

ICR ATTACHMENT B

U.S. Food and Drug Administration
Retail Food Program
Foodborne Illness Risk Factor Study

Marking Instructions for the
Data Collection Form

Health Care, School, and
Retail Food Store Facilities

May 8, 2015

**FDA RETAIL FOOD PROGRAM
FOODBORNE ILLNESS RISK FACTOR STUDY
MARKING INSTRUCTIONS FOR THE DATA COLLECTION FORM**

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I. ESTABLISHMENT INFORMATION / DATA

During the 2015-2016 data will be collected within three industry segments as part of the FDA Retail Food Risk Factor Study:

- Health Care (comprised of Hospitals and Long-Term Care Facilities)
- Schools (K-12)
- Retail Food Store (supermarkets / grocery stores that must have a deli department / operation)

Detailed marking instructions will be provided for each of the sections of the data collections form. With a few exceptions, the data collection form and data items are the same for each of the three industry segments.

For the purposes of assessing potential correlation between unique features of each of these three industry segments and control of foodborne illness risk factors, three separate establishment information sections, page one of the data collection forms, have been developed for the data collection. The following describes each of the establishment information pages and provides definitions and guidance for completing the data entry fields.

A. ESTABLISHMENT INFORMATION – HEALTH CARE FACILITIES

ESTABLISHMENT INFORMATION – HEALTH CARE FACILITIES			
Date:		Data Collector:	
Time In:	Time Out:	Total Time in Minutes:	
Establishment Name:			
Street Address:			
City:	State:	Zip:	County:
Institutional Foodservice Facility Type: <input type="checkbox"/> Healthcare – Hospital <input type="checkbox"/> Healthcare – Long-term Care Facility		Risk Categorization (Select <u>ONE</u> of the following): <input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/> 4	
Total Number of Beds:	Current Occupancy:	Average Number of Meals Per Day:	
Maximum Number of Employees Per Shift:		Number of Employees Present at Time of Visit:	
Activity Level at the Time of Visit (Select <u>ONE</u>): <input type="checkbox"/> Light <input type="checkbox"/> Moderate <input type="checkbox"/> Heavy			
HEALTH CARE FOOD SERVICE MANAGEMENT			
Ownership of Establishment (Select <u>ONE</u> of the following): <input type="checkbox"/> Privately-Owned <input type="checkbox"/> Publicly-Owned			
Establishment is Part of a Multi-Unit Operation: <input type="checkbox"/> YES <input type="checkbox"/> NO			
Number of Individual Units that are Part of the Multi-Unit Operation (Enter the number of units provided by the person in charge):			
Foodservice Operation is Directly Managed By (Select ONE of the following): <input type="checkbox"/> Healthcare Establishment Staff <input type="checkbox"/> Foodservice Management Company <input type="checkbox"/> "Other" If "Other" describe:			
INFORMATION ON INSPECTION OVERSIGHT FOR HEALTHCARE FOODSERVICE			
Description of Entity Providing Regulatory or Audit Inspection Oversight: <input type="checkbox"/> State Health Department/Agency <input type="checkbox"/> County/District/City Health Department/Agency <input type="checkbox"/> Other If "Other" describe:			

- **Date:** The date on which the data collection was conducted at the randomly selected healthcare facility.
- **Data Collector:** First and last name of the individual conducting the data collection and completing the data collection form.
- **Time In:** The time the data collection is initiated at the randomly selected facility. Time to prepare for the data collection and travel time to the healthcare facility are not included. Military time is used for this entry. For example if the data collection began at 9:15AM the entry in the time in field would be 0915. Likewise, if the data collection began at 3:30PM the entry in the time in field would be 1530.

- **Time Out:** The time data collection observations are completed and include the time to conduct the exit interview with the person-in-charge. Time to complete the data collection form and enter it into the database, as well as travel time, are **not** included. Military time is used for this entry.
- **Total Time in Minutes:** The total time in minutes needed to conduct the data collection at the healthcare facility. It encompasses the difference between the recorded “Time In” entry and the “Time Out” entry. The database program will automatically calculate total time in minutes based on the data collector’s entries for “Time In” and “Time Out” but this function is dependent on the use of military time.
- **Establishment Name:** Business name of the randomly selected healthcare facility. If the name is different than the one contained in the GIS database used for the selection of establishments for the Study, enter the current name the healthcare facility is doing business under. **NOTE:** Should an establishment name-change be recorded, the data collector is to notify the study coordinator via e-mail of the name change.
- **Street Address:** Common street listing for the selected healthcare facility.
- **City:** City where the selected healthcare facility is located.
- **Zip:** Zip code for the selected healthcare facility.
- **County:** County where the selected healthcare facility is located.
- **Facility Type:** Two facility types comprise the health care segment of the industry: Hospitals and Long-Term Care facilities. The randomly selected facility should have already been categorized as either a Hospital or Long-Term Care facility by the FDA Biostatistics Branch as part of the random selection process. The data collector should, however, verify that the selected healthcare facility has been properly categorized as a Hospital or Long-Term Care facility prior to initiating the visit. The data collector will use the following definitions when confirming the health care facility type.
 - ✓ **Hospital** – A foodservice operation that provides for the nutritional needs of inpatients, by preparing meals and transporting them to the patient’s room and/or serving meals in a cafeteria setting (meals in the cafeteria may also be served to hospital staff and visitors).
 - ✓ **Long-Term Care** – A foodservice operation that prepares meals for the residents in a group care living setting such as nursing homes and assisted living centers.

NOTE: For the purposes of this study, health care facilities that do not prepare or serve food to a highly susceptible population, such as mental health care facilities, are **not** included in this facility type category.

The data collector enters the appropriate health care facility type based on the definitions above.

NOTE: If the FDA Biostatistics Branch mis-categorized the healthcare facility type, the data collection will still be conducted at the selected establishment. The data collector will enter the correct facility type for the establishment. In addition, the data collector will select a substitute establishment as a replacement from the randomly selected healthcare facility substitution list provided by the FDA Biostatistics Branch. When choosing a substitute establishment from the list it must be selected using the order provided by the Biostatistics Branch.

- **Risk Categorization:** The risk categories listed in Annex 5, Table 1 – Risk Categorization of Food Establishments of FDA *Food Code* contain the descriptions used to classify the selected establishments. Since the foodservice operation in both of the healthcare facility types, Hospitals and Long Term Care establishments, serve a highly susceptible population, risk category 4 will always be selected. The data collector should confirm the risk categorization of the healthcare facility when contacting the jurisdiction with regulatory oversight responsibility prior to initiating the data collection

- **Total Number of Beds:** The number entered into this data collection field represents that maximum number of patients for Hospitals or the maximum number of residents for Long-Term Care facilities that can be cared for at any one time. The data collector does not have to physically count the number of available beds but can use the information provided by the person-in-charge.
- **Current Occupancy:** The number entered into this data collection field represents the current number of patients that have been admitted for stay in the Hospital or Long-Term Care facility at the time of the data collection.
- **Average Number of Meals Per Day:** The average number of meals per day is to include the total number served for **ALL** meal periods during the day. The data collector can use the information provided by the person-in-charge. In providing an estimated number of meals per day, the person-in-charge should base the average on a 7-day, Sunday – Saturday meal production schedule or weekly meal production schedule for the admitted patients or residents. If the person in charge is unable to provide an estimate on the average number of meals per day, the data collector is to enter “0” in the data entry field. The “0” entry will denote an “Unsure” response from the person in charge.
- **Maximum Number of Employees Per Shift:** The maximum number of food employees that can be assigned to a designated work shift regardless of their job responsibility. The data collector can use the information provided by the person-in-charge.
- **Number of Employees Present at Time of Visit** – The total number of food employees that are working within the health care facility’s foodservice operation at the time of the data collection regardless of their job responsibility. The data collector can use the information provided by the person-in-charge.
- **Activity level at the time of the visit:** This element is specific to the activity level occurring in the kitchen and other food preparation areas at the time of the data collection. Based on high peak volume periods that occur within the healthcare foodservice operation, the person-in-charge should be asked if the current activity level in the kitchen is light, moderate, or heavy. The data collector checks the appropriate box based on the response provided by the person-in-charge.
- **Ownership of Establishment:** The data collector will determine if the healthcare facility is privately or publicly owned
 - ✓ **Privately Owned** – The health care facility is run by individuals, a management group, or company for profit. Privately owned health care facilities encompass all the for profit businesses that are not owned or operated by the government.
 - ✓ **Publicly Owned** – the health care facility is a state owned entity or government owned business/corporation that undertakes commercial activities on behalf of the government
- **Establishment is part of a Multi-Unit Operation:** The data collector will determine if the healthcare facility is part of a multi-unit operation. The data collector can use the information provided by the person-in-charge to complete this element.
 - ✓ **YES** – Healthcare facility is part of a multi-unit operation.
 - ✓ **NO** – Healthcare is not part of a multi-unit operation.

If the healthcare facility is part of a multi-unit operation, the data collector will complete the following information field:

- **Number of Units that are Part of the Multi-Unit Operation:** Represents the total number of individual health care facilities that comprise the multi-unit operation. The data collector will enter the number of units provided by the person in charge. If the person in charge is unsure or does not know the number of units, enter “0”.
- **Foodservice Operation is Directly Managed by:** The data collector will complete this information field by selecting **ONE** of the following categories and can use the information provided by the person-in-charge for this element.
 - ✓ **Healthcare Establishment Staff** – The management of the foodservice operation is under the direction, and reports directly to, the individuals, management group, or company that owns the healthcare facility.
 - ✓ **Foodservice Management Company** – The management of the foodservice is part of a company that is separately owned and operated from the healthcare facility. The foodservice management company has been contracted by the ownership of the healthcare facility to manage and oversee the day-to-day activities within the foodservice operation.
 - ✓ **Other** – The management of the healthcare’s foodservice operation is different than the definitions provided for “Healthcare Establishment Staff” and “Foodservice Management Company”. If “Other” is selected the data collector must describe the management structure for the health care foodservice operation.
- **Description of Entity Providing Regulator or Audit Inspection Oversight:** The data collector will complete this information field by selecting **ONE** of the following categories to best describe the regulatory or audit inspection oversight for the healthcare foodservice operation. The data collector can use the information provided by the person-in-charge for this element.
 - ✓ **State Health Department/Agency** – The healthcare foodservice operation is under license/permit of a state health department or state agency which conducts periodic inspections to assess compliance with food safety regulatory requirements.
 - ✓ **County/District/City Health Department/Agency** – The healthcare foodservice operation is under license/permit of a county, district, or city health department / agency which conducts periodic inspections to assess compliance with food safety regulatory requirements.
 - ✓ **Other** – Includes healthcare foodservice operations that are licensed or permitted by a government entity that is not considered a State/County/District/City health department or agency. The “Other” marking should be selected for those facilities whose only inspection oversight of the foodservice operation is conducted by privately owned companies who perform third party audits. If “Other” is selected the data collector must describe the regulatory or audit oversight structure for the health care foodservice operation.

B. ESTABLISHMENT INFORMATION – SCHOOLS

ESTABLISHMENT INFORMATION – SCHOOLS			
Date:		Data Collector:	
Time In:	Time Out:	Total Time in Minutes:	
Establishment Name:			
Street Address:			
City:	State:	Zip:	County:
School Type: <input type="checkbox"/> Public <input type="checkbox"/> Private		Charter School: <input type="checkbox"/> YES <input type="checkbox"/> NO	
NSLP Participation: <input type="checkbox"/> YES <input type="checkbox"/> NO			
Start Grade (Select ONE): <input type="checkbox"/> K <input type="checkbox"/> 4 <input type="checkbox"/> 9 <input type="checkbox"/> 1 <input type="checkbox"/> 5 <input type="checkbox"/> 10 <input type="checkbox"/> 2 <input type="checkbox"/> 6 <input type="checkbox"/> 11 <input type="checkbox"/> 3 <input type="checkbox"/> 7 <input type="checkbox"/> 12 <input type="checkbox"/> 4 <input type="checkbox"/> 8		End Grade (Select ONE): <input type="checkbox"/> 1 <input type="checkbox"/> 5 <input type="checkbox"/> 9 <input type="checkbox"/> 2 <input type="checkbox"/> 6 <input type="checkbox"/> 10 <input type="checkbox"/> 3 <input type="checkbox"/> 7 <input type="checkbox"/> 11 <input type="checkbox"/> 4 <input type="checkbox"/> 8 <input type="checkbox"/> 12	
		Type of Operation: (Select ONE):: <input type="checkbox"/> Base Kitchen <input type="checkbox"/> Onsite Kitchen <input type="checkbox"/> Combination Kitchen	
Is the School foodservice operated by a Food Service Management Company? <input type="checkbox"/> YES <input type="checkbox"/> NO		Risk Categorization (Select ONE of the following): <input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/> 4	
Student Enrollment Number:		Average Number of Meals Per Day:	
Maximum Number of Employees Per Shift:		Number of Employees Present at Time of Visit:	
Activity Level at the Time of Visit (Select ONE): <input type="checkbox"/> Light <input type="checkbox"/> Moderate <input type="checkbox"/> Heavy			
INFORMATION ON SCHOOL DISTRICT			
Name of School District where the Establishment is Located:			
Number of Schools that are Part of the School District:			
District Enrollment Number:			
INFORMATION ON INSPECTION OVERSIGHT FOR SCHOOL FOODSERVICE			
Type of Inspection Oversight Conducted for School Foodservice :			
<input type="checkbox"/> State Health Department/Agency <input type="checkbox"/> City/County/District Health Department/Agency <input type="checkbox"/> Other			
If "Other" describe:			

- **Date:** The date on which the data collection was conducted at the randomly selected school.
- **Data Collector:** First and last name of the individual conducting the data collection and completing the data collection form.
- **Time In:** The time the data collection is initiated at the randomly selected facility. Time to prepare for the data collection and travel time to the school are **NOT** included. Military time is used for this entry.

For example if the data collection began at 9:15AM the entry in the time in field would be 0915. Likewise, if the data collection began at 3:30PM the entry in the time in field would be 1530.

- **Time Out:** The time data collection observations are completed and include the time to conduct the exit interview with the person-in-charge. Time to complete the Data Collection Form and enter it into the database, as well as travel time, are **NOT** included. Military time is used for this entry.
- **Total Time in Minutes:** The total time in minutes needed to conduct the data collection at the school foodservice facility. It encompasses the difference between the recorded “Time In” entry and the “Time Out” entry. The database program will automatically calculate total time in minutes based on the data collector’s entries for “Time In” and “Time Out” but this function is dependent on the use of military time.
- **Establishment Name:** Business name of the randomly selected school. If the name is different than the one contained in the GIS database used for the selection of schools for the Study, enter the current name the school is operating under. **NOTE:** Should a school name-change be recorded, the data collector is to notify the study coordinator via e-mail of the name change.
- **Street Address:** Common street listing for the selected school.
- **City:** City where the selected school is located.
- **Zip:** Zip code for the selected school.
- **County:** County where the selected school is located.
- **School Type:** The data collector will determine whether the school facility is a public or private institution using the definitions below.
 - ✓ **Public** – The foodservice operation prepares and serves meals for an elementary or secondary school supported by public funds providing for free education for children of a community or district
 - ✓ **Private** – The foodservice operation prepares and serves meals for an elementary or secondary school that is established, conducted, and primarily supported by a nongovernment agency usually charging students tuition to support educational services.
- **Charter School:** The data collector will determine whether the facility is Charter School institution using the following criteria.
 - ✓ **YES** – The foodservice operation prepares and serves meals for a public funded independent school established by teachers, parents, or community groups under the terms of a charter with a local or national authority.
 - ✓ **NO** – The foodservice operation **does not** prepare or serve meals for a public funded independent school established by teachers, parents, or community groups under the terms of a charter with a local or national authority
- **National School Lunch Program:** The data collector will determine whether the school facility participates in the National School Lunch Program, a federally assisted meal program operating in public and not for profit private schools. The USDA Food and Nutrition Service administer the program at the federal level. At the state level, the National School Lunch Program is usually administered by state education agencies which operate the program through agreements with school food authorities.
 - ✓ **YES** – The foodservice operation prepares and serves meals for an elementary or secondary school participating in the National School Lunch Program.
 - ✓ **NO** – The foodservice operation **does not** prepare or serve meals for an elementary or secondary school participating in the National School Lunch Program.
- **Start Grade:** Indicates the beginning grade level included in the schools educational structure. The data collector will select the beginning grade level for the school, from **K-12**. FDA’s CFSAN Biostatistics

Branch has conducted preliminary research and included the beginning grade level for the randomly selected school on the data collector’s establishment inventory list. The data collector will confirm the beginning grade level during their data collection at the school facility.

NOTE: A few of the randomly selected schools have a beginning grade level of pre-kindergarten. For the purposes of this Study, the data collector will check the “**K**” box for when the beginning grade level is kindergarten or for a pre-kindergarten age group.

- **End Grade:** Indicates the last/oldest grade level included in the schools educational structure. The data collector will select the end grade level for the school, from **1-12**. FDA’s CFSAN Biostatistics Branch has conducted preliminary research and included the end grade level for the randomly selected school on the data collector’s establishment inventory list. The data collector will confirm the end grade level during their data collection at the school facility.

NOTE: For the purposes of this Study, the end grade level must be 1 or higher.

- **Type of Operation:** The data collector will determine whether the type of school foodservice operation using the following criteria.
 - ✓ **Base Kitchen** – A foodservice facility in which all meals are fully prepared in the on-site kitchen. Some meals are served to students on-site; other meals are shipped to other locations (including multiple locations within the same school).
 - ✓ **On-site Kitchen** – A foodservice operation in which **all** meals are prepared and served on-site.
 - ✓ **Combination Kitchen** – A foodservice operation in which some meals are prepared and served on-site, but some meals are fully or partially prepared in a central or base kitchen.

NOTE: for the purposes of this Study, Central Kitchens prepare meals for serving at receiving/satellite schools, but do not serve any student meals on-site at the Central Kitchen are **not** included as part of the Study sample. In addition, restaurants or other retail food operations that provide meals to school facilities are **not** included as part of the Study sample for schools. In addition, receiving or satellite kitchens that obtain partially or fully prepared meals from a base or central kitchen and conduct little or no food preparation are **not** included as part of this Study.

- **Is the School Foodservice Operated by a Food Service Management Company?** – The data collector will select a YES or NO response based on the following criteria:
 - ✓ **YES** - The management of the foodservice is part of a company that is separately owned and operated from the school facility. The foodservice management company has been contracted by the administrators of the school facility to manage and oversee the day-to-day activities within the foodservice operation.
 - ✓ **NO** – The foodservice operation is **not** part of a company that is separately owned and operated from the school facility.
- **Risk Categorization:** The risk categories listed in Annex 5, Table 1 – Risk Categorization of Food Establishments of FDA *Food Code* contain the descriptions used to classify the selected establishments. An establishment must meet one of the descriptions provided for risk categories 2, 3, or 4. The data collector should confirm the risk categorization of the establishment when contacting the jurisdiction with regulatory oversight responsibility prior to initiating the data collection. If the establishment falls into risk category 1; it is not eligible for the Study. The data collector must select a substitute from the school substitution list provided by FDA’s CFSAN Biostatistics Branch.
- **Student Enrollment Number:** Total number of students enrolled in the school where the foodservice operation prepares and serves meals. The data collector can use the information provided by the person-in-charge of the foodservice operations.

