Surveyor Guidance for Taking Food Temperatures in Nursing Homes

Overview

Introduction

This guidance is offered to assist surveyors to determine whether potentially hazardous food is maintained at proper temperatures during various phases of processing. It is intended to enhance the surveyor’s understanding of the 2001 Food Code, and to promote the consistent application of related regulations as well as the survey protocol.

Background

F371 (CFR 483.35(h)(2)) is one of the most cited regulations in Florida’s nursing homes. Long term care associations’ representatives raised valid issues regarding the time and temperature relationship for potentially hazardous food and how surveyor determine food is not safe following removal from temperature control.

The State Agency uses the 2001 U.S. Department of Health and Human Services, Public Health Services, Food and Drug Administration Food Code as a guide for determining food is stored, prepared, serviced and distributed under sanitary conditions (CFR 483.35(h)(2)).

Chapter 3-501 of the 2001 Food Code states that all potentially hazardous cold food must be maintained at 41°F or less and hot food maintained at 140°F or more, except during preparation, cooling, and service (pg. 68).

Surveyors shall measure food temperature to determine compliance.

Chapter 3-501.19 of the 2001 Food Code also addresses using time as a public health control, rather than temperature (pg. 70). Certain conditions must exist if time only is used as a public health control. 3-501.19 (A) Except as specified under (B) of this section, if time only, rather than time in conjunction with temperature, is used as the public health control for a working supply of potentially hazardous food before cooking, or for ready-to-eat potentially hazardous food that is displayed or held for service for immediate consumption:

1. The food shall be marked or otherwise identified to indicate the time that is 4 hours past the point in time when the food is removed from temperature control.

2. The food shall be cooked and served, served if ready-to-eat food, or discarded, within 4 hours from the point in time when the food is removed from temperature control.

3. The food in unmarked containers or packages or marked to exceed a 4 hour limit shall be discarded, and
(4) Written procedures shall be maintained in the food establishment and made available to the regulatory authority upon request, that ensure compliance with:

(a) Subparagraph (A)(1)-(4) of this section, and
(b) § 3-5.01.14 for food that is prepared, cooked, and refrigerated before time is used as a public health control.

(B) In a food establishment that serves a highly susceptible population, time only, rather than time in conjunction with temperature, may not be used as a public health control for raw eggs (pg. 71).

The resident population served in a nursing home is a **highly susceptible population**. Therefore, nursing homes must be diligent in minimizing food temperature abuse.

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**Legal Authority**

The legal authority governing this procedure:

**Federal Long Term Care Regulations, 42CFR483.35(h)(2), F371**

**State Food Hygiene Code, 64E-11**, the Department of Health has legal authority for enforcement of this code.

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**General Procedure**

During the nursing home survey, surveyors are directed to observe food storage, preparation, service and distribution. Surveyors shall take temperatures of hot and cold food during the various phases of processing to determine that potentially hazardous food is maintained at proper temperatures. Potentially hazardous food temperatures should be assessed in the following situations:

- Refrigerated storage
- Freezer storage
- Hot holding
- Cold holding
- Thawing
- Food preparation
- Reheating
- Cooling

See **Attachment A** for the definition of potentially hazardous foods, according to the FDA Food Code.

According to the FDA Food Code, the following items are considered **critical** when there is a failure to maintain proper food temperatures:

- Holding of hot or cold foods
- Cooling
- Cooking raw animal foods
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- Microwave cooking
- Reheating for hot holding
- Using time, rather than temperature as a public health control

Critical items are Food Code violations that are more likely to contribute to food contamination, illness, or environmental degradation and represent substantial public health hazards.
The following are guidelines for temperature control for food processing:

<table>
<thead>
<tr>
<th>Food Processing Step</th>
<th>Safe temperature guidelines</th>
</tr>
</thead>
<tbody>
<tr>
<td>Receiving and storing of frozen potentially hazardous foods</td>
<td>None stated in Food Code, however, frozen food should be stored at 0°F to maintain quality and prevent the growth of spoilage and harmful microorganisms. Look for signs of thawing and refreezing, such as large ice crystals on the surface of the frozen food and frozen liquids or juices inside the package.</td>
</tr>
<tr>
<td>Receiving and storing refrigerated potentially hazardous foods</td>
<td>41°F or less *Note: there are exceptions to this temperature for existing equipment, to allow for 45°F or less. See §3-501.16 (pg. 68) for details.</td>
</tr>
<tr>
<td><strong>Critical item</strong></td>
<td></td>
</tr>
<tr>
<td>Cooking potentially hazardous foods</td>
<td>Ranges from 145°F to 190°F</td>
</tr>
<tr>
<td><strong>Critical item</strong></td>
<td>Raw shell eggs that are broken and prepared in response to a consumer’s order and for immediate service must be cooked to 63°C (145°F) or above for 15 seconds (see the Food Code for further guidance with eggs).</td>
</tr>
<tr>
<td>Cooling potentially hazardous foods</td>
<td>Cooled from 140°F to 70°F within 2 hours, and from 70°F to 41°F in less than an additional 4 hours.</td>
</tr>
<tr>
<td><strong>Critical item</strong></td>
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<tr>
<td>Reheating potentially hazardous foods for hot holding</td>
<td>Rapid reheating to reach 165°F for 15 seconds (applies to food that was previously cooked and then cooled).</td>
</tr>
<tr>
<td><strong>Critical item</strong></td>
<td></td>
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<tr>
<td>Hot-holding potentially hazardous foods</td>
<td>140°F or more.</td>
</tr>
<tr>
<td><strong>Critical item</strong></td>
<td></td>
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<tr>
<td>Cold-holding potentially hazardous foods</td>
<td>41°F or less.</td>
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</tbody>
</table>
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| Thawing potentially hazardous food | • In a refrigerator at 41°F or less.  
|                                  | • In a microwave, and immediately cooked.  
|                                  | • Under cold running water 70°F in 2 hours or less, or  
|                                  | • Part of the conventional cooking process.  
| Food preparation | During food preparation, food should only be in the danger zone between 41°F and 140°F for a maximum of 4 hours. Some foods may be brought up to room temperature for best preparation.  

