§483.35 Dietary Services
The facility must provide each resident with a nourishing, palatable, well-balanced diet that meets the daily nutritional and special dietary needs of each resident.

§483.35(a) Staffing
The facility must employ a qualified dietitian either full-time, part-time, or on a consultant basis.
§483.35(a)(1) If a qualified dietitian is not employed full-time, the facility must designate a person to serve as the director of food service who receives frequently scheduled consultation from a qualified dietitian.
§483.35(a)(2) A qualified dietitian is one who is qualified based upon either registration by the Commission on Dietetic Registration of the American Dietetic Association, or on the basis of education, training, or experience in identification of dietary needs, planning, and implementation of dietary programs.

Intent: §483.35(a)
The intent of this regulation is to ensure that a qualified dietitian is utilized in planning, managing and implementing dietary service activities in order to assure that the residents receive adequate nutrition.
A director of food services has no required minimum qualifications, but must be able to function collaboratively with a qualified dietitian in meeting the nutritional needs of the residents.

Interpretive Guidelines: §483.35(a)
A dietitian qualified on the basis of education, training, or experience in identification of dietary needs, planning and implementation of dietary programs has experience or training which includes:
• Assessing special nutritional needs of geriatric and physically impaired persons;
• Developing therapeutic diets;
• Developing “regular diets” to meet the specialized needs of geriatric and physically impaired persons;
• Developing and implementing continuing education programs for dietary services and nursing personnel;
• Participating in interdisciplinary care planning;
• Budgeting and purchasing food and supplies; and
• Supervising institutional food preparation, service and storage.

Procedures: §483.35(a)
If resident reviews determine that residents have nutritional problems, determine if these nutritional problems relate to inadequate or inappropriate diet nutrition/assessment and monitoring. Determine if these are related to dietitian qualifications.

Probes: §483.35(a)
If the survey team finds problems in resident nutritional status:
• Do practices of the dietitian or food services director contribute to the identified problems in residents’ nutritional status? If yes, what are they?
• What are the educational, training, and experience qualifications of the facility’s dietitian?
§ 483.35 (b) Standard Sufficient Staff
The facility must employ sufficient support personnel competent to carry out the functions of the dietary service

Interpretive Guidelines: §483.35(b)
“Sufficient support personnel” is defined as enough staff to prepare and serve palatable, attractive, nutritionally adequate meals at proper temperatures and appropriate times and support proper sanitary techniques being utilized.

Procedures: §483.35(b)
For residents who have been triggered for a dining review, do they report that meals are palatable, attractive, served at the proper temperatures and at appropriate times?

Probes: §483.35(b)
Sufficient staff preparation:
• Is food prepared in scheduled timeframes in accordance with established professional practices?
Observe food service:
• Does food leave kitchen in scheduled timeframes? Is food served to residents in scheduled timeframes?

§ 483.35(c) Menus and Nutritional Adequacy
Menus must:
1. Meet the nutritional needs of residents in accordance with the recommended dietary allowances of the Food and Nutrition Board of the National Research Council, National Academy of Sciences;

Intent: §483.35(c)(1)(2)(3)
The intent of this regulation is to assure that the meals served meet the nutritional needs of the resident in accordance with the recommended dietary allowances (RDAs) of the Food and Nutrition Board of the National Research Council, of the National Academy of Sciences. This regulation also assures that there is a prepared menu by which nutritionally adequate meals have been planned for the resident and followed.

Procedures: §483.35(c)(1)
For sampled residents who have a comprehensive review or a focused review, as appropriate, observe if meals served are consistent with the planned menu and care plan in the amounts, types and consistency of foods served.
If the survey team observes deviation from the planned menu, review appropriate documentation from diet card, record review, and interviews with food service manager or dietitian to support reason(s) for deviation from the written menu.

Probes: §483.35(c)(1)
Are residents receiving food in the amount, type, consistency and frequency to maintain normal body weight and acceptable nutritional values?
If food intake appears inadequate based on meal observations, or resident’s nutritional status is poor based on resident review, determine if menus have been adjusted to meet the caloric and nutrient-intake needs of each resident.
If a food group is missing from the resident’s daily diet, does the facility have an alternative means of satisfying the resident’s nutrient needs? If so, does the facility perform a follow-up?
Menu adequately provides the daily basic food groups:
• Does the menu meet basic nutritional needs by providing daily food in the groups of the food pyramid system and based on individual nutritional assessment taking into account current nutritional recommendations?

NOTE: A standard meal planning guide is used primarily for menu planning and food purchasing. It is not intended to meet the nutritional needs of all residents. This guide must be adjusted to consider individual differences. Some residents will need more due to age, size, gender, physical activity, and state of health. There are many meal planning guides from reputable sources, i.e., American Diabetes Association, American Dietetic Association, American Medical Association, or U.S. Department of Agriculture, that are available and appropriate for use when adjusted to meet each resident’s needs.