- **Average Number of Meals Per Day:** The average number of meals per day is to include the total number served for **ALL** meal periods during the day. The data collector can use the information provided by the person-in-charge. If the person in charge is unable to provide an estimate on the average number of meals per day, the data collector is to enter “0” in the data entry field. The “0” entry will denote an “Unsure” response from the person in charge.
- **Maximum Number of Employees Per Shift:** The maximum number of food employees, including student foodservice volunteers that can be assigned to the school’s foodservice operation regardless of their job responsibility. The data collector can use the information provided by the person-in-charge.
- **Number of Employees Present at Time of Visit** – The total number of food employees, including student foodservice volunteer, that are working in the school’s foodservice operation at the time of the data collection regardless of their job responsibility. The data collector can use the information provided by the person-in-charge.
- **Activity Level at the Time of Visit:** This element is specific to the activity level occurring in the school kitchen and food preparation areas at the time of the data collection. Based on high peak volume periods that occur within the establishment, the person-in-charge should be asked if the current activity level in the kitchen is light, moderate or heavy. The data collector checks the appropriate box based on the response provided by the person-in-charge.
- **Name of School District where the Establishment is Located:** The FDA CFSAN Biostatistics Branch has included the name of the school district for the randomly selected school on each of the data collector’s establishment inventory list. The data collector is to confirm the name of the school district with the person-in-charge of the foodservice operation or school administrator during the data collection.
- **Number of Schools that are Part of the School District:** The FDA CFSAN Biostatistics Branch has included the number of schools in the identified school district for the randomly selected school on each of the data collector’s establishment inventory list. The data collector is to confirm the name of school district with the person-in-charge of the foodservice operation or school administrator during the data collection. If the person-in-charge or school administrator is unsure, the data collector should enter the number of schools provided by the FDA CFSAN Biostatistics Branch on their establishment inventory list.
- **District Enrollment Number:** The FDA CFSAN Biostatistics Branch has included the district student enrollment number randomly selected school on each of the data collector’s establishment inventory list. The data collector is to confirm the school district enrollment number with the person-in-charge of the foodservice operation or school administrator during the data collection. If the person-in-charge or school administrator is unsure, the data collector should enter the district student enrollment number provided by the FDA CFSAN Biostatistics Branch on their establishment inventory list.
- **Type of Inspection Oversight Conducted for School Foodservice:** The data collector will complete this information field by selecting **ONE** of the following categories to best describe the regulatory or audit inspection oversight for the school foodservice operation. The data collector can use the information provided by the person-in-charge or school administrator for this element.
 - ✓ **State Health Department/Agency** – The school foodservice operation is under license/permit of a state health department or state agency which conducts periodic inspections to assess compliance with food safety regulatory requirements.
 - ✓ **County/District/City Health Department/Agency** – The school foodservice operation is under license/permit of a county, district, or city health department / agency which conducts periodic inspections to assess compliance with food safety regulatory requirements.

- ✓ **Other** – Includes school foodservice operations that are licensed or permitted by a government entity that is not considered a State/County/District/City health department or agency. The “Other” marking should be selected for those facilities whose only inspection oversight of the foodservice operation is conducted by privately owned companies who perform third party audits. If “Other” is selected the data collector must describe the regulatory or audit oversight structure for the school foodservice operation.

C. ESTABLISHMENT INFORMATION – RETAIL FOOD STORES

ESTABLISHMENT INFORMATION – RETAIL FOOD STORES			
Date:		Data Collector:	
Time In:	Time Out:	Total Time in Minutes:	
Establishment Name:			
Street Address:			
City:	State:	Zip:	County:
Facility Type (Select <u>ONE</u> of the following): Retail Food Store Department / Operation		Risk Categorization (Select <u>ONE</u> of the following):	
<input type="checkbox"/> Deli <input type="checkbox"/> Seafood <input type="checkbox"/> Produce		<input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/> 4	
Establishment is Part of a Multi-Unit Operation: <input type="checkbox"/> YES <input type="checkbox"/> NO			
Number of Individual Units that are Part of the Multi-Unit Operation (Enter the number of units provided by the person in charge):			
Ownership of Establishment (Select <u>ONE</u> of the following):			
<input type="checkbox"/> Company-Owned <input type="checkbox"/> Franchise <input type="checkbox"/> Unsure			
If Franchise – Number of Units Owned by the Franchisee (Enter the number of units provided by the person in charge):			
INFORMATION FOR THE RETAIL FOOD STORE DEPARTMENT / OPERATION			
Maximum Number of Employees Per Shift:		Number of Employees Present at Time of Visit:	
Activity Level at the Time of Visit (Select <u>ONE</u>): <input type="checkbox"/> Light <input type="checkbox"/> Moderate <input type="checkbox"/> Heavy			

- **Date:** The date on which the data collection was conducted at the randomly selected retail food store.
- **Data Collector:** First and last name of the individual conducting the data collection and completing the data collection form.
- **Time In:** The time the data collection is initiated at the randomly selected facility. Time to prepare for the data collection and travel time to the retail food store are **not** included. Military time is used for this entry. For example if the data collection began at 9:15AM the entry in the time in field would be 0915. Likewise, if the data collection began at 3:30PM the entry in the time in field would be 1530.
- **Time Out:** The time data collection observations are completed and include the time to conduct the exit interview with the person-in-charge. Time to complete the data collection form and enter it into the database, as well as travel time, are **not** included. Military time is used for this entry.
- **Total Time in Minutes:** The total time in minutes needed to conduct the data collection at the retail food store. It encompasses the difference between the recorded “Time In” entry and the “Time Out” entry. The database program will automatically calculate total time in minutes based on the data collector’s entries for “Time In” and “Time Out” but this function is dependent on the use of military time.
- **Establishment Name:** Business name of the randomly selected retail food store. If the name is different than the one contained in the GIS database used for the selection of retail food stores for the Study, enter the current name the retail food store is doing business under. **NOTE:** Should a retail food store name-change be recorded, the data collector is to notify the study coordinator via e-mail of the name change.

- **Street Address:** Common street listing for the selected retail food store.
- **City:** City where the selected retail food store is located.
- **Zip:** Zip code for the selected retail food store.
- **County:** County where the selected retail food store is located.
- **Facility Type:** Three departments/operations comprise the retail food store segment of the industry: Deli Departments/Operations; Seafood Departments/Operations; and Produce Departments/Operations. The randomly selected retail food store must have a deli department/operation. If the selected retail food store has a seafood department/operation or a produce department/operation, the data collector will also conduct a data collection for these areas. Each of the retail food store departments/operations described below will be entered as separate data collection into the Study database. The data collector will use the following definitions when entering data for each of the three retail food store departments/operations.

- ✓ **Deli** – Areas in a retail food store where foods, such as luncheon meats and cheeses, are sliced for the customers and where sandwiches and salads are prepared on-site or received from a commissary in bulk containers, portioned, and displayed. Parts of the deli department/operation may include:
 - Salad bars, pizza stations, and other food bars managed by the deli department manager.
 - Areas where meat and poultry products are cooked and offered for sale as ready-to-eat and are managed by the deli department manager.
- ✓ **Seafood** – Areas in a retail food store where seafood is cut, prepared, stored, **or** displayed for sale to the consumer. In retail food stores where the seafood department is combined with another department (e.g. meat), the data collector will only assess the procedures and practices associated with the processing of seafood.

NOTE: In-store sushi bars operated and managed as part of the retail food store business are considered part of the seafood department / operation for the purposes of this Study. If the in-store sushi bar/operation is under the management and operated by a separate business from the retail food store it, is **not** to be included as part of the data collection.

- ✓ **Produce** – Areas in a retail food store where produce is cut, prepared, stored, or displayed for sale to the consumer. A produce operation may include salad bars or juice stations that are operated under the same manager who has responsibility for the produce department.

NOTE: Convenience stores are **not** included as part of the Study sample

- **Risk Categorization:** The risk categories listed in Annex 5, Table 1 – Risk Categorization of Food Establishments of FDA *Food Code* contain the descriptions used to classify the selected retail food store departments / operations. A retail food store department / operation must meet one of the descriptions provided for risk categories 2, 3, or 4. The data collector should confirm the risk categorization of the establishment when contacting the jurisdiction with regulatory oversight responsibility prior to initiating the data collection. If the deli department / operation falls into risk category 1; it is not eligible for the Study. The data collector must select a substitute from the retail food store substitution listed provided by FDA’s CFSAN Biostatistics Branch.
- **Establishment is part of a Multi-Unit Operation:** The data collector will determine if the retail food store is part of a multi-unit operation. The data collector can use the information provided by the person-in-charge to complete this element.
 - ✓ **YES** – Retail food store is part of a multi-unit operation

- ✓ **NO** – Retail food store is not part of a multi-unit operation.

If the retail food store is part of a multi-unit operation, the data collector will complete the following three information fields:

- **Number of Individual Units that are Part of the Multi-Unit Operation:** Represents the total number of individual retail food stores that comprise the multi-unit operation. The total number of retail food stores includes both company owned and franchise units. The data collector will enter the number of units provided by the person in charge. If the person in charge is unsure or does not know the number of units, enter “0”.
- **Ownership of Establishment:** The data collector will complete this information field by selecting **ONE** of the following categories and can use the information provided by the person-in-charge for this element.
 - ✓ **Company Owned** – The retail food store is part of multi-unit operation that is a legally incorporated business association (brand), or owned by an individual or group of individuals. The incorporated business or individual owns the facility and is responsible for its day-to-day operations.
 - ✓ **Franchise** – The retail food store is part of a multi-unit operation that is a legally incorporated business (brand). The corporation has granted ownership privileges to an individual who is responsible for the day-to-day operations of the facility. The owner is responsible for operating the facility in accordance with business specifications outlined by the corporation.
 - ✓ **Unsure** – The person-in-charge is not the owner of the retail food store and is unable to confirm whether the unit is company owned or a franchise.
- **IF Franchise – number of units owned by franchisee:** Represents the total number of retail food stores that are owned by the individual or group of individuals responsible for the day-to-day operations of the facility. Retail food stores that are part of the multi-unit operation but company owned or associated with another franchisee are **not** included in this element because they would not be under the direct control of the franchisee whose establishment has been selected for the Study. The data collector will enter the number of units provided by the person in charge. If the person in charge is unsure or does not know the number of units, enter “0”.
- **Maximum Number of Employees Per Shift:** The maximum number of food employees that can be assigned to a designated retail food store department / operation work shift regardless of their job responsibility. The data collector can use the information provided by the person-in-charge.
- **Number of Employees Present at Time of Visit** – The total number of food employees that are working in the retail food store department / operation at the time of the data collection regardless of their job responsibility. The data collector can use the information provided by the person-in-charge.
- **Activity level at the time of the visit:** This element is specific to the activity level occurring in the retail food store department / operation at the time of the data collection. Based on high peak volume periods that occur within the retail food store department / operation, the person-in-charge should be asked if the current activity level in the kitchen is light, moderate or heavy. The data collector checks the appropriate box based on the response provided by the person-in-charge.

II. INFORMATION ON THE REGULATORY AUTHORITY

INFORMATION ON THE REGULATORY AUTHORITY
Name of Jurisdiction with Regulatory Oversight:
Enrolled in FDA Retail Food Program Standards: <input type="checkbox"/> YES <input type="checkbox"/> NO
Jurisdiction Meets Standard 1 (<i>Select <u>ONE</u> of the following</i>):
<input type="checkbox"/> YES – Self Reported
<input type="checkbox"/> YES – Verified by Audit
<input type="checkbox"/> NO – Jurisdiction does not meet Standard 1

➤ **Name of the Jurisdiction with Regulatory Authority:** The name of the agency that has issued the license / permit to the selected establishment and conducts periodic inspections to assess compliance with applicable food safety regulatory requirements. In situations where one regulatory agency has statutory responsibility for the oversight of the establishment but contracts inspections out to a separate regulatory authority, the data collector is to enter the name of the regulatory jurisdiction whose Food Code or ordinance is being applied as the standard for assessment of that establishment’s operation.

- **Enrolled in FDA Retail Food Program Standards:** The data collector will select either **YES or NO** using the following criteria:
- ✓ **YES** – FDA is in receipt of a Program Standards *National Registry Report* and *Permission to Publish* confirming the jurisdiction’s enrollment.
 - ✓ **NO** – FDA is **not** in receipt of a Program Standards *National Registry Report* and *Permission to Publish* that confirms the jurisdiction’s enrollment.

NOTE – If FDA is **not** in receipt of a Program Standards National Registry Report and Permission to Publish that confirms the jurisdiction’s enrollment, the data collector does not complete the **Jurisdiction Meets Standard 1** section of the data collection form.

- **Jurisdiction Meets Standard 1:** The data collector will select **one** of the following responses based on the criteria provided below:
- ✓ **YES - Self-Reported** – FDA is in receipt of a Program Standards *National Registry Report* and *Permission to Publish* confirming that the jurisdiction has self-reported meeting Standard 1. A Program Standard verification audit has **not** been conducted to confirm the self-assessment findings
 - ✓ **YES - Verified by Audit** – FDA is in receipt of a Program Standards *National Registry Report* and *Permission to Publish* confirming that the jurisdiction has had a Program Standards verification audit confirming that it meets Standard 1.
 - ✓ **NO** – The jurisdiction has **not** reported meeting Standard 1

➤ **Dates of the Two Most Recent Regulatory Routine Inspections:**

Dates of the Two Most Recent Regulatory Routine Inspections: Date 1:	Date 2:
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A routine inspection is a standard inspection conducted at pre-determined regular intervals set by the regulatory authority. A routine inspection is **not** a re-inspection, compliance follow-up inspection, complaint inspection, outbreak investigation, risk assessment review, process review, or a variance review. The data collector will enter the dates of the two most recent inspections using the following criteria:

- ✓ **Date 1:** Represents the date of the most recent routine inspection conducted prior to the data collection.

NOTE – FDA prefers that regulatory authorities not conduct routine inspection during data collections, but if one is conducted it is **not** to be entered as the most recent inspection. The regulatory authority’s most recent inspection must occur prior to the data collection visit.

- ✓ **Date 2:** Represents the date of the second most recent inspection conducted prior to the data collection.

NOTE – The data collector may have a randomly selected establishment that has not been in business long enough to have had two routine inspections conducted. If less than two inspections have been conducted at the facility, enter “NA” in the appropriate date field. If only one routine inspection has been conducted enter it as the most recent inspection and enter “NA” in the **Date 2** field.

➤ **Jurisdiction Uses a Grading System:**

<p>Jurisdiction Uses a Grading System (Select <u>ONE</u> of the following):</p> <p><input type="checkbox"/> YES – Numerical Score</p> <p><input type="checkbox"/> YES – Letter Grade</p> <p><input type="checkbox"/> YES – Color Graphic</p> <p><input type="checkbox"/> YES – Numerical Score and Letter Grade</p> <p><input type="checkbox"/> YES – Numerical Score and Color Graphic</p> <p><input type="checkbox"/> YES – Letter Grade and Color Graphic</p> <p><input type="checkbox"/> YES – Numerical Score, Letter Grade, and Color Graphic</p> <p><input type="checkbox"/> YES – Other</p> <p><input type="checkbox"/> NO – Jurisdiction does not have a grading system</p> <p>If “Other” describe:</p>

The data collector will determine whether or not the jurisdiction incorporates a grading system as part of its retail food inspection program. If the jurisdiction uses a grading system, the data collector will identify which of the following types of systems the jurisdiction has in place. Some jurisdiction may implement a combination of these grading systems:

- ✓ **Letter Grade:** The jurisdiction’s grading system is based on the use of alphabetical letters, (For example: A, B, C), that define levels of food safety compliance with regulatory standards
- ✓ **Numerical Score:** The jurisdiction’s grading system is based on a numerical value that correlates to a specific level of food safety compliance with regulatory standards

- ✓ **Color Graphic:** The jurisdiction’s grading system is based on a color system, for example – green, yellow, red, that define levels of food safety compliance with regulatory standards
- ✓ **Other:** The jurisdiction uses a different grading system than described above. **NOTE:** If the “**Other**” response is selected the data collector **must** describe the grading system in the data entry field – **If “Other” describe.**

From the information received by the jurisdiction, the data collector will select the response from the following list of options that most accurately describes the jurisdiction’s use of a grading system. Only one response selection is to be made.

- ✓ **YES** – Numerical Score
- ✓ **YES** – Letter Grade
- ✓ **YES** – Color Graphic
- ✓ **YES** – Numerical Score and Letter Grade
- ✓ **YES** – Numerical Score and Color Graphic
- ✓ **YES** – Letter Grade and Color Graphic
- ✓ **YES** – Numerical Score, Letter Grade, and Color Graphic
- ✓ **YES** – Other
- ✓ **NO** – Jurisdiction does not have a grading system

NOTE: If the “**Other**” response is selected the data collector **must** describe the type of grading system used by the jurisdiction with regulatory authority in the data entry field – **IF “Other” describe.**

➤ **Jurisdiction’s program includes public reporting of inspection results**

<p>Jurisdiction’s Program Includes Public Reporting of Inspection Results (Select <u>ONE</u> of the following):</p> <p><input type="checkbox"/> YES – Posting on-site</p> <p><input type="checkbox"/> YES – Posting on the Internet</p> <p><input type="checkbox"/> YES – Posting on-site and Posting on the Internet</p> <p><input type="checkbox"/> YES – Other</p> <p><input type="checkbox"/> NO – Jurisdiction does not require inspections to be publically reported</p>
<p>If “Other” describe:</p>

This information field describes the method the jurisdiction uses to communicate inspection results to the public. Some jurisdictions may implement a combination of these reporting systems:

- ✓ **Posting on site:** Inspection reports or grading system status is required by the regulatory authority to be posted within the establishment.
- ✓ **Posting on the Internet:** Inspection reports or grading system status is made available via posting on a dedicated internet web site by the regulatory authority.
- ✓ **Other:** The regulatory authority uses an alternative method besides requiring the establishment to post inspection results on-site or posting to the internet.

NOTE – This element does **not** require the data collector to determine the establishment’s compliance with the regulatory authority’s requirement for reporting inspection results.

From the information received by the jurisdiction, the data collector will select the response from the following list of options that most accurately describes the jurisdiction’s system for publically reporting inspection results. Only **one** response selection is to be made.

- ✓ **YES** – Posting on-site
- ✓ **YES** – Posting on the Internet
- ✓ **YES** – Posting on-site and Posting on the Internet
- ✓ **YES** – Other
- ✓ **NO** – Jurisdiction does not require inspection results to be reported (Other than through the Freedom of Information Act).

NOTE: If the “**Other**” response is selected the data collector **must** describe the type of grading system used by the jurisdiction with regulatory authority in the data entry field – **IF “Other” describe.**

➤ ***Jurisdiction Has a Mandatory Food Protection Manager Certification Requirement***

<p>Jurisdiction Has a Mandatory Food Protection Manager Certification Requirement (Select ONE of the following):</p> <p><input type="checkbox"/> YES – Based <u>ONLY</u> on successful completion of an ANSI Accredited Program</p> <p><input type="checkbox"/> YES – Other Food Protection Manager Certification Program (not an ANSI-Accredited Program)</p> <p><input type="checkbox"/> YES – Other <u>AND</u> Reciprocal Acceptance of an ANSI Accredited Program</p> <p><input type="checkbox"/> NO – Jurisdiction does not have a mandatory Food Protection Manager Certification Requirement</p> <p>If “Other” describe:</p>
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This data field provides information as to whether the regulatory authority has a Food Protection Manager Certification requirement included as part of their regulatory foundation. Regulatory foundation includes any statute, regulation, rule, ordinance, or other prevailing set of regulatory requirements that governs the operation of a health care, school, or retail food establishment. The jurisdiction’s mandatory requirement may contain language specific to one or more of the following types of food protection manager certification programs:

- ✓ **YES – Based ONLY on successful completion of an ANSI Accredited Program** – The jurisdiction’s regulatory foundation includes a Food Protection Manager Certification requirement that is based **solely** on successful completion of an examination administered by an ANSI accredited food protection manager certification program.
- ✓ **YES – Other Food Protection Manager Certification (not an ANSI Accredited Program)** – The jurisdiction’s regulatory foundation does include a Food Protection Manager Certification requirement that is based on certification program that is **not** ANSI accredited. In many cases, these are food protection manager certification programs that have been developed and administered by State, local, or tribal regulatory authorities. These may also include State developed food protection manager certification programs that are required by local agencies as part of the regulatory foundation. The jurisdiction does **not** accept successful completion of an ANSI Accredited food protection manager certification program as meeting the intent of their mandatory requirement.
- ✓ **YES – Other AND Reciprocal Acceptance of an ANSI Accredited Program** – The jurisdiction’s regulatory foundation does include a Food Protection Manager Certification requirement that is based on

certification program that is **not** ANSI accredited. In many cases, these are food protection manager certification programs that have been developed and administered by State, local, or tribal regulatory authorities. These may also include State developed food protection manager certification programs that are required by local agencies as part of the regulatory foundation. The jurisdiction does, however, **accept** successful completion of an ANSI Accredited food protection manager certification program as meeting the intent of their mandatory requirement.

- ✓ **NO – Jurisdiction does not have a mandatory food protection manager certification requirement –**
The jurisdiction’s regulatory foundation does not include a mandatory food protection manager certification requirement.