Getting Ready to Take Food Temperatures

Sanitizing the Thermometer

To measure the temperatures of potentially hazardous foods to determine if they are maintained under proper temperature control:

- The thermometer must be first sanitized and calibrated. Take the temperature of the food with a sanitized calibrated thermometer to determine it is maintained at 41°F or less; or 140°F or more. (See Attachment B for proper thermometer calibration.) The thermometer must be sanitized to avoid contaminating the food being tested. To sanitize the thermometer, wipe off any food, place the stem or probe in a sanitizing solution for at least 5 seconds, then air dry. When monitoring only raw foods, or only cooked foods being held at 140°F, it is acceptable, to wipe the stem of the thermometer with an alcohol swab between measurements. Always clean and sanitize thermometers when testing raw and then ready-to-eat food items.

- The appropriate type of temperature measuring device must be used:
  A bi-metallic, dial stem-type food thermometer may be used. These usually have a temperature range from 0°F to 220°F. There are limitations to the use of this type of thermometer, as discussed further.
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Other types of thermometers may be used, if available.

A digital thermometer or thermistor can also be used, but this type thermometer is not to be immersed in water or liquid (unless it indicates that it is submersible).

Procedures for Taking Food Temperatures

To ensure accurate measurement of the food temperatures, the surveyor must do the following:

- Use an approved temperature measuring device that measures the temperature from 0°F to 220°F. Bi-metallic stem thermometers are not designed to accurately measure the temperature of food less than 2 inches thick; therefore, they are not suitable for taking temperatures of thin meat patties (such as hamburger). The thermistor and the thermocouple do not have these limitations. In addition, the infrared thermometer is intended only for measuring surface temperatures of food products and should not be used to measure and verify critical internal temperatures such as cooking temperatures.

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• Calibrate the thermometer using the ice or boiling point method (for best calibration, both methods should be used; however, the ice method is more accurate, easier, and safer).
• Clean and sanitize the thermometer stem before taking the temperatures.
• Locate the sensing portion of the measuring device. On a bi-metallic stem thermometer, the sensing portion is usually located approximately 1” from the tip. The end of the sensing portion is marked by a “dimple” or small indentation on the stem. Do not use thermometers that have two or more “dimples” on the stem.
• Insert the sensing element of the thermometer into the center of the thickest part of the food.
• Wait until the temperature reading stabilizes.
• The temperature of unopened plastic packaged foods can be taken by placing the stem or probe of the thermometer between two packages or fold the package around the stem or probe to make good contact with the packaging. However, the temperature of a potentially hazardous food itself, rather than the temperature between packages, is necessary to determine regulatory compliance.

After the temperature is taken, and the surveyor finds that the potentially hazardous food is not at the proper temperature, further investigation is required. Interview facility staff to determine:
• What is being done to the food (i.e. preparation, cooling, serving).
• When the food item was removed from temperature control and for how long.
• Where the food was stored before removing it from temperature control.
  o If the food came from a refrigerated unit, look at the thermometer in the unit. It should read 41°F or less. If the thermometer reads greater than 41°F, take the internal temperature of some potentially hazardous foods stored inside the unit, to determine if they are maintained at 41°F. Avoid foods that are in the cooling process and/or have just been put in the refrigerator unit, for this purpose.

Remember that 1 to 2 degrees variance is allowed for accuracy, depending on the scale used, according to the Food Code. In section 4-203.11 (pg. 88), the Food Code states:

(A) Food temperature measuring devices that are scaled only in Celsius or dually scaled in Celsius and Fahrenheit shall be accurate to 1°C in the intended range of use.

(B) Food temperature measuring devices that are scaled only in Fahrenheit shall be accurate to 2°F in the intended range of use. (See Attachment C for additional information on the accuracy of temperature measuring devices.)
Best practice is to use the facility’s thermometers to measure food temperatures. Request the staff to demonstrate his/her usual procedure.

The surveyor may use his/her own thermometer, if the facility does not have a thermometer or their thermometers have been found to be inappropriate or inaccurate.