§483.35(c)(2) and (3) Menus and Nutritional Adequacy

§483.35(c)(2) Be prepared in advance; and

Probes: §483.35(c)(2)

Menu prepared in advance:
Are there preplanned menus for both regular and therapeutic diets?

§483.35(c)(3) Be followed.

Probes: §483.35(c)(3)

Menu followed:
• Is food served as planned? If not, why? There may be legitimate and extenuating circumstances why food may not be available on the day of the survey and must be considered before a concern is noted.

F364

§483.35(d) Food

Each resident receives and the facility provides:
(1) Food prepared by methods that conserve nutritive value, flavor, and appearance;
(2) Food that is palatable, attractive, and at the proper temperature;

Intent: §483.35(d)(1)(2)

The intent of this regulation is to assure that the nutritive value of food is not compromised and destroyed because of prolonged food storage, light, and air exposure; prolonged cooking of foods in a large volume of water and prolong holding on steam table, and the addition of baking soda. Food should be palatable, attractive, and at the proper temperature as determined by the type of food to ensure resident’s satisfaction. Refer to §483.15(e) and/or §483.15(a).

Interpretive Guidelines: §483.35(d)(1)

“Food-palatability” refers to the taste and/or flavor of the food.

“Food attractiveness” refers to the appearance of the food when served to residents.

Procedures: §483.35(d)(1)

Evidence for palatability and attractiveness of food, from day to day and meal to meal, may be strengthened through sources such as: additional observation, resident and staff interviews, and review of resident council minutes. Review nutritional adequacy in §483.25(i)(l).

Probes: §483.35(d)(1)(2)

Does food have a distinctly appetizing aroma and appearance, which is varied in color and texture?

Is food generally well seasoned (use of spices, herbs, etc.) and acceptable to residents?

Conserves nutritive value:
• Is food prepared in a way to preserve vitamins? Method of storage and preparation should cause minimum loss of nutrients.
Food temperature:
• Is food served at preferable temperature (hot foods are served hot and cold foods are served cold) as discerned by the resident and customary practice? Not to be confused with the proper holding temperature.

F365
§483.35(d)(3) Food prepared in a form designed to meet individual needs; and

F366
§483.35(d)(4) Substitutes offered of similar nutritive value to residents who refuse food served
Therapeutic diets must be prescribed by the attending physician.
Procedures §483.35(d)(3)(4)
Observe trays to assure that food is appropriate to resident according to assessment and care plan. Ask the resident how well the food meets their taste needs. Ask if the resident is offered or is given the opportunity to receive substitutes when refusing food on the original menu.
Probes: §483.35(d)(3)(4)
Is food cut, chopped, or ground for individual resident’s needs?
Are residents who refuse food offered substitutes of similar nutritive value?

Interpretive Guidelines §483.35(d)(4)
A food substitute should be consistent with the usual and ordinary food items provided by the facility. For example, if a facility never serves smoked salmon, they would not be required to serve this as a food substitute; or the facility may, instead of grapefruit juice, substitute another citrus juice or vitamin C rich juice that the resident likes.

F367
§483.35(e) Therapeutic Diets
Therapeutic diets must be prescribed by the attending physician.
Intent §483.35(e)
The intent of this regulation is to assure that the resident receives and consumes foods in the appropriate form and/or the appropriate nutritive content as prescribed by a physician and/or assessed by the interdisciplinary team to support the treatment and plan of care.
Interpretive Guidelines: §483.35(e)
“Therapeutic Diet” is defined as a diet ordered by a physician as part of treatment for a disease or clinical condition, or to eliminate or decrease specific nutrients in the diet, (e.g., sodium) or to increase specific nutrients in the diet (e.g., potassium), or to provide food the resident is able to eat (e.g., a mechanically altered diet).
“Mechanically altered diet” is one in which the texture of a diet is altered. When the texture is modified, the type of texture modification must be specific and part of the physicians’ order.
Procedures: §483.35(e)
If the resident has inadequate nutrition or nutritional deficits that manifests into and/or are a product of weight loss or other medical problems, determine if there is a therapeutic diet that is medically prescribed.
Probes: §483.35(e)
Is the therapeutic diet that the resident receives prescribed by the physician?
Also, see §483.25(i), Nutritional Status.