From the information received by the jurisdiction, the data collector will select the response from the following list of options that most accurately describes the jurisdiction’s regulatory requirement for food protection manager certification. Only **one** response selection is to be made.

- ✓ **YES – Based ONLY on successful completion of an ANSI Accredited Program**
- ✓ **YES – Other Food Protection Manager Certification (not an ANSI Accredited Program)**
- ✓ **YES – Other AND Reciprocal Acceptance of an ANSI Accredited Program**
- ✓ **NO – Jurisdiction does not have a mandatory food protection manager certification requirement**

➤ **Food Protection Manager Certification Program Elements**

If “Other” (Select **ONE** of the following)

Other includes a required Training Component

Other includes a Test other than exams offered through an ANSI Accredited Programs

Other includes a required Training Component **AND** Test other than exam offered through an ANSI Accredited Program

If the data collector selects a response that contains “Other” indicating that the jurisdiction’s regulatory foundation includes a Food Protection Manager Certification requirement that is based on certification program that is **not** ANSI accredited, they are to complete this data collection field to describe the elements of the program. The data collector will select **one** of the following responses that best describes the elements that comprise the jurisdiction’s food protection manager certification program.

- ✓ **Other includes a required Training Component –** The jurisdiction’s regulatory foundation requires the Food Protection Manager Certification Program to incorporate a training component. **NOTE:** This information field does **not** attempt to quantify the delivery method for the training, such as web-based vs. classroom, nor does it attempt to determine the required number of training hours. In many cases, the training component will be a requirement the jurisdiction has implemented as a pre-requisite for taking the food protection manager certification examination offered through an ANSI accredited program or one developed by the regulatory authority.
- ✓ **Other includes a Test other than exams offered through an ANSI Accredited Program –** The jurisdiction’s regulatory foundation requires the Food Protection Manager Certification Program to incorporate a test component. The required test is one developed by the regulatory authority or some other entity that is **not** an ANSI accredited program. **NOTE:** This information field does **not** attempt to determine whether the test was developed or administered in accordance with sound psychometric best practices.

- ✓ **Other includes a required Training Component AND Test other than exam offered through an ANSI-Accredited Program** – The regulatory authority administers a certification program that has a required training component and test other than an exam offered through an ANSI Accredited Program. If the regulatory authority accepts certification from ANSI-Accredited programs but also administers their own program or accepts others, the data collector is to mark this information field **YES** and select the “**Other**” option to describe the combination of certification processes recognized by the regulatory authority.
- ✓ **Other** – The data collector must select this option when the regulatory authority recognizes a certification program that is **not** ANSI-accredited. If the “**Other**” response is selected the data collector **must** describe the type of Food Protection Manager Certification programs recognized by the regulatory authority in the data entry field provided – **If “Other” describe.**

From the information received by the jurisdiction, the data collector will select the response from the following list of options that most accurately describes the program elements that comprise the jurisdiction’s regulatory requirement for food protection manager certification. Only **one** response selection is to be made.

- ✓ **YES – Based ONLY on successful completion of an ANSI Accredited Program**
- ✓ **YES – Other Food Protection Manager Certification (not an ANSI Accredited Program)**
- ✓ **YES – Other AND Reciprocal Acceptance of an ANSI Accredited Program**
- ✓ **NO – Jurisdiction does not have a mandatory food protection manager certification requirement**

➤ **Scope of Food Protection Manager Certification Requirement**

<p>Scope of Food Protection Manager Certification Requirement (Select ONE of the following):</p> <p><input type="checkbox"/> Person in Charge – One Per Establishment</p> <p><input type="checkbox"/> Person in Charge – Present at All Times</p> <p><input type="checkbox"/> Supervisory Employee – One Per Establishment</p> <p><input type="checkbox"/> Supervisory Employee – Present at All Times</p> <p><input type="checkbox"/> Other</p>
<p>If “Other” describe:</p>

The data collector will confirm with the regulatory authority, who within the food establishment must obtain a Food Protection Manager Certification based on the language contained in the jurisdiction’s regulatory foundation. The data collector will select **one** of the following responses that best describes the scope of the jurisdiction’s food protection manager certification requirement:

- ✓ **Person-in-Charge – One Per Establishment** – The person in charge is an employee that has supervisory and management responsibility and the authority to direct and control food preparation and service. The jurisdiction’s regulatory language requires the person in charge to obtain Food Protection Manager Certification. **NOTE:** The data collector simply has to determine if the language in the jurisdiction’s regulatory foundation incorporates the term “Person-in-Charge” and is specific to having one per establishment. The data collector does **not** have to determine whether the definition of “Person-in-Charge” is consistent with the 2013 *Food Code*.
- ✓ **Person-in-Charge – Present at All Times** – An employee that has supervisory and management responsibility and the authority to direct and control food preparation and service is required to obtain Food Protection Manager Certification. **NOTE:** The data collector determines if the language in the jurisdiction’s regulatory foundation incorporates the term “Person-in-Charge” and is specific to having a person in charge who is a certified food protection manager present at all time of operation.

- ✓ **Supervisory Employee – One Per Establishment** – The data collector determines if the language in the jurisdiction’s regulatory foundation is consistent with Section 2-102.12, Certified Food Protection Manager, **to require that at least one food establishment employee with management and supervisory responsibility be a Certified Food Protection Manager (CFPM)**. **NOTE:** The data collector determines whether the regulatory language is consistent with Section 2-102.12 of the 2013 *Food Code*.
- ✓ **Supervisory Employee – Present at all Times** – The data collector determines if the language in the jurisdiction’s regulatory foundation is consistent with Section 2-102.12 Certified Food Protection Manager of the 2013 *Food Code*. In addition, the regulatory jurisdiction requires that a certified food protection manager be present during all times of operation.
- ✓ **Other** – The scope of the jurisdiction Food Protection Manager Certification requirement is different from the four response options provided above. **NOTE:** If the “**Other**” response is selected the data collector **must** describe the scope of the Food Protection Manager Certification regulation in the data entry field – **IF “Other” describe.**

From the information received by the jurisdiction, the data collector will select the response from the following list of options that most accurately describes the scope of the jurisdiction’s regulatory requirement for food protection manager certification. Only **one** response selection is to be made.

- ✓ **Person in Charge – One Per Establishment**
- ✓ **Person in Charge – Present at All Times**
- ✓ **Supervisory Employee – One Per Establishment**
- ✓ **Supervisory Employee – Present at All Time**
- ✓ **Other**

➤ **Jurisdiction Requires Food Handler Card:**

Jurisdiction Requires Food Handler Card (Select **ONE** of the following):

- YES – Required Training**
- YES – Required Test**
- YES – Required Training and Test**
- YES – Other**
- NO – Jurisdiction does NOT require Food Handler Cards**

If “Other” describe:

This data field provides information as to whether the regulatory authority requires food workers to obtain food handler cards that are usually based on successful completion of some type of training / testing requirement. This information field represents the regulatory authority’s requirement for food employees. The Food Handler Card is **not** Food Protection Manager Certification. A Food Handler Card represents a level of food safety knowledge for non-managers who prepare or serve food. The jurisdiction’s mandatory food handler card requirement may contain language specific to one or more of the following types of programs:

- ✓ **YES - Required Training** – Food employees must attend classroom or web-based training that addresses food safety principles and procedures. The training can be conducted by the regulatory authority or their designated agent. Passing an examination or test **is not** required for obtaining the Food Handler Card.

NOTE: This element makes **no** attempt to evaluate the curriculum or assess length of the classroom training required by the regulatory authority. However, if the jurisdiction simply distributes a booklet to food handlers to read prior to taking a test, this is **not** to be considered a training program.

- ✓ **YES – Required Test** – Food employees must successfully complete an examination or test administered by the regulatory authority or their designated agent. Participation in a training course is **not** a prerequisite for obtaining the Food Handler Card. **NOTE:** This element makes **no** attempt to evaluate the knowledge domains covered in the exam or the test development process used by the regulatory authority.
- ✓ **YES - Required Training and Test** – Food employees must attend classroom or web-based training that addresses food safety principles and procedures. The training can be conducted by the regulatory authority or their designated agent. Passing an examination or test **is** a requirement for obtaining the Food Handler Card.
- ✓ **Other** – The regulatory authority requires food handler cards based on an alternative approach to training and/or testing or a combination of both. **NOTE:** If the “Other” response is selected the data collector **must** describe the Food Handler Card program in the data entry field – **If “Other” describe**
- ✓ **NO – Jurisdiction does NOT require Food Handler Cards** – The data collector will select this response when the jurisdiction’s regulatory foundation does **NOT** include a requirement for food workers to obtain food handler cards.

NOTE: The data collector does **not** have to verify the establishment’s compliance with the regulatory authority’s Food Handler Card requirement.

From the information received by the jurisdiction, the data collector will select the response from the following list of options that most accurately describes the jurisdiction’s food handler card requirement. Only **one** response selection is to be made.

- ✓ **YES – Required Training**
- ✓ **YES – Required Test**
- ✓ **YES – Required Training and Test**
- ✓ **YES - Other**
- ✓ **NO – Jurisdiction does NOT require Food Handler Cards**

III. MANAGER CERTIFICATION

This section will review the marking instructions for the data collection to assess the status of manager certification for an establishment. Though the manager certification data collection fields for healthcare facilities, and schools are exactly the same, the approach for retail food stores is slightly different. Part A of this section will focus on the manager certification data collection for health care and school facilities. Part B will provide an overview of the manager certification data collection for retail food stores.

A. Manager Certification – Healthcare Facilities and Schools

➤ **1. Is there a certified food protection manager EMPLOYED at the establishment?**

MANAGER CERTIFICATION
<p>1. Is there a certified food protection manager <u>EMPLOYED</u> at the establishment (Select <u>ONE</u>)?</p> <p><input type="checkbox"/> YES – Certificate Available</p> <p><input type="checkbox"/> YES – Certificate <u>NOT</u> Available</p> <p><input type="checkbox"/> NO – No certified food protection managers are employed at the establishment</p> <p>If the marking above contains a “YES” response, indicate the Type of Certification below (Select <u>ONE</u>)</p> <p><input type="checkbox"/> ANSI-Accredited</p> <p><input type="checkbox"/> Other</p> <p><input type="checkbox"/> Unsure</p>

The data collector will determine whether a certified food protection manager is employed at the establishment. The employee that is a certified food protection manager does **not** have to be present at the time of the data collection. The data collector will select **one** of the following three responses that best reflects the information obtain during the data collection:

- ✓ **YES Certificate Available** – indicates that a certified food protection manager is employed by the selected establishment. The certified food protection manager may or may not be present at the establishment during the data collection. There must be a copy of a current certificate from the certification program provider on site during the data collection to mark this option.
- ✓ **YES Certificate NOT Available** – indicates that a certified food protection manager is employed at the selected establishment. The certified food protection manager may or may not be present at the establishment during the data collection. A current certificate from the certification program provider is **NOT** available on site during the data collection to verify the YES response.
- ✓ **NO** – The person-in-charge indicates that there are **no** certified food protection managers or is uncertain as to whether a certified food protection manager is employed at the food establishment. **NOTE:** The data collector is to mark this option if the certificate / certification for the identified employee has exceeded the expiration date for renewal.

If the data collector selects a response that contains “YES” indicating that a certified food protection manager is employed at the selected establishment, information is to be obtained as to the food protection manager certification organization that issued the certificate. This information may be obtained from the certificate or be based on verbal information provided during the data collection. The data collector will select **one** of the

following responses that best describes the food protection manager certification organization that issued the certificate:

- ✓ **ANSI-Accredited** – The data collector will select this option if the certificate provided is from a food protection manager certification organization that is accredited by the American National Standards Institute (ANSI). At the start of the 2015-2016 data collection, the following four food protection manager certification program had received ANSI accreditation:
 - 360 Training
 - Environmental Health Testing, LLC (National Registry of Food Safety Professionals)
 - National Restaurant Association (ServSafe Food Protection Manager Certification Program)
 - Prometric, Inc.
- ✓ **Other** – The data collector will select this option if the certificate provided is from a food protection manager certification organization that is **not** accredited by the American National Standards Institute. This may occur when a State or local regulatory agency administers its own food protection manager certification program and issues a certificate upon the candidate’s successful completion of the program.
- ✓ **Unsure** – The data collector will select this option if information is obtained that a certified food protection manager is employed at the establishment but no certificate is available **and** the person in charge or food employee is unsure which food protection manager certification program they attended.

➤ **2. Is there an employee who is a certified food protection manager PRESENT during the data collection?**

<p>2. Is there an employee who is a certified food protection manager <u>PRESENT</u> during the data collection (Select <u>ONE</u>)?</p> <p><input type="checkbox"/> YES – Certificate Available</p> <p><input type="checkbox"/> YES – Certificate <u>NOT</u> Available</p> <p><input type="checkbox"/> NO – No certified food protection managers are present during the data collection</p> <p>If the marking above contains a “YES” response, indicate the Type of Certification below (Select <u>ONE</u>)</p> <p><input type="checkbox"/> ANSI-Accredited</p> <p><input type="checkbox"/> Other</p> <p><input type="checkbox"/> Unsure</p>
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The data collector will determine whether a certified food protection manager is present at the establishment during the data collection. **NOTE:** The certified food protection manager can be any employee that is present during the data collection and does **not** have to be the person in charge. The data collector will select **one** of the following three responses that best reflects the information obtain during the data collection:

- ✓ **YES Certificate Available** – indicates that a certified food protection manager is present at the establishment during the data collection. There must be a copy of a current certificate from the certification program provider on site during the data collection.
- ✓ **YES Certificate NOT Available** – indicates that a certified food protection manager is present at the selected establishment during the data collection. A current certificate from the certification program provider is **not** available on site during the data collection to verify the YES response.
- ✓ **NO** – A certified food protection manager is **not** present at the establishment during the data collection. **NOTE:** The data collector is to mark this option if the certificate / certification for the individual present at the time of the data collection has exceeded the expiration date for renewal.

If the data collector selects a response that contains “YES” indicating that a certified food protection manager is present at the selected establishment during the data collection, information is to be obtained as to the food protection manager certification organization that issued the certificate. This information may be obtained from the certificate OR be based on verbal information provided during the data collection. The data collector will select **one** of the following responses that best describes the food protection manager certification organization that issued the certificate:

- ✓ **ANSI-Accredited** – The data collector will select this option if the certificate provided is from a food protection manager certification organization that is accredited by the American National Standards Institute. At the start of the 2015-2016 data collection, the following four food protection manager certification programs have received ANSI accreditation:
 - 360 Training.com, Inc.,
 - National Registry of Food Safety Professionals
 - National Restaurant Association
 - Prometric, Inc.
- ✓ **Other** – The data collector will select this option if the certificate provided is from a food protection manager certification organization that is **not** accredited by the American National Standards Institute. This may occur when a State or local regulatory agency administers its own food protection manager certification program and issues a certificate upon the candidate’s successful completion of the program.
- ✓ **Unsure** – The data collector will select this option if information is obtained that a certified food protection manager is employed at the establishment but no certificate is available **and** the person in charge or food employee is unsure which food protection manager certification program they attended.

➤ **3. Is the PERSON IN CHARGE at the time of the data collection a certified food protection manager?**

3. Is the PERSON IN CHARGE at the time of the data collection a certified food protection manager (Select ONE)?

YES – Certificate Available

YES – Certificate **NOT** Available

NO – The person in charge at the time of the data collection is **NOT** a certified food protection manager

If the marking above contains a “YES” response, indicate the Type of Certification below (Select ONE)

ANSI-Accredited

Other

Unsure

The data collector will determine whether the person in charge at the time of the data collection is a certified food protection manager. **NOTE:** The person in charge means the individual present at the food establishment who is responsible for the operation at the time of the data collection. The data collector will select **ONE** of the following three responses that best reflects the information obtain during the data collection:

- ✓ **YES Certificate Available** – indicates that the person in charge at the time of the data collection is a certified food protection manager. There must be a copy of a current certificate from the certification program provider on site during the data collection.
- ✓ **YES Certificate NOT Available** – indicates that the person in charge at the time of the data collection is a certified food protection manager. A current certificate from the certification program provider is **not** available on site during the data collection to verify the YES response.

- ✓ **NO** – The person in charge at the time of the data collection is **not** a certified food protection manager. **NOTE:** The data collector is to mark this option if the certificate / certification for the person in charge has exceeded the expiration date for renewal.

If the data collector selects a response that contains “YES” indicating that the person in charge at the time of the data collection is a certified food protection manager, information is to be obtained as to the food protection manager certification organization that issued the certificate. This information may be obtained from the certificate OR be based on verbal information provided during the data collection. The data collector will select **one** of the following responses that best describes the food protection manager certification organization that issued the certificate:

- ✓ **ANSI-Accredited** – The data collector will select this option if the certificate provided is from a food protection manager certification organization that is accredited by the American National Standards Institute. At the start of the 2015-2016 data collection, the following four food protection manager certification programs had received ANSI accreditation:
 - 360 Training.com, Inc.,
 - National Registry of Food Safety Professionals
 - National Restaurant Association
 - Prometric, Inc.
- ✓ **Other** – The data collector will select this option if the certificate provided is from a food protection manager certification organization that is **not** accredited by the American National Standards Institute. This may occur when a State or local regulatory agency administers its own food protection manager certification program and issues a certificate upon the candidate’s successful completion of the program.
- ✓ **Unsure** – The data collector will select this option if information is obtained that a certified food protection manager is employed at the establishment but no certificate is available **and** the person in charge or food employee is unsure which food protection manager certification program they attended.

➤ **4. Is the policy within the establishment to have a certified manager present at all times?**

4. Is the establishment’s policy to have a certified food protection manager present at all times?	<input type="checkbox"/> YES	<input type="checkbox"/> NO
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The data collector will select either **YES** or **NO** using the following criteria:

- ✓ **YES** – indicates that the selected establishment has a policy that requires a certified food protection manager to be present at all times. **NOTE:** This is the establishment’s policy and is **not** to be confused with the regulatory jurisdiction’s requirement. The policy does **not** have to be written. The data collector can use the information provided by the person in charge to complete this element.
- ✓ **NO** – indicates that the selected establishment does **not** have a policy that requires a certified food protection manager to be present at all times.

B. Manager Certification – Retail Food Stores

The manager certification data collection for retail food stores is conducted slightly different than for the other facility types. The retail food store data collection form contains two additional questions that attempt to distinguish between certification of a store level manager and certification of a manager assigned to one of the departments /operations (deli, seafood, or produce) within the retail food store.

Manager Certification – Store Level Manager

The first two questions in the manager certification section for retail food stores focuses on the **store level manager**.

MANAGER CERTIFICATION – STORE LEVEL MANAGER
<p>1. Is the <u>PERSON IN CHARGE</u> of the retail food store at the time of the data collection a certified food protection manager (Select <u>ONE</u>)?</p> <p><input type="checkbox"/> YES – Certificate Available</p> <p><input type="checkbox"/> YES – Certificate <u>NOT</u> Available</p> <p><input type="checkbox"/> NO – The person in charge at the time of the data collection is <u>NOT</u> a certified food protection manager</p> <p>If the marking above contains a “YES” response, indicate the Type of Certification below (Select <u>ONE</u>)</p> <p><input type="checkbox"/> ANSI-Accredited</p> <p><input type="checkbox"/> Other</p> <p><input type="checkbox"/> Unsure</p>
<p>2. Is the <u>PERSON IN CHARGE</u> of the retail food store the same as the <u>PERSON IN CHARGE</u> of the department / operation where the data collection was conducted?</p> <p><input type="checkbox"/> YES</p> <p><input type="checkbox"/> NO</p>

➤ ***1. Is the PERSON IN CHARGE of the retail food store at the time of the data collection a certified food protection manager?***

The data collector will determine whether the person in charge of the retail food store operation at the time of the data collection is a certified food protection manager. **NOTE:** For this question, the person in charge means the individual present who is a store level manager responsible for the retail store operation at the time of the data collection. The data collector will select **one** of the following three responses that best reflects the information obtain during the data collection:

- ✓ ***YES Certificate Available*** – indicates that the person in charge at the time of the data collection who is responsible for the operation of the retail food store is a certified food protection manager. There must be a copy of a current certificate from the certification program provider on site during the data collection.
- ✓ ***YES Certificate NOT Available*** – indicates that the person in charge at the time of the data collection who is responsible for the operation of the retail food store is a certified food protection. A current certificate from the certification program provider is **not** available on site during the data collection to verify the YES response.

