

PROPOSED GUIDELINES

F371 SANITARY CONDITIONS: INTERPRETIVE GUIDELINES AND SEVERITY GUIDANCE

INTENT: (F371) CFR 483.35(h)(2) Sanitary Conditions

The intent of this requirement is to ensure that the facility follows proper sanitation and food preparation, storage and handling procedures to prevent foodborne illness. This includes:

! Procuring, storing, preparing, and distributing/serving food under sanitary conditions; and

! Eliminating food handling practices that compromise food safety in nursing homes in order to prevent the outbreak of foodborne illness.

DEFINITIONS

Definitions are provided to clarify terms related to sanitary conditions and the prevention of foodborne illness.

! “Approved Source” refers to a source of natural and synthetic food and food products that is acceptable to the regulatory authority because it complies with generally recognized approaches, principles, and practices to protect public health.

! “Cross Contamination” refers to the transfer of harmful substances or diseasecausing microorganisms between food and other sources (e.g., food to food, people to food, food to equipment, and equipment to food).

! “Danger Zone” refers to temperatures between 41 degrees Fahrenheit (5°C) and 135 degrees Fahrenheit (57°C) that allow the rapid growth of pathogenic microorganisms that can cause foodborne illness.

! “Dry Storage” usually refers to storing/maintaining of dry foods (canned goods, flour, sugar, etc.) and supplies (disposable dishware, napkins, and kitchen cleaning supplies).

! “Food Contamination” refers to the presence in food of harmful, unpalatable, adulterated, or otherwise objectionable foreign substances (e.g., chemicals, microorganisms, or physical objects) before, during, or after processing or storage.

! “Food Preparation” refers to the series of operational processes involved in getting foods ready for serving, such as: washing, thawing, mixing ingredients, cutting, slicing, diluting concentrates, cooking, pureeing and blending, cooling, and reheating.

! “Food Service/Distribution” refers to 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, delivering trays to resident’s room or units, etc.

! “Food Spoilage” refers to varying degrees of physical, chemical, and/or biological deterioration of food sensory properties, nutrient content, and/or safety.

! “Foodborne Illness” refers to illness occurring after ingestion of a food or beverage that is contaminated with disease-causing microorganisms or toxins produced by microorganisms.

! “Highly Susceptible Population” refers to persons who are more likely than the general population to experience foodborne illness because of the setting (e.g., a nursing home) or their susceptibility (e.g., due to immunocompromised health status) to becoming ill if they ingest microorganisms or toxins.

! “Pathogen” refers to a disease producing organism (e.g., bacterium, parasite, and virus).

! “Potentially Hazardous Food (PHF) or Time/Temperature Control for Safety

(TCS) Food” refers to a food that requires time/temperature control for safety to limit the growth of pathogens or toxin formation.

! “Ready-to-Eat Food” refers to food that is edible without additional preparation to achieve food safety (e.g., cooking). It also includes foods that may receive additional preparation for palatability or culinary purposes, such as mixing with other ingredients (e.g., meat type salads such as tuna, chicken, or egg salad).

! “Refrigerated Storage” refers to a method (refrigeration and freezing) of keeping/maintaining foods at proper cold temperatures.

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

! “Toxins” refers to poisonous substances that are produced by living cells or organisms (e.g., pathogenic bacteria) that cause foodborne illness when the toxins are ingested. Toxins are not necessarily destroyed by high temperatures.

OVERVIEW

Food is an integral aspect of everyone’s daily life and is often viewed as a quality of life measure as well as a source of comfort and fulfillment for residents. Sanitary food handling practices are important because food service represents a potential source of exposure to pathogens for residents. Nursing home residents are at high risk for The effectiveness of the facility to store, prepare, distribute and serve food under sanitary conditions influences food safety, including the likelihood of food contamination. Enduring or recurrent problems in this area could indicate inadequate or ineffective facility practices.

Over the years, national attention has emphasized the importance of food safety. One effective approach to preventing foodborne illness is the use of Hazard Analysis and Critical Control Point (HACCP) Principles.¹ A HACCP plan involves identifying hazards (biological, chemical, or physical) at specific points during food handling and preparation and identifying how the hazards can be prevented, eliminated or reduced to a safe level. HACCP focuses 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 the food being unsafe to eat. Some operational steps that are critical to control in nursing homes to prevent or eliminate food safety hazards are cooking, cooling, holding, reheating of foods, and employee hygienic practices. Web sites for additional information regarding HACCP, foodborne illness, safety recommendations, and FDA (Food and Drug Administration) Food Code guidelines with annexes include:

! United States Food & Drug Administration Food Code website at <http://www.cfsan.fda.gov/~dms/fc05-toc.html>;

! National Food Safety Information Network’s Gateway to Government Food Safety Information at www.FoodSafety.gov; and

! United States Food & Drug Administration Hazard Analysis Critical Control Point websites at www.cfsan.fda.gov/~lrd/haccp.html,

<http://www.cfsan.fda.gov/~dms/hret2toc.html>, (Operator’s Manual) and <http://www.cfsan.fda.gov/~dms/hret3toc.html> (Regulator’s manual).

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TYPES OF FOOD CONTAMINATION

Food contaminants fall into three categories: biological, chemical, and physical.

