

# Soup Kitchen Food Safety Self-Assessment Guide

NEW YORK STATE DEPARTMENT OF HEALTH  
Division of Nutrition Hunger Prevention and Nutrition Assistance Program

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Name of Agency: \_\_\_\_\_

Review Conducted: \_\_\_\_ / \_\_\_\_ / \_\_\_\_  
Month Day Year

Assessment completion verified during food bank visit or program review:

\_\_\_\_ / \_\_\_\_ / \_\_\_\_  
Month Day Year

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## Section A: Kitchen Practices (Critical)

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### Food Contamination by workers

1. Do soup kitchen workers wash hands, generating lather, as often as needed, to avoid contamination? For example:

Yes  No

- At the start of the workday?

Yes  No

- After using the bathroom?

Yes  No

- After smoking?

Yes  No

- After touching the face, nose or hair?

Yes  No

- In between handling raw and cooked food?



2. Are soup kitchen workers sent home or assigned to non-food contact jobs if they have illnesses, which are transmittable through foods (ex: diarrhea, stomach flu, jaundice, acute respiratory infections, vomiting, colds, etc.)?

Yes  No

3. Are soup kitchen workers sent home or assigned to non-food contact jobs if they have infected burns, cuts or boils?

Yes  No

4. Are plastic gloves worn when touching or preparing ready-to-eat foods?

Yes  No

### Equipment and utensils

\*1. Is food preparation equipment (ex: storage pots, slicers, mixers, cutting boards, knives, etc.) cleaned, rinsed and sanitized after each use to prevent contamination?

Yes  No

2. Are utensils (ex: serving spoons, forks, tongs, etc.) used when handling or serving food?

Yes  No

3. If food is tasted, is a clean spoon used once for each taste?

Yes  No

### Bathrooms

1. Are the bathrooms adequate? For example:

- Are the toilets functioning?

Yes  No

- Is there hot and cold running water for handwashing?

Yes  No

- Is soap provided?

Yes  No

- Are single-use disposable paper hand towels provided?

Yes  No

*\* Note: It can lead to a very serious problem if any equipment is first used with raw foods and then with cooked foods without a thorough cleaning between uses.*

## **Section A: Kitchen Practices (General)**

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### **Hygiene and activity of Food Workers**

1. Are soup kitchen workers wearing clean aprons or outer clothing and hair covered?  Yes  No
2. Do soup kitchen workers remove rings, dangling bracelets wristwatches etc. while preparing or handling food?  Yes  No
3. Is smoking prohibited in the food preparation or serving areas?  Yes  No
4. Does someone taste the food before it is served?  Yes  No
5. Are there adequate handwashing facilities in the food handling area, for example:
  - Hot and cold running water?  Yes  No
  - Soap?  Yes  No
  - Single-use paper hand towels?  Yes  No

### **Cleaning and Washing Equipment and Food Areas**

1. Are the food preparation and serving areas generally clean?  Yes  No
2. Are eating and drinking utensils cleaned, sanitized and stored in a way that will protect them from contamination when not in use?  Yes  No
3. For those kitchens with several seatings during meal service, are the tables wiped off between seatings with a sanitizing solution?  Yes  No
4. Are the floors in the food preparation and serving areas clean and dry?  Yes  No

### **Maintenance of the Facility**

1. There are no signs of insects or rodents in the food preparation, serving or dining areas of the soup kitchen?  Yes  No
2. Are animals prohibited in the soup kitchen?  Yes  No
3. Is trash stored away from the food preparation, serving and dining areas of the soup kitchen?  Yes  No
4. Is there a cleaning/maintenance schedule that clearly lists:
  - What should be cleaned?  Yes  No
  - Recommended procedures for cleaning?  Yes  No
  - How often equipment should be cleaned?  Yes  No
  - Is there a person who verifies these procedures were completed  Yes  No

## **Section B: Refrigerator and Freezer Storage (Critical)**

### **Temperature**

1. Is there a thermometer in each refrigerator and freezer, being used?  Yes  No

*\* If you answered no, please buy or request a thermometer so you can be sure your refrigerator/freezer is holding foods at a safe temperature*

2. For each refrigerator and freezer, check and record the temperature now:

Refrigerator Temperature

Freezer Temperature

*\* Is the refrigerator temperature below 41°F? Is the freezer temperature 0°F or below?  
**If yes, good! If no, throw out the food and contact a repair person.***