- ✓ **NO** – The person in charge at the time of the data collection who is responsible for the operation of the retail food store is **not** a certified food protection manager. **NOTE:** The data collector is to mark this option if the certificate / certification for the person in charge has exceeded the expiration date for renewal.

If the data collector selects a response that contains “YES” indicating that the person in charge at the time of the data collection who is responsible for the operation of the retail food store is a certified food protection manager, information is to be obtained as to the food protection manager certification organization that issued the certificate. This information may be obtained from the certificate OR be based on verbal information provided during the data collection. The data collector will select **one** of the following responses that best describes the food protection manager certification organization that issued the certificate:

- ✓ **ANSI-Accredited** – The data collector will select this option if the certificate provided is from a food protection manager certification organization that is accredited by the American National Standards Institute. At the start of the 2015-2016 data collection, the following four food protection manager certification programs had received ANSI accreditation:
 - 360 Training.com, Inc.,
 - National Registry of Food Safety Professionals
 - National Restaurant Association
 - Prometric, Inc.
- ✓ **Other** – The data collector will select this option if the certificate provided is from a food protection manager certification organization that is **not** accredited by the American National Standards Institute. This may occur when a State or local regulatory agency administers its own food protection manager certification program and issues a certificate upon the candidate’s successful completion of the program.
- ✓ **Unsure** – The data collector will select this option if information is obtained that a certified food protection manager is employed at the establishment but no certificate is available **and** the person in charge or food employee is unsure which food protection manager certification program they attended.

➤ **2. Is the PERSON IN CHARGE of the retail food store the same as the PERSON IN CHARGE of the department / operation where the data collection was conducted?**

- ✓ **YES** – indicates that the person in charge at the time of the data collection who is responsible for the operation of the retail food store is also the person in charge of the department / operation (deli; seafood; or produce) where the data collection is conducted.
- ✓ **NO** – indicates that the person in charge of the department / operation (deli, seafood, or produce) selected for the data collection is a different person than the individual who is the person in charge of the retail food store operation.

Manager Certification for the Retail Food Store Department / Operation

The marking instructions for the four questions pertaining to assessing manager certification within the selected retail food store department / operation (deli; seafood; or produce) are the same as those provided on pages 22-25 for the health care, and school facility types. For the four questions listed under the header, “Manager Certification for the Retail Food Store Department / Operation”, the data collector should view the selected department / operation (deli; seafood; or produce) as a stand-alone establishment.

MANAGER CERTIFICATION FOR THE RETAIL FOOD STORE DEPARTMENT / OPERATION
<p>1. Is there a certified food protection manager <u>EMPLOYED</u> at the department / operation (Select <u>ONE</u>)?</p> <p><input type="checkbox"/> YES – Certificate Available</p> <p><input type="checkbox"/> YES – Certificate <u>NOT</u> Available</p> <p><input type="checkbox"/> NO – No certified food protection managers are employed at the establishment</p> <p>If the marking above contains a “YES” response, indicate the Type of Certification below (Select <u>ONE</u>)</p> <p><input type="checkbox"/> ANSI-Accredited</p> <p><input type="checkbox"/> Other</p> <p><input type="checkbox"/> Unsure</p>
<p>2. Is there an employee who is a certified food protection manager <u>PRESENT</u> at the department / operation during the data collection (Select <u>ONE</u>)?</p> <p><input type="checkbox"/> YES – Certificate Available</p> <p><input type="checkbox"/> YES – Certificate <u>NOT</u> Available</p> <p><input type="checkbox"/> NO – No certified food protection managers are present during the data collection</p> <p>If the marking above contains a “YES” response, indicate the Type of Certification below (Select <u>ONE</u>)</p> <p><input type="checkbox"/> ANSI-Accredited</p> <p><input type="checkbox"/> Other</p> <p><input type="checkbox"/> Unsure</p>
<p>3. Is the <u>PERSON IN CHARGE</u> at the time of the data collection of the department / operation a certified food protection manager (Select <u>ONE</u>)?</p> <p><input type="checkbox"/> YES – Certificate Available</p> <p><input type="checkbox"/> YES – Certificate <u>NOT</u> Available</p> <p><input type="checkbox"/> NO – The person in charge at the time of the data collection is <u>NOT</u> a certified food protection manager</p> <p>If the marking above contains a “YES” response, indicate the Type of Certification below (Select <u>ONE</u>)</p> <p><input type="checkbox"/> ANSI-Accredited</p> <p><input type="checkbox"/> Other</p> <p><input type="checkbox"/> Unsure</p>
<p>4. Is the department’s / operation’s policy to have a certified food protection manager present at all times?</p> <p><input type="checkbox"/> YES <input type="checkbox"/> NO</p>
<p>If “Other” for one or more of the responses to questions 1 – 3, describe:</p>

IV. EMPLOYEE HEALTH POLICY

- **1. Food employees exhibiting certain illness symptoms or conditions that require exclusion or restriction in the Food Code ARE OBSERVED within the establishment during the data collection.**

EMPLOYEE HEALTH POLICY
<p>1. Food employees exhibiting certain illness symptoms or conditions that require exclusion or restriction in the Food Code, ARE OBSERVED within the establishment during the data collection.</p> <p><input type="checkbox"/> YES – Employees exhibiting illness symptoms or conditions observed within the establishment</p> <p><input type="checkbox"/> NO – Employees exhibiting illness symptoms or conditions NOT observed within the establishment</p>

The data collector will select either **YES or NO** using the following criteria:

- ✓ **YES** – During the data collection, observations indicate the presence of food employees that have illness symptoms or conditions requiring exclusion or restriction as described in Chapter 2 of the *Food Code*.
- ✓ **NO** – During the data collection, observations indicate there are **NO** food employees present that have illness symptoms or conditions requiring exclusion or restriction as described in Chapter 2 of the *Food Code*.

- **2. Are food employees and conditional employees informed of their responsibility to report to the person in charge illness symptoms as specified in Section 201.11 of the Food Code?**

<p>2. Are food employees and conditional employees informed of their responsibility to report to the person in charge illness SYMPTOMS as specified in Section 2-201.11 of the Food Code?</p> <p><input type="checkbox"/> YES – Policy is ORAL and based on the current version of the <i>FDA Food Code</i></p> <p><input type="checkbox"/> YES – Policy is WRITTEN and based on the current versions of the <i>FDA Food Code</i></p> <p><input type="checkbox"/> NO – Policy only partially developed or non-existent</p>

The data collector will determine whether an employee health policy is in place that addresses the responsibility of food employees to report illness symptoms to the person in charge. The data collector will select **ONE** of the following responses that best describes the establishment’s employee health policy as it relates to food employees reporting illness symptoms.

- ✓ **YES – Policy is ORAL and based on the current version of the FDA Food Code** – The data collector will select this option if the food establishment has an employee health policy based on the current version of the *FDA Food Code* that covers the responsibility of food employees to report illness symptoms to the person in charge and the policy is primarily communicated verbally with little or no written documentation. The person in charge satisfactorily demonstrates during the data collection, that all food employees and conditional employees are informed of their responsibility to report to management information about their health and activities as they relate to illness symptoms including vomiting, diarrhea, jaundice, sore throat with fever or lesion containing pus or infected wound that is open and draining (unprotected), as specified in Subparagraph 2-201.11(A)(1) of the *Food Code*. In lieu of written documentation, the data collector is to randomly select **ONE** food employee (other than the person in charge) and confirm whether management has provided information as to their responsibility to report illness symptoms to the person in charge.
- ✓ **YES – Policy is WRITTEN and based on the current version of the FDA Food Code** – The data collector will select this option if the food establishment has an employee health policy based on the

current version of the FDA *Food Code* that covers the responsibility of food employees to report illness symptoms to the person in charge and the policy is primarily in written form. The person in charge provides documentation or otherwise satisfactorily demonstrates during the data collection, that all food employees and conditional employees are informed of their responsibility to report to management information about their health and activities as they relate to illness symptoms including vomiting, diarrhea, jaundice, sore throat with fever or lesion containing pus or infected wound that is open and draining (unprotected), as specified in Subparagraph 2-201.11(A)(1) of the *Food Code*. Satisfactory compliance may be demonstrated by management when documentation indicates that all food employees are required to complete and sign Form 1-B contained in FDA’s *Employee Health and Hygiene Handbook*; **OR** there is a documented training program based on all the information contained in Form 1-B; **OR** the establishment uses a combination of training, signs, pocket cards, or other methods to convey the information in Form 1-B.

- ✓ **NO – Policy only partially developed or non-existent** – The person-in-charge does **NOT** provide documentation or otherwise satisfactorily demonstrate that all food employees and conditional employees are informed of their responsibility to report to management information about their health and activities as they relate to illness symptoms as specified in Subparagraph 2-201.11(A)(1) of the *Food Code*, **OR** the selected food employee is **NOT** able to confirm that management has provided information as to their responsibility to report illness symptoms to the person in charge.

➤ **3. Are food employees and conditional employees informed of their responsibility to report to the person in charge diagnosis with, or exposure to, the specific ILLNESSES specified in Section 201.11 of the *Food Code*?**

3. Are food employees and conditional employees informed of their responsibility to report to the person in charge diagnosis with, or exposure to, the specific ILLNESSES specified in Section 2-201.11 of the *Food Code*?

YES – Policy is **ORAL** and based on the current version of the *FDA Food Code*

YES – Policy is **WRITTEN** and based on the current version of the *FDA Food Code*

NO – Policy only partially developed or non-existent

The data collector will determine whether an employee health policy is in place that addresses the responsibility of food employees to report diagnosis with, or exposure to, specific illnesses specified in Section 2-201.11 of the *Food Code* to the person in charge. The data collector will select **ONE** of the following responses that best describes the establishment’s employee health policy as it relates to diagnosis with, or exposure to, the specific illnesses.

- ✓ **YES – Policy is ORAL and based on the current version of the FDA Food Code** – The data collector will select this option if the food establishment has an employee health policy based on the current version of the *FDA Food Code* that covers the responsibility of food employees to report diagnosis with, or exposure to, the specific illnesses specified in Section 2-201.11 of the *Food Code* to the person in charge and the policy is primarily communicated verbally with little or no written documentation. The person in charge satisfactorily demonstrates during the data collection, that all food employees and conditional employees are informed of their responsibility to report to management information about their health and activities as they relate to diagnosis with, or exposure to, specific illnesses including, Norovirus, Hepatitis A virus, *Shigella* spp., Shiga Toxin-Producing *Escherichia coli*, or *Salmonella* Typhi, or non-typhoidal *Salmonella* as specified in Subparagraph 2-201.11(A)(2) of the *Food Code*. In lieu of written documentation, the data collector is to randomly select **ONE** food employee (other than

the person in charge) and confirm whether management has provided information as to their responsibility to report specific illnesses to the person in charge.

- ✓ **YES – Policy is WRITTEN and based on the current version of the FDA Food Code** – The data collector will select this option if the food establishment has an employee health policy based on the current version of the *FDA Food Code* that covers the responsibility of food employees to report diagnosis with, or exposure to, the specific illnesses specified in Section 2-201.11 of the *Food Code* to the person in charge and the policy is primarily in written form. The person in charge provides documentation or otherwise satisfactorily demonstrates during the data collection, that all food employees and conditional employees are informed of their responsibility to report to management information about their health and activities as they relate to diagnosis with, or exposure to, specific illnesses including, Norovirus, Hepatitis A virus, *Shigella* spp., Shiga Toxin-Producing *Escherichia coli*, or *Salmonella* Typhi, or non-typhoidal *Salmonella*, as specified in Subparagraph 2-201.11(A)(2) of the *Food Code*. Satisfactory compliance may be demonstrated by management when documentation indicates that all food employees are required to complete and sign Form 1-B contained in FDA’s *Employee Health and Hygiene Handbook*; **OR** there is a documented training program based on all the information contained in Form 1-B; **OR** the establishment uses a combination of training, signs, pocket cards, or other methods to convey the information in Form 1-B.
 - ✓ **NO – Policy only partially developed or non-existent** – The person-in-charge does **NOT** provide documentation or otherwise satisfactorily demonstrate during the data collection, that all food employees and conditional employees are informed of their responsibility to report to management information about their health and activities as they relate to illness diagnosis with, or exposure to, specific illnesses as specified in Subparagraph 2-201.11(A)(2) of the *Food Code*, **OR** the selected food employee is **NOT** able to confirm that management has provided information as to their responsibility to report specific illnesses to the person in charge.
- **4. Is management aware of its responsibility to NOTIFY THE REGULATORY AUTHORITY when a food employee is jaundice or diagnosed with an illness due to a pathogen specified in Section 2-201.11 of the Food Code?**

<p>4. Is management aware of its responsibility to NOTIFY THE REGULATORY AUTHORITY when a food employee is jaundiced or diagnosed with an illness due to a pathogen specified in Section 2-201.11 of the Food Code?</p> <p><input type="checkbox"/> YES – Policy is ORAL and based on the current version of the FDA Food Code</p> <p><input type="checkbox"/> YES – Policy is WRITTEN and based on the current version of the FDA Food Code</p> <p><input type="checkbox"/> NO – Policy only partially developed or non-existent</p>

The data collector will determine whether an employee health policy is in place that addresses management’s responsibility to notify the regulatory authority when a food employee is jaundiced or diagnosed with an illness due to a pathogen specified in the *Food Code*. The data collector will select **ONE** of the following responses that best describes the establishment’s employee health policy as it relates to management’s responsibility to notify the regulatory authority.

- ✓ **YES – Policy is ORAL and based on the current version of the FDA Food Code** – The data collector will select this option if the food establishment has an employee health policy based on the current version of the *FDA Food Code* that covers the responsibility of the person in charge to notify the regulatory authority when a food employee is jaundice or diagnosed with an illness due to a pathogen specified in Section 2-201.11 of the *Food Code* and the policy is primarily communicated orally.

- ✓ **YES – Policy is WRITTEN and based on the current version of the FDA Food Code** – The data collector will select this option if the food establishment has an employee health policy based on the current version of the *FDA Food Code* that covers the responsibility of the person in charge to notify the regulatory authority when a food employee is jaundice or diagnosed with an illness due to a pathogen specified in Section 2-201.11 of the *Food Code* and the policy is primarily in written form
 - ✓ **NO – Policy only partially developed or non-existent** – The person-in-charge is **NOT** aware of their responsibility to notify the regulatory authority when a food employee is jaundice or diagnosed with an illness due to a pathogen specified in Section 2-201.11 of the *Food Code*.
- **5. Is the management’s employee health policy consistent with Section 2-201.12 of the Food Code for EXCLUDING AND RESTRICTING food employees and conditional employees on the basis of their health and activities as they relate to diseases that are transmitted through foods?**

5. Is the management’s employee health policy consistent with 2-201.12 of the *Food Code* for EXCLUDING AND RESTRICTING food employees and conditional employees on the basis of their health and activities as they relate to diseases that are transmitted through foods?

YES – Policy is ORAL and based on the current version of the *FDA Food Code*

YES – Policy is WRITTEN and based on the current version of the *FDA Food Code*

NO – Policy only partially developed or non-existent

The data collector will determine whether an employee health policy is in place that addresses exclusion and restriction of food employees on the basis of their health and activities as they relate to diseases that transmitted through foods. The data collector will select **ONE** of the following responses that best describes the establishment’s employee health policy as it relates to exclusion and restriction of food employees on the basis of their health and activities related to diseases transmitted through foods.

- ✓ **YES – Policy is ORAL and based on the current version of the FDA Food Code** – The data collector will select this option if the food establishment has an employee health policy based on the current version of the *FDA Food Code* that covers exclusion and restriction of food employees on the basis of their health activities as they relate to diseases that are transmitted through foods and the policy is primarily communicated verbally. The person in charge is able to demonstrate implementation of employee health exclusion and restriction policy consistent with Tables 1a, 1b, 2, 3, and 4 contained in the *FDA Employee Health and Personal Hygiene Handbook*. **NOTE:** Non-typhoidal Salmonella had not been included in the handbook when this guidance was developed. Reference the Section 2-201.12 of the 2013 *Food Code*. In lieu of written documentation, the person-in-charge can state their exclusion / restriction policy that addresses each of the illnesses identified in Subparagraph 2-201.11(A) (2) of the *Food Code* and can associate the required exclusion / restriction criteria contained in Section 201.12 of the *Food Code* for each of the illnesses. **NOTE:** It is acceptable for the establishment’s employee health policy to be more stringent than the current version of the *Food Code*.
- ✓ **YES – Policy is WRITTEN and based on the current version of the FDA Food Code** – The data collector will select this option if the food establishment has an employee health policy based on the current version of the *FDA Food Code* that covers exclusion and restriction of food employees on the basis of their health activities as they relate to diseases that are transmitted through foods and the policy is primarily in written form. The person in charge is able to demonstrate implementation of employee health exclusion and restriction policy consistent with Tables 1a, 1b, 2, 3, and 4 contained in the *FDA Employee Health and Personal Hygiene Handbook*. **NOTE:** Non-typhoidal Salmonella had not been included in the handbook when this guidance was developed. Reference the Section 2-201.12 of the 2013 *Food Code*. Satisfactory compliance may be demonstrated when the person in charge has

available and references the FDA *Employee Health and Person Hygiene Handbook* and tables as their exclusion / restriction policy or produces similar written documents consistent with the exclusion / restriction requirements contained in the handbook and tables. **NOTE:** It is acceptable for the establishment’s employee health policy to be more stringent than the current version of the *Food Code*.

- ✓ **NO – Policy only partially developed or non-existent** – The person-in-charge does **NOT** provide documentation or otherwise satisfactorily demonstrate during the data collection, that all food employees and conditional employees are excluded or restricted as per Section 2-201.12 of the *Food Code*.

➤ **6. Is the management’s employee health policy consistent with Section 2-201.13 of the Food Code for removal of exclusions and restrictions of food employees and conditional employees on the basis of their health and activities as they relate to diseases that are transmitted through foods?**

6. Is the management’s employee health policy consistent with 2-201.13 of the *Food Code* for **REMOVAL OF EXCLUSIONS AND RESTRICTIONS** of food employees and conditional employees on the basis of their health and activities as they relate to diseases that are transmitted through foods?

YES – Policy is **ORAL** and based on the current version of the *FDA Food Code*

YES – Policy is **WRITTEN** and based on the current version of the *FDA Food Code*

NO – Policy only partially developed or non-existent

The data collector will determine whether an employee health policy is in place that addresses removal of exclusions and restrictions of food employees on the basis of their health and activities as they relate to diseases that transmitted through foods. The data collector will select **ONE** of the following responses that best describes the establishment’s employee health policy as it relates to the removal of exclusions and restrictions of food employees on the basis of their health and activities related to diseases transmitted through foods.

- ✓ **YES – Policy is ORAL and based on the current version of the FDA Food Code** – The data collector will select this option if the food establishment has an employee health policy based on the current version of the *FDA Food Code* that covers the removal of exclusions and restrictions of food employees on the basis of their health activities as they relate to diseases that are transmitted through foods and the policy is primarily communicated verbally. The person in charge is able to demonstrate a policy for removal of employee health exclusions and restrictions that is consistent with Tables 1a, 1b, 2, 3, and 4 contained in the *FDA Employee Health and Personal Hygiene Handbook*. **NOTE:** Non-typhoidal Salmonella had not been included in the handbook when this guidance was developed. Reference the Section 2-201.12 of the 2013 *Food Code*. In lieu of written documentation, the person in charge can state their exclusion / restriction removal policy that addresses each of the illnesses identified in Subparagraph 2-201.11(A)(2) of the *Food Code* and can associate the required exclusion / restriction removal criteria contained in Section 2-201.12 of the *Food Code* for each of the illnesses. **NOTE:** It is acceptable for the establishment’s employee health policy to be more stringent than the current version of the *Food Code*.
- ✓ **YES – Policy is WRITTEN and based on the current version of the FDA Food Code** – The data collector will select this option if the food establishment has an employee health policy based on the current version of the *FDA Food Code* that covers removal of exclusions and restrictions of food employees on the basis of their health activities as they relate to diseases that are transmitted through foods and the policy is primarily in written form. The person in charge is able to demonstrate a policy for removal of employee health exclusions and restrictions that is consistent with Tables 1a, 1b, 2, 3, and 4 contained in the *FDA Employee Health and Personal Hygiene Handbook*. **NOTE:** Non-typhoidal Salmonella had not been included in the handbook when this guidance was developed. Reference the

Section 2-201.12 of the 2013 *Food Code*. Satisfactory compliance may be demonstrated when the person in charge has available and references the FDA *Employee Health and Personal Hygiene Handbook* and tables as their exclusion / restriction removal policy or produces similar written documents consistent with the exclusion / restriction removal requirements contained in the handbook and tables. **NOTE:** It is acceptable for the establishment’s employee health policy to be more stringent than the current version of the *Food Code*.