All observations shall be documented on the appropriate surveyor worksheets.
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<table>
<thead>
<tr>
<th>Cold Food Storage</th>
<th>SPECIFIC GUIDANCE FOR VARIOUS PHASES OF FOOD PROCESSES</th>
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</thead>
<tbody>
<tr>
<td>Refrigerated Storage</td>
<td>The surveyor must check the temperatures of refrigerated units. It is optimal to check the temperatures during times when production is low in the kitchen. The surveyor should look at the thermometers in each refrigerated unit. These measure the ambient air temperature in the unit. Thermometers should read 41°F or less. If the thermometer reads greater than 41°F, take the internal temperature of some potentially hazardous foods stored inside the unit with a sanitized, calibrated thermometer, to determine if they are maintained at 41°F or less. Also, check the internal temperature of the food if the air does not seem cold and the thermometer in the unit is 41°F or less. Avoid taking temperatures of the food that are in the cooling process and/or have just been put in the refrigerator unit for this purpose. Also, if the refrigerator thermometer reads 32 °F or less and the food does not appear to be frozen, take the internal temperature of the food. Ask the staff for temperature records kept (not required) to determine if there have been any previous problems with the refrigerated unit temperatures. Interview staff to determine when the last time the temperature of the unit was checked. Interview the person who checked the temperature last. Ask the staff about their procedure when the refrigerated unit is not maintaining temperature. The facility should take the following actions:</td>
</tr>
<tr>
<td>Critical item</td>
<td>• Call the maintenance staff and/or service representative to determine if the temperature can be lowered immediately.</td>
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<tr>
<td></td>
<td>• If the refrigerated unit cannot be adjusted/repaired immediately, the food must be moved to another refrigerator unit that reliably maintains proper temperature. The surveyor must determine if the food has been subjected to temperature abuse and is safe for consumption. Follow the procedures in the section titled “Determination of Foodborne Illness.”</td>
</tr>
<tr>
<td></td>
<td>*Note: there are exceptions to this temperature for existing equipment, to allow for 45°F or less. See §3-501.16 (pg. 68), for details.</td>
</tr>
<tr>
<td>Frozen storage</td>
<td>The FDA Food Code states that frozen food must be kept frozen, (§3-501.11, pg. 65). It does not provide a specific temperature. However, frozen food should be stored at 0°F or less to maintain quality and prevent the growth of spoilage and harmful microorganisms, especially if stored long term.</td>
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<tr>
<td></td>
<td>Observe the thermometer inside the freezer and record the temperature. Look for signs of thawing and refreezing, such as large ice crystals on the surface of the frozen food and frozen liquids or juices inside the package. Also, touch the frozen food to determine if it is solidly frozen (with clean hands). The March 2003</td>
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<td></td>
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</tbody>
</table>
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temperature of the food should be taken if the following conditions are found:
- There are signs of thawing and refreezing of the food.
- The freezer thermometer reads greater than 32°F but 41°F or less and there are signs of thawing and refreezing of the food.
- The frozen food does not feel solidly frozen.
- The freezer thermometer reads greater than 41°F.

The temperature of the frozen food can be taken by inserting the sensing portion of the thermometer between two packages. Determine if the freezer unit is in a defrost cycle. The interior temperature may rise 10 to 20°F during the defrost cycle, but food thawing should not occur (see Attachment D for further information). If it has been determined that the freezer is not in a defrost cycle, ask the staff for any temperature records kept (not required) to determine if there have been any previous problems with the freezer unit temperatures. Interview staff to determine when the last time the temperature of the unit was checked. Interview the person who checked the temperature last. Ask the staff about their procedure when they discover the freezer unit is not maintaining temperature. The facility staff should take similar actions for correction, as described under the above section about refrigerated storage.

The facility staff should move the food to another freezer unit if there is any doubt about whether the unit can keep the food frozen. They can also use dry ice as temporary method to maintain the temperature or thaw, prepare and serve the food.

If the surveyor suspects that the food has been subjected to temperature abuse and may not be safe for consumption, they must follow the procedures in the section titled “Determination of Foodborne Illness”.

<table>
<thead>
<tr>
<th>Food Holding</th>
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<tbody>
<tr>
<td>Hot Food Holding</td>
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<tr>
<td>Critical item</td>
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</table>

The surveyor should take temperatures of hot food held during meal service. This can be done any time during the tray line service; however, keep in mind that if temperatures are taken near the completion of the tray line service, there may not be enough food left in the steam table pans to take an accurate temperature.

Typically, in nursing homes, hot food is held in a steam table during tray assembly. Using a sanitized, calibrated thermometer, take some temperatures of potentially hazardous food on the steam table. The hot foods should be maintained at 140°F or more at all times. If the temperature of the hot food is discovered to be less than 140°F, determine how long it has been out of proper temperature range. The surveyor must inform the kitchen staff immediately. The surveyor should ask when the last time the temperature was monitored by staff. The staff should be given the opportunity to rapidly reheat the food to bring the temperature up. After the food is reheated, the temperature must be checked again before the food is placed back into the steam table. The surveyor should observe to see if the kitchen staff continue to monitor the
temperatures of the hot food on the steam table through the remainder of the tray line. The surveyor should recheck the temperature about 10-15 minutes after the food that was reheated was returned to the steam table. If the temperature of the same food drops below 140°F again on the steam table, it is likely due to equipment malfunction. Ask the facility staff about the operation and maintenance of the equipment. At that point, the surveyor must determine if the food has been subjected to temperature abuse and is safe for consumption. Follow the procedures in the section titled “Determination of Foodborne Illness”. Additionally, the surveyor should look at concerns regarding retaining nutrient value of the food, as well as the attractiveness and palatability of the food (42CFR483.35(d)(1)(2), F364).

If the surveyor notices hot foods that are not held on a heat source, take the temperature of these foods to determine if they are maintained at 140 °F. If not, follow the guidance provided above.

Cold Food Holding

Critical item

To maintain the proper temperature of cold foods, the food must be held on ice or in refrigerated holding equipment, such as cold counters, and air curtains, during the tray line. If large quantities of cold food are set out at room temperature, it is unlikely the proper temperature can be maintained. Food may be brought out in small quantities at a time during a tray line service, but this practice may be impractical for a large volume tray assembly. The surveyor must check the temperatures of cold foods on the tray line. The cold food must be held at 41 °F or less. Note how the cold food is held on the tray line (i.e. on ice, in a refrigerator unit, or “air curtain”). If the cold food is held in a refrigerated unit, check the thermometer in the unit, if there is a problem with the internal temperature of the cold food. If the surveyor suspects that the food has been subjected to temperature abuse and may not be safe for consumption, they must follow the procedures in the section titled “Determination of Foodborne Illness.”