*\* Thermometers should be checked at the beginning and end of every day the soup kitchen is open. The refrigerator temperature should stay at or below 41°F and the freezer temperature should stay at or below 0°F. The thermometer should be accurate within 2°F*

3. Are all potentially hazardous foods kept under refrigeration at 41°F?  Yes  No

*\*\* Potentially hazardous foods are extra-sensitive to contamination and need special care when being stored and handled. Germs will more easily grow and multiply in them than in other foods. These foods include:*

- Raw or cooked meats, poultry, fish*
- Eggs and egg mixtures cooked or raw*
- Fresh milk and milk products cooked or uncooked*



**Keep at or below 41°F**

### **Bacteria and food spoilage**

1. Are there any odors in the refrigerators or freezers (which might be a sign of spoiled food or food not covered tightly enough)?  Yes  No

*If yes, have refrigerator cleaned/sanitized as soon as possible*

2. Are raw foods (ex: thawing chicken) stored below ready-to-eat foods so that juices and drippings will not accidentally fall into the other foods?  Yes  No

**\*\*Note:** *To be on the safe side, handle all foods with special care!*

## Section B: Refrigerator and Freezer Storage (General)

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### Cleanliness

1. Do refrigerators and freezers look clean? For example:

- Are they free of mold, debris, food husks, etc?  Yes  No
  - Is the shelving and walls clean?  Yes  No
  - Is the area free of spills?  Yes  No
  - Are there any other problems? If yes, describe the problem: \_\_\_\_\_
- 

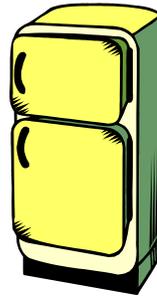
### Air Circulation

1. Is there enough space in refrigerators and freezers so that air circulates around stored food? For example:

- Food stays on shelves when the door is opened (does not tumble out)?  Yes  No
  - Shelving is free of linings that block air circulation (ex: paper towel)?  Yes  No
  - If the unit has a fan, is it working?  Yes  No
  - Are the doors sealed tight  Yes  No
  - Are there any other problems? If yes, describe the problem: \_\_\_\_\_
- 

2. Are open door periods kept to a minimum so that the:

- Temperature in the refrigerator stays at or below 41°F?  Yes  No
- Temperature in the freezer stays at or below 0°F?  Yes  No



***\*Keep door closed so cold air stays inside refrigerator***

### Food Storage

1. Are foods in refrigerators and/or freezers stored on the floor and/or stacked from the floor to the ceiling?

Yes  No

2. How are foods stored in refrigerators and/or freezers? For example:

- In their original containers?  Yes  No
- Wrapped in moisture-proof materials (ex: wax-coated paper, plastic)?  Yes  No
- Stored in clean, sanitized, tightly covered containers?  Yes  No
- Other methods of storing perishable foods? \_\_\_\_\_

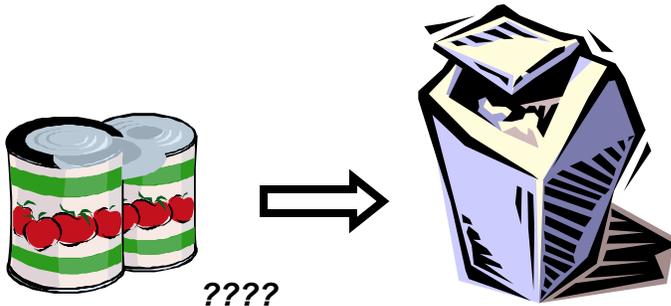
3. Are the containers or wrapping materials holding stored foods labeled and dated so the contents and storage date can be seen?

Yes  No

**Section C: Dry Storage (Critical)**

1. Take a look at all the canned items in the storage area. Record your findings and throw out any:

- |   | <u>Found</u>   | <u>Date Discarded</u> |
|---|--|-----------------------|
| • Cans that bulge, swell, leak or have open seams   | <input type="checkbox"/> Yes <input type="checkbox"/> No | _ _ / _ _ / _ _ _ _   |
| • Cans with rust that cannot be wiped off and/or cans with very sharp dents                         | <input type="checkbox"/> Yes <input type="checkbox"/> No | _ _ / _ _ / _ _ _ _   |
| • Cans with dents on their seams and/or rims, or cans holding foods that are foul-smelling or foamy | <input type="checkbox"/> Yes <input type="checkbox"/> No | _ _ / _ _ / _ _ _ _   |
| • Cans, jars or bottles with popped-up safety seals or loosened lids                                | <input type="checkbox"/> Yes <input type="checkbox"/> No | _ _ / _ _ / _ _ _ _   |



**\*\*When in doubt, throw it out.**

2. Do you have a policy against accepting home-canned goods?  Yes  No

**\*\*Note: Throw out any food that is home canned or appears to be home canned.**

3. Take a look at all the packaged items. Note which items have a single layer of packaging and those which have two layers of packaging (inner bag/outer box).