- ✓ **NO – Policy only partially developed or non-existent** – The person in charge does **NOT** provide documentation or otherwise satisfactorily demonstrate during the data collection, a policy for the removal of exclusions and restrictions of food employees on the basis of their health activities and as they relate to diseases that are transmitted through foods as per Section 2-201.13 of the *Food Code*.

➤ **7. Management has a copy of the FDA’s Employee Health and Personal Hygiene Handbook?** The data collector will select **YES or NO** using the following criteria:

<p>7. Management has a copy of FDA’s Employee Health and Personal Hygiene Handbook <u>OR</u> cd database?</p> <p><input type="checkbox"/> YES</p> <p><input type="checkbox"/> NO</p>

- ✓ **YES** – A copy of the *FDA’s Employee Health and Personal Hygiene Handbook* or cd is present in the food establishment at the time of the data collection.
- ✓ **NO** – A copy of the *FDA’s Employee Health and Personal Hygiene Handbook* or cd is **NOT** present in the food establishment at the time of the data collection.

V. FOODSERVICE FOR HIGHLY SUSCEPTIBLE POPULATIONS

This section of the data collection form is only to be completed for the healthcare facility types, Hospitals and Long-Term Care facilities. The five questions are specific to foodservice for establishments that prepare and serve meals to a highly susceptible population.

- **1. Is it this establishment’s practice to serve prepackaged juice/beverages that have not been processed to eliminate pathogens or prepackaged juice/beverage that bears a warning label?**

FOODSERVICE FOR HIGHLY SUSCEPTIBLE POPULATIONS
<p>1. Is it this establishment’s practice to serve prepackaged juice/beverages that have not been processed to eliminate pathogens or prepackaged juice/beverage that bears a warning label?</p> <p><input type="checkbox"/> YES</p> <p><input type="checkbox"/> NO</p>
<p>COMMENTS:</p>

The data collector will select either a YES or NO response based upon discussions with the person in charge or food employees during the visit. Actual observation of the practice is not a requirement for entering a response for this data entry field. If an actual observation of the practice is made, the data collector must describe their observation in the comment section provided under the question.

- ✓ **YES** – The person in charge or food employees indicate that prepackaged juices/beverage that have not been processed to eliminate pathogens or prepackaged juice beverages that bear a warning label are served to patients or residents of the healthcare facility.
- ✓ **NO** – The person in charge or food employees indicate that prepackaged juices/beverage that have not been processed to eliminate pathogens or prepackaged juice beverages that bear a warning label are **not** served to patients or residents of the healthcare facility.

- **2. Is it this establishment’s practice to serve raw or partially cooked animal foods?**

<p>2. Is it this establishment’s practice to serve raw or partially cooked animal foods?</p> <p><input type="checkbox"/> YES</p> <p><input type="checkbox"/> NO</p>
<p>COMMENTS:</p>

The data collector will select either a YES or NO response based upon discussions with the person in charge or food employees during the visit. Actual observation of the practice is not a requirement for entering a response for this data entry field. If an actual observation of the practice is made, the data collector must describe their observation in the comment section provided under the question.

- ✓ **YES** – The person in charge or food employees indicate that raw or partially cooked animal foods are served to patients or residents of the healthcare facility.
- ✓ **NO** – The person in charge or food employees indicate that raw or partially cooked animal foods are **not** served to patients or residents of the healthcare facility.

NOTE: The data collector is to note exceptions contained in Paragraph 3-801.11(F) for instances where unpasteurized eggs can be used:

- (1) The raw eggs are combined immediately before cooking one consumer’s serving at a single meal, cooked as specified in Section 3-401.11(A)(1), and served immediately, such as an omelet, soufflé, or scrambled eggs;
- (2) The raw eggs are combined as an ingredient immediately before baking and the eggs are thoroughly cooked to a ready-to-eat form, such as a cake, muffin or bread; or
- (3) The preparation of the food is conducted under a HACCP Plan

If one of the above exceptions is conducted in the facility and no other raw or partially cooked animal foods are served to the patients or residents in the healthcare facility, the data collector is to mark **YES** as the response and must provide a comment to describe the practice.

➤ **3. Is it this establishment’s practice to serve raw seed sprouts?**

<p>3. Is it this establishment’s practice to serve raw seed sprouts?</p> <p><input type="checkbox"/> YES</p> <p><input type="checkbox"/> NO</p>
<p>COMMENTS:</p>

The data collector will select either a YES or NO response based upon discussions with the person in charge or food employees during the visit. Actual observation of the practice is not a requirement for entering a response for this data entry field. If an actual observation of the practice is made, the data collector must describe their observation in the comment section provided under the question.

- ✓ **YES** – The person in charge or food employees indicate that raw seed sprouts are served to patients or residents of the healthcare facility.
- ✓ **NO** – The person in charge or food employees indicate that raw seed sprouts are **not** served to patients or residents of the healthcare facility.

➤ **4. Is it this establishment’s practice to use raw/unpasteurized eggs in recipes that may not be fully cooked prior to service or that call for combining eggs prior to cooking?**

<p>4. Is it this establishment’s practice to use raw/unpasteurized eggs in recipes that may not be fully cooked prior to service or that call for combining of eggs prior to cooking?</p> <p><input type="checkbox"/> YES</p> <p><input type="checkbox"/> NO</p>
<p>COMMENTS:</p>

The data collector will select either a YES or NO response based upon discussions with the person in charge or food employees during the visit. Actual observation of the practice is not a requirement for entering a response for this data entry field. If an actual observation of the practice is made, the data collector must describe their observation in the comment section provided under the question.

- ✓ **YES** – The person in charge or food employees indicate that raw/unpasteurized eggs are used in recipes that may not be fully cooked prior to service or that call for combining of eggs prior to cooking.
- ✓ **NO** – The person in charge or food employees indicate that raw/unpasteurized eggs are **not** used in recipes that may not be fully cooked prior to service or that call for combining of eggs prior to cooking.

NOTE: The data collector is to note exceptions contained in Paragraph 3-801.11(F) for instances where unpasteurized eggs can be used:

- (1) The raw eggs are combined immediately before cooking one consumer’s serving at a single meal, cooked as specified in Section 3-401.11(A)(1), and served immediately, such as an omelet, soufflé, or scrambled eggs;
- (2) The raw eggs are combined as an ingredient immediately before baking and the eggs are thoroughly cooked to a ready-to-eat form, such as a cake, muffin or bread; or
- (3) The preparation of the food is conducted under a HACCP Plan

If one of the above exceptions is conducted in the facility and no other raw or partially cooked animal foods are served to the patients or residents in the healthcare facility, the data collector is to mark **YES** as the response and must provide a comment to describe the practice.

➤ **5. Is it this establishment’s practice to allow food employees to contact ready-to-eat foods with their bare hands?**

<p>5. Is it this establishment’s practice to allow food employees to contact ready-to-eat foods with their bare hands?</p> <p><input type="checkbox"/> YES</p> <p><input type="checkbox"/> NO</p> <hr/> <p>COMMENTS:</p>
--

The data collector will select either a YES or NO response based upon discussions with the person in charge or food employees during the visit. Actual observation of the practice is not a requirement for entering a response for this data entry field. If an actual observation of the practice is made, the data collector must describe their observation in the comment section provided under the question.

- ✓ **YES** – The person in charge or food employees indicate that ready-to-eat foods are contacted with bare hands.
- ✓ **NO** – The person in charge or food employees indicate that ready-to-eat -foods are **not** contacted with bare hands.

NOTE: The data collector is to note exceptions contained in Paragraph 3-301.11(D) for instances where food employee may contact ready-to-eat foods with bare hands:

- (1) The ready-to-eat food is being added as an ingredient to a food that contains a raw animal food and is to be cooked to heat all parts of the food to the minimum temperature requirements in Section 3-401.11 of the *Food Code*;
- (2) The ready-to-eat food is being added as an ingredient to a food that does not contain a raw animal food but is to be cooked in the healthcare facility to heat all parts of the food to a temperature of a least 63°C (145°F).

If one of the above exceptions is conducted in the facility and no other raw or partially cooked animal foods are served to the patients or residents in the healthcare facility, the data collector is to mark **YES** as the response and must provide a comment to describe the practice.

VI. GENERAL MARKING INSTRUCTIONS

A. ORIENTATION TO THE DATA COLLECTION FORM

IN	OUT	NO	NA	
<input type="checkbox"/>	<input type="checkbox"/>			1. Employees practice proper handwashing
IN	OUT	NO	NA	Description of HANDWASHING OBSERVATIONS
<input type="checkbox"/>	<input type="checkbox"/>			A. Hands are cleaned and properly washed using hand cleanser / water supply / appropriate drying methods / length of time as specified in Section 2-301.12 of the <i>Food Code</i>
<input type="checkbox"/>	<input type="checkbox"/>			B. Hands are cleaned and washed when required as specified in Section 2-301.14 of the <i>Food Code</i>
COMMENTS:				

FOOD SAFETY MANAGEMENT SYSTEM ASSESSMENT											
PROCEDURES				TRAINING				MONITORING			
<input type="checkbox"/>	1	COMMENTS:		<input type="checkbox"/>	1	COMMENTS:		<input type="checkbox"/>	1	COMMENTS:	
<input type="checkbox"/>	2			<input type="checkbox"/>	2			<input type="checkbox"/>	2		
<input type="checkbox"/>	3			<input type="checkbox"/>	3			<input type="checkbox"/>	3		
<input type="checkbox"/>	4			<input type="checkbox"/>	4			<input type="checkbox"/>	4		
<input type="checkbox"/>	NA			<input type="checkbox"/>	NA			<input type="checkbox"/>	NA		

Data Items – The data collection form consists of 19 data items. The data items are listed numerically and in **BOLD TYPE**. In the above illustration, **Employees practice proper handwashing** is the data item. For the purposes of this Study, data items 1 through 10 are considered “primary data items”. The information collected for these data items will be the Study focus for assessing control of foodborne illness risk factors and determining improvement and/or regression trends over time.

Primary Data Items

Each of the primary data items has been placed under the appropriate FDA Foodborne Illness Risk Factor category.

- **Risk Factor – Poor Personal Hygiene**
 - #1 – Employees practice proper handwashing
 - #2 – Food Employees do not contact ready-to-eat foods with bare hands
- **Risk Factor – Contaminated Equipment / Protection from Contamination**
 - #3 – Food is protected from cross-contamination during storage, preparation, and display
 - #4 – Food contact surfaces are properly cleaned and sanitized
- **Risk Factor – Improper Holding / Time and Temperature**
 - #5 – Foods requiring refrigeration are held at the proper temperature
 - #6 – Foods displayed or stored hot are held at the proper temperature
 - #7 – Foods are cooled properly
 - #8 – Refrigerated, ready-to-eat foods are properly date marked and discarded within 7 days of preparation or opening

➤ **Risk Factor – Inadequate Cooking**

#9 – Raw animal foods are cooked to required temperatures

#10 – Cooked foods are reheated to required temperatures

Other Areas of Interest

Data items 11 through 19 presented below are listed under a section titled “Other Areas of Interest”

➤ **Other Areas of Interest**

#11 – Handwashing facilities are accessible and properly maintained

#12 – Employees practice good hygiene

#13 – Consumers are properly advised of risks of consuming raw or undercooked animal foods

#14 – Time alone is properly used as a public health control

#15 – Facilities have adequate equipment and tools for ensuring food temperature control and sanitization of food contact surfaces

#16 – Special processes are conducted in compliance with issued variance / HACCP Plan when required

#17 – Food is received from safe sources

#18 – Toxic materials are identified, used, and stored properly

#19 – Management and food employees are trained in food allergy awareness as it relates to their assigned duties

The data items included under the “Other Areas of Interest” section enhance the quality of the Study in one or more of the following ways:

- The data item represents a food safety practice that was part of FDA’s first 10-year Study. Including the data item as part of the current FDA Study provides a mechanism for comparing the data from both studies.
- The data item represents a food safety practice that supports or enables control of one of the primary data items. For example, accessible, properly maintained handsinks facilitate the ability of food employees to properly wash their hands.
- The data item provides a method to obtain important information on a food safety practice or procedure that may be a component of another agency food safety initiative.

Data collectors will attempt to record observations of **ALL** 19 data items during a visit to an establishment that has been selected for the Study.

Information Statements / Descriptors – Under most of the data items, a list of information statements is provided. These information statements are preceded by a letter for organization purposes and describe a specific observation (food safety practice) associated with the overarching data item it is listed under. Using the illustration from the previous page, the information statements for the data item – **Employees practice proper handwashing** are:

- A. Hands are cleaned and properly washed using hand cleanser / water supply / appropriate drying methods / length of time as specified in Section 2-301.12 of the *Food Code*.
- B. Hands are cleaned and washed when required as specified in 2-301.14 of the *Food Code*

The information statements provide a method for:

- Conducting comparisons with the previous FDA ten-year risk factor study. Some of the information statements were included as data items on the data collection form used for the first study.
- Recording observations made. Data collectors have an option to check a box rather than write a narrative statement.
- Enhancing quality assurance pertaining to the interpretation of the data collected. Standard statements provide a means for maintaining uniformity and consistency among multiple data collectors.

B. MARKINGS FOR DATA ITEMS AND INFORMATION STATEMENTS

Using the current version of the *FDA Food Code*, the data collector will determine whether the observations made of the employee food safety practices or behaviors contained in the information statements were **IN** Compliance, **OUT** of Compliance, **Not Observed (NO)**, or **Not Applicable (NA)**. The recorded markings of the information statements are then used to determine the compliance status of the corresponding data item.

An observation is based on an evaluation of one or more occurrences of a data item or information statement at an establishment. Specific instructions for marking each data item and information statement are presented later in this document. The four marking options are defined as follows:

- **IN** – means that all observed occurrences were **IN** Compliance with the appropriate *FDA Food Code* provision for the data item or information statement.
- **OUT** – means that one or more of the observations made were **OUT** of Compliance with the appropriate *FDA Food Code* provision for the data item or information statement. An explanation of the specific criteria used for determining **OUT** of Compliance for each data item is to be recorded by the data collector on the data collection form.
- **NO** – means the data item or information statement was **Not Observed** during the inspection. The **NO** marking is used when an information statement is a usual practice in the food establishment, but the practice is **NOT** observed during the time of the inspection. For example, if a retail food store that seasonally serves shellfish was selected for the study but the inspection occurred during non-shellfish season, then the information statements “B” and “F” are marked NO for the overarching data item #17 – **Food is received from safe sources** as illustrated below.

I N	OU T	N O	NA	
<input type="checkbox"/>	<input type="checkbox"/>			17. Food is received from safe sources
IN	OUT	NO	NA	Description of FOOD SOURCE OBSERVATIONS
<input type="checkbox"/>	<input type="checkbox"/>			A. All food is from regulated food processing plants / No home prepared/canned foods
<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	B. Shellfish are from NSSP-listed sources. No recreationally caught shellfish are received/sold
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		C. Food is protected from contamination during transportation/receiving
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		D. TCS Food is received at a temperature of 41°F (5°C) or below OR according to Law
<input type="checkbox"/>	<input type="checkbox"/>			E. Food is safe and unadulterated
<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	F. Shellstock tags/labels are retained for 90 days and filed in chronological order from the date the container is emptied

<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	G. Written documentation of parasite destruction is maintained for 90 days for fish products
<input type="checkbox"/>	<input type="checkbox"/>		<input type="checkbox"/>	H. Other (describe in Comments Section below)

➤ **NA** – means the data item or information statement is Not Applicable. The NA marking is used when a data item or information statement is **NOT** a function of the food establishment. Using the data item table below as an example, if a health care facility does NOT cool cooked foods (information statement “A”), or does NOT cool foods prepared at ambient temperatures (information statement “B”), then ALL the information statements pertaining to cooling foods under data item 7 are marked NA. Since all the information statements (A through D) for this data item were marked NA, the data item will also be marked NA. More on the marking relationships between information statements and data items is presented in the next section.

IN	OUT	NO	NA	
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	7. Foods are cooled properly
IN	OUT	NO	NA	Description of Cooling Temperature OBSERVATIONS
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	A. Cooked TCS Food is cooled from 135°F (57°C) to 70°F (21°C) within 2 hours and from 135°F (57°C) to 41°F (5°C) or below within 6 hours
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	B. TCS Food (prepared from ingredients at ambient temperature) is cooled to 41°F (5°C) or below within 4 hours
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	C. Proper cooling methods / equipment are used
<input type="checkbox"/>	<input type="checkbox"/>		<input checked="" type="checkbox"/>	D. Other (describe in the temperature chart and comments section below)

Not all four marking options (IN, OUT, NO, NA) are used for every data item. For instance, in the case of cold holding, all health care, school, or retail food store facilities included for this data collection period will need to cold hold PHF/TCS food (Data item 5 – **Food requiring refrigeration are held at the proper temperature**). As a result, the “Not Observed” (NO) and “Not Applicable” (NA) marking options are inappropriate and are “blacked out” in the graphic displayed below, given that an observation for cold holding is not only applicable in every case, but is also observable during the data collection.

IN	OUT	NO	NA	
<input type="checkbox"/>	<input type="checkbox"/>			5. Foods requiring refrigeration are held at the proper temperature
IN	OUT	NO	NA	Description of Cold Holding Temperature OBSERVATIONS
<input type="checkbox"/>	<input type="checkbox"/>			A. TCS Food is maintained at 41°F (5°C) or below, except during preparation, cooking, cooling, or when time is used as a public health control
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	B. Raw shell eggs are stored under refrigeration that maintains ambient air temperature of 45°F (7°C) or less
<input type="checkbox"/>	<input type="checkbox"/>		<input type="checkbox"/>	C. Other (describe in the temperature chart and comments section below)

C. RELATIONSHIP BETWEEN DATA ITEMS AND INFORMATION STATEMENTS

The marking of a data item is predicated on the observations the data collector has made and recorded for the information statements. **REMINDER:** The information statements listed under each data item pertain to specific food safety practices related to the overarching data item.

Rule #1 for Marking Data Items

*One of the four marking options, (IN, OUT, NO, NA) **MUST** be completed by the data collector for **EACH** of the information statements listed under an overarching data item.*

Using the illustration below, the two information statements (A and B) under the data item #1 – **Employees practice proper handwashing** contains an “X” for one of the marking options.

IN	OUT	NO	NA	
<input type="checkbox"/>	<input checked="" type="checkbox"/>			1. Employees practice proper handwashing
IN	OUT	NO	NA	Description of HANDWASHING OBSERVATIONS
<input type="checkbox"/>	<input checked="" type="checkbox"/>			A. Hands are cleaned and properly washed using hand cleanser / water supply / appropriate drying methods / length of time
<input checked="" type="checkbox"/>	<input type="checkbox"/>			B. Hands are cleaned and washed when required as specified in Section 2-301.14 of the Food Code
COMMENTS: Observed food employee washing hands at hand sink located near flat grill. Food employee did not use any type of hand soap or cleanser as part of the handwashing procedure.				

Rule #2 for Marking Data Items

*If **ANY** of the information statements are marked **OUT** of Compliance, the data collector must mark the overarching data item **OUT** of Compliance.*

Using the above illustration, note the markings of observations for the two information statements under the **Employees practice proper handwashing** data item. Since **information statement “A” is marked OUT of Compliance, the Employees practice proper handwashing data item** must be marked OUT of Compliance.

Rule #3 for Marking Data Items

If an observation (IN or OUT) is made of any information statement, the overarching data item **CANNOT** be marked Not Observed (NO) or Not Applicable (NA).