F368
§483.35(f) Frequency of Meals
(1) Each resident receives and the facility provides at least three meals daily, at regular times comparable to normal mealtimes in the community.
(2) There must be no more than 14 hours between a substantial evening meal and breakfast the following day, except as provided in (4) below.
(3) The facility must offer snacks at bedtime daily.
(4) When a nourishing snack is provided at bedtime, up to 16 hours may elapse between a substantial evening meal and breakfast the following day if a resident group agrees to this meal span, and a nourishing snack is served.
Intent: §483.35(f)(1-4)
The intent of this regulation is to assure that the resident receives his/her meals at times most accepted by the community and that there are not extensive time lapses between meals. This assures that the resident receives adequate and frequent meals.
Interpretive Guidelines: §483.35(f)(1-4)
A “substantial evening meal” is defined as an offering of three or more menu items at one time, one of which includes a high-quality protein such as meat, fish, eggs, or cheese. The meal should represent no less than 20 percent of the day’s total nutritional requirements.
“Nourishing snack” is defined as a verbal offering of items, single or in combination, from the basic food groups. Adequacy of the “nourishing snack” will be determined both by resident interviews and by evaluation of the overall nutritional status of residents in the facility, (e.g., Is the offered snack usually satisfying?)
Procedures: §483.35(f)(1-4)
Observe meal times and schedules and determine if there is a lapse in time between meals. Ask for resident input on meal service schedules, to verify if there are extensive lapses in time between meals

F369
§483.35(g) Assistive Devices
The facility must provide special eating equipment and utensils for residents who need them.
Intent: §483.35(g)
The intent of this regulation is to provide residents with assistive devices to maintain or improve their ability to eat independently. For example, improving poor grasp by enlarging silverware handles with foam padding, aiding residents with impaired coordination or tremor by installing plate guards, or providing postural supports for head, trunk, and arms.
Procedures: §483.35(g)
Review sampled residents comprehensive assessment for eating ability. Determine if recommendations were made for adaptive utensils and if they were, determine if these utensils are available and utilized by resident. If recommended but not used, determine if this is by resident’s choice. If utensils are not being utilized, determine when these were recommended and how their use is being monitored by the facility and if the staff is developing alternative recommendations
§483.35(i) Sanitary Conditions
The facility must--

F371
(Rev. 48; Issued: 06-12-09; Effective/Implementation Date: 06-12-09)
§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.

- **"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.

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;

**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:
  o 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 large, commercial food service establishments, and in nursing facilities. 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,
  o Poor personal hygiene;
  o Improper sanitation; and
  o Contact with raw food (e.g., poultry, eggs, seafood, and meat).

• Unsafe Food Sources

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. 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 residents.

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 source. Further, the primary control strategies list the preventive actions to inhibit the growth of these organisms.

<table>
<thead>
<tr>
<th>Source of Contamination</th>
<th>Primary Agents of Concern</th>
<th>Primary Control Strategies</th>
</tr>
</thead>
<tbody>
<tr>
<td>Eggs, raw or unpasteurized</td>
<td>Salmonella, PHF/TCS</td>
<td>Cook to proper temperature, Prevention of cross-contamination to ready-to-eat foods</td>
</tr>
<tr>
<td>Poultry, raw</td>
<td>Campylobacter, Salmonella, PHF/TCS</td>
<td></td>
</tr>
</tbody>
</table>
• Cook to proper temperature
• Prevention of cross-contamination to ready-to-eat foods
• Clostridium perfringens
• PHF/TCS
• Cook to proper temperature
Meat, raw
• E. coli 0157:H7
• Salmonella
• Campylobacter
• PHF/TCS
• Cook to proper temperature
• Prevention of cross-contamination to ready-to-eat foods
• Clostridium perfringens
• PHF/TCS
• Cook to proper temperature
Infectious food workers
• Norovirus
• Hepatitis A virus
• Shigella
• Salmonella
• Exclusion of infectious food workers
• Proper hand-washing procedures
• Avoid bare-hand contact with ready-to-eat foods
• Staphylococcus aureus
• 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
• E. coli O157:H7
• Salmonella
• Norovirus
• Hepatitis A virus
• Shigella
• Wash prior to use (unless pre-washed)
• Keep cut and raw fruits and vegetables refrigerated
Ready-to-eat meat and poultry products
• Listeria monocytogenes
• Proper refrigeration during storage
Pasteurized dairy products
• Listeria monocytogenes
• Proper refrigeration during storage
Ice
• Norovirus
• 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 setting.

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 food.

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:
  o Monitoring food temperatures and functioning of the refrigeration equipment daily and at routine intervals during all hours of operation;
  o Placing hot food in containers (e.g., shallow pans) that permit the food to cool rapidly;
  o 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
  o 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:
  o 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;
  o 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; - 145 degrees F for 15 seconds; until the white is completely set and the yolk is congealed; and
  - 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 egg products in foods that require pooling of eggs or foods that will not be thoroughly cooked, such as but not limited to Caesar dressing, Hollandaise or Béarnaise sauce and French toast. 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 reheating.