Biological Contamination

Biological contaminants are pathogens or pathogen-produced toxins 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.

Pathogenic Bacteria. Not all bacteria in food make a person sick. For example, live cultures of *Lactobacillus* bacteria are added to yogurt to enhance digestion. However, some bacteria are pathogenic (i.e., they may cause illness or death). Food may already be contaminated before entering the nursing home; therefore, it is vital to control the growth of the bacteria during food storage and preparation.

Several factors which may influence the growth of bacteria include:

! 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, chicken, fish, seafood, eggs, milk, yogurt and cottage cheese. Other less obvious examples include sliced fruit, sprouts and garlic in oil mixtures;

NOTE: Some foods, because of their preparation, ingredients, or density may be considered a PHF/TCS food needing time/temperature control for safety to limit pathogenic microorganism growth or toxin formation.

Examples include foods held warm for extended periods of time (e.g., cooked rice, grilled sautéed onions, baked potatoes in foil), which potentially allow the spore form of any contaminating organism to vegetate.

! Acidity (pH) of the food. More acidic (i.e., pH < 7.0) food inhibits bacterial growth;

! Temperature. Bacteria multiply rapidly between the temperatures of 41 degrees F and 135 degrees F (i.e., in the danger zone). Freezing does not kill bacteria.

Rapid death of most bacteria occurs at 165 degrees F or above; and

! Time. Bacteria can reproduce to dangerous levels rapidly in an environment conducive to their growth. This time is cumulative and may begin before the nursing home receives the food.

Toxins. Toxins are poisonous substances that come from a variety of sources. Some pathogens (e.g., *Staphylococcus aureus* and *Clostridium botulinum*) produce toxins as a byproduct of their growth. Most toxins are not destroyed by high temperatures. A PHF/TCS food that is allowed to remain in the danger zone long enough for the bacteria to produce toxins will become unsafe to eat.

Spores. A spore is an inactive form of an organism that is highly resistant to extreme temperatures, acidity, and dehydration for extended periods of time. The organism is reactivated once conditions become favorable for their growth. Two common sporeforming pathogens are *Bacillus cereus* and *Clostridium botulinum*. Temperature control is the only way to minimize the danger associated with spore-forming organisms.

Viruses. Viruses cannot reproduce without a living host (animal or human). While they cannot reproduce in or on food, viruses may survive long enough in or on a food to be transmitted to a new host. Two viruses that are well known for being spread by poor food handling practices are *Hepatitis A* and *Norovirus* (formerly known as *Norwalk virus*).

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 facility staff in the course of their duties may contaminate food if the food is exposed to the chemical (e.g., if a spray cleaner is used on a work table surface while food is being prepared there). 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 cleaning products (e.g., white granulated cleaner that looks

like salt) may be inadvertently added to food and cause illness.

Physical Contamination

Physical contaminants are foreign objects that accidentally enter the food. Examples of items that fit into this category include staples, fingernails, hair, glass, metal shavings from can openers, and pieces of bones.

FACTORS IMPLICATED IN FOODBORNE ILLNESSES

The Centers for Disease Control and Prevention has received reports from State epidemiologists that reflect their findings in foodborne outbreak investigations. They identified several factors that may contribute to foodborne outbreaks in facilities. These factors include:

- ! Improper holding temperatures;
- ! Inadequate cooking;
- ! Poor personal hygiene;
- ! Contaminated equipment; and
- ! Unsafe food sources.

Time, coupled with temperature, is the key control factor in foodborne illness. Improper holding temperature was the most commonly reported food preparation practice that contributed to foodborne illness, and inadequate cooking of food was the second most common.² Food obtained from an unsafe source was reported as the least common factor.

Food that was not adequately cooked after contamination by equipment or by poor personal hygiene may be a source of foodborne illness. PHF/TCS foods require adequate cooking and proper holding temperatures because they readily support the rapid or progressive growth of infectious or toxigenic microorganisms.

Specific examples of PHF/TCS foods include animal foods (raw or cooked) such as meats, dairy products and eggs; raw seed sprouts; fruits and vegetables that are heat-treated (cooked) or skin breached (cut, peeled, diced) such as cut melons; and salad dressings that are not acidified (e.g., garlic and oil) or modified during food processing to inhibit growth of microorganisms. Foods that, because of certain intrinsic or extrinsic factors, do not support the growth or toxin formation of pathogenic microorganisms (e.g., foods with low pH or low moisture content, air-cooled hard-boiled eggs with an intact shell, etc.) are not considered to be PHF/TCS foods.

NOTE: The facility is not permitted to use home-canned and home-prepared foods for service to nursing home residents.⁴ Family members who bring in foods for their resident's consumption are not subject to this prohibition.

PHF/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.⁵ Holding hot food products at 135° F or above and keeping cold food products at or below 41° F is effective in preventing or limiting microbial growth and production of toxins.

