

**§483.35(i) Sanitary Conditions
(F371) Surveyor Training:
Interpretive Guidance
Investigative Protocol**

With regard to the revised guidance F371 Sanitary Conditions, there have been significant changes. Specifically, F370 and F371 were merged. However, the regulatory language has remained the same. The revisions to F371 were made to provide definition, education, explanation, and examples for the surveyors to reference.

Federal Regulatory Language

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

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

- Obtains food for residents' consumption from approved sources, and
- Follows proper sanitation and food handling practices to prevent the outbreak of foodborne illnesses.

Training Objectives

- Describe the relationship between the regulation and the interpretive guidance
- Describe how to use the investigative protocol
- Describe and apply components of the investigative protocol

Training Objectives (cont'd)

- Identify areas of non-compliance with the sanitary conditions regulation
- Appropriately categorize the scope and severity of noncompliance

Definitions

- **Cross-contamination**
- **Danger Zone**
- **Dry Storage**
- **Food Contamination**
- **Food Preparation**
- **Food Service/Distribution**
- **Foodborne Illness**
- **Highly Susceptible Population**
- **Pathogen**
- **Potentially Hazardous Food (PHF)**
- **Ready-to-Eat Food**
- **Storage**
- **Toxins**

Cross-contamination

The transfer of harmful substances or disease-causing microorganisms 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 foods. Cross-contamination can also occur when raw food touches or drips onto cooked or ready-to-eat foods.

Danger Zone

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 or Time/Temperature Control for Safety 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 if consumed.

Dry Storage

Storing/maintaining dry foods (e.g., canned goods, flour, sugar) and supplies (disposable dishware, napkins and kitchen cleaning supplies).

Storage

The retention of food (before and after preparation) and associated dry goods.

Food Contamination

The unintended presence of potentially harmful substances, including but not limited to microorganisms, chemicals or physical objects in food.

Food Preparation

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.

Foodborne Illness

- **Illness caused by the ingestion of contaminated food or beverages**

Food Service/Distribution

The processes of getting food to the resident:

- Holding foods hot on the steam table or under refrigeration for cold temperature control
- Dispensing food portions for individual residents
- Family style and dining room service
- Delivering trays to residents' rooms or units

Highly Susceptible Population

- 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 (e.g., immunocompromised, chronic disease and advanced age).

Ready-to-Eat Food

Pathogen

An organism capable of causing a disease (e.g., pathogenic bacteria or viruses).

Potentially Hazardous Food (PHF or TCS)

Food that requires time/temperature control for safety to limit the growth of pathogens or toxin formation

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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., tuna, chicken or egg salad).

Toxins

- Poisonous substances that are produced by living cells or organisms (e.g., pathogenic bacteria) that cause foodborne illness when ingested.

Interpretive Guidance Overview

- The risk of foodborne illness
- Importance of effective food safety systems
- Identification of hazards and Critical Control Points (CCPs)
- Operational steps to eliminate hazards

Interpretive Guidance- Types of Food Contamination

- Biological
- Chemical
- Physical

Interpretive Guidance - Biological Contamination

- Most common types of disease producing organisms
- Pathogenic bacteria, viruses, toxins, and spores contaminate food
- Parasites

Pathogenic Bacteria

- Non-harmful vs. harmful bacteria
- Food storage and preparation

Factors Influencing Bacterial Growth

- Hazardous nature of the food
- Acidity (pH) of the food
- Water percent of the food
- Time and temperature control of the food

Viruses

- Require a host for reproduction
- Examples:
 - Hepatitis A
 - Norovirus (formerly known as Norwalk virus)

Toxins

- Origin
 - Staphylococcus aureus
 - Clostridium botulinum
- Poisonous substances
- Variety of sources

Spores

- Origin
- Reactivation and favorable conditions for growth
- Temperature control

Chemical Contamination

- Cleaning supplies should be stored separately from food items.
- The most common chemicals include but are not limited to glass cleaners, soaps, oven cleaners and insecticides.

Chemical Contamination (cont'd)

- An inadequately identified chemical inadvertently mistaken as a food product added to food can cause illness.

Physical Contamination

Foreign objects that may inadvertently enter food.

Examples:

- Hair
- Fingernails
- Pieces of glass

Other Factors Implicated In Foodborne Illnesses

- Poor personal hygiene
- Inadequate cooking and improper holding temperatures
- Contaminated equipment
- Unsafe food sources

Surveying Facilities That Receive Food Prepared By Off-site Kitchens

When a nursing home receives food services from an off-site location, the surveyor must assess whether the facility is compliant with 42 CFR 483.35 (i).

Culture Change Provisions

- Family members or other resident guests who bring in food for the resident's consumption are not regulated under this Federal tag.
 - Many State regulations address this issue.