**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.

**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):
  - Wash 150-165 degrees F wash; and
  - 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):
  - Wash 120 degrees F wash; and
  - 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
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6 U.S. Department of Health and Human Services, Public Health Service, Food and Drug
7 International Association of Food Protection. (1999). Procedures to Investigate Foodborne
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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);
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;

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

Observe staff preparing modified consistency (e.g., pureed, mechanical soft) PHF/TCS foods to determine whether food safety was compromised.

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.

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.

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.

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.

**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
• The facility purchased unpasteurized shell eggs for all cooking purposes. The cook prepared and served sunny-side-up eggs with barely cooked yolks (i.e., not cooked to at least 145 degrees F for at least 15 seconds) for fourteen residents’ breakfasts. Using unpasteurized, shell eggs to prepare undercooked eggs for eating increased the risk of residents being infected with Salmonella, which could lead to a life-threatening illness. The facility did not have a system in place to minimize foodborne illness in the preparation of undercooked unpasteurized eggs.

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.

F372
§483.35(i)(3) Dispose of Garbage and Refuse Properly

Interpretive Guidelines: §483.35(i)(3)
The intent of this regulation is to assure that garbage and refuse be properly disposed.

Procedures: §483.35(i)(3)
Garbage/refuse:
Observe garbage and refuse container construction, and outside storage receptacles.

Probes: §483.35(i)(3)
Are garbage and refuse containers in good condition (no leaks) and is waste properly contained in dumpsters or compactors with lids or otherwise covered?
Are areas such as loading docks, hallways, and elevators used for both garbage disposal and clean food transport kept clean, free of debris and free of foul odors and waste fat?
Is the garbage storage area maintained in a saunter condition to prevent the harborage and feeding of pests?
Are garbage receptacles covered when being removed from the kitchen area to the dumpster?

§483.35(h) Paid Feeding Assistants-

F373
(Rev. 26; Issued: 08-17-07; Effective/Implementation Dates: 08-17-07)
§483.35(h) - Paid Feeding Assistants
(1) State-approved training course. A facility may use a paid feeding assistant, as defined in §488.301 of this chapter, if—
(i) The feeding assistant has successfully completed a State-approved training course that meets the requirements of §483.160 before feeding residents; and
(ii) The use of feeding assistants is consistent with State law.
(2) Supervision.
(i) A feeding assistant must work under the supervision of a registered nurse (RN) or licensed practical nurse (LPN).
(ii) In an emergency, a feeding assistant must call a supervisory nurse for help on the resident call system.

(3) Resident selection criteria.
(i) A facility must ensure that a feeding assistant feeds only residents who have no complicated feeding problems.
(ii) Complicated feeding problems include, but are not limited to, difficulty swallowing, recurrent lung aspirations, and tube or parenteral/IV feedings.
(iii) The facility must base resident selection on the charge nurse’s assessment and the resident’s latest assessment and plan of care.

NOTE: One of the specific features of the regulatory requirement for this tag is that paid feeding assistants must complete a training program with the following minimum content as specified at §483.160:

a. Minimum training course contents. A State-approved training course for paid feeding assistants must include, at a minimum, 8 hours of training in the following:
   (1) Feeding techniques;
   (2) Assistance with feeding and hydration;
   (3) Communication and interpersonal skills;
   (4) Appropriate responses to resident behavior;
   (5) Safety and emergency procedures, including the Heimlich maneuver;
   (6) Infection control;
   (7) Resident rights; and
   (8) Recognizing changes in residents that are inconsistent with their normal behavior and the importance of reporting those changes to the supervisory nurse.

b. Maintenance of records. A facility must maintain a record of all individuals, used by the facility as feeding assistants, who have successfully completed the training course for paid feeding assistants.

**Intent: §483.35(h)**
The intent of this regulation is to ensure that employees who are used as paid feeding assistants are:
• Properly trained (in accordance with the requirements at §483.160, including maintenance of records);
• Adequately supervised;
• Assisting only those residents without complicated feeding problems and who have been selected as eligible to receive these services from a paid feeding assistant; and
• Providing assistance in accordance with the resident’s needs, based on individualized assessment and care planning.

**Definitions**
“Paid feeding assistant” is defined in the regulation at 42 CFR 488.301 as “an individual who meets the requirements specified at 42 CFR 483.35(h)(1)(i) of this chapter and who is paid to feed residents by a facility, or who is used under an arrangement with another agency or organization.”

**NOTE:** The regulation uses the term, “paid feeding assistant.” While we are not using any other term, facilities and States may use whatever term they prefer, such as dining assistant, meal assistant, resident assistant, nutritional aide, etc. in order to convey more respect for the resident.
Facilities may identify this position with other titles; however, the facility must be able to identify those employees who meet the requirements under the paid feeding assistant regulation. These requirements do not apply to family and/or volunteers who may be providing the resident with assistance.