PATHOGENIC MICROORGANISMS AND TOXINS THAT CAN CAUSE FOODBORNE ILLNESS⁶

The information in this section is provided to help the surveyor understand the types of contaminants that may affect the food supply and the implications and/or potential outcomes to the nursing home resident. Microorganisms involved in outbreaks of foodborne illnesses include (but are not limited to) the bacteria, viruses, and parasites listed in the following table (microorganisms are placed in alphabetical order and do not reflect the severity of illness or frequency of occurrence):

Table of Pathogenic Microorganisms

Name	Incubation Period	Signs and Symptoms of Related Illness
Bacteria		
<i>Bacillus cereus</i>	2-16 hours	vomiting, abdominal cramps, diarrhea, nausea
<i>Campylobacter jejuni</i>	2-5 days	diarrhea (may be bloody), cramps, fever, abdominal pain, nausea, headache, muscle pain, vomiting
<i>Clostridium botulinum</i>	12-72 hours, usually 18-36 hours	paralysis, blurred and/or double vision, weakness, difficulty swallowing
<i>Clostridium perfringens</i>	8-22 hours	abdominal cramps, watery diarrhea, nausea
<i>Escherichia coli</i> (E. coli 0157:H7)	1 to 8 days	severe diarrhea (often bloody), abdominal pain, vomiting, occasional low-grade fever, hemolytic uremic syndrome
<i>Listeria monocytogenes</i>	2 to 6 weeks	fever, muscle aches, nausea, diarrhea, bacteremia, meningitis
<i>Salmonella</i>	1 to 3 days (6-72 hours, usually 12-36 hours)	abdominal cramps, vomiting, headache, fever, diarrhea
<i>Shigella species</i>	24-48 hours	abdominal cramps, fever, diarrhea
<i>Staphylococcus aureus</i>	30 minutes to 8 hours, usually 2-6 hours	vomiting, nausea, some diarrhea
Viruses		
<i>Hepatitis A</i>	30 days, with a range of 15-50 days	diarrhea, dark urine, jaundice, flu-like symptoms
Parasites		
<i>Giardia lamblia</i>	1 to 4 weeks	acute or chronic diarrhea, flatulence, bloating
<i>Toxoplasma gondii</i>	10 to 23 days	symptoms can be acute (with mild flu-like symptoms) or chronic.

Most people infected with the parasite do not have any symptoms

PREVENTION OF FOODBORNE ILLNESS

Food Handling and Preparation

Proper food preparation, storage, and handling practices are essential in preventing foodborne illness. Education, training, and monitoring of all staff involved in food service, as well as establishing effective infection control and quality assurance programs help maintain safe food preparation practices.

Approaches to creating a homelike environment or to providing accessible nourishments may include a variety of non-conventional, non-institutional food services. Food may be served by non-dietary staff at times other than scheduled meal times; convenience foods,

pre-packaged and ready-to-eat foods may be stored and microwaved on the nursing units; and food may be brought in from a variety of approved sources. Whatever the approach, staff should follow practices to prevent foodborne illness.

Employee Health. Employees who handle food must be free of communicable diseases or infected skin lesions (see the requirement at 42 CFR 483.65(b)(2) regarding preventing spread of infection). Uncovered hand infections can also contaminate food. Bare hand contact with ready-to-eat food should not occur.

Hand Washing, Gloves, and Antimicrobial Agents. Since the skin carries bacteria and viruses, it is critical that staff involved in food preparation consistently utilize good hygienic practices and techniques. Staff should have access to hand washing facilities with available soap (regular or anti-bacterial), hot water, and disposable towels and/or heat/air drying methods. Antimicrobial agents do not substitute for proper hand washing techniques. Staff must wash their hands in an appropriate hand washing sink before preparing foods, before putting on gloves to work with food, after handling soiled equipment or utensils, when changing tasks (e.g., when switching between handling raw foods and ready-to-eat foods), after bathroom use, and after engaging in other activities that contaminate the hands.

The appropriate use of utensils such as gloves, tongs, and deli paper is also essential in preventing foodborne illness. Failure to change gloves between tasks can contribute to cross-contamination. Disposable gloves are a single use item and should be discarded after each use.

NOTE: The use of disposable gloves is not a substitute for hand washing. The FDA Food Code prohibits bare hand contact with ready-to-eat food for food employees in food establishments serving highly susceptible populations.

Hair Restraints/Jewelry/Nail Polish.⁷ Dietary staff must wear hair restraints (e.g., hairnet, hat, and/or beard restraint) to keep their hair from contacting exposed food. Microorganisms can be harbored under or around fingernails or jewelry. Dietary staff who wish to wear nail polish or artificial fingernails should be required to wear intact gloves in good repair at all times. Jewelry, other than a plain ring, should not be worn while preparing or serving food.

Food Storage

When food is brought into the facility, proper storage helps ensure its quality and safety. Important measures include keeping track of when to discard perishable foods, and covering, labeling, and dating all foods stored in the refrigerator or freezer. Controlling temperature, humidity, rodent and insect infestation within the dry storage area helps prevent deterioration or contamination of the food.

Dry Food Storage. Dry storage may be 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 nonrefrigerated foods, disposable dishware, and napkins in a clean, dry area, which is free from contaminants. Dry foods and goods should be handled and stored to maintain the integrity of the packaging until they are ready to use. Foods stored in bins (e.g., flour, sugar) should be removed from their original packaging.

Avoiding extremes of heat and humidity, keeping food off the floor and clear of ceiling sprinklers, sewer/waste disposal pipes, and vents, and maintaining the storage space free of rodent infestation and insects will help maintain food quality and prevent contamination. Desirable facility practices include managing receipt and storage of dry food, removing foods not safe for consumption, keeping dry food products in closed containers, and rotating supplies.