In the illustration presented below, note the markings of observations for the 6 information statements under the data item #9 – **Raw animal foods are cooked to required temperatures.**

I N	OU T	N O	NA	
<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	9. Raw animal foods are cooked to required temperatures
IN	OUT	NO	NA	Description of Cooking Temperature OBSERVATIONS
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	A. Raw shell eggs broken for immediate service are cooked to 145°F (63°C) for 15 seconds. Raw shell eggs broken but not prepared for immediate service cooked to 155°F (68°C) for 15 seconds
<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	B. Pork; Fish; Beef; Commercially-raised Game Animals are cooked to 145°F (63°C) for 15 seconds
<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	C. Comminuted Fish, Meats, Commercially-raised Game Animals are cooked to 155°F (68°C) for 15 seconds
<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	D. Poultry; stuffed fish; stuffed meat; stuffed pasta; stuffed poultry; stuffed ratite; or stuffing containing fish, meat, poultry, or ratites; wild game animals are cooked to 165°F (74°C) for 15 seconds
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	E. Roasts, including formed roasts, are cooked to 130°F (54°C) for 112 minutes or as Chart specifies and according to oven parameters per Chart (NOTE: This data item includes beef roasts, corned beef roasts, pork roasts, and cured pork roasts such as ham).
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	F. Other Cooking Observations (describe in the Comment Section and Temperature Chart below)

In the example above, the data collector was only able to observe and record the final cooking temperatures for hamburgers which would be included under information statement “C”. All the other animal food product statements were marked either Not Observed (NO) or Not Applicable (NA). Since one of the food safety procedures is observed (information statement “C”), the data item **Raw animal foods are cooked to required temperatures** is observed and must reflect the marking (IN for this example) for that observation. This would be true regardless of the number of Not Observed (NO) or Not Applicable (NA) markings that may be associated with the other information statements for that data item.

Rule #4 for Marking Data Items

If **no observations** (IN or OUT) are made of any information statements but **one or more** of the information statements is marked **Not Observed** (NO) the overarching data item **MUST** be marked **Not Observed** (NO) regardless of the number of information statements for that data item that are marked Not Applicable (NA).

The graphic below illustrates the data item marking instruction for Rule #4.

I N	OU T	N O	NA	
<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	16. Special processes are conducted in compliance with issued variance / HACCP Plan, when required
IN	OUT	NO	NA	Description of OBSERVATIONS of Specialized Processes
<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	A. Food establishment conducts reduced oxygen packaging without a variance as specified in Section 3-502.12 of the <i>Food Code</i>
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	B. Food establishment performs specialized process in accordance with approved variance and HACCP Plan when required
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	C. Juice packaged in the food establishment is treated under a HACCP Plan to reduce pathogens or labeled as specified in Section 3-404.11 of the <i>Food Code</i>
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	D. Other (describe in the comments section below)

A data item can only be marked Not Applicable (NA) if **ALL** the information statements listed are also marked Not Applicable (NA).

Rule #5 for Marking Data Items

If the observations for all the information statements under a given data item are marked the same, then the overarching data item **MUST** be marked the same as the information statements. This is illustrated in the following graphic where the information statements A through D are marked NA (Not Applicable), therefore Data Item 7 – **Foods are Cooled Properly** is also marked NA.

IN	OUT	NO	NA	
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	7. Foods are cooled properly
IN	OUT	NO	NA	Description of Cooling Temperature OBSERVATIONS
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	A. Cooked TCS Food is cooled from 135°F (57°C) to 70°F (21°C) within 2 hours and from 135°F (57°C) to 41°F (5°C) or below within 6 hours
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	B. TCS Food (prepared from ingredients at ambient temperature) is cooled to 41°F (5°C) or below within 4 hours
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	C. Proper cooling methods / equipment are used
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	D. Other (describe in the temperature chart and comments section below)

Rule #6 for Marking Data Items

If the information statement labeled **“Other”** is selected to describe a specific food safety practice related to the overarching data item, the data collector **MUST** describe that food safety practice in the **“Comment”** section box.

Most of the data items have an information statement labeled “Other”. The inclusion of this information statement is intended to provide the data collector the opportunity to record an observation of a food safety practice or procedure that applies to the overarching data item but does not fit into one of the other pre-determined information statements.

Summary of the Six Rules for Marking Data Items

NOTE: All six rules for marking data items, summarized in the table below, have been programmed into the database. The correct marking for the overarching data item will automatically be entered into the system based on the data collector’s markings for the listed information statements.

Summary of the Six Rules for Marking Data Items	
Rule 1	One of the four marking options, (IN, OUT, NO, NA) MUST be completed by the data collector for EACH of the information statements listed under an overarching data item.
Rule 2	If ANY of the information statements are marked OUT of Compliance, the data collector must mark the overarching data item OUT of Compliance.
Rule 3	If an observation (IN or OUT) is made of any information statement, the overarching data item CANNOT be marked Not Observed (NO) or Not Applicable (NA).
Rule 4	If no observations (IN or OUT) are made of any information statements but one or more of the information statements is marked Not Observed (NO,) the overarching data item MUST be marked Not Observed (NO) regardless of the number of information statements for that data item that are marked Not Applicable (NA).
Rule 5	If the observations for all the information statements under a given data item are marked the same, then the overarching data item MUST be marked the same as the information statements.
Rule 6	If the information statement labeled “ Other ” is selected to describe a specific food safety practice related to the overarching data item, the data collector MUST describe that food safety practice in the “ Comment ” section box.

D. COMMENT SECTION FOR EACH DATA ITEM

A “Comments” section is provided for each of the data items as presented in the illustration below.

IN	OUT	NO	NA	
<input type="checkbox"/>	<input checked="" type="checkbox"/>			3. Food is protected from cross-contamination during storage, preparation, and display
IN	OUT	NO	NA	Description of FOOD Contamination OBSERVATIONS
<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	A. Raw animal foods are separated from ready-to-eat foods
<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	B. Different raw animal foods are separated from each other
<input checked="" type="checkbox"/>	<input type="checkbox"/>			C. Food is protected from environmental contamination – actual contamination observed
<input checked="" type="checkbox"/>	<input type="checkbox"/>			D. Food is protected from environmental contamination – potential contamination
<input type="checkbox"/>	<input type="checkbox"/>		<input checked="" type="checkbox"/>	E. Other (<i>describe in the comments section below</i>)
COMMENTS: 3A - Observed raw chicken breasts stored in direct contact with ready-to-eat deli meats in the Walk-in Cooler				

The data collector is to use the comment section to provide a complete description or clarity to the observations made of the data item. If a data item or information statement is marked **OUT** of Compliance, a clear description of the observation **must** be provided by the data collector.

Anytime the “**Other**” information statement is selected as “IN” or “OUT”, the data collector **must** provide a complete description of the observation regardless of whether it is IN or OUT of Compliance with the *Food Code*.

VII. FOOD PRODUCT TEMPERATURE CHARTS

A. DATA ITEMS WITH FOOD PRODUCT TEMPERATURE CHARTS

Food product temperature charts are included for the following five data items:

- #5 – Foods requiring refrigeration are held at the proper temperature
- #6 – Foods displayed or stored hot are held at the proper temperature
- #7 – Foods are cooled properly
- #9 – Raw animal foods are cooked to required temperatures
- #10 – Cooked foods are reheated to required temperatures

An illustration of the food product temperature chart for data item #5 – **Foods requiring refrigeration are held at the proper temperature** is presented below.

Cold Holding Temperatures Recorded During the Data Collection (List all temperatures taken)							
FOOD PRODUCT	FOOD TEMP.	FOOD CODE CRITICAL LIMIT	TYPE OF COLD HOLDING EQUIPMENT	FOOD PRODUCT	FOOD TEMP.	FOOD CODE CRITICAL LIMIT	TYPE OF COLD HOLDING EQUIPMENT
Cooked Chicken	40°F	41°F	Walk-in Cooler	Diced Ham	44°F	41°F	Refrigerated Sandwich Preparation Table
Raw Hamburger Patty	52°F	41°F	Refrigeration Drawer Preparation Line	Cooked Pasta	39°F	41°F	Walk-in Cooler
Sliced Tomatoes	48°F	41°F	Refrigerated Sandwich Preparation Table	Cooked Ribs	41°F	41°F	Walk-in Cooler
Egg Salad	42°F	41°F	Refrigerated Sandwich Preparation Table	Tuna Salad	42°F	41°F	Refrigerated Sandwich Preparation Table

Food product temperatures **must** be taken to make a determination of compliance or non-compliance for data items 5, 6, 7, 9, and 10. Data collectors are **not** to rely solely upon discussions with managers or foodservice personnel to make a determination of compliance or non-compliance.

The data collector is **not** to stop taking temperature because an OUT of Compliance observation was recorded. During this version of the Study, FDA is attempting to better quantify the scope of the problem. It is understood that taking a temperature of every food product is not feasible nor is it necessary. It is essential for the data collector to obtain a representative sampling of product temperatures held in temperature storage units or observed being cooked, reheated, or cooled. Quantifying the scope of the problem will be important when attempts are made during the data analysis to draw correlations related to the impact of food safety management systems on controlling risk factors that are dependent upon a temperature critical limit for controlling food safety hazards.

All food product temperature observations (both IN and OUT) **must** be entered by the data collector into the food product temperature charts provided. If **one** food item is found OUT of temperature the overarching data item covering the specific food safety practice **must** be marked OUT of Compliance.

Description of Column Headings Contained in Temperature Charts

- **Consumer Advisory (specific to the temperature chart for data item #9 – Raw animal foods are cooked to required temperatures)** – Using the current version of the *FDA Food Code*, the data collector will determine whether a consumer advisory containing both a disclosure and reminder as specified with Section 3-603.11 of the *Food Code* accompanied the raw animal food product from which a final cooking temperature was obtained. The data collector will select either **YES** or **NO** using the following criteria:
 - ✓ **YES** – means that the customer ordered the raw animal food to be undercooked **and** the food establishment had a consumer advisory for that menu item that met the disclosure and reminder requirements specified in Section 3-603.11 of the *Food Code*.
 - ✓ **NO** – means that the customer did **not** specifically order the raw animal food to be undercooked **or** the food establishment did **not** have a consumer advisory for that menu item that met the disclosure and reminder requirements specified in Section 3-603.11 of the *Food Code*.
- **Final Cook Temp.** – Final internal temperature of a food product measured by the data collector immediately upon completion of the cooking process, using a calibrated temperature measuring device.
- **Final Reheat Temp.** – Final internal temperature of a food product measured by the data collector immediately upon completion of the reheating process, using a calibrated food temperature measuring device.
- **Food Code Critical Limit** – *The quantitative temperature measurement provided in the FDA Food Code for controlling microbiological food safety hazards associated with the data item.*
- **Food Product** – Common name or menu designation associated with the food product. The data collector is **not** expected to list all ingredients that may be part of a product, such as a casserole. Identifying the primary ingredient is sufficient, such as the designation tuna casserole.
- **Food Temp.** – Internal food product temperature measured by the data collector using a calibrated food temperature measuring device.
- **Food Cooling Temp. #1** – Initial internal product temperature of cooked TCS food or TCS food prepared from ambient ingredients that are in the process of cooling. The data collector **must** make every effort to assess cooling processes in the early part of the data collection and record this *Food Temp. #1* at the beginning, or near the beginning, of the establishment visit
NOTE: The data collector may encounter instances where a cooked time-temperature control for safety food product was prepared the day before and is still going through the cooling process the next morning. In such cases, the data collector will enter “UNK” in the Food Cooling Temp. #1 data entry field because the product was put into the cooling process the night before and an initial temperature was not obtainable.
- **Food Cooling Temp. #2** – Internal product temperature of cooked TCS food or TCS food prepared from ambient ingredients that the data collector assessed near the end of the data collection. This second temperature reading is from the same food product observed cooling at the beginning of the inspection from which Food Cooling Temp. #1 (above) was obtained. It provides a method for assessing the cooling rate based on the elapsed time between the first and second temperature measurements.
- **Total Time in Minutes** – Represents the total elapsed time in minutes between the data collector’s *Food Temp. #1* measurement and their *Food Temp. #2* measurement of the cooked TCS food or TCS food

prepared from ambient ingredients that are in the process of cooling.

NOTE: For instance where the time-temperature control for safety food had been prepared the day before and is still in the cooling process the next day, the data collector will enter “**O/N**” in the Total Time in Minutes data entry field. If the data collector entered “**UNK**” in the Food Cooling Temp. #1 field as described in the note section of that item on the previous page, the database will automatically default to the “**O/N**” entry.

- ***Type of (Cold Holding / Hot Holding / Used to Cool Food) Equipment*** – A drop down menu is included in the database listing different types of equipment used to maintain or achieve control of food product temperature. Make and model numbers of the equipment are **NOT** required. Data collectors are to select their equipment type entry from the menu list. Data collectors can select the “Other” option if the equipment type is not present on the drop down menu. After selecting the “Other” option, the data collector is to enter the equipment type in the comment section for that data item making a reference to the food product to which it relates.

B. SUMMARY – PRODUCT TEMPERATURE CATEGORIES

Summary tables for food product temperatures categories are included for the following four data items:

- #5 – Foods requiring refrigeration are held at the proper temperature
- #6 – Foods displayed or stored hot are held at the proper temperature
- #9 – Raw animal foods are cooked to required temperatures
- #10 – Cooked foods are reheated to required temperatures

An illustration of the product temperature summary tables for data item #5 – **Foods requiring refrigeration are held at the proper temperature** is present below.

Cold Holding Temperatures Recorded During the Data Collection (List all temperatures taken)							
FOOD PRODUCT	FOOD TEMP.	FOOD CODE CRITICAL LIMIT	TYPE OF COLD HOLDING EQUIPMENT	FOOD PRODUCT	FOOD TEMP.	FOOD CODE CRITICAL LIMIT	TYPE OF COLD HOLDING EQUIPMENT
Cooked Chicken	40°F	41°F	Walk-in Cooler	Diced Ham	44°F	41°F	Refrigerated Sandwich Preparation Table
Raw Hamburger Patty	52°F	41°F	Refrigeration Drawer Preparation Line	Cooked Pasta	39°F	41°F	Walk-in Cooler
Sliced Tomatoes	48°F	41°F	Refrigerated Sandwich Preparation Table	Cooked Ribs	41°F	41°F	Walk-in Cooler
Egg Salad	42°F	41°F	Refrigerated Sandwich Preparation Table	Tuna Salad	42°F	41°F	Refrigerated Sandwich Preparation Table
NUMBER OF FOOD PRODUCT TEMPERATURES				SUMMARY COLD HOLDING PRODUCT TEMPERATURE CATEGORIES			
3	I. – Number of product temperature measurements IN Compliance with <i>Food Code</i> critical limits						
2	II. – Number of OUT of Compliance product temperature measurements 1°F - 2°F above <i>Food Code</i> critical limits						
1	III. – Number of OUT of Compliance product temperature measurements 3°F - 4°F above <i>Food Code</i> critical limits						
1	IV. – Number of OUT of Compliance product temperature measurements 5°F - 9°F above <i>Food Code</i> critical limits						
1	V. – Number of OUT of Compliance product temperature measurements 10°F or more above <i>Food Code</i> critical limits						

After the data collection has been completed, the results of the compliance status of observations made of all internal food product temperatures will be recorded in the summary table provided for data items #5, #6, #9, and #10.

The retail food risk factor study database has been designed to automatically populate the temperature summary table with the total number of internal food product temperatures recorded in the data item temperature chart for each of the following five categories:

- I. Number of food product temperature measurements **IN** Compliance with *Food Code* critical limits.
- II. Number of **OUT** of Compliance food product temperature measurements **1°F - 2°F** (above / below) *Food Code* critical limits.
- III. Number of **OUT** of Compliance food product temperature measurements **3°F - 4°F** (above / below) *Food Code* critical limits.
- IV. Number of **OUT** of Compliance food product temperature measurements **5°F - 9°F** (above / below) *Food Code* critical limits.
- V. Number of **OUT** of Compliance food product temperature measurements **10°F or more** (above / below) *Food Code* critical limits.

NOTE: The data collector should verify that the temperature summary tables display the total number of internal food temperature for the five categories described above.

VIII. FOOD SAFETY MANAGEMENT SYSTEM ASSESSMENTS

A. PROTOCOL FOR CONDUCTING A FOOD SAFETY MANAGEMENT SYSTEM ASSESSMENT

The design of the Study includes the collection of information on the industry food safety management system in place to control four key risk factor areas and selected data items for each as presented below:

1 – Poor Personal Hygiene

Data Item #1 – Employees practice proper handwashing

Data Item #2 – Employees do not contact ready-to-eat foods with bare hands

2 – Protection from Contamination / Contaminated Equipment

Data Item #3 – Food is protected from cross-contamination during storage, preparation, and display

Data Item #4 – Food contact surfaces are properly cleaned and sanitized

3 – Improper Holding / Time and Temperature

Data Item #5 – Foods requiring refrigeration are held at the proper temperature

Data Item #6 – Foods displayed or stored hot are held at the proper temperature

Data Item #7 – Foods are cooled properly

Data Item #8 – Refrigerated, ready-to-eats foods are properly date marked and discarded within 7 days of preparation or opening

4 – Inadequate Cooling / Reheating

Data Item #9 – Raw animal foods are cooked to required temperatures

Data Item #10 – Cooked foods are reheated to required temperatures

Each food establishment selected for the study will have a food safety management system assessment conducted for **one** of the four risk factor areas described above. The Biostatistics Branch will randomly select the risk factor area that will be the focus of the food safety management system assessment within each of the establishments.

The data collector will evaluate the presence of three key food safety management system elements (procedures, training, and monitoring) for all the **primary data items** listed under the assigned risk factor.

- **Procedures** – A defined set of actions adopted by food service management for accomplishing a task in a way that minimizes food safety risks.
- **Training** – Management informs employees what the procedures are and teaches the employees how to carry them out. This is **not** to be used for determining manager knowledge or certification
- **Monitoring** – Routine observations and measurements made by management to determine if procedures are being followed and maintained.

For each of these three food safety management system elements, the data collector will determine if the information provided by the establishment management adequately addresses the essential critical limits for the assigned risk factor area. In addition to covering the pertinent critical limits pertaining to the assigned risk factor area, industry management is to provide a clear, understandable description of the system in place for procedures, training, and monitoring using the guidance at the top the following page.

A food safety management system assessment questionnaire has been developed for each of the foodborne illness risk factor areas. These assessment tools are included as Appendices with these instructions.

- Attachment A – Food Safety Management System Assessment – Poor Personal Hygiene Risk Factor
- Attachment B – Food Safety Management System Assessment - Protection from Contamination / Contaminated Equipment Risk Factor
- Attachment C – Food Safety Management System Assessment – Improper Holding / Time and Temperature Risk Factor
- Attachment D – Food Safety Management System Assessment – Inadequate Cooking / Reheating Risk Factor

For each of the data items listed under the risk factor area on the previous page, the data collector will individually assess each of the three food safety management system elements (Procedures, Training, and Monitoring). The chart below contains the four statements related to handwashing procedures.

HANDWASHING

PROCEDURES	YES	NO
Management is able to describe the critical limits for handwashing as they apply to their establishment.	<input type="checkbox"/>	<input checked="" type="checkbox"/>
Management is able to describe the steps / tasks (how and when) that are performed to ensure that the identified critical limits for handwashing are achieved.	<input checked="" type="checkbox"/>	<input type="checkbox"/>
Management is able to identify specific employees that have been assigned the responsibility to correctly perform the handwashing procedure (for handwashing – reference to a system-wide policy for all employees is acceptable).	<input checked="" type="checkbox"/>	<input type="checkbox"/>
Management is able to produce written materials (SOPs; posters; wall charts; wallet cards; etc.) that support the implementation of their handwashing procedure within their establishment.	<input type="checkbox"/>	<input type="checkbox"/>

Using an effective interview process the data collector will solicit information from the person in charge to respond “Yes” or “No” to the four statements listed under each of the Procedures, Training, and Monitoring elements.

NOTE: *Data collectors are strongly encouraged to use a conversational approach to obtain information from the person in charge on their food safety management system rather than using the tool to drive questions in the order the statements appear.*

Using the information gathered from the interview, the data collector will answer “YES” or “NO” to each of the first three statements under the food safety management system element (Procedures, Training, or Monitoring) they are assessing. Each of the three statements is to be answered independently of one another.