**Important Point:**

Once the tray is assembled and placed on the cart, the hot food is not expected to be maintained at 140°F or more, and the cold food is not expected to be maintained at 41°F or less, as long as the food is to be delivered promptly. If the tray carts are intended for food holding, then the proper food temperatures must be maintained. When the food is delivered to the resident, hot food is not expected to be 140°F or more, nor cold food at 41°F or less.

**Food Thawing**

If thawing of frozen potentially hazardous food is observed, assess whether proper methods are being used. The following are acceptable thawing methods, according to the Food Code:

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Potentially hazardous food (3-501.13) shall be thawed (pg. 65):
(A) Under refrigeration that maintains the food temperature at 5°C (41°F) or less, or at 7°C (45°F) or less as specified under ¶ 3-501.16(A)(2)(b) of the Food Code; or
(B) Completely submerged food under running water:
   (1) At a water temperature of 21°C (70°F) or below,
   (2) With sufficient water velocity to agitate and float off loose particles in an overflow, and
   (3) For a period of time that does not allow thawed portions of ready-to-eat food to rise above 5°C (41°F), or 7°C (45°F) as specified under ¶ 3-501.16(A)(2)(b), or
   (4) For a period of time that does not allow thawed portions of a raw animal food requiring cooking as specified under ¶ 3-401.11(A) or (B) to be above 5°C (41°F), or 7°C (45°F) as specified under ¶ 3-501.16(A)(2)(b), for more than 4 hours including:
      (a) The time the food is exposed to the running water and the time needed for preparation for cooking, or
      (b) The time it takes under refrigeration to lower the food temperature to 5°C (41°F), or 7°C (45°F) as specified under ¶ 3-501.16(A)(2)(b);
(C) As part of a cooking process if the food that is frozen is:
   (1) Cooked as specified under ¶ 3-401.11(A) or (B) or 3-401.12, or (2) Thawed in a microwave oven and immediately transferred to conventional cooking equipment, with no interruption in the process; or
(D) Using any procedure if a portion of frozen ready-to-eat food is thawed and prepared for immediate service in response to an individual consumer’s order.

If the surveyor suspects proper methods are not being used, the internal temperature of the food should be taken, if possible. The surveyor should also ask how long the food has been thawing.

If the food is thawing under flowing water, the surveyor may take the temperature of the water to ensure it is 70°F or below.
Follow the procedures in the section titled “Determination of Foodborne Illness,” if there is suspicion the food has been subjected to temperature abuse and may not be safe for consumption.

<table>
<thead>
<tr>
<th>Food Preparation</th>
<th>Critical item</th>
</tr>
</thead>
<tbody>
<tr>
<td>The surveyor should observe food preparation methods. If food is left out at room temperature, determine if the food has been subjected to temperature abuse. Follow the guidance on page 5 through 7 for taking the internal food temperatures. Document observations on the appropriate surveyor worksheet.</td>
<td></td>
</tr>
<tr>
<td>- If the food item has been left out at room temperature for more than</td>
<td></td>
</tr>
</tbody>
</table>
four hours, and the internal temperature is not 41°F or less, or not
140°F or more, then the food item has been subjected to temperature
abuse. Follow the procedures in the section titled “Determination of
Foodborne Illness.”

Food must be cooked to the proper internal temperatures. Please refer to the
Food Code for this information. **Pay particular attention to the cooking of
ground beef, poultry and eggs.**

**Important Point:**
A steam table or hot holding equipment is not intended to cook food to
the proper internal temperature or for the rapid reheating of food.

Follow the procedures in the section titled “Determination of Foodborne
Illness,” if there is suspicion the food has been subjected to temperature abuse
and may not be safe for consumption.

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**Cooling**

**Critical item**

Determine proper procedures are being used when food being cooled is observed.

The following are the standards for cooling according to the Food Code:

**3-501.14 Cooling** (pg. 66)

(A) Cooked potentially hazardous food shall be cooled:

1. Within 2 hours from 60°C (140°F) to 21°C (70°F); and
2. Within 6 hours from 60°C (140°F) to 5°C (41°F) or less, or to 7°C
   (45°F) or less as specified under ¶ 3-501.16 (A)(2)(b).

(B) Potentially hazardous food shall be cooled within 4 hours to 5
°C (41°F) or less, or to 7°C (45°F) as specified under & 3-501.16(A)(2)(b) if prepared from
ingredients at ambient temperature, such as reconstituted foods and canned
tuna.

(C) Except as specified in ¶ (D) of this section, a potentially hazardous food
received in compliance with laws allowing a temperature above 5°C (41°F)
during shipment from the supplier as specified in & 3-202.11(B), shall be
cooled within 4 hours to 5°C (41°F) or less, or 7°C (45°F) or less as specified
under & 3-501.16(A)(2)(b).

(D) Raw shell eggs shall be received as specified under ¶ 3-202.11(C) and
immediately placed in refrigerated equipment that maintains an ambient air
temperature of 7°C (45°F) or less.

**3-501.15 Cooling Methods** (pg. 67).

(A) Cooling shall be accomplished in accordance with the time and
temperature criteria specified under ¶ 3-501.14 by using one or more of the
following methods based on the type of food being cooled:

1. Placing the food in shallow pans;
2. Separating the food into smaller or thinner portions;
3. Using rapid cooling equipment;
4. Stirring the food in a container placed in an ice water bath;
5. Using containers that facilitate heat transfer;
(6) Adding ice as an ingredient; or
(7) Other effective methods.

(B) When placed in cooling or cold holding equipment, food containers in which food is being cooled shall be:

(1) Arranged in the equipment to provide maximum heat transfer through the container walls; and
(2) Loosely covered, or uncovered if protected from overhead contamination as specified under Subparagraph 3-305.11(A)(2), during the cooling period to facilitate heat transfer from the surface of the food.