NOTE: Chemical products, including cleaning supplies, should be stored away from food items.

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. While the FDA Food Code does not specify a temperature for freezing, it requires that stored frozen food is kept frozen (Section 3-501.11).

Refrigeration prevents food from becoming a hazard by significantly slowing the growth of most microbes. 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.

Some other practices involved in maintaining safe refrigerated storage include:

- ! Monitoring food temperatures and functioning of the refrigeration equipment;

- ! Placing hot items in containers (e.g., shallow pans) that permit them to cool rapidly;

- ! Separating raw animal foods (e.g., beef, fish, lamb, pork, and poultry) from each other and storing raw meats on a shelf below fruits, vegetables or other ready-to-eat foods (FDA Food Code section 3-302.11(A)(1)(2)) so that meat juices do not drip onto ready-to-eat foods; and

- ! Labeling, dating, and monitoring refrigerated food, including leftovers, so it is used by its use-by date.

Safe Food Preparation

Many steps in safe food preparation must be controlled or monitored to prevent foodborne illness. Identification of potential hazards in the food preparation process and critical control points (CCPs) where specific actions can reduce risk of food contamination helps to prevent foodborne illness.

Cross Contamination. Cross contamination is one of the leading causes of foodborne illness. The following practices can prevent cross contamination:

- ! Raw meat and seafood should be stored in a drip-proof container and in a manner that prevents cross-contamination of other food in the refrigerator. Different types of raw meat and seafood should not be stored in the same container;

- ! Towels/cloths used for wiping surfaces during the kitchen's daily operation should be stored between uses in containers filled with sanitizing solution at the appropriate concentration per manufacturer's specifications (see Manual Washing section of guidance) and tested periodically;

- ! Cutting boards made of acceptable materials (e.g., hardwood, acrylic, etc.) need to be washed and sanitized between uses, consistent with applicable code;⁹ and

- ! Work surfaces and food-contact equipment (e.g., food processors, blenders and slicers) should be cleaned and sanitized between uses.

Thawing. Thawing frozen foods is often the first step in food preparation. Thawing food at room temperature is not acceptable because the food is within the danger zone for rapid bacterial proliferation. 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 that is running fast enough to agitate and float off loose ice particles;

- ! Thawing the item in a microwave oven, then cooking or serving it immediately afterward; or

- ! As part of a continuous cooking process.

Final Cooking Temperatures. Cooking is a critical control point in preventing foodborne illness. Cooking foods to heat all parts of the food to the temperature and for the time specified below will either kill dangerous organisms or injure them sufficiently that there is little risk to the resident if the food is eaten promptly after cooking.

According to the FDA Food Code, foods should reach the following internal temperatures:

! Poultry and stuffed foods: 165 degrees F or above for 15 seconds;
! Ground meat (e.g., ground beef), ground fish, and eggs held for service: at least 155 degrees F for 15 seconds;
! Fish, meat (other than ground meat) and unspecified meats: 145 degrees F for 15 seconds;
! Eggs, unless pasteurized, if cooked to order for immediate service upon resident request: 145 degrees F for 15 seconds until the white is completely set and the yolk begins to thicken, to be eaten promptly after cooking;
! Fresh, frozen, or canned fruits and vegetables that are cooked do not require the same level of microorganism destruction as raw animal 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; and
! When cooking in the microwave, foods must be rotated and stirred during the cooking process so that all parts of the food are heated to a temperature of at least 165 degrees F.

Reheating Foods. Reheated cooked foods (leftovers) present a risk because they have passed through the danger zone multiple times during cooking, cooling and reheating. 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 15 seconds before holding for hot service. Ready-to-eat food taken directly from a hermetically sealed container or an intact package from an approved food processing plant should be heated to at least 135 degrees F for holding for hot service.

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

Although proper reheating will kill most organisms of concern, some toxins, such as that produced by *Staphylococcus aureus* cannot be inactivated by reheating food. Contamination of food after cooking must be minimized to prevent the introduction of microorganisms and production of toxins.

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 roast, turkeys, soups, stews, legumes, and chili require special consideration. These foods take a long time to cool because of their mass and volume. If the hot food container is tightly covered, the cooling rate will be further slowed leading to longer cooling times in which the food remains in the danger zone. Reducing the volume of the food in an individual container (e.g., placing in shallow containers) and leaving an opening for heat to escape by keeping the cover loose or the food uncovered during cooling can markedly increase the rate of cooling. The FDA Food Code specifies cooling cooked PHF/TCS food within 2 hours from 135 degrees F (57 degrees C) to 70 degrees F (21 degrees C); and within a total of 6 hours from 135 degrees F (57 degrees C) to 41 degrees F (5 degrees C) or less. Note there are some exceptions in specific circumstances.

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.

Eggs. Based on Food and Drug Administration (FDA) recommendations¹¹ for preventing salmonella infections associated with eggs, the facility should:

! Avoid the use or eating of raw or undercooked shell eggs;

! Substitute pasteurized eggs or egg products for raw or undercooked eggs in foods that will not be thoroughly cooked, such as Caesar dressing, hollandaise or Béarnaise sauce and French toast;

! Wash hands, cooking utensils, and food preparation surfaces with soap and water after contact with raw eggs; and

! Not use raw eggs with damaged shells because of potential contamination.