As an example, the chart presented on this page contains an assessment of the procedures in place for handwashing. During the interview process, the person in charge described a handwashing procedure that included critical limits that did not meet minimum requirements for controlling hazards of concern. Therefore

the data collector marked “NO” to the first statement. The person in charge was, however, able to provide a sound management structure for how and when handwashing is done in the facility and who is responsible for following the procedure. The data collector marked statements #2 and #3 “YES” based on this information. After marking the first three statements, the data collector reviews the responses. If ALL three statements are marked “YES”, the data collector will then mark a response “YES” or “NO” to the last question in the shaded row. The fourth question in the shaded row is designed to assess whether there are written materials to support the food safety management system element (Procedures, Training, or Monitoring).

If any of the first three statements have been marked “NO”, the data collector does not enter a response for the shaded statement. The first three statements MUST be marked “YES” for the data collector to enter a response for the fourth statement.

B. FOOD SAFETY MANAGEMENT SYSTEM ASSESSMENT – RATING SYSTEM

The data collector is to use the chart provided under each of the data items on the data collection form to document the rating level for each of the three food safety management system elements (procedures, training, monitoring). An example of this food safety management system chart is displayed below.

FOOD SAFETY MANAGEMENT SYSTEM ASSESSMENT									
PROCEDURES			TRAINING				MONITORING		
<input type="checkbox"/>	1	COMMENTS:	<input type="checkbox"/>	1	COMMENTS:	<input type="checkbox"/>	1	COMMENTS:	
<input type="checkbox"/>	2		<input type="checkbox"/>	2		<input type="checkbox"/>	2		
<input type="checkbox"/>	3		<input type="checkbox"/>	3		<input type="checkbox"/>	3		
<input type="checkbox"/>	4		<input type="checkbox"/>	4		<input type="checkbox"/>	4		
<input type="checkbox"/>	NA		<input type="checkbox"/>	NA		<input type="checkbox"/>	NA		

The food safety management system assessment will be conducted during the same establishment visit but independent from the determination of compliance with the *Food Code* for each of the data items.

Using the food safety management system assessment tool, the data collector will add up the total number of “YES” responses for each of the management system elements (Procedures, Training, and Monitoring). The number of “YES” responses on the assessment tool will determine how to mark the Procedures, Training, And Monitoring sections for the data item on the data collection form.

Each rating number is broadly defined below:

- 1. Non-Existent** – No system in place or haphazardly implemented (no defined structure or frequency for implementation). If the number of “YES” responses is “0” or “1”, mark the data collection form “1” for that management system (Procedures, Training, or Monitoring) element.
- 2. Underdeveloped** – System is in early development. Efforts are being made, but there are crucial gaps in completeness and/or consistency. If the number of “YES” responses is “2”, mark the data collection form “2” for that management system (Procedures, Training, or Monitoring) element.
- 3. Well Developed** – System is complete, consistent and oral or a combination of oral and written. The preponderance of the management system is oral. . If the number of “YES” responses is “3”, mark the data collection form “3” for that management system (Procedures, Training, or Monitoring) element.

4. Well Developed and Documented – System is complete, consistent and primarily written. The preponderance of the management system is written. This is the goal for all establishments. If the number of “YES” responses is “4”, mark the data collection form “4” for that management system (Procedures, Training, or Monitoring) element.

In the “COMMENT” section of the data collection form, provide a description of any scenarios that presented some challenges in assigning a 1-4 marking for a management system element.

It is quite possible that an establishment may not perform all the food safety practices listed under a specific risk factor area. For example, if the Improper Holding / Time and Temperature risk factor is selected for a food safety management system assessment, four different food safety practices (data items) are to be included as part of the review process:

- Data Item #5 – Cold Holding of TCS Food
- Data Item #6 – Hot Holding of TCS Food
- Data Item #7 – Cooling of TCS Food
- Data Item #8 – Date Marking of Ready-to-Eat TCS Food

There may be instances where an establishment may not perform all the food safety practices that comprise the risk factor. Using the above example, if the establishment does not perform cooling of time-temperature control for safety foods, Data Item #7 – Cooling of TCS Foods would be marked “NA”. Since the establishment does not conduct any cooling processes, the data collector would **not** conduct a food safety management assessment of cooling practices. The data collector would mark “NA” for the Procedure; Training; and Monitoring assessment of Data Item #7 because the cooling foods was not done in the facility.

FOOD SAFETY MANAGEMENT SYSTEM ASSESSMENT											
PROCEDURES				TRAINING				MONITORING			
<input type="checkbox"/>	1	COMMENTS:		<input type="checkbox"/>	1	COMMENTS:		<input type="checkbox"/>	1	COMMENTS:	
<input type="checkbox"/>	2			<input type="checkbox"/>	2			<input type="checkbox"/>	2		
<input type="checkbox"/>	3			<input type="checkbox"/>	3			<input type="checkbox"/>	3		
<input type="checkbox"/>	4			<input type="checkbox"/>	4			<input type="checkbox"/>	4		
<input checked="" type="checkbox"/>	NA			<input checked="" type="checkbox"/>	NA			<input checked="" type="checkbox"/>	NA		

The “NA” marking can only be used for the Procedures; Training; and Monitoring assessment when the overall data item is marked “NA” as well.

IX. HANDWASHING FREQUENCY ASSESSMENT

A. HANDWASHING FREQUENCY ASSESSMENT PROTOCOL

The data collector will record all of his or her handwashing observations during the regular data collection using the “Handwashing Frequency Assessment” located under **data item #1 – Employees practice proper handwashing** on the Data Collection Form. Over the course of the data collection visit, the Specialist will record a tally of each time an employee is observed doing the following:

- Washing hands properly and when required,
- Washing hands improperly, or
- Failing to wash hands when required.

IN	OUT	NO	NA	
<input type="checkbox"/>	<input checked="" type="checkbox"/>			1. Employees practice proper handwashing
IN	OUT	NO	NA	Description of HANDWASHING OBSERVATIONS
<input type="checkbox"/>	<input checked="" type="checkbox"/>			A. Hands are cleaned and properly washed using hand cleanser / water supply / appropriate drying methods / length of time as specified in Section 2-301.12 of the <i>Food Code</i>
<input type="checkbox"/>	<input checked="" type="checkbox"/>			B. Hands are cleaned and washed when required as specified in Section 2-301.14 of the <i>Food Code</i>
COMMENTS:				
HANDWASHING FREQUENCY ASSESSMENT				
	<u>C1</u>	<u>C2</u>	<u>C3</u>	
	Employee observed washing hands properly and when required	Employee observed washing hands improperly	Employee observed failing to wash hands when required	
TOTAL COUNT	///	///	///	

Additional time should **not** be allocated for the observation of handwashing practices. It should be collected through the normal course of conducting observations of other food safety procedures during the data collection visit. Data collectors should recognize their limitations with this aspect of the study. The assessment of handwashing frequency in the context of this study is to provide a broad-based indicator of handwashing practices and will not be used to draw statistical conclusions. It will be impossible to assess every activity during which handwashing should occur so the precision needed for statistical analysis will not be achievable. Assessing handwashing frequency is intended to provide some context to the IN / OUT marking for **Data Item #1 – Employees practice proper handwashing**.

The data collector should do their best to assess handwashing when the opportunity arises during the normal course of the visit. The data collector should **not** forgo an opportunity to observe and assess a food safety

practice or procedure related to a primary data item in order to follow an employee to determine if hands are washed when needed using effective cleaning procedures.

NOTE: The adherence to good handwashing practices may vary greatly from one facility to another. The expectation for the data collector is to make observations of employees washing their hands when they should and washing their hands properly. Should a data collector observe continued failure of employees to wash their hands when they should, immediate corrective action should be taken with the person-in-charge or directly with the food employee to ensure proper handwashing takes place and is observed. If the data collector needed to take corrective action to observe handwashing procedures, it **must** be noted in the “Comment” section under data item #1.

B. ASSURING MARKING CONSISTENCY WITH DATA ITEM

The data collected on the **Handwashing Frequency Assessment** form should match the data results recorded for **data item #1 – Employees practice proper handwashing**. For example, if any observations are recorded under column C2 or C3 in the above Handwashing Frequency Assessment form, then data item #1 – **Employees practice proper handwashing**” on the data collection form for that establishment should be marked “**OUT**”.

X. DATA ITEMS AND INFORMATION STATEMENTS

REMINDER – SIX RULES FOR MARKING DATA ITEMS

NOTE: All six rules for marking data items, summarized in the table below, have been programmed into the database. The correct marking for the overarching data item will automatically be entered into the system based on the data collector’s markings for the listed information statements.

Summary of the Six Rules for Marking Data Items	
Rule 1	One of the four marking options, (IN, OUT, NO, NA) MUST be completed by the data collector for EACH of the information statements listed under an overarching data item.
Rule 2	If ANY of the information statements are marked OUT of Compliance, the data collector must mark the overarching data item OUT of Compliance.
Rule 3	If an observation (IN or OUT) is made of any information statement, the overarching data item CANNOT be marked Not Observed (NO) or Not Applicable (NA).
Rule 4	If no observations (IN or OUT) are made of any information statements but one or more of the information statements is marked Not Observed (NO,) the overarching data item MUST be marked Not Observed (NO) regardless of the number of information statements for that data item that are marked Not Applicable (NA).
Rule 5	If the observations for all the information statements under a given data item are marked the same, then the overarching data item MUST be marked the same as the information statements.
Rule 6	If the information statement labeled “Other” is selected to describe a specific food safety practice related to the overarching data item, the data collector MUST describe that food safety practice in the “Comment” section box.

1. Employees practice proper handwashing

IN	OUT	NO	NA	
<input type="checkbox"/>	<input type="checkbox"/>			1. Employees practice proper handwashing
IN	OUT	NO	NA	Description of HANDWASHING OBSERVATIONS
<input type="checkbox"/>	<input type="checkbox"/>			A. Hands are cleaned and properly washed using hand cleanser / water supply / appropriate drying methods / length of time as specified in Section 2-301.12 of the <i>Food Code</i> .
<input type="checkbox"/>	<input type="checkbox"/>			B. Hands are cleaned and washed when required as specified in Section 2-301.14 of the <i>Food Code</i>

- Data collectors **CANNOT** select marking options that have been **BLACKED-OUT** for the above data item and information statements.

NOTE: The data item *Employees practice proper handwashing* **MUST** be marked **IN** or **OUT** of compliance. The data collector **must** be in the selected facility long enough to make observations of handwashing practices for both information statement 1A **and** 1B. The data collector is to rely only on actual observations of handwashing practices. Should a data collector observe continued failure of employees to wash their hands when they should, immediate corrective action should be taken with the person-in-charge or directly with the food employee to ensure proper handwashing takes place and is observed. If the data collector needed to take corrective action to observe handwashing procedures, it **must** be noted in the “Comment” section under data item #1.

INFO ITEM	MARKING INSTRUCTIONS
A	<p style="text-align: center;">FOOD CODE REFERENCE: 2-301.12^P</p> <p>IN – Mark IN when food employees are observed washing their hands as specified in Section 2-301.12 of the <i>Food Code</i></p> <p>OUT – Mark OUT when ONE or MORE food employees are observed failing to follow the handwashing procedures specified in Section 2-301.12 of the <i>Food Code</i>.</p> <p>This information statement CANNOT be marked NO or NA</p>
B	<p style="text-align: center;">FOOD CODE REFERENCE: 2-301.14(A-I)^P</p> <p>IN – Mark IN when food employees are observed washing hands when required as specified in Section 2-301.14 of the <i>Food Code</i></p> <p>OUT – Mark OUT when ONE or MORE food employees are observed failing to wash their hand when required as specified in Section 2-301.14 of the <i>Food Code</i></p> <p>NOTE: Change / Clarification included in the 2013 Food Code – If an employee washes their hands before beginning a food procedure and then dons gloves, they are not required to wash their hands between subsequent glove changes if they do not change tasks.</p> <p>This information statement CANNOT be marked NO or NA</p>

2. Food employees do not contact ready-to-eat foods with bare hands

IN	OUT	NO	NA	
<input type="checkbox"/>	<input type="checkbox"/>			2. Food employees do not contact ready-to-eat foods with bare hands

- Data item 2 does not contain any information statements. The language in the data item is intended to be all encompassing of observations related to bare hand contact of exposed ready-to-eat-foods
- All selected establishments for the Study will have processes that include preparation or service of ready-to-eat foods.

INFO ITEM	MARKING INSTRUCTIONS
	<p style="text-align: center;">FOOD CODE REFERENCE: 3-301.11(B)^P</p> <p>IN – Mark IN when food employees are observed using suitable utensils or single-use gloves to prevent bare hand contact with exposed ready-to-eat foods <u>OR</u> are observed properly following a pre-approved alternative procedure to no bare hand contact. NOTE: When fruits and vegetables are being washed, food employees may touch them with their bare hands.</p> <p>OUT – Mark OUT when ONE or MORE food employees are observed touching exposed ready-to-eat foods with their bare hands <u>OR</u> are observed NOT properly following a pre-approved alternative procedure to no bare hand contact. NOTE: This data item MUST be marked OUT of compliance if one person is observed touching exposed ready-to-eat foods with their bare hands.</p> <p>This information statement CANNOT be marked NO or NA</p>

3. Food is protected from cross-contamination during storage, preparation, and display

IN	OUT	NO	NA	
<input type="checkbox"/>	<input type="checkbox"/>			3. Food is protected from cross-contamination during storage, preparation, and display
IN	OUT	NO	NA	Description of FOOD Contamination OBSERVATIONS
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	A. Raw animal foods are separated from ready-to-eat foods
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	B. Different raw animal foods are separated from each other
<input type="checkbox"/>	<input type="checkbox"/>			C. Food is protected from environmental contamination – actual contamination observed
<input type="checkbox"/>	<input type="checkbox"/>			D. Food is protected from environmental contamination – potential contamination
<input type="checkbox"/>	<input type="checkbox"/>		<input type="checkbox"/>	E. Other (<i>describe in the comments section below</i>)

- Data collectors **CANNOT** select marking options that have been **BLACKED-OUT** for the above data item and information statement.

INFO ITEM	MARKING INSTRUCTIONS
A	<p style="text-align: center;">FOOD CODE REFERENCE: 3-302.11(A)(1)^P</p> <p>IN – Mark IN when direct observations of food storage and handling practices verifies separation of raw animal foods from ready-to-eat foods. Frozen, commercially packaged raw animal food stored or displayed with or above frozen, commercially packaged ready-to-eat foods is to be marked IN.</p> <p>OUT – Mark OUT when direct observations of food storage and handling practices indicates a lack of proper, adequate separation of ONE or MORE raw animal foods from ready-to-eat foods.</p> <p>NO – Mark NO when raw animal foods are used or served periodically but none are present at the time of the data collection <u>and</u> the data collector is unable to observe raw animal food storage and handling practices.</p> <p>NA – Mark NA when there are no raw animal foods used in the facility or only prepackaged foods are served.</p>
B	<p style="text-align: center;">FOOD CODE REFERENCE: 3-302.11(A)(2)^P</p> <p>IN – Mark IN when direct observations of food storage and handling practices verifies separation of raw animal foods by species based on minimum cooking temperatures by spacing or placing in separate containers.</p> <p>OUT – Mark OUT when direct observation of food storage and handling practices indicates a lack of proper, adequate separation of ONE or MORE raw animal foods by species based on minimum cooking temperatures.</p> <p>NO – Mark NO when MORE THAN ONE raw animal food species are used or served periodically but none are present at the time of the data collection <u>and</u> the data collector is unable to observe food storage and handling practices related to multiple raw animal food species.</p> <p>NA – Mark NA when there are no raw animal foods used in the facility or only one raw animal food is used or only prepackaged foods are sold.</p>
C	<p style="text-align: center;">FOOD CODE REFERENCES: 3-302.11(A)(4-8)^C; 3-304.11(B)^P; 3-304.15(A)^P; 3-306.13(A)^P</p> <p>IN – Mark IN when direct observations of food storage and handling practices verifies NO instances of ACTUAL environmental contamination of food (such as compressor drainage dripping on food; splash from mop water contacting food; etc.).</p> <p>OUT – Mark OUT when direct observation of food storage and handling practices indicates ACTUAL environmental contamination of ONE or MORE foods (i.e., compressor drainage is dripping on food; splash from mop water is observed making contact with food, etc.)</p> <p>This information statement CANNOT be marked NO or NA</p>

(Marking Instructions for information statement 3D and 3E continues on the next page)

(Continued from the previous page – marking instructions for information statements 3D and 3E)

3. Food is protected from cross-contamination during storage, preparation, and display

IN	OUT	NO	NA	
<input type="checkbox"/>	<input type="checkbox"/>			3. Food is protected from cross-contamination during storage, preparation, and display
IN	OUT	NO	NA	Description of FOOD Contamination OBSERVATIONS
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	A. Raw animal foods are separated from ready-to-eat foods
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	B. Different raw animal foods are separated from each other
<input type="checkbox"/>	<input type="checkbox"/>			C. Food is protected from environmental contamination – actual contamination observed
<input type="checkbox"/>	<input type="checkbox"/>			D. Food is protected from environmental contamination – potential contamination
<input type="checkbox"/>	<input type="checkbox"/>		<input type="checkbox"/>	E. Other (<i>describe in the comments section below</i>)

- Data collectors **CANNOT** select marking options that have been **BLACKED-OUT** for the above data item and information statement.

INFO ITEM	MARKING INSTRUCTIONS
D	<p>FOOD CODE REFERENCES: 3-302.11(A)(4-8)^C; 3-304.11(B)^P; 3-304.15(A)^P; 3-306.11^P; 3-306.12(A)^C; 3-306.13(A)^P</p> <p>IN – Mark IN when direct observations of food storage and handling practices verifies NO POTENTIAL for environmental contamination of food (such as food in uncovered containers; hermetically sealed containers of food that are visibly soiled before opening;; food set out for display unprotected from potential contamination by the public, etc.).</p> <p>OUT – Mark OUT when direct observations of food storage and handling practices create conditions for POTENTIAL environmental contamination of food (such as food in uncovered containers; hermetically sealed containers of food that are visibly soiled before opening;; food set out for display unprotected from potential contamination by the public, etc.).</p> <p>This information statement CANNOT be marked NO or NA</p>
E	<p>Marked IN / OUT when a food procedure or practice pertaining to protecting food from cross contamination IS observed and not accurately described in the previous information statements for this data item and represents a food procedure / practice that is designated as a PRIORITY ITEM in the <i>Food Code</i>. If the “Other” information statement is marked IN or OUT, the data collector MUST provide a description of the observation in the “Comment” section for the data item.</p> <p>NA – Mark NA when no additional food procedures or practices to the ones presented in the previous information statements for foods protected from contamination are observed.</p> <p>The NO marking is NOT used for the “Other” information statement.</p>

4. Food contact surfaces are properly cleaned and sanitized

IN	OUT	NO	NA	
<input type="checkbox"/>	<input type="checkbox"/>			4. Food contact surfaces are properly cleaned and sanitized
IN	OUT	NO	NA	Description of Food Contact Surfaces OBSERVATIONS
<input type="checkbox"/>	<input type="checkbox"/>			A. Food contact surfaces and utensils are clean to sight and touch and sanitized before use
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	B. Equipment food contact surfaces and utensils are cleaned and sanitized properly using manual warewashing procedures
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	C. Equipment food contact surfaces and utensils are cleaned and sanitized properly using mechanical warewashing equipment
<input type="checkbox"/>	<input type="checkbox"/>		<input type="checkbox"/>	D. Other (describe in the comments section below)

- Data collectors **CANNOT** select marking options that have been **BLACKED-OUT** for the above data item and information statement.
- **NOTE:** This item will require some judgment to be used when marking the information statements IN or OUT of compliance. The information statement should be marked OUT of compliance if observations are made that **support a pattern** of non-compliance with the procedure or practice. One soiled utensil or food contact surface or one sanitizer container without sanitizer, would not necessarily support an OUT of Compliance marking. The data collector **MUST** complete the comment section when an OUT of Compliance marking is documented for one or more of the information statements.