	<u>Found</u>	<u>Date Discarded</u>
<u>Single layer of packaging:</u> Discard any with breaks, tears or other Openings, if you can see contamination (ex: stains, off-odors), or if there has been a taped repair made before you got it.	<input type="checkbox"/> Yes <input type="checkbox"/> No	_ _ / _ _ / _ _ _ _

<u>Double layer of packaging:</u> Discard if the inner packaging has any Break, tear, other opening, shows sign of contamination or if Inner vacuum packs have lost their seal.	<input type="checkbox"/> Yes <input type="checkbox"/> No	_ _ / _ _ / _ _ _ _
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**\*Note: If any of these packaging problems exist, discard the entire package.**

4. Are all toxic materials (ex: cleaners, degreasers, dish detergent):

- |                                       |  |
|---------------------------------------|--|
| • Stored away from food?              | <input type="checkbox"/> Yes <input type="checkbox"/> No |
| • Clearly labeled?                    | <input type="checkbox"/> Yes <input type="checkbox"/> No |
| • Stored only in original containers? | <input type="checkbox"/> Yes <input type="checkbox"/> No |
| • Used properly?                      | <input type="checkbox"/> Yes <input type="checkbox"/> No |

## Section C: Dry Storage (General)

### Insect/Rodent Control

1. Does an exterminator come to your kitchen on a regular basis?

If yes, how often? \_\_\_\_\_

Yes  No



2. Are actions taken if there are any signs of insects or rodents?  
(ex: insect webbing, tracks, gnawing marks, rodent droppings)

Yes  No

2. Are conditions that are likely to harbor pests corrected when discovered  
(ex: holes in floors, walls, ceiling, screens installed during fly season, etc.)?

Yes  No

4. Are canned goods removed from cartons to shelving as much as possible  
to prevent insect or rodent nesting?

### Stock

1. Do you use a first in, first out system of storage so that older stock is distributed  
before newer stock?

Yes  No

2. Do you use a food inventory sheet or card to keep track of what foods are on  
hand and/or what is needed?

Yes  No

3. Is everything in your dry storage area labeled and dated so the contents and  
storage date can be seen?

Yes  No

**\*\*Note: It is recommended that you date food/cans as they come in and  
unpack it so you know what to use first.**

### Organization

1. Have empty cartons and other trash been removed from the storage area?

Yes  No

2. Are single-service items (ex: disposable plates, forks, spoons etc.) covered, so  
that dust and debris does not settle on them?

Yes  No

3. Is everything stored on shelves, racks or platforms (no food on floor)?

Yes  No

4. Is everything stored away from walls and ceiling (to decrease rodent access  
and allow air circulation)?

Yes  No

5. Are heavy packages stored on lower shelves so that shelving does not tip over?

Yes  No

6. Are bulk foods (ex: sugar, flour, dried beans, etc.) stored:

• In their original containers?

Yes  No

• In tightly covered, clean and sanitized containers?

Yes  No

7. Is the storage room fairly dry and well ventilated?

Yes  No

## Section D: Food Preparation and Cooking (Critical)

1. When preparing foods to be cooked, do you limit the time that potentially hazardous foods remain out of the refrigerator to less than two hours (this includes preparation, service and cleanup)?  Yes  No
  2. Are food thermometers available and used to help guarantee that foods are cooked to adequate internal temperatures?  Yes  No
- \*Note:** Product thermometers should have a range of 0° F to 220° F. If you answered **NO** please buy or request a probe thermometer so you can be sure all foods are cooked to a safe temperature.
3. Before cooking any food, do you check for signs the food may be spoiled (ex: foul smell, off-color, slimy)?  Yes  No
  4. Are potentially hazardous foods reheated in steam tables, warmers, crock-pots or similar hot-holding units? (If yes, **DO NOT**, this equipment will not get food hot fast enough)  Yes  No
  5. The chart below lists the adequate internal temperature of each potentially hazardous food. Record the actual internal temperature in the space next to the food cooked.