Interpretive Guidance - Pathogenic Microorganisms and Strategies for Their Control

- Commonly identified ingestible items associated with illness-producing organisms
- Primary agents of concern (hazards) are organisms associated with the food source
- PHF/TCS primary control strategies to minimize potential for foodborne illness outbreak

Interpretive Guidance

Source of Contamination	Primary Agents of Concern	PHF/TCS Primary Control Strategies
Fruits and vegetables, fresh	E. coli O157:H7 Salmonella Norovirus Hepatitis A virus Shigella	Cook to proper temperature Prevention of cross- contamination to ready-to-eat foods
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

Interpretive Guidance

Source of Contamination	Primary Agents of Concern	PHF/TCS Primary Control Strategies
Eggs, raw or unpasteurized	Salmonella	Cook to proper temperature Prevention of cross-contamination to ready-to-eat foods
Poultry, raw	Campylobacter Salmonella Clostridium perfringens	Cook to proper temperature Prevention of cross-contamination to ready-to-eat foods
Meat, raw	E. coli 0157:H7 Salmonella Campylobacter Clostridium perfringens	Cook to proper temperature Prevention of cross-contamination to ready-to-eat foods
Infectious food workers	Norovirus Hepatitis A virus Shigella Salmonella Staphylococcus aureus	Exclusion of infectious food workers Proper hand washing procedures Avoid bare-hand contact with ready to-eat foods

Prevention of Foodborne Illness

- Food Handling and Preparation
- Employee Health
- Hand washing, Gloves, Antimicrobial Gel
- Hair Restraints/Jewelry/Nail Polish

Safe Food Storage

- Dry Food Storage should be maintained in a clean and dry area free of contaminants
- Refrigerator Storage Safe Practices include:
 - Monitoring temperatures
 - Proper handling of hot food
 - Separation of raw animal foods and vegetables
 - Labeling, dating and monitoring foods

Interpretive Guidance - Safe Food Preparation

- Cross-Contamination
- Thawing
- Final Cooking Temperatures
- Reheating Food

Interpretive Guidance

Process	Food Item	Temperatures
Final Cooking Temperatures	Poultry and stuffed foods	165 degrees F
	Ground Meat	155 degrees F
	Fish and other meats	145 degrees F
	Unpasteurized eggs	145 degrees F
Reheating foods	Internal temperature	165 degrees F
	Intact package	135 degrees F

Interpretive Guidance

Process	Time	Temperatures
Cooling	Within 2 hours	From 135 degrees F to 70 degrees F
	Within 4 hours	Cooled to 41 degrees F
	Total time cooling not to exceed 6 hours	Cooled from 135 degrees F to 41 degrees F

Interpretive Guidance - Prevention of Foodborne Illness

- Cooling
- Modified Consistency
- Pooled Eggs

Food Service and Distribution

- Tray line, alternative meal preparation and service area
- Food distribution
- Snacks
- Special events
- Transported foods
- Ice
- Refrigeration

Interpretive Guidance - Equipment and Utensil Cleaning and Sanitization

- Machine Washing and Sanitizing
- Manual Washing and Sanitizing
- Cleaning Fixed Equipment

Interpretive Guidance - Equipment and Utensil Cleaning and Sanitization (cont'd)

Wiping Cloths

- Service area wiping cloths are cleaned and dried, or
- Placed in a chemical sanitizing solution of appropriate concentration.

Investigative Protocol Sanitary Conditions

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

Interpretive Guidance Objectives

- To determine if the facility procured food from approved sources
- To determine if the facility stores, prepares, distributes, and serves food in a sanitary manner to prevent foodborne illness

Interpretive Guidance - Objectives (cont'd)

To determine if the facility has systems (e.g. policies, procedures, training, and monitoring) in place to prevent the spread of foodborne illness and compromising of food safety

Interpretive Guidance - Objectives (cont'd)

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

Interpretive Guidance - Procedures

- Observations
- Interviews
- Record Reviews
- Review of Facility Practices

Interpretive Protocol - Observe Food Procurement Procedures

- Observe when, where and how food is procured
- Concurrently with the observations, review:
 - Invoices
 - Vendor records
 - Source verification

Interpretive Protocol - Observe Food Preparation Procedures

- Food handling practices
- Food labeling and dates
- Hand washing
- Handling of potential cross-contamination foods
- Acceptable cooking and cooling temperatures

Interpretive Protocol - Observe Service of Food during Trayline Operations

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

Interpretive Protocol - Observe Dish Room Operations

- Observe whether staff are properly operating dish machine and evaluate sanitization processes
- Check for proper equipment and supplies to evaluate dish machine operation
- Observe the three-step process of manual pot and pan washing

Interpretive Protocol - Observe Service of Food after Meal Times

- Observe stored dishes, utensils, pots/pans, and equipment for evidence of soiling
- Evaluate whether proper hand washing is occurring between handling soiled and clean dishes to prevent cross-contamination of the clean dishes

Interpretive Protocol - Observe Food Storage

- Look for evidence of pests, rodents and droppings and other sources of contamination
- Observe whether foods are labeled and dated
- Observe whether foods are stored off of the floor

Interpretive Protocol - Observe Food Storage (cont'd)

- Check for canned goods that have a compromised seal
- Observe whether staff access bulk foods without touching the food

Interpretive Protocol - Interview

During the course of the survey, interview multiple staff who perform the task, about the procedures they follow to procure, store, prepare, distribute and serve food to residents.