“Resident call system,” for the purposes of this requirement includes not only the standard hardwired call system, but other means in an emergency situation by which a paid feeding assistant can achieve timely notification of a supervisory nurse (when not present in the room).

OVERVIEW

The intent behind the use of paid feeding assistants by nursing homes is to provide nutrition and hydration support to residents who may be at risk for unplanned weight loss and dehydration. These are residents with no complicated problems associated with eating or drinking, who cannot or do not eat independently due to physical or cognitive disabilities, or those who simply need cueing or encouragement to eat. The use of paid feeding assistants is intended to supplement certified nurse aides, not substitute for nurse aides or licensed nursing staff. Use of paid feeding assistants is an option for nursing homes if their state approves the use of paid feeding assistants and establishes a mechanism to approve training programs for paid feeding assistants.

Interpretive Guidelines §483.35(h)

NOTE: The regulation at §483.30(a)(2) requires that "Except when waived under paragraph (c) of this section, the facility must designate a licensed nurse to service as a charge nurse on each tour of duty." In the paid feeding assistant regulation, the term charge nurse is used to identify who is responsible for assessing the eligibility of a resident to be assisted by a paid feeding assistant. The regulation also states that a paid feeding assistant must work under the supervision of an RN or LPN, and they must call the supervisory nurse in case of an emergency. Therefore, a facility that has received a waiver and does not have either an RN or LPN available in the building cannot use paid feeding assistants during those times.

Charge Nurse Assessment of Resident Eligibility for Feeding Assistance

The facility must base resident selection on the charge nurse’s (RN, or LPN if allowed by State law) current assessment of the resident’s condition and the resident’s latest comprehensive assessment and plan of care. Charge nurses may wish to consult with interdisciplinary team members, such as speech-language pathologists or other professionals, when making their decisions.

Paid feeding assistants are permitted to assist only those residents who have no complicated eating or drinking problems. This includes residents who are dependent in eating and/or those who have some degree of dependence, such as needing cueing or partial assistance, as long as they do not have complicated eating or drinking problems.

Paid feeding assistants are not permitted to assist residents who have complicated eating problems, such as (but not limited to) difficulty swallowing, recurrent lung aspirations, or who receive nutrition through parenteral or enteral means. Nurses or nurse aides must continue to assist residents to eat or drink who require the assistance of staff with more specialized training. Facilities may use paid feeding assistants to assist eligible residents to eat and drink at meal times, snack times, or during activities or social events as needed, whenever the facility can provide the necessary supervision.

Supervision (by RN/LPN) of Paid Feeding Assistants

A paid feeding assistant must work under the supervision of an RN or LPN. While we are not prescribing the exact means by which facility RNs and LPNs assert their supervisory responsibilities, we expect that facilities will do so in a way that avoids negative outcomes for
their residents. If a facility chooses to use paid feeding assistants, it is the facility’s responsibility to ensure that adequate supervisory nursing staff are available to supervise these assistants. The supervisory nurse should monitor the provision of the assistance provided by paid feeding assistants to evaluate on an ongoing basis:

- Their use of appropriate feeding techniques;
- Whether they are assisting assigned residents according to their identified eating and drinking needs;
- Whether they are providing assistance in recognition of the rights and dignity of the resident; and
- Whether they are adhering to safety and infection control practices.

Adequate supervision by a supervising nurse does not necessarily mean constant visual contact or being physically present during the meal/snack time, especially if a feeding assistant is assisting a resident to eat in his or her room. However, whatever the location, the feeding assistant must be aware of and know how to access the supervisory nurse immediately in the event that an emergency should occur. Should an emergency arise, a paid feeding assistant must immediately call a supervisory nurse for help on the resident call system.

The charge nurse and the supervisory nurse may or may not be the same individuals.

**Resident Call System**

The regulatory language at this Tag states that, "in an emergency, a feeding assistant must call a supervisory nurse for help on the resident call system." Residents may be receiving assistance in eating or drinking in various locations throughout the facility, such as dining areas, activity rooms, or areas such as patios or porches in which a resident call system is not readily available. The resident call system requirement at §483.70(f), F463, only specifies that the call system be available in the residents rooms and bathrooms. Regardless of where a resident is being assisted to eat or drink, in the case of an emergency, the facility needs to have a means for a paid feeding assistant to obtain timely help of a supervisory nurse. Therefore, for the purposes of this requirement, a “resident call system” includes not only the standard hard-wired or wireless call system, but other means in an emergency situation by which a paid feeding assistant can achieve timely notification of a supervisory nurse.

**Use of Existing Staff as Paid Feeding Assistants**

Facilities may use their existing staff to assist eligible residents to eat and drink. These employees must have successfully completed a State-approved training course for paid feeding assistants, which has a minimum of 8 hours of training as required in §483.160. Staff may include, for example, administrative, clerical, housekeeping, dietary staff, or activity specialists. Employees used as paid feeding assistants, regardless of their position, are subject to the same training and supervisory requirements as any other paid feeding assistant.