Food Service and Distribution

Several systems are available for serving and distributing food items to residents. These include tray lines, portable steam tables transported to a unit or dining area, open shelved food transport carts with covered trays, or enclosed carts that may 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 and prevention of 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/closed carts without a heated and cooled environment.

The FDA Food Code allows the re-service of only non-PHF/TCS food from one individual to another if the food is dispensed so that it is protected from contamination and the container is closed between uses, such as a narrow-neck bottle containing catsup, steak sauce, or wine; or if the food such as crackers, salt, or pepper, is in an unopened original package and is maintained in sound condition. This does not include re-service to or from residents who are under contact precautions or protective environment isolation.¹²

Tray line. The tray line includes the steam table where hot, prepared foods are held and served and the chilled area where cold foods and other food items are held and served. A resident's meal tray may consist of a combination of foods that each requires a different temperature. Common food handling problems/risks associated with the tray line include:

! Holding foods at temperatures between 41 degrees F and 135 degrees F (i.e., the danger zone);

! Using the steam table to heat food instead of just to hold it;

! Serving meals on soiled plates/utensils; and

! Handling food with bare hands or improperly handling equipment and utensils.

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. Food handling problems/risks associated with food distribution include:

! Staff distributing trays without first washing their hands;

! Allowing residents to handle food and eating utensils without washing their hands, especially after toilet use; and

! Serving fresh trays to residents after collecting soiled plates and food waste, without staff first washing their hands.

Nourishments. Nourishments refer to those foods that are served between meals and at hour of sleep (h.s.). Temperature control and freedom from contamination are also important when packaged or prepared food items for nourishments are sent to the unit and are held for delivery, or stored at the nursing station, in a unit refrigerator, or unit cupboards. Common food handling risks associated with food stored on the units may include:

! Food left on trays or countertops beyond safe time and/or temperature requirements;

! Food left in refrigerators beyond safe "use by" dates (including foods that have

been opened but were not labeled, etc.);

! Food stored in a manner that allows cross-contamination (open containers, lack of covers, spillage from one food item onto another, etc); and

! Refrigerated food temperatures not maintained at safe levels.

Special Events. Facility sponsored special events, such as cookouts and picnics where food may not be prepared in the kitchen and is served outdoors or in other locations, require similar food safety considerations. If volunteers assist in food handling/service, the facility is still responsible for food safety. If residents take prepared foods with them out of the facility (e.g., bag lunches for residents attending sporting events or workshops, etc.), the foods are handled and transported with the same safety and sanitary standards as practiced within the primary food preparation and service areas of the facility.

Appropriate food transport equipment or another system to maintain safe temperatures for food at special events help prevent foodborne illness.

Ice. Appropriate ice and water handling practices prevent contamination and the potential for waterborne illness. Ice that is used to cool food items (e.g., milk cartons sitting in a pan of ice) may not be ingested. Keeping the ice machine clean and sanitary will help prevent contamination of the ice. Risks associated with ice and water handling practices include:

! Contamination of ice from poor staff hygiene and handling practices including: not washing hands; touching the ice with bare hands; not utilizing clean utensils to pass fresh water and ice products; not following appropriate infection control practices when distributing water; or not storing the ice scoop consistent with acceptable infection control/safety standards; and

! Unclean equipment, including the internal components of ice machines that are not drained, cleaned, and sanitized.

EQUIPMENT AND UTENSIL CLEANING AND SANITIZATION

A potential cause of foodborne outbreaks is improper cleaning (washing and sanitizing) of contaminated equipment. Dishwashing machines, operated according to the manufacturer specifications, wash, rinse, and sanitize dishes and utensils using either heat or chemical sanitization. Manual dishwashing is often used for pots and pans, or when the dishwashing machine is not operational.

Machine Washing and Sanitizing

Dishwashing machines use either heat or chemical sanitization methods. The following specifications for each method are described below.

! High Temperature Dishwasher (heat sanitization):

- 150-165 degrees F wash (or according to manufacturer's specifications); and
- 180 degrees F final rinse (160 degrees F at the rack level/dish surface reflects 180 degrees F at the manifold) and not more than 194 degrees F; or
- 165 degrees F for a stationary rack, single temperature machine.

! Low Temperature Dishwasher (chemical sanitization):

- 120 degrees F wash (or according to manufacturer's specifications); and
- 50 ppm (parts per million) hypochlorite (chlorine) on dish surface in final rinse.

Manual Washing and Sanitizing

A 3-step process is used to manually wash, rinse, and sanitize dishware correctly. The first step is washing, using hot water and detergent. The second is rinsing off food particles and soap residue with hot water. The third step is sanitizing with either hot water or a chemical solution maintained at the correct concentration, based on periodic testing, and for the effective contact time according to manufacturer's guidelines.

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. The recommended sanitization concentrations are as follows:

- | | | |
|-------------------|------------------|--|
| ○ Chlorine | 50 ppm minimum | 10 second contact time |
| ○ Iodine | 12.5 ppm minimum | 30 second contact time |
| ○ QAC (Quaternary | 200 ppm | (contact time per Ammonium
Ammonium Compound)
manufacturer's instructions) |

NOTE: Rinsing or any other cleaning process should not take place after sanitization. Equipment and utensils are air dried only. The use of towels for drying, polishing, or any other purpose can re-contaminate equipment and utensils with bacteria.