Record Reviews

- Resident records
- Dietary/kitchen policies and procedures
- Maintenance records, such as work orders and manufacturer's specifications, related to equipment used to store, prepare, and serve food
- Facility infection control records

Interpretive Protocol - Review of Facility Practices

Review facility documents and interview staff to establish if the facility has processes and practices to promote food safety and prevent the spread of foodborne illness

42 CFR 483.35(i) (1)(2) Sanitary Conditions

DETERMINATION OF COMPLIANCE (Appendix P)

Determination of Compliance

Did the facility:

- Procure food from approved sources?
- Properly store, prepare, distribute and serve foods for residents' consumption?

Criteria for Compliance with F371

The facility is in compliance if staff:

- Procures, stores, handles, prepares, distributes, and serves food to minimize the risk of foodborne illness
- Maintains PHF/TCS foods at safe temperatures, cools food rapidly, and prevents contamination during storage

Criteria for Compliance with F371 (Cont'd)

The facility is in compliance if staff:

- Cook food to the appropriate temperature and hold PHF/TCS foods cold or hot
- Utilizes proper hand washing and personal hygiene practices to prevent food contamination
- Maintains equipment and food contact surfaces to prevent food contamination

Noncompliance with F371

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

Procure, store, handle, prepare, distribute, and serve food in accordance with the standards summarized in this guidance

Noncompliance with F371 (cont'd)

Failure to:

- 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)
 - Exception: during preparation, cooking, or cooling
- Ensure that PHF/TCS food plated for transport was not out of temperature control for more than four hours.

Noncompliance with F371 (cont'd)

Failure to:

- Store raw foods properly to reduce the risk of contamination of cooked or ready-to-eat foods
- Ensure that foods are cooked to the appropriate temperature and cooled properly to prevent foodborne illness

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Additional Investigation

Potential Tags for Additional Investigation

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DEFICIENCY CATEGORIZATION (Part IV, Appendix P)

Severity Determination Key Components

- Harm/negative outcome(s) or potential for negative outcomes due to a failure of care and services,
- Degree of harm (actual or potential) related to noncompliance, and
- Immediacy of correction required.

Determining Actual or Potential Harm

Actual or potential harm/negative outcomes for F371 may include:

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

Determining Degree of Harm

How the facility practices caused, resulted in, allowed, or contributed to harm (actual/potential)

- If harm has occurred, determine if the harm is at the level of serious injury, impairment, death, compromise, or discomfort; and
- If harm has not yet occurred, determine how likely the potential is for serious injury, impairment, death, compromise or discomfort to occur to the resident.

Severity Level 4 Deficiency Categorization

Immediate Jeopardy to
Resident's Health or Safety

Level 4 Immediate Jeopardy

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

Severity Determination Level 4 Immediate Jeopardy (cont.)

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

Level 4 Example

- A roast 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.

Level 4 Example

- The facility had a recent outbreak of Norovirus as a result of a food worker experiencing episodes of vomiting and diarrhea, and the facility allowed the staff to continue preparing food.
- Observations and interviews indicate that there are other food service staff experiencing gastrointestinal illnesses who are still permitted to prepare food.

Severity Level 3 Deficiency Categorization

Actual Harm that is *not* Immediate Jeopardy

The negative outcome may 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.

Level 3 Example

An outbreak of nausea and vomiting occurs in the facility related to the inadequate sanitizing of dishes and utensils.

Level 3 Example

A mild episode of food poisoning occurred because the facility had a special event in which tuna, chicken, and potato salads served in bulk were not kept adequately chilled and were left out for eating after 5 hours.

Severity Level 2 Deficiency Categorization

**No Actual Harm with potential
for more than minimal harm that
is not Immediate Jeopardy**

Level 2 Deficiency Categorization

- 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.

Level 2 Example

- Food service workers sliced roast pork on the meat slicer.
- The meat slicer was not washed, rinsed, and sanitized after usage.
- During the dietary service system assessment, two days later, the surveyor observed the meat slicer soiled with dried meat underneath the blade.
- The facility failed to educate and train staff on how to clean and sanitize all kitchen equipment.

Level 2 Example

- During the 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.

Severity Level 1 Deficiency Categorization

No Actual Harm with Potential for
Minimal Harm

Level 1 Deficiency Categorization

- 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.

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Questions?