If food is being cooled, the surveyor should take the internal temperature of the food with a sanitized, calibrated thermometer. Interview the staff how the food is being cooled.

Follow the procedures in the section titled “Determination of Foodborne Illness,” if the food has not been cooled properly and may not be safe for consumption.
Determination Of Risk Of Food Borne Illness

If the surveyor determines a *potentially hazardous* food has been subjected to temperature abuse, the facility is out of compliance with F371. The facility is also out of compliance with F371, if food was not properly cooked, cooled, thawed, stored and/or held at proper temperatures. The surveyor must then determine if the food is safe for consumption as follows:

- Take the internal temperature of the food subjected to temperature abuse. Document the temperature on the appropriate surveyor worksheet.
- Interview the facility staff regarding the handling of the food from the time it was received by the facility to the present situation. Document the type of processing (thawing, cooking, cooling, preparation, etc.) and the duration.
- Request copies of policies and procedures regarding food processes/food handling. Review temperature records, if available (not required).
- Request copies of the prior county sanitation inspection reports to detect any previous problems related to improper food temperatures.
- Request copies of menus and/or recipes to verify the preparation and serving of potentially hazardous foods.
- Request staff in-service records to determine whether staff received training on food safety.
- Refer to the 2001 Food Code for guidance on acceptable standards for food handling.
- Determine if the issue is a **critical item** as indicated by the Food Code.
- Consult with the field office dietitians for guidance as necessary.

If the surveyor strongly believes residents would be at risk for acquiring food borne illness from consuming the food item, proceed with the following actions:

- Tell the food manager not to serve the food to anyone. If possible, have another surveyor as a witness. Do not ask them to discard the food in the trash *yet*, but label the food as unsafe and place in a refrigerated unit to hold until the health department arrives. Monitor to make sure that the food is not served to anyone or tampered with. Keep in mind that these actions may disrupt the meal service. If the staff is not cooperative, explain the consequences of their actions.
- Notify the team leader and team members of the situation immediately (if a team exists). Additional evidence gathering and decision-making
may be in order to determine the existence of immediate jeopardy.

- Inform the nursing home administrator of the situation.
- Inform the Field Office Manager or designee immediately.
- Notify the local Health Department immediately and request on-site assistance the same day.
- The Health Department representative may take a sample of the food for analysis and wish to see the evidence before taking further administrative actions.
- The Health Department has the legal authority to confiscate food that is deemed unsafe, and cease operations of the food service establishment.
- AHCA is responsible for ensuring the protection of the residents from foodborne illness. If Health Department representatives do not become involved, or there is no analysis of the food, ensure the food is properly disposed, so residents do not consume it.
- Notify the facility Medical Director.

As these steps are taken, the team must meet to determine if immediate jeopardy exists. The team must refer to Appendix Q for guidance. As part of the investigation the nurse surveyor(s) should review the facility’s infection control program to determine if there have been any recent outbreak of infections, involving symptoms of diarrhea and/or vomiting.

**Hazard Analysis (what is the risk of foodborne illness and how dangerous is the situation?):**

- **Ingredients**
  How likely are the food ingredients to have microbiological hazards (i.e. *Salmonella*) or chemical hazard (aflatoxin)?

- **Intrinsic factors of food**
  - Does the food permit survival or multiplication of pathogens and/or toxin formation before or during preparation?
  - Will the food permit survival or multiplication of pathogens and/or toxin formation during subsequent steps of preparation, storage, or consumer possession?

- **Procedures used for preparation/processing**
  - Is the food still undergoing preparation or is it ready-to-eat?
  - Does the preparation procedure or process include a controllable step that destroys pathogens or their toxins? Consider both vegetative cells and spores.
  - Is the product subject to recontamination between the preparation step (i.e. cooking) and service?

- **Microbial content of the food**
  - Is the food commercially sterile (i.e. a low-acid canned food)?
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- Is it likely that the food will contain viable pathogens?
- What is the normal microbial content of the food stored under proper conditions?
- Does the microbial population change during the time the food is stored before consumption?
- Does that change in microbial population alter the safety of the food?

**Nature of the foodservice production:**
The more complex the preparation and delivery system in foodservice settings, the more food safety issues to consider.
- What type of food processes?
  - Traditional, cook/serve system
  - Cook/chill or cook/freeze system
- What type of menu served, simple vs. select?
- Quantity of meals served?
- Number of staff involved and competency?

**Intended consumer/host susceptibility:**
The survey team should gather information about the intended consumer and the nursing home population at risk for susceptibility to foodborne illness.
The following individuals who have the highest susceptibility to foodborne illness:
- Elders
- Infants
- Young children
- Individuals with suppressed immune systems (such as HIV/AIDS, chemotherapy, long term therapy with glucocorticoids, or other immunosuppressive agents, organ transplants)

For these individuals, the symptoms and duration of the foodborne illness can be serious, even resulting in death.

Individuals with the following conditions or treatments may have an increased risk of foodborne illness:
- Radiation therapy or antimicrobial treatment
- Autoimmune disorders such as Crohn’s disease and lupus
- Cirrhosis or alcoholism
- Diabetes
- Hypochlohydra, as either a primary condition or secondary to use of medications that decrease gastric acid production.
- Undernourished

Pregnant women and their fetuses are a highly susceptible population for contracting listeriosis and toxoplasmosis.