Cleaning Fixed Equipment

When cleaning fixed equipment (e.g., mixers, slicers, and other equipment that cannot readily be immersed in water), the removable parts should be washed and sanitized. The non-removable parts should be cleaned with detergent and hot water, rinsed, air dried and sprayed with a sanitizing solution (at the effective concentration). Finally, the equipment should be reassembled and any food contact surfaces that may have been contaminated during the process should be resanitized.

INVESTIGATIVE PROTOCOL

SANITARY CONDITIONS

Objectives

! To determine if the facility stored, prepared, distributed, and served food in a sanitary manner to prevent foodborne illness; and

! To determine if the facility has a structure and process in place to prevent the spread of foodborne illness and minimize those food preparation and handling practices that could cause food contamination and could compromise food safety.

Use

Use this protocol to investigate compliance at F371 (483.35(h)(2)).

Procedures

During the initial tour of the facility, the assigned surveyor observes the facility kitchen and food service area and corroborates observations through interview and record review. The surveyor should follow the sanitation requirements that the facility has established when accessing the kitchen, such as use of head coverings, lab coats, etc. Kitchen observations should be made during times when food is being prepared, cooked, plated, transported, and distributed to determine if safe food handling practices are being followed.

1. Observation

Conduct the following observations:

! Food preparation procedures:

- Evaluate staff food handling practices, such as hand washing, appropriate use of utensils and gloves, etc.;
- Evaluate food handling practices that have significant potential for crosscontamination (e.g., use of food preparation surfaces, wiping cloths, equipment, etc.);
- Evaluate if food reached the acceptable final cooking temperatures, if food is suspected of being undercooked. For example, insert stem of thermometer in middle or thickest part of the food;
- If a PHF/TCS food (e.g., tuna salad) is prepared from ingredients at ambient (room) temperature, determine if it was cooled to 41 degrees F within 4 hours (e.g., ask staff when the tuna salad was prepared, then measure the current temperature); and

- Observe staff preparing pureed and other modified consistency foods to determine whether food safety was compromised.
- ! Food service (e.g., tray line) during meal times. Observe the staff measuring the temperature of all hot and cold menu items prior to being served and determine if food is in the danger zone (between 41 and 135 degrees F).
- ! Food storage areas, including:
 - Refrigerator:
 - Measure temperature of a PHF/TCS food that has been in refrigerator at least 24 hours, while it is in the refrigerator
 - Measure the temperature of any PHF/TCS food that appears to have been improperly stored for rapid cooling (e.g., in a large, deep, tightly covered container, etc.). Ask questions about how the food is cooled and try to identify how long the food has been in the cooling process. If temperature is in the danger zone, determine if the food item cooled from 135 to 70 degrees F within 2 hours and from 135 to 41 degrees F within 6 hours;
 - Observe for potential cross-contamination (e.g., raw meat stored above cooked or ready-to-serve items); and
 - Observe labeling/dating of prepared foods (e.g., leftovers).
 - Note:** During food preparation, the refrigerator doors are opened frequently making the inside air temperature rise. If there is a concern regarding the temperature in the refrigerator, take the temperature of a potentially hazardous food.
 - Freezer: Check the firmness of frozen foods (frozen foods are to be maintained at a temperature to keep the food frozen solid) and that the wrapping/packaging protects the food;
 - Dry food storeroom: Look for evidence of pests, other sources of contamination, and open food packaging and containers (a previously opened and partially used container or package can be stored again if it is closed and/or sealed to prevent spoilage and contamination);
- ! Dishwashing and pot/pan washing:
 - Observe dishwashing procedures. Evaluate sanitization with a thermometer (for a high temperature machine) or chlorine test tape (for a low temperature machine):
 - For a high temperature machine, affix a paper thermometer (calibrated to 160 degrees F) to glass or ceramic dish or use a minmax digital thermometer, place on the rack and send through the dishwasher. The paper will turn black to indicate acceptable temperature for sanitization, or the thermometer will record the maximum temperature reached at the plate level (temperature should be at least 160 degrees F); or
 - For a low temperature machine, dip chlorine test strip in water, drop on dish after cycle is completed and compare to color scale. 50 ppm is an acceptable concentration for sanitization.
 - Evaluate sanitization during manual pot/pan washing (3-step process) by testing final rinse water temperature or concentration of chemical sanitizer using the appropriate test strip for the chemical used; and
 - Evaluate whether hand washing is occurring between handling soiled and clean dishes to prevent cross-contamination of the clean dishes.

2. Interview

If any concerns were identified, request clarification from the dietary supervisor/manager or dietitian. Also interview staff as needed about the procedures they follow to receive, store, prepare, distribute, and serve food to residents. Inquiries could include:

- ! What time a PHF/TCS food item that is not being stored at an appropriate temperature was placed in the refrigerator;
- ! How the facility ensures that food is served at the correct temperature (cold food at or below 41 degrees F and hot food at or above 135 degrees F) during the tray

line;

! If there is a problem with equipment, how staff notify maintenance and how maintenance responds;

! Determine if the facility monitored staff practices and determined training needs in safe food handling; and

! Determine if the dietary staff received in-service training on foodborne illness and/or food safety.