Food	Adequate Internal Temperature	Actual Internal Temperature
Fish	145°F	°F
Poultry, stuffing, all chicken products, casseroles	165°F	°F
Pork roasts, pork products, beef steaks	145°F	°F
Ground beef, ground pork, sausage	155°F	°F
Eggs	145°F	°F
Microwave oven	165°F	°F

**\*Note:** Because microwave ovens tend to cook foods unevenly, make several temperature checks to assure that none of the temperatures are below 165°F.

**\*Note:** For meat products, check the temperature at its thickest part.

6. Over the next couple of days, check the temperature of three of your most frequently served potentially hazardous foods, other than those which you checked above, and record in this chart.

Food	Adequate Internal Temperature	Actual Internal Temperature
<i>Ex: baked macaroni and cheese</i>	165°F or above	166°F
1.	165°F or above	°F
2.	165°F or above	°F
3.	165°F or above	°F

**\*\*\*The holding of perishable or potentially hazardous foods between 41° F and 140° F will increase the possibility of food poisoning. This is the food temperature danger zone in which growth of bacteria may cause illness.**

## **Section D: Food Preparation and Cooking (General)**

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1. Are all raw foods thoroughly washed prior to serving/and or cooking?  Yes  No

2. How do you thaw frozen food, for example:

**Recommended:**

- Under refrigeration at temperatures at or below 41°F?  Yes  No
- Under running water at a temperature of 70°F or below for no longer than 2 hours?  Yes  No
- Placed in water-tight plastic bag, covered with cold tap water-changing water every 30 minutes?  Yes  No
- In a microwave oven followed immediately by cooking?  Yes  No
- Does all the food preparation take place on the same day the food is served?  Yes  No

**Not Recommended:**

- Thawing on the counter?  Yes  No
- Any other methods?  Yes  No  
If yes, please describe: \_\_\_\_\_  
\_\_\_\_\_

## Section E: Holding Hot Foods Hot (Critical)

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1. For kitchens using hot-holding or warming equipment (ex: warming racks or cabinets, steam tables, chafing dishes) to keep foods hot, please complete the chart below:

Type of Warming Equipment	Number of Each Type
_____	_____
_____	_____
_____	_____

2. Over the next couple of days, check the temperature of three of your most frequently served hot foods after the food has been in the warming equipment for at least 30 minutes. The food thermometer should be placed in the center of the food.

Hot Foods	Adequate Internal Temperature	Actual Internal Temperature
<i>Ex: rice and beans</i>	140°F or above	142°F
1.	140°F or above	
2.	140°F or above	
3.	140°F or above	

**\*Note: The temperature of the hot food should not fall below 140°F. Check food temperatures at least once an hour.**

3. Is there enough warming equipment to keep hot foods held at 140°F or above?  Yes  No

4. If your kitchen has no hot-holding or warming equipment, how do you keep foods at 140°F or higher? \_\_\_\_\_
- \_\_\_\_\_
- \_\_\_\_\_



**Hold Hot Foods at  
or above 140° F**

## Section E: Holding Cold Foods Cold (Critical)

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**\*\*\*Remember the holding of perishable or potentially hazardous foods between 41°F and 140°F must, at all times, be kept to a minimum because of the possibility of food poisoning. This is the food temperature danger zone in which the growth of bacteria may cause illness.**

1. Use the chart below to record the temperatures of 3 cold foods on the serving line:

Cold Foods	Adequate Temperature	Actual Temperature
<i>Ex: macaroni salad</i>	41°F	38°F
1.	41°F	°F
2.	41°F	°F
3.	41°F	°F

**\*Note:** Check food temperatures at least once an hour to prevent rise above 41°F.

2. Are potentially hazardous foods such as cold macaroni, egg or potato salads prepared using pre-chilled ingredients?  Yes  No
3. Are cold foods (ex: salads, pudding):  Yes  No
- Taken directly from the refrigerator as needed?  Yes  No
  - Being held at temperatures of 41°F or lower during the entire meal service?  Yes  No
  - Never exposed to room temperature for more than one hour without some means to keep these foods at 41°F  Yes  No
  - Other method to keep foods 41°F or lower: \_\_\_\_\_  
\_\_\_\_\_

## Section F: Leftovers (Critical)

1. Are all leftover foods (hot and cold) placed in the refrigerator or freezer within 30 minutes after food service?  Yes  No

