



Center for Clinical Standards and Quality/Survey & Certification Group

Ref: S&C: 14-34-NH

DATE: May 20, 2014

TO: State Survey Agency Directors

FROM: Director
Survey and Certification Group

SUBJECT: Advance Copy of Revised F371; Interpretive guidance and Procedures for Sanitary Conditions, Preparation of Eggs in Nursing Homes

Memorandum Summary

- **Guidance for Nursing Homes:** Skilled nursing and nursing facilities should use pasteurized shell eggs or liquid pasteurized eggs to eliminate the risk of residents contracting Salmonella Enteritidis (SE). The use of pasteurized eggs allows for resident preference for soft-cooked, undercooked or sunny-side up eggs while maintaining food safety. In accordance with the Centers for Disease Control and Prevention (CDC) and the U.S. Food and Drug Administration (FDA) standards, skilled nursing and nursing facilities should not prepare nor serve soft-cooked, undercooked or sunny-side up eggs from unpasteurized eggs.
- **Guidance for Surveyors:** Signed health release agreements between the resident (or the resident's representative) and the facility that acknowledges the resident's acceptance of the risk of eating undercooked unpasteurized eggs are not permitted. Pasteurized eggs are commercially available and allow the safe consumption of eggs. If the facility prepares or serves unpasteurized or undercooked eggs which are not cooked until both the yolk and white are completely firm, surveyors should consider citing deficiencies at F371. Determination of the appropriate scope and severity shall be based upon the actual or potential negative resident outcomes in accordance with guidance given at F371. We are revising F371 to clarify this section; a revised F371 is attached.

The Centers for Medicare & Medicaid Services (CMS) is clarifying the acceptability of long-term care (LTC) facilities serving soft-cooked, undercooked or sunny-side up eggs to their residents. 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 a safe and sanitary manner. Therefore, while honoring resident requests for soft cooked or sunny side up eggs is an appropriate practice

as outlined in §483.15(b) Self Determination and Participation, however the CDC and the FDA *strongly advise against serving unpasteurized, undercooked eggs* to highly susceptible populations which includes elders and persons residing in LTC facilities. Specifically, CDC literature states, “Although anyone can get a Salmonella infection, older adults, infants and people with impaired immune systems are at increased risk for serious illness. In these people, a relatively small number of Salmonella bacteria can cause severe illness.”¹ The CDC states, “A person who eats eggs can lower the risk of SE infection by eating eggs that are thoroughly cooked, or by eating foods that are made from pasteurized eggs.”² CMS agrees with the FDA and CDC’s guidance against serving unpasteurized, undercooked eggs to LTC facility residents.

CMS is aware of facilities having secured signed health release agreements from residents (or the resident’s representative) requesting to be served undercooked eggs. Health release agreements allowing soft-cooked, undercooked or sunny-side up unpasteurized eggs for resident preference are not acceptable.

Eggs are the most common food source linked to SE infections, and the predominant route of egg contamination is transovarian. SE will infect the ovaries and oviducts of some egg-laying hens, permitting transovarian contamination of the interior of the egg while the egg is still inside the hen.³ If unpasteurized eggs contaminated with SE are eaten raw or undercooked the bacterium can cause illness and death particularly in the elderly, infants, and those with impaired immune systems. Shell egg safe handling labeling specifically states, “To prevent illness from bacteria: keep eggs refrigerated, cook eggs until yolks are firm, and cook foods containing eggs thoroughly”.⁴

The FDA Food Code which has been adopted by all 50 states, the US territories and most of the tribal Nations, advises that eggs prepared and served to highly susceptible persons in nursing homes should be pasteurized or cooked until both the yolk and whites are firm.⁵ Pasteurized shell eggs are commercially available, are clearly labeled and allow the safe consumption of undercooked eggs. Federal regulations expect nursing facilities to make reasonable efforts to respect resident choices and can honor resident choice while maintaining health and safety standards through the use of pasteurized eggs.

If a skilled nursing or nursing facility has a resident who prefers undercooked eggs such as soft-cooked or sunny-side up, the facility must use pasteurized eggs.⁶ If the facility uses unpasteurized shell eggs for individual resident consumption, those eggs must be cooked until both the yolk and white are completely firm and served immediately.