**Maintenance of Training Records**

The facility must maintain a record of all employees used by the facility as paid feeding assistants. The record should include verification that they have successfully completed a State-approved training course for paid feeding assistants.

**INVESTIGATIVE PROTOCOL**

**Use of Paid Feeding Assistants**

**Objectives**

The objectives of this protocol are to determine, for a facility that uses paid feeding assistants:

- If individuals used as paid feeding assistants successfully completed a State-approved training course;
• If sampled residents who were selected to receive assistance from paid feeding assistants were assessed by the charge nurse and determined to be eligible to receive these services based on the latest assessment and plan of care; and
• If the paid feeding assistants are supervised by an RN or LPN.

Use
This protocol is used when a surveyor identifies concerns through observation; interview with residents, family, or staff; or record review, that the facility may not be following the requirements regarding paid feeding assistants, including proper training and supervision of feeding assistants, and proper selection of residents for feeding assistance.

Procedures
Briefly review the comprehensive assessment and interdisciplinary care plan to guide observations to be made. The team coordinator assigns one surveyor to obtain the facility’s records of all employees, used by the facility as paid feeding assistants, for review for completion of the training course for paid feeding assistants.

Observations
If the concern was discovered through resident or family interview, observe the resident while they are being assisted to eat and drink by a paid feeding assistant. Determine if the assistant is using proper feeding technique and is providing the type of assistance specified in the resident’s care plan. Note the resident’s condition and observe for the presence of complicated feeding problems.
If the concern was discovered through observations that were already made, only conduct additional observations if necessary to complete the investigation.

Interviews
Resident and Family Interviews
If a resident is selected for this protocol through surveyor observation that they are having difficulties in eating or drinking and they are being assisted by a paid feeding assistant, interview the resident if the resident is interviewable. Ask questions to gain information about why the resident is receiving these services and the resident's experience with receiving assistance to eat and drink. If concerns are identified, inquire if they have reported these problems to a nurse. If the resident is not interviewable, ask these questions of a family member.
If the concern was discovered through resident or family interviews already conducted as part of Task 5D, focus any additional interview on questions specific to the investigation.

Paid Feeding Assistant Interviews
Interview the paid feeding assistant who was assisting the selected resident. Determine whether there are concerns with the paid feeding assistant’s training, supervision, or the selection of the resident such as:
• What training did you successfully complete in providing feeding assistance?
• What information did you receive about this resident's needs for assistance (type of assistance needed, any precautions)?
• In what manner and by whom are you supervised while assisting residents?
• What issues/problems do you report (such as coughing, choking, changes in the resident’s usual responses, or level of alertness) and to whom do you report?
• What would you do if an emergency occurred while you were assisting a resident to eat or drink? Who would you contact and how would you contact them if you are not near the resident call system?

Charge Nurse Interview
Interview the charge nurse who is responsible for assessing this resident as eligible to receive assistance by a paid feeding assistant. Ask:
- How they determined that this resident has no complicated feeding problems and is eligible to be assisted by a paid feeding assistant;
- How they determine that each eligible resident remains free of emergent complicated feeding problems;
- Who supervises paid feeding assistants and how is the supervision accomplished;
- Describe the processes in place to handle emergencies when a supervisor is not present in the area where paid feeding assistants are assisting residents.

**Supervisory Nurse Interview**

Interview the nurse who is supervising the resident during the meal or other times when the paid feeding assistant is assisting the resident to eat or drink. Ask how they supervise paid feeding assistants.

**Review of Assessment of Eligibility to Receive Assistance from a Paid Feeding Assistant**

Determine whether the charge nurse based her/his assessment of the resident's ongoing eligibility to be assisted by a paid feeding assistant on identification of the current condition of the resident and any additional or new risk factors or condition changes that may impact on the resident's ability to eat or drink. This information may be contained in the RAI or in other supporting documents such as progress notes, etc. The assessment of eligibility to receive assistance from a paid feeding assistant is ongoing and should be in place from the day of admission.

**Requirements for Training of Paid Feeding Assistants**

Determine how the facility identifies that paid feeding assistants have successfully completed a State-approved training course that meets the requirements at 42 CFR 483.160 before they are allowed to assist eligible residents with eating and drinking.

If the facility uses temporary (agency) staff as paid feeding assistants, request documentation that these staff have met the minimum training requirements specified by the State.

**DETERMINATION OF COMPLIANCE (TASK 6, APPENDIX P)**

The information below should be used by the survey team for their deficiency determination at Task 6 in Appendix P. The survey team must evaluate the evidence documented during the survey to determine if a deficiency exists due to a failure to meet a requirement, and if there are any negative resident outcomes or potential for negative outcomes due to the failure.