2. Which methods do you use to promote the rapid cooling of hot leftover foods?

### Recommended

• Placing in an ice-water bath prior to refrigeration?  Yes  No

• In shallow pans, not exceeding a food fill of 4 inches in refrigerator storage?  Yes  No

*\*Note: Do not cover until 45° F or below.*

• In containers, of pieces no heavier than 5 lbs, in refrigerator storage?  Yes  No

### Not Recommended

• Cooling on the counter?  Yes  No

• Any other methods? Please describe: \_\_\_\_\_

***\*\*\*Note: When placing shallow, covered pans in the refrigerator, the pans should not be stacked on top of one another. When pans are stacked, the cold refrigerator air is not able to circulate between the pans and the food is not cooled rapidly enough. This could lead to food poisoning. Code requires food temperatures are reduced from 140° F to 70° F within 2 hours then to 41° F or lower in additional 4 hours. Total time: 6 hours.***

3. How many days do you keep leftover food in the refrigerator before serving again? \_\_\_\_\_

4. Are the containers or wrapping materials, which hold leftover foods labeled and dated so that the contents and storage date can be seen.  Yes  No

5. How many times do you serve leftover foods from the original batch of leftovers? \_\_\_\_\_

6. Use the chart below to record all leftover food items reheating temperature and reheating time:

Leftover Food Item	Adequate Internal Temperature	Actual Internal Temperature	Maximum Reheating Time	Actual Reheating Time
<i>Ex: beef stew</i>	165°F or >	170°F	120 minutes	70 minutes
1.	165°F or >	°F	120 minutes	
2.	165°F or >	°F	120 minutes	
3.	165°F or >	°F	120 minutes	

7. Are leftover foods that have been cooked and then refrigerated, reheated in steam tables, warmers, crockpots or similar hot-holding units?  Yes  No

***\*\*Remember: This equipment will not get food hot fast enough***

**\*\*If your soup kitchen does not transport meals, skip section G.**

### **Section G: 1. Transporting Foods To Satellite Feeding Sites (Critical)**

1. What kind of food carriers or food carrying chests are you using? \_\_\_\_\_  
\_\_\_\_\_
2. Are the lids or covers for these carriers tight fitting?  Yes  No
3. Are the carriers nearly full at the start of the delivery route?  Yes  No
4. Generally, how long does it take to:
  - Portion and pack one batch of food into the carrier? \_\_\_\_\_
  - Pack all the food carriers before delivery? \_\_\_\_\_
  - Deliver all the meals? \_\_\_\_\_
5. Does the temperatures of potentially hazardous foods get taken at the time of packing and/or time of delivery and recorded at both ends every time this process occurs?  Yes  No

### **Section G: 2. Transporting Foods To Satellite Feeding Sites (Critical)**

1. Check the temperatures of hot main dishes before delivering and after transporting them. Use the following chart to record the actual internal temperature of food being cooked is held at an adequate temperature.

**\*\*\*Important: Food temperatures can drop by as much as 30+ degrees during the**

- **portioning and packing of the foods, and**
- **while transporting foods to the satellite feeding site**

**Make sure the hot foods are very hot prior to packing. Hot food must be 165° F or greater when delivered. Remember, the food will cool down during transit.**

2. Do you use a supplemental heat source for the food in transit?  Yes  No  
Check the box for the type of heat source you use?:
  - *Recommended:* Hot wax-filled bottles or hot wax packs  Yes  No
  - *Not recommended:* Hot water bottles  Yes  No
  - Another method? Please describe: \_\_\_\_\_

**\*\*Note: Because heat rises, be sure that the hot wax packs are placed at the bottom of the food carriers. It is useless to place these packs at the top of the carriers. They will not keep food warm from that position.**

### **Section G: 3. Holding Cold Foods Cold in Transit (Critical)**

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1. Are cold foods refrigerated until packing time?  Yes  No
2. Are food carriers pre-chilled by:
- Holding in walk-in-refrigerator/cooler with the lid off overnight?  Yes  No
  - Any other methods used? Please describe: \_\_\_\_\_
- 
3. Do you use a supplemental cooling source such as frozen ice packs or “blue ice” inside the carrier?  Yes  No

**\*\*Note:** Check the temperatures of cold foods before delivering and after transporting them. Make sure the cold foods are very cold prior to packing. Cold food must be 41 °F or cooler when delivered. Remember, the food will warm up during transit.

**\*\*Note:** Because heat rises, be sure that the ice packs are covering the cold food at the top of the carrier. The ice packs must be placed there because that is the warmest part of the food carrier.