The surveyor interpretive guidance in Appendix PP at F371 will be revised in two ways to provide additional clarification: (1) unpasteurized eggs must be cooked until both the yolk and white are completely firm; and (2) deletion of the example of a negative outcome that could rise to the level of immediate jeopardy. For all other forms of egg preparation, including hot holding of eggs, and pooling (combining) of eggs for recipes where more than one egg is broken and the eggs are pooled and used as an ingredient immediately before baking, such as in a meat loaf mixture, muffins or cake,

the eggs must be pasteurized or thoroughly cooked to an internal temperature of 160°F (71°C).^{7, 8, 9}

If the facility serves soft-cooked, undercooked or sunny-side up unpasteurized eggs, surveyors should determine the appropriate scope and severity based upon the negative actual and potential outcomes and in accordance with instructions and guidance given at F371. To determine whether the evidence rises to the level of an immediate jeopardy, surveyors are expected to review evidence about resident's immediate risk of serious injury, harm, impairment or death, the number of residents affected, the surveyor's observations of egg availability, food preparation and meals and other system failures of the facility that could lead to food borne illness (i.e. whether undercooked, unpasteurized eggs are served widely to many residents, and the result of interviewing facility staff to identify additional system failures).

An advance copy of the guidance revisions is attached. The final version of this document, when published may differ slightly from this advanced copy.

Effective Date: Immediately. Please ensure that all appropriate staff are fully informed within 30 days of the date of this memorandum.

Training: The information must be shared with all nursing home survey and certification staff, surveyors, managers, and the State and CMS regional office training coordinators.

/s/

Thomas E. Hamilton

Attachment:

Advance Copy of Revised F371; Sanitary Conditions

cc: Survey and Certification Regional Office Management

References:

¹ Salmonella is a Sneaky Germ: Seven Tips for Safer Eating
<http://www.cdc.gov/features/vitalsigns/foodsafety/>

² Salmonella serotype Enteritidis
http://www.cdc.gov/nczved/divisions/dfbmd/diseases/salmonella_enteritidis/

³ Federal Register / Vol. 74, No. 130 / Thursday, July 9, 2009 / Rules and Regulations. (Final Rule) Page 33032. <http://www.gpo.gov/fdsys/pkg/FR-2009-07-09/pdf/E9-16119.pdf>

⁴ <http://www.fda.gov/downloads/food/resourcesforyou/consumers/ucm278445.pdf>

⁵ U.S. Food and Drug Administration Food Code
Section 3-401.11(A) (Note the word “except”); > 3-401.11(D)(1). Note “not” highly susceptible population”.
<http://www.fda.gov/food/guidanceregulation/retailfoodprotection/foodcode/ucm374275.htm>

⁶ U.S. Food and Drug Administration Food Code. Section 3-801.11 (C) (2).
<http://www.fda.gov/Food/GuidanceRegulation/RetailFoodProtection/FoodCode/ucm374275.htm>

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⁷ Centers for Disease Control and Prevention - Tips to Reduce Your Risk of Salmonella from Eggs <http://www.cdc.gov/features/salmonellaeggs/>

⁸ U. S. Food and Drug Administration - Playing It Safe With Eggs
<http://www.fda.gov/food/resourcesforyou/Consumers/ucm077342.htm>

⁹ Multistate Outbreak of Human Salmonella Enteritidis Infections Associated with Shell Eggs (Final Update) <http://www.cdc.gov/salmonella/enteritidis>

F371

(Rev.)

§483.35(i) - Sanitary Conditions

The facility must –

§483.35(i)(1) - Procure food from sources approved or considered satisfactory by Federal, State or local authorities; and

§483.35(i)(2) - Store, prepare, distribute and serve food under sanitary conditions

INTENT: (Tag F371) 42 CFR 483.35(i) Sanitary Conditions

The intent of this requirement is to ensure that the facility:

- Obtains food for resident consumption from sources approved or considered satisfactory by Federal, State or local authorities; and
- 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.

DEFINITIONS

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

- **“Cross-contamination”** refers to 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.¹
- **“Danger Zone”** refers to 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”** refers to storing/maintaining dry foods (canned goods, flour, sugar, etc.) and supplies (disposable dishware, napkins, and kitchen cleaning supplies).