**Synopsis of Regulation (42 CFR 483.35)**

The paid feeding assistant requirement has five aspects:
- Staff who are used as paid feeding assistants must have completed a State-approved training course;
- The facility must base resident selection to be fed by a paid feeding assistant on the charge nurse’s assessment and resident’s latest assessment and care plan;
- Paid feeding assistants must work under the supervision of an RN or LPN, and, in an emergency, must call a supervisory nurse for help on the resident call system;
- Paid feeding assistants assist only residents who have no complicated health problems related to eating or drinking that make them ineligible for these services; and
- The facility must maintain a record of all individuals used by the facility as paid feeding assistants, and must maintain documentation of successful completion of a State-approved training course by these individuals.

**Criteria for Compliance**

Compliance with 42 CFR 483.35(h), F373, Paid Feeding Assistants
The facility is in compliance with this requirement if all the following are met:

- The facility only employs paid feeding assistants who have successfully completed a State-approved training course before providing assistance;
- The facility selected qualified residents based on the charge nurse’s ongoing assessment and the latest assessment and plan of care;
- The facility provides supervision by an RN or LPN;
- The facility provides in cases of emergency a working call system (and other means for areas without a call system) for the paid feeding assistant to summon help in an emergency;
- The facility ensures that the paid feeding assistant only assists residents who have no complicated health problems related to eating or drinking that make them ineligible for these services; and
- The facility maintains a record of all individuals used by the facility as paid feeding assistants, and maintains documentation of each paid feeding assistant’s successful completion of a State-approved training course.

If not, cite F373.

**Non-compliance for F373**

After completing the investigative protocol, determine whether or not noncompliance with the regulation exists. Noncompliance for F373 may include, but is not limited to, one or more of the following:

- An employee of the facility (permanent or temporary) who has not successfully completed the State-approved training course is assisting a resident to eat/drink;
- The facility allowed an employee who has completed a course that is not State-approved to assist a resident to eat or drink;
- A paid feeding assistant was observed assisting a resident in a location without a call system available or other means of emergency notification;
- A resident who was assessed by the charge nurse as ineligible for services due to complicated eating/drinking problems, or a resident who has not been assessed for eligibility, is being assisted by a paid feeding assistant;
- A paid feeding assistant was not being supervised by a RN or LPN;
- RN or LPN staff members assigned to supervise paid feeding assistants were observed to be unavailable (e.g., not in reach of contact);
- The clinical record of a resident being assisted by a paid feeding assistant did not show evidence that the resident was eligible to receive assistance from a paid feeding assistant;
- The facility did not maintain records of paid feeding assistants working in the facility; or
- The facility did not maintain documentation of a paid feeding assistant’s successful completion of a State-approved paid feeding training course.

**Potential Tags for Additional Investigation**

During the investigation of F373, the surveyor may have identified concerns with additional requirements related to outcome, process, and/or structure requirements. The surveyor is cautioned to investigate these related requirements before determining whether non-compliance may be present at these other tags. Examples of some of the related requirements that may be considered when non-compliance has been identified include the following (but are not limited to):

- 42 CFR 483.15(a), F241, Dignity
  - Determine if staff are attentive and responsive to the resident’s requests, and if they provide assistance to eat in a manner that respects the resident’s dignity, meets needs in a timely manner,
and minimizes potential feelings of embarrassment, humiliation, and/or isolation related to inability to assist themselves with food or fluid intake.

- **42 CFR 483.20(b), F272, Comprehensive Assessments**
  - Review whether the facility initially and periodically conducted a comprehensive, accurate assessment of the resident’s ability to eat and drink with or without assistance and/or identified a condition that makes the resident ineligible for this service.

- **42 CFR 483.20(k)(1), F279, Comprehensive Care Plans**
  - Review whether the facility developed a comprehensive care plan that was based on the assessment of the resident’s conditions, needs, and behaviors, and was consistent with the resident’s goals in order to provide assistance with nutrition and hydration as necessary.

- **42 CFR 483.20(k)(2)(iii), F280, Comprehensive Care Plan Revision**
  - Determine if the care plan was reviewed and revised periodically, as necessary, related to eligibility to eat and drink with assistance of a paid feeding assistant.

- **42 CFR 483.25(i)(1), F325, Nutritional Parameters**
  - Review if the facility had identified, evaluated, and responded to a change in nutritional parameters, anorexia, or unplanned weight loss, dysphagia, and/or swallowing disorders in relation to the resident’s ability to eat.

- **42 CFR 483.25(i)(2), F327, Hydration**
  - Review if the facility had identified, evaluated, and responded to a change in the resident’s ability to swallow liquids.