**Manifestation of Clinical Disease**
The clinical manifestation of the foodborne disease must be considered. Foodborne illness caused by some microorganisms is
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acute and fatal, if untreated, while others result in minor gastrointestinal symptoms. The most common types of foodborne illness are bacterial and viral. Parasitic and chemical foodborne illness is less common and will not be addressed here. Additionally, Creutzfeldt-Jacob disease (CJD) or bovine spongiform encephalophy (mad cow disease), which is caused by a prion and is inevitably fatal, will not be addressed here. Although, most pathogens cause acute disease, some have been linked to certain chronic diseases. The following information provides some background on the clinical manifestations of foodborne illness.

- **Bacteria**
  
  *Clostridium botulinum* causes the most serious bacterial foodborne illness. The neurotoxin produced by the bacteria causes the acute illness. *Clostridium botulinum* Toxin is the most deadly biological toxin known to man, as a very small amount can cause death (the LD<sub>50</sub> is 0.001 µg/kg, which is the lethal dose for 50 percent of the population, for substance administered.). *Clostridium botulinum* can be found in improperly canned or fermented foods, vacuum packed refrigerated foods; and cooked foods in an anaerobic mass. To illustrate the seriousness of *C. botulinum*, a 100% fatality rate may result from consumption of a quantity food product contaminated by a small single can of tomato paste containing *C. botulinum*. The prevalence of foodborne illness caused by *C. botulinum* is small compared to other microorganisms, as the annual estimated prevalence in the U.S. is 58 illnesses and 4 deaths (FDA/CFSAN, 2002; Mead et al. 1999).

  *Shigella spp.*, *Clostridium perfringens*, *Staphylococcus aureus enterotoxin*, and *Bacillus cereus* also produce toxins; however, the clinical manifestations are usually less serious than *C. botulinum*. The prevalence of foodborne illnesses from these microorganisms is much greater.

The clinical manifestations of *Escherichia coli O157:H7* can also be serious, particularly in children and the elderly. The bacteria are commonly associated with undercooked ground beef. Hemolytic Uremic Syndrome (HUS) can develop from enterohemorrhagic *E. coli* that can lead to acute kidney failure. The estimated annual prevalence of foodborne illness caused by *E. coli O157:H7* is over 62,000, resulting in 52 deaths (FDA/CFSAN, 2002; Mead et al. 1999).

Although *Listeria monocytogenes* may cause flu-like symptoms in healthy adults, it can cause serious complications in at-risk populations and pregnant women and their fetuses. For the at-risk population, it can lead to septicemia, meningitis, encephalitis, and birth defects. It can cause miscarriage and stillborn babies. *L. monocytogenes* is found in raw milk, dairy foods, raw meats,
refrigerated ready-to-eat foods, raw vegetables, and seafood. The estimated annual prevalence of foodborne illness caused by this microorganism is almost 2,500, resulting in 499 deaths (FDA/CFSAN, 2002; Mead et al. 1999).

*Vibrio vulnificus* is another bacteria that can cause serious consequences in an at-risk population. For individuals with existing liver disease, it can be fatal. *V. vulnificus* causes few cases of illnesses, but many are fatal. It is found in raw or recontaminated oysters, clams and crabs.

Foodborne illness caused by *Campylobacter jejuni* and *Salmonella spp.* is very common. However, the illness is usually limited to the gastrointestinal tract, causing vomiting and diarrhea. Healthy individuals with this type of foodborne illness recover quickly and often do not seek medical attention. Individuals who have existing disease and/or are malnourished may develop serious complications. The food sources of *Campylobacter jejuni* and *Salmonella spp.*, poultry, meats, eggs and milk products are widely consumed in the U.S.

- **Viruses**
  
  Hepatitis A causes the most serious recognized foodborne viral infection in the U.S. This foodborne illness can cause infectious hepatitis, a serious liver disease. The common sources are raw seafood and contaminated water, but ready-to-eat food can be contaminated from human contact. Hepatitis A is less prevalent than other foodborne viruses.

  The Norwalk-like virus (NLV) is most prevalent foodborne viral infection, and is responsible for 66.6% of illnesses attributed to known foodborne pathogens. However, the fatality rate is very small. NLVs account for 33% of hospitalizations among all of the illnesses that are attributable to known foodborne illness pathogens (IFT Report).

- **Contributing factors leading to foodborne illness outbreaks:**

  According to Centers for Disease Control and Prevention (CDC), March 17, 2000 Morbidity and Mortality Weekly Review (MMWR) publication, which featured, “Surveillance for Foodborne Disease Outbreaks --United States, 1993-1997”, the major contributing factor leading to foodborne disease outbreaks was **improper holding temperatures**. The second contributing factor was **inadequate cooking of food**.

  Food temperature abuse is one factor that may result in foodborne illness. The team must review other foodservice practices to determine the seriousness of the risk of food borne illness. The survey team should identify system failures the facility staff could have prevented or corrected immediately to determine the facility’s
culpability.

- **Imminent Health Hazards:**
  According to the section, Imminent Health Hazard. §8-404.11 Ceasing Operations and Reporting (pg. 187), in the Food Code, the following are examples of situations that present as an imminent health hazard, that would cause immediate discontinuation of food service operations:
  
  - An emergency such as a fire, flood, extended interruption of electrical or water service
  - Sewage backup
  - Misuse of poisonous or toxic materials
  - Onset of an apparent foodborne illness outbreak
  - Gross unsanitary occurrence or condition
  - Or other circumstance that may endanger public health

The survey team members must be familiar with the current Food Code standards to determine food borne illness would likely occur should the highly susceptible nursing home resident population consume the food.