- **“Food Contamination”** refers to the unintended presence of potentially harmful substances, including, but not limited to microorganisms, chemicals or physical objects in food.²
- **“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, 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, or delivering trays to residents’ rooms or units, etc.
- **“Foodborne Illness”** refers to illness caused by the ingestion of contaminated food or beverages.
- **“Highly Susceptible Population”** refers to persons who are more likely than the general population to experience foodborne illness because of their susceptibility to becoming ill if they ingest microorganisms or toxins. Increased susceptibility may be associated with immuno-compromised health status, chronic disease and advanced age. **The Food and Drug Administration’s Food Code (Section 3-801.11) includes nursing facilities in its definition of a “highly susceptible population.”**
- **“Pathogen”** refers to an organism capable of causing a disease (e.g., pathogenic bacteria or viruses).
- **“Potentially Hazardous Food (PHF)”** or **“Time/Temperature Control for Safety (TCS) Food”** refers to 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 with little or no preparation to achieve food safety. It includes foods requiring minimal preparation for palatability or culinary purposes, such as mixing with other ingredients (e.g., meat type salads such as tuna, chicken, or egg salad).
- **“Storage”** refers to the retention of food (before and after preparation) and associated dry goods.
- **“Toxins”** refer to poisonous substances that are produced by living cells or organisms (e.g., pathogenic bacteria) that cause foodborne illness when ingested.

OVERVIEW

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 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 www.FoodSafety.gov;
- United States Food & Drug Administration Food Code Web site at <http://www.cfsan.fda.gov/~dms/primecon.html>;
- United States Food & Drug Administration Hazard Analysis Critical Control Point <http://www.cfsan.fda.gov/~dms/hret2toc.html>, (Operator's Manual) and <http://www.cfsan.fda.gov/~dms/hret3toc.html> (Regulator's manual).

NOTE: References to non-CMS sources or sites on the Internet are provided as a service and do not constitute or imply endorsement of these organizations or their programs by CMS or the U.S. Department of Health and Human Services. CMS is not responsible for the content of pages found at these sites. The uniform resource locator addresses were current as of the date of this publication.

TYPES OF FOOD CONTAMINATION

Food contaminants fall into 3 categories: biological, chemical, and physical.

Biological Contamination

Biological contaminants 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.

- **Pathogenic Bacteria** - Not all bacteria in food cause illness in humans. For example, live cultures of Lactobacillus bacteria are added to yogurt to enhance digestion. However, some bacteria can be pathogenic and thus may cause illness or death (e.g., some strains of Escherichia Coli). It is vital to control the growth of bacteria during food storage and preparation because raw or uncooked food may naturally contain pathogenic organisms (e.g., Salmonella in poultry).

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, poultry, chicken, seafood (fish or shellfish), cut melon, unpasteurized eggs, milk, yogurt and cottage cheese;

- o Acidity (pH) of the food. More acidic food (i.e., pH < 5), such as pineapple, vinegar, and lemon juice, inhibits bacterial growth;
- o Water percentage of the food. Foods that have a high level of water (e.g., fruits and vegetables) encourage bacterial growth; and
- o 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.

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, refried beans, grilled sautéed onions, or baked potatoes).

- **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).
- **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. The organism is reactivated once conditions become favorable for its growth. Two common spore-forming pathogens are Bacillus cereus and Clostridium botulinum. Temperature control is the way to minimize the danger associated with spore-forming organisms.

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. It is recommended that chemical products including, but not limited to cleaning supplies, be stored separately from food items.

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 of bones.

FACTORS IMPLICATED IN FOODBORNE ILLNESSES

Many pathogens contribute to foodborne outbreaks in facilities. Several factors that cause pathogen growth include, but are not limited to:

- Poor Personal Hygiene - Employee health and hygiene are significant factors in preventing foodborne illness. This has been demonstrated in the population at large³, commercial food service establishments⁴, and in nursing facilities⁵. Foodborne illness in nursing homes has been associated with Norovirus. Because "infectious" individuals (persons capable of transmitting an infection or communicable disease whether they be colonized or infected) are a source of Norovirus, proper hand washing techniques and exclusion of infectious workers from handling food are critical for prevention of foodborne illness.
- Inadequate Cooking and Improper Holding Temperatures - Poorly cooked food promotes the growth of pathogens that may cause foodborne illness. The PHF/TCS foods require adequate cooking and proper holding temperatures to reduce the rapid and progressive growth of illness producing microorganisms, such as Salmonellae and Clostridium botulinum.
- 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 - Unsafe food sources are sources not approved or considered satisfactory by Federal, State, or local authorities. Nursing homes are not permitted to use home-prepared or home-preserved (e.g., canned, pickled) foods for service to residents³.