- **42 CFR 483.25(a)(3) F312, ADL Assistance for Dependent Residents**
  - Determine if staff identified and implemented appropriate measures to provide food and fluids for the resident who cannot perform relevant activities of daily living.

- **42 CFR 483.30(a), F353, Sufficient Staff**
  - Determine if the facility has qualified staff in sufficient numbers to provide assistance to eat or drink to those residents who require such assistance. For residents who are not eligible to receive assistance from paid feeding assistants, determine if there are sufficient CNAs to provide this assistance to these residents in a timely fashion.

- **42 CFR 483.75(i)(2), F501, Medical Director**
  - Determine whether the medical director collaborates with the facility to help develop, implement, and evaluate resident care policies and procedures based on current standards of practice, e.g., the use of paid feeding assistants, their supervision, and the criteria for determining which residents are eligible to receive assistance to eat or drink from paid feeding assistants.

### IV. DEFICIENCY CATEGORIZATION (Part IV, Appendix P)

Once the team has completed its investigation, analyzed the data, reviewed the regulatory requirement, and identified any deficient practice(s) that demonstrate that non-compliance with the regulation at F373 exists, the team must determine the severity of the deficient practice(s) and the resultant harm or potential for harm to the resident. The key elements for severity determination for F373 are as follows:

1. **Presence of harm/negative outcome(s) or potential for negative outcomes because of lack of appropriate use of paid feeding assistants.**

Non-compliance related to an actual or potential harm/negative outcome for F373 may include, but is not limited to:

- A resident who is not eligible to receive these services is assisted by a paid feeding assistant; or
• A resident who is eligible to receive these services is assisted by a paid feeding assistant and develops coughing and/or choking episodes related to the paid feeding assistant using poor techniques indicating lack of appropriate supervision.

2. Degree of harm (actual or potential) related to the non-compliance:
Identify how the facility practices 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 how likely is 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 non-compliance 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 F373. 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, Guidelines for Determining Immediate Jeopardy.)

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

Severity Level 4 Considerations: Immediate Jeopardy to Resident Health or Safety
Immediate Jeopardy is a situation in which the facility’s non-compliance with one or more requirements of participation:
• Has allowed/caused/resulted in, or is likely to cause/allow/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 preventative or corrective measures.
Examples of the facility’s non-compliance that may cause or contribute to negative outcomes at severity level 4 include, but are not limited to:
• An eligible resident in an activity room who is being improperly assisted to eat by a paid feeding assistant, experiences choking, there was no call system readily available, and/or the supervising nurse was not available to assist, and the resident expired;
• A resident who is not eligible to receive these services due to complicated feeding problems is assisted by a paid feeding assistant, whether or not the resident has experienced negative outcomes.

NOTE: If immediate jeopardy has been ruled out based upon the evidence, then evaluate whether actual harm that is not immediate jeopardy exists at severity level 3.

Severity Level 3 Considerations: Actual Harm that is not Immediate Jeopardy
Level 3 indicates non-compliance that results in actual harm, and can include but may not be limited to clinical compromise, decline, or the failure to maintain and/or reach the resident’s highest practicable well-being.
Examples of the facility’s non-compliance that may cause or contribute to negative outcomes at severity level 3 include, but are not limited to:
• An eligible resident who was assessed to have the potential to improving their eating ability was assisted to eat by a paid feeding assistant. The assistant provided too much food, too quickly and the resident was pocketing the food in her cheeks. The resident experienced choking and coughing and subsequently vomited. As a result, the resident became fearful, refused solid foods, and would only consume liquid dietary supplements.

**NOTE:** If severity level 3 (actual harm that is not immediate jeopardy) has been ruled out based upon the evidence, then evaluate as to whether level 2 (no actual harm with the potential for more than minimal harm) exists.

**Severity Level 2 Considerations: No Actual Harm with potential for more than minimal harm that is Not Immediate Jeopardy**

Level 2 indicates non-compliance 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.

Examples of the facility’s non-compliance that may cause or contribute to negative outcomes at severity level 2 include, but are not limited to:

• Paid feeding assistants are assisting eligible residents to eat in an area with no call system, and the supervising nurses are not nearby, but there have been no resident outcomes; and

• Eligible residents are being assisted to eat by employees who have not successfully completed a State-approved paid feeding assistant training course and who otherwise by State law would not be allowed to feed residents (such as RNs, LPNs or CNAs), and there were no resident negative outcomes.

**Severity Level 1: No actual harm with potential for minimal harm**

Level 1 is a deficiency that has the potential for causing no more than a minor negative impact on the resident(s).

Examples of the facility’s non-compliance that may cause or contribute to negative outcomes at severity level 1 include, but are not limited to:

Facility did not maintain a record of employees who had completed a State approved paid feeding assistant training program and were used by the facility as paid feeding assistants.