**References:**

The 2001 U.S. Public Health Service, Food and Drug Administration, Food Code


Food and Drug Administration website: [http://www.fda.gov/](http://www.fda.gov/)


March 2003

Division of Health Quality Assurance
Field Operations
ATTACHMENT A

Food Code Definition:

Potentially Hazardous Food, pg. 12

(a) "Potentially hazardous food" means a food that is natural or synthetic and that requires temperature control because it is in a form capable of supporting:
   (i) The rapid and progressive growth of infectious or toxigenic microorganisms;
   (ii) The growth and toxin production of Clostridium botulinum; or
   (iii) In raw shell eggs, the growth of Salmonella Enteritidis.

(b) "Potentially hazardous food" includes an animal food (a food of animal origin) that is raw or heat-treated; a food of plant origin that is heat-treated or consists of raw seed sprouts; cut melons; and garlic-in-oil mixtures that are not modified in a way that results in mixtures that do not support growth as specified under Subparagraph (a) of this definition.

(c) "Potentially hazardous food" does not include:
   (i) An air-cooled hard-boiled egg with shell intact, or a shell egg that is not hard-boiled, but has been treated to destroy all viable Salmonellae;
   (ii) A food with an aw value of 0.85 or less;
   (iii) A food with a pH level of 4.6 or below when measured at 24 °C (75 °F);
   (iv) A food, in an unopened hermetically sealed container, that is commercially processed to achieve and maintain commercial sterility under conditions of nonrefrigerated storage and distribution;
   (v) A food for which laboratory evidence demonstrates that the rapid and progressive growth of infectious or toxigenic microorganisms or the growth of S. Enteritidis in eggs or C. botulinum can not occur, such as a food that has an aw and a pH that are above the levels specified under Subparagraphs (c)(ii) and (iii) of this definition and that may contain a preservative, other barrier to the growth of microorganisms, or a combination of barriers that inhibit the growth of microorganisms; or
   (vi) A food that does not support the growth of microorganisms as specified under Subparagraph (a) of this definition even though the food may contain an infectious or toxigenic microorganism or chemical or physical contaminant at a level sufficient to cause illness.

"aw" means water activity, which is a measure of the free moisture in a food, is the quotient of the water vapor pressure of the substance divided by the vapor pressure of pure water at the same temperature, and is indicated by the symbol aw.
ATTACHMENT A

Potentially Hazardous Foods

Examples of possible potentially hazardous foods:

- Red meat
- Poultry
- Fish
- Shellfish
- Soy products, such as Tofu
- Eggs
- Milk and milk products
- Cooked rice and noodles
- Baked and boiled potatoes
- Cooked beans
- Cooked and rehydrated onions
- Raw seed sprouts
- Cut melons
- Garlic and oil mixtures
- Sauces, bread, and pastries containing potentially hazardous foods

These foods may not be potentially hazardous, if have been irradiated, dried or salted.

A water activity meter and/or pH meter can be used to determine if a food’s water activity or pH level meets the criteria defined in the Food Code as food that is not potentially hazardous.
Before taking food temperatures, the thermometer must be calibrated. If the surveyor’s thermometer is used, the calibration should be documented on a worksheet and, if possible, observed by another surveyor. If the facility staff’s thermometer is to be used facility staff or surveyor must calibrate the thermometer.

Interview facility staff regarding calibration methods and ask for a demonstration as appropriate. Thermometers used on a continual basis should be calibrated at least once a day. Calibration is appropriate should the thermometer be dropped, before it is first used, and when going from one temperature extreme to another.

There are two methods for calibrating thermometers: the ice water method and the boiling point method.

The staff must calibrate their thermometers using either method (note to remember: ice point method is more accurate and easier to do).

**Ice Water**

To use the ice water method, fill a large glass with finely crushed ice. Add clean tap water to the top of the ice and stir well. Immerse the food thermometer stem a minimum of 2 inches into the mixture, touching neither the sides nor the bottom of the glass. Make sure that the sensor part of the stem is in contact with the ice (look for an indentation in the thermometer stem). Wait a minimum of 30 seconds before adjusting. (For ease in handling, the stem of the food thermometer can be placed through the clip section of the stem sheath and, holding the sheath horizontally, lowered into the water.) Without removing the stem from the ice, hold the adjusting nut under the head of the thermometer with a suitable tool and turn the head so the pointer reads 32 °F.

If finely crushed ice is not available and ice cubes are used, add clean tap water to about halfway to the ice. Make sure that the sensor part of the probe is in contact with the ice water mixture, to ensure a freezing point environment (32 °F). A freezing point environment is achieved when more ice is added to the mixture and it does not melt. (This may take a few minutes to achieve).
Boiling Water

To use the boiling water method, bring a pot of clean tap water to a full rolling boil. Immerse the stem of a food thermometer in boiling water a minimum of 2 inches and wait at least 30 seconds. (For ease in handling, the stem of the food thermometer can be placed through the clip section of the stem sheath and, holding the sheath horizontally, lowered into the boiling water.) Without removing the stem from the pan, hold the adjusting nut under the head of the food thermometer with a suitable tool and turn the head so the thermometer reads 212 °F.