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

Pathogenic Microorganisms and Strategies for their Control

The table below illustrates the more commonly identified ingestible items which have been associated with the listed illness-producing organisms. The primary agents are the organisms that have been associated with the ingestible food source⁷. Further, the primary control strategies list the preventive actions to inhibit the growth of these organisms.

| 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, raw or unpasteurized | <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 ready-to-eat 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 ready-to-eat 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 ready-to-eat 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 • Avoid bare-hand contact with ready-to-eat foods |
| | <ul style="list-style-type: none"> • Staphylococcus aureus | <ul style="list-style-type: none"> • PHF/TCS • Proper hand-washing procedures • Avoid bare-hand contact with ready-to-eat foods |
| B. Hazards that may occur as a result of adulteration of food products, and for which good food handling practices are needed to minimize the potential for foodborne illness transmission. | | |
| 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 prior to use (unless pre-washed) • 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 according to manufacturers' guidelines |
|--|--|---|

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 and volunteers involved in food service, as well as establishing effective infection control and quality assurance programs help maintain safe food handling practices.

Approaches to create a homelike environment or to provide accessible nourishments may include a variety of unconventional and non-institutional food services. Meals or snacks may be served at times other than scheduled meal times and convenience foods, ready-to-eat foods, and pre-packaged foods may be stored and microwave heated on the nursing units. Whatever the approach, it is important that staff follow safe food handling practices.

Employee Health

Employees who handle food must be free of communicable diseases and infected skin lesions. (See the requirement at 42 CFR 483.65(b) (2) regarding preventing the spread of infection.) Bare hand contact with foods is prohibited.

Hand Washing, Gloves, and Antimicrobial Gel

Since the skin carries microorganisms, it is critical that staff involved in food preparation 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 setting⁸.

The appropriate use of utensils such as gloves, tongs, deli paper and spatulas is essential in preventing foodborne illness. Gloved hands are considered a food contact surface that can get contaminated or soiled. 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 proper hand washing with soap and water.

Hair Restraints/Jewelry/Nail Polish

Dietary staff must wear hair restraints (e.g., hairnet, hat, and/or beard restraint) to prevent their hair from contacting exposed food. Dietary staff maintaining nails that are clean and neat, and wearing intact disposable gloves in good condition, and that are changed appropriately will also

help reduce the spread of microorganisms. Since jewelry can harbor microorganisms, it is recommended that dietary staff keep jewelry to a minimum and cover hand jewelry with gloves when handling food⁹.

Food Receiving and Storage

When food is brought into the nursing home, inspection for safe transport and quality upon receipt and proper storage helps ensure its safety. Keeping track of when to discard perishable foods and covering, labeling, and dating all foods stored in the refrigerator or freezer is indicated.

When food is brought into the facility from an off-site kitchen (any kitchen that is not operated by the facility) and the food preparation entity is approved or considered satisfactory by and is inspected by other federal, State, or local authorities, verify the last approved inspection of the supplier and continue to inspect the facility for safe food handling and storage and food quality.

- **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, rodent and insect infestation helps prevent deterioration or contamination of the food. Dry foods and goods should be handled and stored to maintain 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.

Keeping food off the floor and clear of ceiling sprinklers, sewer/waste disposal pipes, and vents can also help 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 animal 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.

NOTE: Chemical products, including, but not limited to cleaning supplies, should be stored away from food items.

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 adhering to critical control points can reduce the risk of food contamination and thereby prevent foodborne illness.

Commercially pre-washed, pre-cut, and pre-packaged lettuce and other fruits and vegetables are considered edible without further preparation.

