIGATION §483.60(i)(1)-(2)

During the investigation of F812, the surveyor may have identified concerns with additional requirements related to outcome, process, and/or structure requirements. The surveyor is advised to investigate these related requirements before determining whether non-compliance may be present at these other tags. Examples of some of the related requirements that may be considered when non-compliance has been identified include, but are not limited to, the following:

- §483.25(g)(1)-(5), F692, Nutrition/Hydration Status and F693, Tube Feeding
 - Determine if residents have experienced nausea, vomiting, diarrhea, or other gastrointestinal symptoms as a result of the failure to store, handle, administer, or remove and discard tube feeding solutions in a safe and sanitary manner.
- §483.35(a), F725 Sufficient Staffing

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- o Determine if the facility has sufficient staffing to meet the needs of the residents.
- §483.60(a)(1)(2), *F801*, Dietary Services - Staffing
 - o Determine if the facility employs or consults with a qualified dietitian. If not employed full-time, determine if the director of food service receives scheduled consultation from the dietitian concerning storage, preparation, distribution and service of food under sanitary conditions.
- §483.60(a)(3), *F802*-Standard Sufficient Staff
 - o Determine if the facility employs sufficient support personnel competent to carry out the functions of the dietary service.
- §483.60(h), *F811*, Paid Feeding Assistants
 - o Determine if the Paid Feeding Assistant(s) has/have successfully completed a State-approved training course that meets Federal requirements and that the Feeding Assistant(s) is/are utilizing proper techniques to prevent foodborne illness.
- §483.80, *F880*, Infection Control
 - o Determine if the facility's infection control program includes investigation, control, and prevention of foodborne illness.
 - o Determine if the facility has practices in place to prevent the spread of infection, including proper hand washing techniques.
- §483.90(c)(2), *F908*, Maintain All Essential Equipment
 - o Determine if the equipment in the kitchen, such as refrigerators, food carts, tray line equipment, freezers, dishwashers, ovens, stoves, and ranges etc. is maintained in safe operating condition and according to manufacturers' specifications.
- §483.90(i)(4), *F925*, Effective Pest Control Program
 - o Determine if the facility has maintained an effective pest control program so that it remains free of pests and rodents. Determine whether there is evidence of insect larvae, roaches, ants, flies, mice, etc. in food storage, preparation and service areas.
- §§483.75(d), (e), and (g)(1)-(2), *F867*, *F868*, Quality Assessment and Assurance
 - o Determine whether the quality assessment and assurance committee seeks and reviews concerns related to foodborne illness, and food safety and sanitation to develop and implement appropriate actions to correct identified quality deficiencies when indicated.

KEY ELEMENTS OF NONCOMPLIANCE:

To cite F812, the surveyor's investigation will generally show the facility failed to do any one or more of the following:

- Procure, store, handle, prepare, distribute, and serve food in accordance with the standards summarized in this guidance; *or*
- Maintain PHF/TCS foods at safe temperatures, at or below 41 degrees F (for cold foods) or at or above 135 degrees F (for hot foods) except during preparation, cooking, or cooling, and ensure that PHF/TCS food plated for transport was not out of temperature control for more than four hours from the time it is plated; *or*
- Store raw foods (e.g., meats, fish) in a manner to reduce the risk of contamination of cooked or ready-to-eat foods; *or*
- Cook food to the appropriate temperature to kill pathogenic microorganisms that may cause foodborne illness; *or*
- Cool food in a manner that prevents the growth of pathogenic microorganisms; *or*