For true accuracy, distilled water must be used and the atmospheric pressure must be one atmosphere (29.921 inches of mercury). A consumer using tap water in unknown atmospheric conditions would probably not measure water boiling at 212 °F. Most likely, it would boil at least 2 °F, and perhaps as much as 5 °F, lower. Remember water boils at a lower temperature in a high altitude area. Check with the local Cooperative Extension Service or Health Department for the exact temperature of boiling water.
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Even if the food thermometer cannot be calibrated, it should still be checked for accuracy using either method. Any inaccuracies can be taken into consideration when using the food thermometer, or the food thermometer can be replaced. For example, water boils at 212 °F. If the food thermometer reads 214 °F in boiling water, it is reading 2 degrees too high. Therefore, 2 degrees must be subtracted from the temperature displayed when taking a reading in food to find out the true temperature. In another example, for safety, ground beef patties must reach 160 °F. If the thermometer is reading 2 degrees too high, 2 degrees would be added to the desired temperature, meaning hamburger patties must be cooked to 162 °F.
Point to Remember:
The boiling point of water decreases as elevation increases:

<table>
<thead>
<tr>
<th>Altitude (elevation above sea level)</th>
<th>Water Boiling Point</th>
</tr>
</thead>
<tbody>
<tr>
<td>0 (sea level)</td>
<td>212 ° F (100 ° C)</td>
</tr>
<tr>
<td>1000 feet (305 meters)</td>
<td>210 ° F (98.9 ° C)</td>
</tr>
<tr>
<td>2000 feet (610 meters)</td>
<td>208 ° F (97.8 ° C)</td>
</tr>
<tr>
<td>3000 feet (914 meters)</td>
<td>206.4 ° F (96.9 ° C)</td>
</tr>
<tr>
<td>4000 feet (1219 meters)</td>
<td>204.5 ° F (95.8 ° C)</td>
</tr>
<tr>
<td>5000 feet (1524 meters)</td>
<td>202.75 ° F (94.9 ° C)</td>
</tr>
<tr>
<td>8000 feet (2438 meters)</td>
<td>197.5 ° F (91.9 ° C)</td>
</tr>
</tbody>
</table>

Source: Food and Drug Administration
Surveyor Guidance for Taking Food Temperatures in Nursing Homes

ATTACHMENT C

Food Code Standard:

Accuracy of Temperature Measuring Devices, pg. 88

4-203.11 Temperature Measuring Devices, Food
(A) Food temperature measuring device that are scaled only in Celsius or dually scaled in Celsius and Fahrenheit shall be accurate to 1°C in the intended range of use.
(B) Food temperature measuring device that are scaled only in Fahrenheit shall be accurate to 2°F in the intended range of use.

4-203.12 Temperature Measuring Devices, Ambient Air and Water.
(A) Ambient air and water temperature measuring device that are scaled in Celsius or dually scaled in Celsius and Fahrenheit shall be designed to be easily readable and accurate to 1.5°C in the intended range of use.
(B) Ambient air and water temperature measuring device that are scaled only in Fahrenheit shall be accurate to 3°F in the intended range of use.
Information about Freezer Defrost Cycles

Most walk-in freezers have regular defrost cycles. Typically, after the freezer operates for approximately 6 hours, the evaporator coils will be frosted and will require defrost. Electric heaters, controlled by an electric time clock, defrost the evaporator coils. During the freezer defrost cycle, the evaporator fans do not run.

Ordinarily, the walk-in freezer will be programmed at the factory to have four defrost cycles per day, at 4 a.m., 10 a.m., 4 p.m., and 10 p.m. The defrost cycles usually run for 30 minutes. The defrost cycles can be adjusted to accommodate the number of door openings and the ambient climate.

The interior temperature of the walk-in freezer unit may rise 10-20°F during the defrost cycle. However, food should not thaw. After the defrost cycle is complete, the unit will return to proper temperature.

The standard defrosting procedure is described below:
- The timer starts the defrost cycle.
- Liquid line solenoid valve closes, evaporator fans stop, and the defrost heaters start up.
- The compressor stops.
- The heaters warm the coil, melt the frost, and trip the termination thermostat at the set temperature.
- The defrost cycle ends, the liquid line solenoid opens, and the defrost heaters power down.
- The pressure switch closes and the compressor starts the refrigeration cycle.
- The evaporator fans will remain off until the evaporator coil temperature reaches approximately 20°F.
- If the termination thermostat fails to end the defrost cycle, the timer fail-safe is designed to end after 30 minutes.

The defrost cycle should end immediately after all the ice has been cleared from the coil surface to achieve the best defrost. Otherwise, if the cycle runs too long or too short, energy will be wasted, and the frozen food may not be maintained at proper temperatures.

*Remember that defrosting procedures may vary according to the equipment manufacturer; if specific information is needed, request to review the operational instructions of the equipment.*

**Signs of defrost cycle problems:**
- **Ice droplet formation on the ceiling of the walk-in.**
  This may indicate that the defrost cycle is running too long after the ice clears the coils.
- **Ice build-up on the back of the evaporator coil.**
  This may indicated that the defrost cycle is not long enough.

Adjustments to the timer can usually correct these problems. If there is excessive ice build-up, the system may have to be turned off to manually defrost the coil.
Glossary

**Foodborne disease outbreak** - defined as an incident in which two or more people experience a similar illness after eating a common food. Epidemiological analysis confirms the food as the source of illness.

**Food infection** - caused by eating food that contains living disease causing microorganisms (i.e. *Salmonella*).

**Foodborne illness** - a disease caused by the consumption of contaminated food.

**Food intoxication** - caused by eating food that contains a harmful chemical or toxin produced by bacteria or other source. Examples are *Clostridium botulinum* and *Staphylococcus aureus*.

**Food poisoning** - an illness caused by a chemical poison in the food, not caused by a microorganism.

**Microorganism** - bacteria, virus, mold, and other tiny organisms that is too small to be seen without the aid of a microscope. Not all microorganisms in food are harmful and some occur naturally on food products.

**Pathogen** - a disease-causing microorganism. Although bacteria are associated as the main cause of foodborne illness, **viruses, protozoan parasites, marine biotoxins, and mycotoxins** also cause foodborne illness.

**Spoilage microorganisms** - cause food to deteriorate, which may result in taste and odor changes. These microorganisms may not be pathogenic.

**Toxin-mediated infection** - caused by eating a food that contains harmful microorganisms that will produce a toxin once inside the human gut (i.e. *Clostridium perfringens*).