- **Cross-Contamination** - Cross-contamination can occur when harmful substances or disease-causing microorganisms are transferred to food by hands, food contact surfaces, sponges, cloth towels, or utensils that are not cleaned after touching raw food and then touch ready-to-eat goods. 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 (see Manual Washing and Sanitizing section). Periodically testing the sanitizing solution helps assure that it maintains the correct concentration¹⁰.

Wash and sanitize cutting boards made of acceptable materials (e.g., hardwood, acrylic) between uses, consistent with applicable code¹¹, and
 - Clean and sanitize work surfaces and food-contact equipment (e.g., food processors, blenders, preparation tables, knife blades, can openers, and slicers) 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. 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** - Cooking is a critical control point in preventing foodborne illness. Cooking to heat all parts of 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 for 15 seconds determines when microorganisms can no longer survive and food is safe for consumption.
- Foods should reach the following internal temperatures:
 - Poultry and stuffed foods - 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 meats - 145 degrees F for 15 seconds;
 - **Unpasteurized eggs when cooked to order in response to resident request and to be eaten promptly after cooking must be cooked until all parts of the egg are completely firm;**
 - When cooking raw animal foods in the microwave, foods should 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, 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 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.

- **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 the 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.

- **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.
- **Pooled 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. **Salmonella infections associated with unpasteurized eggs can be prevented by using pasteurized shell eggs or be substituted for raw 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 toast¹³.**

The U.S. Department of Agriculture, Food Safety and Inspection Service, Salmonella Enteritidis (SE) Risk Assessment states "A partial list of persons with increased susceptibility to infectious agents includes persons with chronic diseases, and nursing home residents. The elderly are particularly susceptible to infectious agents such as SE for a number of reasons. The disproportionate impact of severe complications and death from Salmonellosis in the elderly is illustrated by epidemiologic evidence." Waivers to allow undercooked unpasteurized eggs for resident preference are not acceptable. Pasteurized shell eggs are available and allow for safe consumption of undercooked eggs.

NOTE: 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.

The maximum length of time that foods can be held on a steam table is a total of 4 hours. Monitoring of the temperature by food service workers while food is on the steam table is essential. Foods may be reheated (only once) to 165 degrees F. Reheated foods are best discarded if not eaten within two hours after reheating¹².

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 those foods that are 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; or stored at the nursing station, in a unit refrigerator or unit cupboards. 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;

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.

***Nursing Home Gardens** – Nursing homes with gardens are compliant with the food procurement requirements as long as the facility has and follows policies and procedures for maintaining the gardens. The facility should immediately report any outbreaks of food borne illnesses, for any cause, to their local health department.*

***NOTE:** If there are local or State requirements related to food grown on the facility grounds for resident consumption, facilities are to be in compliance with the specific State requirement.*

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 prevent 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 who use poor hygiene, fail to wash hands adequately, or handle ice with their bare hands are not following appropriate infection control practices when dispensing water and 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.

Refrigeration - A potential cause of foodborne illness is improper storage of PHF/TCS food. The refrigerator must be in good repair and keep foods at or below 41 degrees F. 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 that has been inside for at least 24 hours 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.

EQUIPMENT AND UTENSIL CLEANING AND SANITIZATION

A potential cause of foodborne outbreaks is improper cleaning (washing and sanitizing) of contaminated equipment. Protecting equipment from contamination via splash, dust, grease, etc. is indicated. 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 are specifications according to the U.S. Department of Health and Human Services, Public Health Services, Food and Drug Administration Food Code (or according to manufacturer's directions) for each method.

- High Temperature Dishwasher (heat sanitization):
 - o Wash 150-165 degrees F wash; and
 - o Final Rinse 180 degrees F final rinse (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):
 - o Wash 120 degrees F wash; and
 - o Final Rinse 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 thorough washing using hot water and detergent after food particles have been scraped. 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, 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. If explicit instructions are not provided by the manufacturer, the recommended sanitization concentrations are as follows:
 - o Chlorine 50-100 ppm minimum 10 second contact time
 - o Iodine 12.5 ppm minimum 30 second contact time
 - o QAC space (Quaternary) 150-200 ppm concentration and contact time per Manufacturer's instructions (Ammonium Compound)

A high concentration of sanitation solutions may be potentially hazardous (see manufacturer's instructions). 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 are washed and sanitized and non-removable parts are 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.