3. Record Review

In order to identify food safety concerns or to investigate identified food safety concerns, review supporting data as necessary, including but not limited to:

! Any facility documentation related to compliance with food sanitation and safety, such as HACCP plans;

! Food temperature records from the tray line, refrigerator/freezer temperature records, and dishwasher records (if available);

! Dietary maintenance records, such as work orders, and manufacturer's specifications;

! Dietary policies and procedures and inservice training records, quality assurance (QA) monitoring tools if available; and

! Facility infection control records regarding surveillance for foodborne illness and actions related to suspected or confirmed outbreaks of gastrointestinal illnesses.

4. Review of Facility Practices

Review of facility practices may include a review of policies and procedures, staffing, staff training, and manufacturer's information, as well as interviews with management.

Determine if the facility has a process in place to prevent the spread of foodborne illness by:

! Identifying potential food safety concerns;

! Monitoring whether staff appropriately store, prepare, distribute, and serve food;

! Identifying, analyzing, and addressing pertinent issues and underlying causes (e.g., refrigerator malfunction) of a food safety concern;

! Implementing interventions and prioritizing actions based on immediacy and severity of the concern; and

! Monitoring implementation of interventions and determining if additional modification is needed.

DETERMINATION OF COMPLIANCE (Task 6, Appendix P)

Synopsis of Regulation (F371)

This regulation requires the facility to store, prepare, distribute and serve food under sanitary conditions to prevent foodborne illness and reduce those practices that result in food contamination and compromised food safety.

Criteria for Compliance

The facility is in compliance with 42 CFR 483.35(h)(2), Sanitary Conditions, if staff has:

! Stored, handled, prepared, transported, and served food in accordance with standards summarized in this guidance;

! Maintained PHF/TCS foods at safe temperatures, cooled food rapidly, and prevented contamination during storage;

! Cooked food to the appropriate temperature and maintained PHF/TCS food at temperatures outside of the danger zone (between 41 and 135 degrees F) for prolonged periods of time; and

! Utilized proper personal hygiene practices and maintained clean equipment and food contact surfaces to prevent food contamination.

If not, cite at F371.

Noncompliance for F371

After completing the Investigative Protocol, analyze the data in order to determine whether noncompliance with the regulation exists. Noncompliance for F371 may

include, but is not limited to, one or more of the following, including failure to:

! Store, handle, prepare, transport, and serve food in accordance with standards summarized in this guidance;

! 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;

! Store raw foods (e.g., meats) in a manner to avoid contamination of cooked or ready-to eat foods;

! Cook food to the appropriate temperature to kill pathogenic microorganisms that may cause foodborne illness;

! Cool food rapidly to prevent the growth of pathogenic microorganisms;

! Utilize proper personal hygiene practices (e.g., hand washing and appropriate use of gloves) to prevent contamination of food; and

! Maintain clean equipment and food contact surfaces (e.g., cutting boards, dishes, and utensils) to prevent food contamination.

Potential Tags for Additional Investigation

During the investigation of 42 CFR 483.35(h)(2), the surveyor may have identified concerns related to outcome, process, and/or structure requirements. The surveyor should investigate these requirements before determining whether noncompliance may be present. The following are examples of related outcome, process, and/or structure requirements that should be considered:

! 42 CFR 483.25(g)(2), F322, Nasogastric Tubes

- Determine if staff is using universal precautions and clean technique when administering enteral feedings, using hang time recommendations by the manufacturer to prevent excessive microbial growth, and implementing procedures to ensure cleanliness of supplies.

! 42 CFR 483.35(a)(1)(2), F361, Dietary Services - Staffing

- 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.

! 42 CFR 483.35(h)(1), F370, Food Procured from Approved Sources

- Determine if the facility obtained food from approved sources that are recognized as adhering to public health standards.

! 42 CFR 483.65(a), F441, Infection Control

- Determine if the facility's infection control program included investigation, control, and prevention of infections caused by foodborne illness.

! 42 CFR 483.70(c)(2), F456, Maintain All Essential Equipment

- Determine if the equipment in the kitchen, such as refrigerators, dishwasher, stove, etc. is maintained in safe operating condition.

! 42 CFR 483.70(h), F465, Other Environmental Conditions

- Determine if the kitchen physical environment, such as, floors, walls, ceilings, stove and vent hoods are safe, functional, and sanitary.

! 42 CFR 483.70(h)(4), F469, Effective Pest Control Program

- Determine if the facility has taken steps to eradicate pests (e.g., roaches, ants, flies, mice, etc.) from areas of food storage, preparation, and service, and the facility remains pest free.

! 42 CFR 483.70(o)(2)(i)(ii), F521, Quality Assessment and Assurance

- Determine whether the quality assessment and assurance committee has identified issues, and developed and implemented appropriate plans of action to correct identified quality deficiencies in relation to sanitary conditions.

IV. DEFICIENCY CATEGORIZATION (Part IV, Appendix P)

Once the survey team has completed its investigation, analyzed the data, reviewed the regulatory requirements, and determined that noncompliance exists, the team must determine the severity of each deficiency, based on the resultant effect or potential for harm to the resident.