**Keep Ice pack on top of Cold food**

## Section H: Workplan

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<b>THESE MUST BE CORRECTED</b>
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### Critical Food Safety issues

<b>PROBLEM</b>	<b>WORK PLAN</b>
<b>Section A: Kitchen Practices</b>	If yes to the following, discard or reheat to 165°F: - Sick worker is working - Direct hand contact with ready-to-eat food observed - Raw food contaminated other ready-to-eat foods - Equipment/utensils are contaminated  Date problem resolved __ / __ / ____
<b>Section B: Refrigerator/Freezer Storage</b>	Food temperature for potentially hazardous foods: -if more than 41°F for more than 2 hours, discard Food Bank -if more than 70°F discard food immediately  Who will correct the problem? _____  Date problem resolved __ / __ / ____
<b>Section C: Dry Storage</b>	If yes to any can questions in section C: Critical, dispose of cans  Who will correct the problem?  Date problem resolved __ / __ / ____
<b>Section D: Food Preparation And Cooking</b>	Food temperature prior to cooking: -if more than 41°F, for more than 2 hours, discard food - if more than 70°F, discard food immediately  Who will correct the problem?  Date problem resolved __ / __ / ____  <i>**Food Temperature When Cooking, continue cooking until food temperature at thickest part is more than or equal to temperatures on page 8.</i>

## Cont. Section H: Workplan- Critical

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### Section E: Holding Foods

Hot holding food temperature:

- if below 140°F, for **more** than 2 hours, discard
- if below 140°F, for **less** than 2 hours, reheat to 165°F

Cold holding potentially hazardous food:

- if temperature is between 41°F-70°F for **more** than 2 hours, discard
- if **less** than 2 hours, serve or refrigerate
- if temperature is more than 70°F, discard immediately

Who will correct the problem? \_\_\_\_\_

Date problem resolved \_\_ / \_\_ / \_\_\_\_\_

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### Section F: Leftovers

For cooling leftovers, Food Temperature:

- if temperature is 120°F-70°F for more than 2 hours, discard
- if temperature is 70°F- 41°F for more than 4 hours, discard
- if temperature is greater than 41°F after 6 hours, discard

Reheating, Food Temperature:

- if temperature is less than 165°F for **more** than 2 hours, discard
- if **less** than 2 hours, continue reheating

Who will correct the problem? \_\_\_\_\_

Date problem resolved \_\_ / \_\_ / \_\_\_\_\_

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### Section G: Transporting Foods

Hot holding potentially hazardous food in transport:

- if temperature is below 140°F for **more** than 2 hours, discard
- if temperature is below 140°F for **less** than 2 hours, reheat to 165°F and hold at 140°F.

Cold holding potentially hazardous food in transport:

- if temperature is 41°F- 70°F for **more** than 2 hours, discard
- if **less** than 2 hours, serve or refrigerate

Who will correct the problem? \_\_\_\_\_

Date problem resolved \_\_ / \_\_ / \_\_\_\_\_

## Section H: Workplan

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### General Food Safety Issues

#### PROBLEM

#### WORK PLAN

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##### Section A: Kitchen Practices

Can the problem be corrected?  
If no, why not? \_\_\_\_\_

Yes  No

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##### Section B: Refrigerator/Freezer Storage

Can the problem be corrected?  
If no, why not? \_\_\_\_\_

Yes  No

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##### Section C: Dry Storage

Can the problem be corrected?  
If no, why not? \_\_\_\_\_

Yes  No

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##### Section D: Food Preparation And Cooking

Can the problem be corrected?  
If no, why not? \_\_\_\_\_

Yes  No

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**You Are Finished!**

## Contact Information:

Name: \_\_\_\_\_

Phone number: \_\_\_\_\_

E-mail: \_\_\_\_\_

## For Further Information view the following websites:

1. **Food Safety and Inspection Service U.S. Department of Agriculture**
  - <http://www.fsis.usda.gov>
2. **Government food safety information**
  - <http://www.FoodSafety.gov>
3. **U.S. Centers for Disease Control and Prevention (CDC) Food Safety Initiative**
  - <http://www.cdc.gov/foodsafety>
4. **U.S. Food and Drug Administration, Center for Food Safety and Applied Nutrition**
  - <http://www.cfsan.fda.gov>
5. **National Food Safety Programs: Information Network**
  - <http://vm.cfsan.fda.gov/~dms/fs-toc.html>