Endnotes

- ¹ The Partnership for Food Safety and Education. (2006). Food Safety Glossary. Retrieved September 25, 2006 from <http://www.fightbac.org/content/view/15/22/>.
- ² The Partnership for Food Safety and Education. (2006). Food Safety Glossary. <http://www.cdc.gov/mmwr/preview/mmwrhtml/ss4901a1.htm>
- ³ Mead, P.S., Slutsker, L., Dietz, V., McCaig, L.F., Bresee, J.S., Shapiro, C., Griffin, P.M., & Tauxe, R.V. (1999). Food-related illness and death in the United States. *Emerging Infectious Diseases*, 5(5), 607-625.
- ⁴ Hedberg, C.W., Smith, S.J., Kirkland, E., Radke, V., Jones, T.F., Selman, C.A., & EHS-NET Working Group. (2006). Systematic environmental evaluations to identify food safety differences between outbreak and non-outbreak restaurants. *Journal of Food Protection*, 69(9). Need Pages
- ⁵ Centers for Disease Control and Prevention Outbreak Surveillance Data. (2006). Annual Listing of Foodborne Disease Outbreaks, United States, 1990-2004. Retrieved September 25, 2006 from http://www.cdc.gov/foodborneoutbreaks/outbreak_data.htm
- ⁶ U.S. Department of Health and Human Services, Public Health Service, Food and Drug Administration. (2005). Code (p. 48).
- ⁷ International Association of Food Protection. (1999). *Procedures to Investigate Foodborne Illness* (5th edition). Des Moines, IA: Author. [Prepared by the Committee on Communicable Diseases Affecting Man.]
- ⁸ U.S. Department of Health and Human Services, Public Health Service, Food and Drug Administration. (2005). Food Code (p. 43).
- ⁹ U.S. Department of Health and Human Services, Public Health Service, Food and Drug Administration. (2005). Food Code (pp. 43-45).
- ¹⁰ U.S. Department of Health and Human Services, Public Health Service, Food and Drug Administration. (2005). Food Code (p. 66).
- ¹¹ U.S. Department of Health and Human Services, Public Health Service, Food and Drug Administration. (2005). Food Code (pp. 103-104; 123).
- ¹² U.S. Department of Health and Human Services, Public Health Service, Food and Drug Administration. (2005). Food Code (p. 114).
- ¹³ **U.S. Food and Drug Administration Food Code**
<http://www.fda.gov/Food/GuidanceRegulation/RetailFoodProtection/FoodCode/ucm374275.htm>. Section 3-801.11(B).

INVESTIGATIVE PROTOCOL

SANITARY CONDITIONS

Objectives

- To determine if the facility obtained food safe for consumption from approved sources;
- To determine if the facility stores, prepares, distributes, and serves food in a sanitary manner to prevent foodborne illness;
- To determine 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
- To determine 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.

Use

Use this protocol to investigate compliance at F371 (§483.35(i) (1) and (2)).

Procedures

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. During the initial tour of the facility and throughout the survey, observe the kitchen(s) and food service area(s) and review planned menus to determine when to assess food preparation processes. Observe subsequent kitchen/food services 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.

NOTE: When a facility receives food from an off-site kitchen (any kitchen not operated by the facility), determine whether the food was obtained from an approved source.

1. Observation

Conduct the following observations:

- Food procurement procedures:
 - o Determine whether food meets safe and sanitary conditions related to when, where, and how the food was received for residents consumption.
 - o Check invoices from food vendors when necessary to verify the source of food acquisition and the date of delivery.
- Food preparation procedures:
 - o Observe staff food handling practices, such as proper hand washing, the appropriate use of utensils, glove, and hairnets;

- o Observe food labeling and dates (e.g., used by dates);
- o 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);
- o If the facility is cooking a PHF/TCS food, evaluate if the food reached the acceptable final cooking temperatures, by inserting the stem of a calibrated thermometer into the middle or thickest part of the food;
- o If a PHF/TCS food is prepared from ingredients at room temperature, determine if it was cooled to 41 degrees F within 4 hours. For example, when observing tuna or chicken salad preparation, determine when the salad was prepared, then measure the current temperature; and
- o Observe staff preparing modified consistency (e.g., pureed, mechanical soft) PHF/TCS foods to determine whether food safety was compromised.
- o **Observe the facility's egg products to determine if the facility is using pasteurized shell eggs, liquid pasteurized eggs or unpasteurized shell eggs. If the staff is preparing resident requests for soft cooked and undercooked eggs (i.e. sunny side up, soft scrambled, soft boiled), determine if pasteurized shell eggs, liquid pasteurized eggs or unpasteurized shell eggs were used.**

Service of food during meal times -

- Observe the staff measuring the temperature of all hot and cold menu items. Cold foods should be at or below 41 degrees F when served. Hot foods should be at 135 degrees F or above when served.