The key elements for severity determination for F371 are as follows:

1. Presence of harm/negative outcome(s) or potential for negative outcomes because of presence of unsanitary conditions. Actual or potential harm/negative outcome for F371 may include but is not limited to:

! Foodborne illness; and

! Ingestion or potential ingestion of food that was not stored, prepared, distributed or served under sanitary conditions.

2. Degree of harm (actual or potential) related to the noncompliance. Identify how the facility noncompliance caused, resulted in, allowed or contributed to the actual or potential for harm.

! If harm has occurred, determine if the harm is at the level of serious injury, impairment, death, compromise, or discomfort; and

! If harm has not yet occurred, determine the potential for serious injury, impairment, death, or compromise or discomfort to occur to the resident.

3. The immediacy of correction required. Determine whether the noncompliance requires immediate correction in order to prevent serious injury, harm, impairment, or death to one or more residents.

The survey team must evaluate the harm or potential for harm based upon the following levels of severity for tag F371. First, the team must rule out whether Severity Level 4, Immediate Jeopardy to a resident's health or safety exists by evaluating the deficient practice in relation to immediacy, culpability, and severity. (Follow the guidance in Appendix Q.)

Severity Level 4 Considerations: Immediate Jeopardy to Resident Health or Safety

Immediate Jeopardy is a situation in which the facility's noncompliance with one or more requirements of participation:

! Has allowed/caused/resulted in or is likely to allow/cause/result in serious injury, harm, impairment, or death to a resident; and

! Requires immediate correction, as the facility either created the situation or allowed the situation to continue by failing to implement preventive or corrective measures.

NOTE: The death or transfer of a resident who was harmed or injured as a result of facility noncompliance does not remove a finding of immediate jeopardy. The facility is required to implement specific actions to remove the jeopardy and correct the noncompliance which allowed or caused the immediate jeopardy.

Examples of negative outcomes that occurred or have the potential to occur as a result of the facility's deficient practices may include:

! Foodborne illness or the potential for foodborne illness due to the facility's failure to prevent cross-contamination of raw or ready-to-eat foods with raw meat products (i.e., blood or bloody meat/poultry juices) and remove the contaminated food items. The facility could not show that it provided ongoing staff training and monitoring of food handling practices;

! A turkey that finished cooking at 8:00 p.m., was not removed from the bones, and was wrapped in foil and placed in the refrigerator. The next day at 11:00 a.m., staff removed the turkey from the refrigerator, prepared sandwiches and proceeded to serve the sandwiches to the residents at the noon meal. However, the temperature of the turkey slices was 60 degrees F; and

! The facility had a recent outbreak of foodborne illness related to improper food

handling practices, including a lack of hand washing when handling raw and cooked meat products and those practices have continued.

Severity Level 3 Considerations: Actual Harm that is Not Immediate Jeopardy

The risk of developing a foodborne illness occurs after the resident consumes the contaminated food. Therefore, Severity Level 3 does not apply for this regulatory requirement since a deficiency for food storage, preparation, distribution and service is either a potential for foodborne illness at Level 4 or 2, or actual harm has occurred that rises to the level of immediate jeopardy.

Severity Level 2 Considerations: No Actual Harm with Potential for More Than Minimal Harm that is Not Immediate Jeopardy

Severity Level 2 indicates noncompliance that results in a resident outcome of no more than minimal discomfort and or has the potential to compromise the resident's ability to maintain or reach his or her highest practicable level of well being. Therefore, there is the potential for greater harm to residents' well being if interventions or better facility practices are not implemented.

As a result of the facility's noncompliance, the potential for food contamination and/or growth of pathogenic microorganisms exists. Examples may include, but are not limited to:

! Soiled food preparation areas or food-contact surfaces such as kitchen equipment (dishes, pots/pans, utensils) were used to prepare or serve foods that will not be cooked again before being served;

! Potential for foodborne illness because dietary staff did not wash their hands in an appropriate hand washing sink before preparing/serving food, after handling soiled dishes or utensils, or when changing tasks; and

! Potential for foodborne illness due to non-pasteurized shell eggs being undercooked (i.e., not cooked at 145 degrees F for 15 seconds so that the white is completely set and the yolk begins to thicken) and served to residents (poached or soft boiled eggs).

Severity Level 1 Considerations: No Actual Harm with Potential for Minimal Harm

Level 1 indicates noncompliance that results in outcomes with no actual harm but which have the potential for causing no more than minimal harm.

Severity Level 1 represents outcomes that have the potential for food contamination to occur but that the growth of pathogens is of minimal risk and likely to result in only minimal harm to the resident. Examples include:

! Non-refrigerated foods were stored in open containers and there were signs of insects in the sugar and flour receptacles;

! There were rodent droppings on countertops and/or along walls in the dry food storage area

! Non refrigerated foods were not handled and stored to maintain the integrity of the packaging until ready for use, or were stored improperly in open containers or packages;

! PHF/TCS food that was not labeled to identify the contents and was consumed more than two days after it's use-by date; and

! Food was served on unsanitized dishes/utensils due to lack of monitoring temperature/sanitizer concentrations for machine and manual dishwashing to ensure that the sanitizer was at the correct concentration.