Service after meal times:

- Observe whether facility personnel are operating the dish washing machine according to the manufacturer's specifications. Evaluate sanitization with a calibrated thermometer (for a high temperature machine), chlorine test tape (for a low temperature machine), or other manufacturer recommended method;
- Check whether the facility has the appropriate equipment and supplies to evaluate the safe operation of the dish machine and the washing of pots and pans (e.g., maximum registering thermometer, appropriate chemical test strips, and paper thermometers);
- Evaluate sanitization during manual pot and pan washing (3-step process). Test the final rinse water temperature if using hot water for sanitization or the concentration of chemical sanitizer being used. Determine if the appropriate test strip for that chemical is being utilized;

- 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.

Storage of food:

- Observe for evidence of pests, rodents and droppings and other sources of contamination in food storage areas;
- Observe food labeling and dates (e.g., used by dates);
- Observe that foods are stored off of the floor, and clear of ceiling sprinklers, sewer/waste disposal pipes and cleaning chemicals;
- Observe whether the facility has canned goods that have a compromised seal (e.g., punctures); and
- Observe whether staff access bulk foods without touching the food.

2. Interview

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. Request clarification from the dietary supervisor/manager or qualified dietitian concerning the following:

- 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;
- How does the facility identify problems with time and temperature control of PHF/TCS foods and what are the processes to address those problems;
- 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.
- **Is the facility aware of current CDC and FDA nursing home egg handling and preparation polices and does the facility have written egg storage and preparation policies that honor resident preferences safely.**

3. 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. Determine if the food service employees have received training related to such compliance;
- Food temperature records from the tray line, refrigerator/freezer temperature records, and dishwasher records;
- Maintenance records, such as work orders and manufacturer's specifications, related to equipment used to store, prepare, and serve food; and
- Facility infection control records regarding surveillance for foodborne illness and actions related to suspected or confirmed outbreaks of gastrointestinal illnesses.
- *The policies and procedures for maintaining nursing home gardens should be reviewed, if there is an outbreak of food borne illness and the facility's primary food service has been ruled out as the cause of the outbreak.*

4. 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 (e.g., refrigerator or dishwasher malfunction);
- 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.
- *Identify if negative outcomes are the result of system failure by interviewing dietary managers and staff to ascertain egg storage and preparation knowledge.*

DETERMINATION OF COMPLIANCE (TASK 6, APPENDIX P)

Synopsis of Regulation (F371)

The sanitary conditions requirement has two aspects. The first aspect requires that the facility procures food from sources approved or considered satisfactory by Federal, State, or local authorities. The second aspect requires that the facility stores, prepares, distributes, and serves food under sanitary conditions to prevent foodborne illness.

Criteria for Compliance

The facility is in compliance with 42 CFR 483.35(i) (1)(2), Sanitary Conditions, if staff:

- Procures, stores, handles, prepares, distributes, and serve food to minimize the risk of foodborne illness;
- Maintains PHF/TCS foods at safe temperatures, cools food rapidly, and prevents contamination during storage;
- Cooks food to the appropriate temperature and holds PHF/TCS food at or below 41 degrees F or at or above 135 degrees F;
- Utilizes proper hand washing and personal hygiene practices to prevent food contamination; and
- Maintains equipment and food contact surfaces to prevent food contamination.

If not, cite at Tag F371.

Noncompliance for F371

After completing the Investigative Protocol, analyze the data in order to determine whether noncompliance with the regulation exists. Noncompliance for Tag F371 may include, but is not limited to, failure to do one or more of the following:

- Procure, store, handle, prepare, distribute, and serve food in accordance with the 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, 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;
- Store raw foods (e.g., meats, fish) in a manner to reduce the risk of 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 in a manner that prevents the growth of pathogenic microorganisms;
- Utilize proper personal hygiene practices (e.g., proper hand washing and the appropriate use of gloves) to prevent contamination of food; and
- Use and maintain equipment and food contact surfaces (e.g., cutting boards, dishes, and utensils) to prevent cross-contamination.
- *Failure to report a food borne illness outbreak to the local health department.*

Potential Tags for Additional Investigation

During the investigation of 42 CFR §483.35(i)(1)(2), the surveyor may have identified concerns related to these requirements. The surveyor should investigate these requirements before determining whether noncompliance may be present. The following are related outcome, process, and structure requirements that may be considered:

- 42 CFR 483.25(g)(2), F322, Nasogastric Tubes
 - o 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.
- 42 CFR 483.25(i), F325, Nutrition
 - o Determine if multiple residents have experienced nausea, vomiting, diarrhea, or other gastrointestinal symptoms related to foodborne illness, which may impact their nutritional status.
- 42 CFR 483.30(a)(b), F353 Sufficient Staffing
 - o Determine if the facility has sufficient staffing to meet the needs of the resident.
- 42 CFR 483.35(a)(1)(2), F361, 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.
- 42 CFR 483.35(b), F362, Standard Sufficient Staff
 - o Determine if the facility employs sufficient support personnel competent to carry out the functions of the dietary service.
- 42 CFR 483.35(h) Paid Feeding Assistant
 - o Determine if the Feeding Assistant has successfully completed a State-approved training course that meets Federal requirements and that the Feeding Assistant is utilizing proper techniques to prevent foodborne illness.
- 42 CFR 483.65(a), F441, Infection Control
 - o Determine if the facility's infection control program included investigation, control, and prevention of foodborne illness.
- 42 CFR 483.65(b)(3), F444, Handwashing Techniques
 - o Determine if the facility has practices in place to prevent the spread of infection, including proper hand washing techniques.
- 42 CFR 483.70(c)(2), F456, 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.

- 42 CFR 483.70(h), F465, Other Environmental Conditions
 - o Determine if the kitchen physical environment, such as, floors, walls, ceilings, and vent hoods are safe, clean, and sanitary.
- 42 CFR 483.70(h)(4), F469, 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 roaches, ants, flies, mice, etc. in food storage, preparation and service areas.
- 42 CFR 483.70(o) (2) (i) (ii), F520, 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.

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 Tag F371 are as follows:

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

- Foodborne illness; or
- Ingestion or potential ingestion of food that was not procured from approved sources, and stored, prepared, distributed or served under sanitary conditions.

2. Degree of harm (actual or potential) related to the noncompliance. Identify how the facility's 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; or
- 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 at Severity Level 4 as a result of the facility's deficient practices may include:

- 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 not discarded and 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. Observations and interviews indicate that other food service staff with gastrointestinal illnesses are also permitted to prepare food; and

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

Severity Level 3 indicates noncompliance that results in actual harm that is not immediate jeopardy. The negative outcome can include but may not be limited to clinical compromise, decline, or the resident's inability to maintain and/or reach his/her highest practicable level of well-being. Therefore, a Level 3 deficiency is indicated when unsafe food handling and inadequate sanitary conditions result in actual harm to residents.

Examples of avoidable actual or potential resident outcomes that demonstrate severity at Level 3 may include, but are not limited to:

- Outbreak of nausea and vomiting occurs in the facility related to the inadequate sanitizing of dishes and utensils; and

- Episode of food poisoning occurs because facility had an event in which tuna, chicken, and potato salads served in bulk were not kept adequately chilled and were still left out for eating after 5 hours.

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. The potential exists for greater harm to occur if interventions are not provided.

As a result of the facility's noncompliance, the potential for food contamination and/or growth of pathogenic microorganisms exists. Examples of avoidable actual or potential resident outcomes that demonstrate severity at Level 2 may 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 usage. The facility failed to educate and train staff on how to clean and sanitize all kitchen equipment;
- 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; and
- 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.

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

The failure of the facility to procure, prepare, store, distribute and handle food under sanitary conditions places this highly susceptible population at risk for more than minimal harm. Therefore, Severity Level 1 does not apply for this regulatory requirement.