INFO ITEM	MARKING INSTRUCTIONS
A	<p>FOOD CODE REFERENCES: 4-601.11(A)^{PF}(B)^C; 4-602.11^{P&C}; 4-602.12^C; 4-702.11^P</p> <p>NOTE: Information statement “A” is specific to observations of clean and sanitized dishware, utensils, and cookware that have been stored and are considered ready-for-use. Do NOT include observations made of food contact surfaces and utensils that are part of a manual warewashing procedure or cleaning / sanitizing in place equipment which are addressed in information statement “B”. Do NOT include observations of food contact surfaces and utensils as part of a mechanical warewashing procedure which is addressed in information statement “C”.</p> <p>IN – Based on an overall assessment of the establishment’s operation, mark IN when direct observations indicate a substantive pattern for properly cleaning and sanitizing dishware, utensils, and cookware considered ready-for-use.</p> <p>OUT – Based on an overall assessment of the establishment’s operation, mark OUT when direct observations indicate a substantive pattern of soiled and/or un-sanitized dishware, utensils, and cookware considered ready-for-use.</p> <p>This information statement CANNOT be marked NO or NA</p>

(Marking Instructions for information statements 4B continues on the next page)

(Continued from the previous page – marking instructions for information statement 4B)

4. Food contact surfaces are properly cleaned and sanitized

IN	OUT	NO	NA	
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	4. Food contact surfaces are properly cleaned and sanitized
IN	OUT	NO	NA	Description of Food Contact Surfaces OBSERVATIONS
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	A. Food contact surfaces and utensils are clean to sight and touch and sanitized before use
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	B. Equipment food contact surfaces and utensils are cleaned and sanitized properly using manual warewashing procedures
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	C. Equipment food contact surfaces and utensils are cleaned and sanitized properly using mechanical warewashing equipment
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	D. Other (describe in the comments section below)

- Data collectors **CANNOT** select marking options that have been **BLACKED-OUT** for the above data item and information statement.
- **NOTE:** This item will require some judgment to be used when marking the information statements IN or OUT of compliance. The information statement should be marked OUT of compliance if observations are made that **support a pattern** of non-compliance with the procedure or practice. One soiled utensil or food contact surface or one sanitizer container without sanitizer, would not necessarily support an OUT of Compliance marking. The data collector **MUST** complete the comment section when an OUT of Compliance marking is documented for one or more of the information statements.

INFO ITEM	MARKING INSTRUCTIONS
B	<p>FOOD CODE REFERENCES: 4-303.11; 4-501.111^P; 4-501.114^P; 4-501.115^C; 4-703.11(A), (B), or (C)^P</p> <p>NOTE: Information statement “B” is specific to observations of cleaned and sanitized food contact surfaces as part of a manual warewashing or clean-in-place procedure. Do NOT include observations of cleaned and sanitized dishware, utensils, and cookware that have been stored and are considered ready-for-use which are addressed as part of information statement “A”. Do NOT include observations of food contact surfaces and utensils as part of a mechanical warewashing procedure which is addressed in information statement C.</p> <p>IN – Mark IN when direct observations indicate the proper washing and sanitizing of dishes / utensils using a MANUAL procedure or clean-in-place procedures for equipment such as a meat slicer, large mixer, microwave oven, tilting kettle, etc., result in food contact surfaces that are cleaned and sanitized. Examples for this information statement would include observations of food contact surfaces and equipment being properly washed, rinsed, and sanitized in a three compartment sink or observations of the cleaning and sanitization of a tilting kettle (CIP).</p> <p>OUT – Mark OUT when direct observations indicate the lack of, or improper methods / procedures for, washing and sanitizing of dishes / utensils using a MANUAL procedure or clean-in-place equipment such as a meat slicer, large mixer, microwave oven, tilting kettle, etc., result in food contact surfaces that are NOT cleaned and sanitized. Examples would include observations of food contact surfaces and equipment immersed in sanitizing concentrations lower than the critical limits contained in the <i>Food Code</i>; or washing food contact surfaces in dirty water containing little of no detergent solution; or washing food contact surfaces using an improper set-up of the three compartment sink, such as wash-sanitize-rinse; etc. NOTE: Lack of temperature measuring devices and/or chemical tests kits for determining sanitizing rinse temperatures and/or sanitizer concentration is NOT marked under information statement “B” --- mark these observations under information statement “15E”.</p> <p>NO – Mark NO when washing and sanitizing dishes / utensils using a MANUAL procedure is part of the establishment’s operation but is not conducted during the data collection.</p> <p>NA – Mark NA when all equipment and utensils are washed and sanitized in a mechanical dish machine.</p>

(Marking Instructions for information statement 4C continues on the next page)

(Continued from the previous page – marking instructions for information statement 4C)

4. Food contact surfaces are properly cleaned and sanitized

IN	OUT	NO	NA	
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	4. Food contact surfaces are properly cleaned and sanitized
IN	OUT	NO	NA	Description of Food Contact Surfaces OBSERVATIONS
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	A. Food contact surfaces and utensils are clean to sight and touch and sanitized before use
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	B. Equipment food contact surfaces and utensils are cleaned and sanitized properly using manual warewashing procedures
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	C. Equipment food contact surfaces and utensils are cleaned and sanitized properly using mechanical warewashing equipment
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	D. Other (describe in the comments section below)

- Data collectors **CANNOT** select marking options that have been **BLACKED-OUT** for the above data item and information statements
- **NOTE:** This item will require some judgment to be used when marking the information statements IN or OUT of compliance. The information statement should be marked OUT of compliance if observations are made that **support a pattern** of non-compliance with the procedure or practice. One dirty utensil, food contact surface or one sanitizer container without sanitizer, would not necessarily support an OUT of Compliance marking. The data collector **MUST** complete the comment section when an OUT of Compliance marking is documented for one or more of the information statements.

INFO ITEM	MARKING INSTRUCTIONS
C	<p>FOOD CODE REFERENCES: 4-303.11; 4-501.113^C; 4-501.114^P; 4-703.11(B) and (C)^P</p> <p>NOTE: <u>Information statement “C”</u> is specific to observations of cleaned and sanitized food contact surfaces as part of a mechanical warewashing procedure. Do NOT include observations of cleaned and sanitized dishware, utensils, and cookware that have been stored and are considered ready-for-use which are addressed as part of information statement “A”. Do NOT include observations of food contact surfaces and utensils as part of a manual warewashing procedure or clean-in-place equipment such as a meat slicer which is addressed in information statement “B”.</p> <p>NOTE: Observations related to accurate temperature measuring devices and/or test kits provided and accessible for use to measure sanitization rinse temperatures and/or sanitization concentration are recorded under information statement “15E”.</p> <p>IN – Mark IN when direct observations of food contact surfaces and utensils indicate the proper washing and sanitizing of dishes / utensils using a MECHANICAL procedure. An example would include observations (visual inspection) of dishware indicating no food debris remaining on surfaces after the mechanical warewashing process has been completed and proper sanitization temperature or concentration has been measured and meets <i>Food Code</i> critical limits.</p> <p>OUT – Mark OUT when direct observations of dishware and food contact surfaces indicate the lack of, or improper methods / procedures for, washing and sanitizing of dishes / utensils using a MECHANICAL procedure resulting in dishware or food contact surfaces that are NOT cleaned and sanitized. Examples of observations include a pattern of dishware containing food debris after the mechanical warewashing procedure has been completed; or measurements of the hot water or chemical sanitization in the final rinse cycle does NOT meet <i>Food Code</i> critical limits. Observations of this information statement are specific to whether the food contact surface is cleaned and sanitized. Do NOT mark observations of equipment defects, such as a broken temperature gauge, missing baffle plate, etc., under this information statement. NOTE: Lack of temperature measuring devices and/or chemical tests kits for determining sanitizing rinse temperatures and/or sanitizer concentration is NOT marked under information statement “C”--- mark these observations under information statement “15E”.</p> <p>NO – Mark NO when washing and sanitizing dishes / utensils using a MECHANICAL procedure is part of the establishment’s operation but is not conducted during the data collection.</p> <p>NA – Mark NA when all equipment and utensils are washed and sanitized using a manual procedure.</p>

(Marking Instructions for information statement 4D continues on the next page)

(Continued from the previous page – marking instructions for information statement 4D)

4. Food contact surfaces are properly cleaned and sanitized

IN	OUT	NO	NA	
<input type="checkbox"/>	<input type="checkbox"/>			4. Food contact surfaces are properly cleaned and sanitized
IN	OUT	NO	NA	Description of Food Contact Surfaces OBSERVATIONS
<input type="checkbox"/>	<input type="checkbox"/>			A. Food contact surfaces and utensils are clean to sight and touch and sanitized before use
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	B. Equipment food contact surfaces and utensils are cleaned and sanitized properly using manual warewashing procedures
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	C. Equipment food contact surfaces and utensils are cleaned and sanitized properly using mechanical warewashing equipment
<input type="checkbox"/>	<input type="checkbox"/>		<input type="checkbox"/>	D. Other (describe in the comments section below)

- Data collectors **CANNOT** select marking options that have been **BLACKED-OUT** for the above data item and information statements
- **NOTE:** This item will require some judgment to be used when marking the information statements IN or OUT of compliance. The information statement should be marked OUT of compliance if observations are made that **support a pattern** of non-compliance with the procedure or practice. One dirty utensil, food contact surface or one sanitizer container without sanitizer, would not necessarily support an OUT of Compliance marking. The data collector **MUST** complete the comment section when an OUT of Compliance marking is documented for one or more of the information statements.

INFO ITEM	MARKING INSTRUCTIONS
D	<p>Marked IN / OUT when a food procedure / practice related to the cleaning and sanitizing of food contact surfaces IS observed and not accurately described in the previous information statements for this data item, and represents a food procedure / practice that is designated as a PRIORITY ITEM in the <i>Food Code</i>. If the “Other” information statement is marked IN or OUT, the data collector MUST provide a description of the observation in the “Comment” section for the data item.</p> <p>NA – Mark NA when no additional food procedures or practices to the ones presented in the previous information statements for the cleaning and sanitizing of food contact surfaces are observed.</p> <p>The NO marking is NOT used for the “Other” information statement.</p>

5. Foods requiring refrigeration are held at the proper temperature

IN	OUT	NO	NA	
<input type="checkbox"/>	<input type="checkbox"/>			5. Foods requiring refrigeration are held at the proper temperature
IN	OUT	NO	NA	Description of Cold Holding Temperature OBSERVATIONS
<input type="checkbox"/>	<input type="checkbox"/>			A. TCS Food is maintained at 41°F (5°C) or below, except during preparation, cooking, cooling or when time is used as a public health control.
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	B. Raw shell eggs are stored under refrigeration that maintains ambient air temperature of 45°F (7°C) or less
<input type="checkbox"/>	<input type="checkbox"/>		<input type="checkbox"/>	C. Other (describe in the temperature chart and comments section below)

- Data collectors **CANNOT** select marking options that have been **BLACKED-OUT** for the above data item and information statements.
- **NOTE: ALL** observations **MUST** be based on actual food product temperature measurements using a calibrated food temperature measuring device. The data collector should verify that the TCS food requiring refrigeration is not in the process of cooling, or being held using time as a public health control; or has been processed in such a manner as to render it a non-TCS food. **ALL** food product temperatures taken are to be recorded in the temperature chart on the data collection form. If **ONE** product is found to be out of temperature, the appropriate information statement for that food product is marked **OUT** of Compliance.
- **NOTE:** Observations made of procedures where Time, is used as a Public Health Control as it pertains to TCS foods that would normally be held under refrigeration temperatures are to be recorded for information statement “14B”. Do **NOT** record any product temperatures in the cold food product temperature log if it is the intention of the operation’s management to use Time as a Public Health Control.

INFO ITEM	MARKING INSTRUCTIONS
A	<p>FOOD CODE REFERENCE: 3-501.16(A)(2)^P</p> <p>IN – Mark IN when ALL product temperatures taken of TCS food requiring refrigeration are 41°F or below.</p> <p>OUT – Mark OUT when ONE or MORE product temperatures taken of TCS food requiring refrigeration are above 41°F,</p> <p>NOTE: Do NOT assess the cold holding of raw shell eggs as part of this information statement. Cold holding of raw shell eggs is assessed under information statement 6(B).</p> <p>This information statement CANNOT be marked NO or NA.</p>
B	<p>FOOD CODE REFERENCE: 3-501.16(B)^P</p> <p>IN – Mark IN when the AMBIENT air temperature of the refrigeration equipment used for the storage of raw shell eggs is maintaining 45°F or below.</p> <p>OUT – Mark OUT when the AMBIENT air temperature of the refrigeration equipment used for the storage of raw shell eggs is above 45°F.</p> <p>NO – Mark NO when the establishment receives raw shell eggs but there were no raw shell eggs on the premises at the time of the data collection.</p> <p>NA – Mark NA when the establishment does not receive raw shell eggs</p>
C	<p>Mark IN / OUT when a cold holding procedure or practice IS observed and not accurately described in the previous information statements for this data item. If the “Other” information statement is marked IN or OUT, the data collector MUST provide a description of the observation in the “Comment” section for the data item.</p> <p>NA – Mark NA when no additional food procedures or practices to the ones presented in the previous information statements for cold holding are observed.</p> <p>The NO marking is NOT used for the “Other” information statement.</p>

6. Foods displayed or stored hot are held at the proper temperature

IN	OUT	NO	NA	
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	6. Foods displayed or stored hot are held at the proper temperature
IN	OUT	NO	NA	Description of Hot Holding Temperature OBSERVATIONS
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	A. TCS Food is maintained at 135°F (57°C) or above, except during preparation, cooking, cooling, or when time is used as a public health control.
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	B. Roasts are held at a temperature of 130°F (54°C) or above
<input type="checkbox"/>	<input type="checkbox"/>		<input type="checkbox"/>	C. Other (describe in the temperature chart and comments section below)

- Data collectors **CANNOT** select marking option that has been **BLACKED-OUT** for the above information statement.
- **NOTE: ALL** observations **MUST** be based on actual food product temperature measurements using a calibrated food temperature measuring device. **ALL** food product temperatures taken are to be recorded in the temperature chart on the data collection form. If **ONE** product is found to be out of temperature the appropriate information statement for that food product is marked **OUT** of Compliance.

NOTE: Observations made of procedures where Time, is used as a Public Health Control as it pertains to TCS foods that would normally be held hot are to be recorded for information statement “14A”. Do **NOT** record any product temperatures in the hot food product temperature log if it is the intention of the operation’s management to use Time as a Public Health Control.

INFO ITEM	MARKING INSTRUCTIONS
A	FOOD CODE REFERENCE: 3-501.16(A)(1)^P
	<p>NOTE: Do NOT assess hot holding of roasts as part of this information statement. Hot holding of roasts is assessed under information statement 7(B).</p> <p>IN – Mark IN when ALL product temperatures taken of TCS food that is being held hot are 135°F or above.</p> <p>OUT – Mark OUT when ONE or MORE product temperatures taken of TCS food that is being held hot are below 135°F,</p> <p>NO – Mark NO when the establishment does not hold foods, but no foods are being held hot during the data collection.</p> <p>NOTE: Every attempt should be made to conduct the data collection during a time when hot holding temperatures can be taken.</p> <p>NA – Mark NA when the establishment does not hot hold food.</p>
	FOOD CODE REFERENCE: 3-501.16(A)(1)^P
B	<p>IN – Mark IN when ALL product temperatures taken of ROASTS that are being held hot are 130°F or above.</p> <p>OUT – Mark OUT when ONE or MORE product temperatures taken of ROASTS that are being held hot are less than 130°F., AND time is not used as a public health control.</p> <p>NO – Mark NO when the establishment hot holds cooked roasts but no roasts are being held hot during the data collection.</p> <p>NA – Mark NA when the establishment does not prepare or serve roasts</p>
	<p>Mark IN / OUT when a hot holding procedure or practice IS observed and not accurately described in the previous information statements for this data item. If the “Other” information statement is marked IN or OUT, the data collector MUST provide a description of the observation in the “Comment” section for the data item.</p> <p>NA – Mark NA when no additional food procedures or practices to the ones presented in the previous information statements for hot holding are observed.</p> <p>The NO marking is NOT used for the “Other” information statement.</p>

7. Foods are cooled properly

IN	OUT	NO	NA	
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	7. Foods are cooled properly
IN	OUT	NO	NA	Description of Cooling Temperature OBSERVATIONS
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	A. Cooked TCS Food is cooled from 135°F (57°C) to 70°F (21°C) within 2 hours and from 135°F (57°C) to 41°F (5°C) or below within 6 hours
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	B. TCS Food (prepared from ingredients at ambient temperature) is cooled to 41°F (5°C) or below within 4 hours
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	C. Proper cooling methods / equipment are used
<input type="checkbox"/>	<input type="checkbox"/>		<input type="checkbox"/>	D. Other (describe in the temperature chart and comments section below)

- Data collectors **CANNOT** select marking option that has been **BLACKED-OUT** for the above information statement.
- **NOTE:** Production documents, as well as statements from managers, the person-in-charge, and food employees regarding the time the cooling process was initiated, may be used to supplement actual observations. The data collector **MUST** make every effort to assess cooling processes in the early part of the data collection. If TCS foods are in the cooling process during the data collection visit, a **MINIMUM** of two food product time and temperature checks are to be obtained and recorded in the temperature chart provided on the data collection form. **Food Cooling Temperature #1** is the initial internal product temperature of a cooked TCS food OR TCS food prepared from ambient ingredients that is taken at the beginning, or near the beginning, of the establishment visit. **Food Cooling Temperature #2** is the internal product temperature of the cooked TCS food OR TCS food prepared from ambient ingredients that the data collector assessed near the end of the data collection. This second temperature reading is from the same TCS food observed cooling at the beginning of the data collection from which Food Cooling Temperature #1 was obtain. These two temperature measurements provide a method for assessing the cooling rate based on the elapsed time between the first and second temperature measurements.
- **NOTE:** The predictive modeling for cooling rates as presented in FDA’s FD 218 Risk Based Inspection course can be used as a supplemental reference to determine compliance status for cooling observations. The predictive modeling guidance (included as Attachment E) is **NOT** to be used only in conjunction with quantitative temperature measurements but **MUST** be used as part of a holistic assessment of **ALL** information obtained during the data collection regarding the cooling process, equipment, methods, records, etc.

INFO ITEM	MARKING INSTRUCTIONS
A	<p style="text-align: center;">FOOD CODE REFERENCE: 3-501.14(A)^P</p> <p>IN – Mark IN when ALL product temperatures taken of cooked TCS foods that are being cooled meet the <i>Food Code</i> time-temperature critical limits of 135°F to 70°F within 2 hours AND from 135°F to 41°F or below within 6 hours</p> <p>OUT – Mark OUT when ONE or MORE product temperatures taken of cooked TCS food that are being cooled do NOT meet the <i>Food Code</i> time-temperature critical limits of 135°F to 70°F within 2 hours AND/OR from 135°F to 41°F or below within 6 hours.</p> <p>NOTE: Quantitative measurements MUST be used in conjunction with an assessment of ALL information obtained during the data collection including cooling methods, equipment, records, and information provided by food management and food employees.</p> <p>NO – Mark NO when the establishment does cool cooked TCS foods, but no TCS foods are being cooled during the data collection. NOTE: Not Observed (NO) can also be marked when the data collector is uncertain, based on the time-temperature assessment conducted during the data collection, whether the cooked TCS food will cool within the appropriate time frames.</p> <p>NOTE: An IN or OUT marking of information statements C regarding cooling methods / equipment CAN still be recorded even though quantitative measurements fail to provide definitive information as to the cooling rate of the food.</p> <p>NA – Mark NA when the establishment does not cool cooked TCS food.</p>

(Marking Instructions for information statement 7B continues on the next page)

(Continued from the previous page – marking instructions for information statement 7B)

7. Foods are cooled properly

IN	OUT	NO	NA	
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	7. Foods are cooled properly
IN	OUT	NO	NA	Description of Cooling Temperature OBSERVATIONS
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	A. Cooked TCS Food is cooled from 135°F (57°C) to 70°F (21°C) within 2 hours and from 135°F (57°C) to 41°F (5°C) or below within 6 hours
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	B. TCS Food (prepared from ingredients at ambient temperature) is cooled to 41°F (5°C) or below within 4 hours
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	C. Proper cooling methods / equipment are used
<input type="checkbox"/>	<input type="checkbox"/>		<input type="checkbox"/>	D. Other (describe in the temperature chart and comments section below)

- Data collectors **CANNOT** select marking option that has been **BLACKED-OUT** for the above information statement.
- **NOTE:** Production documents, as well as statements from managers, the person-in-charge, and food employees regarding the time the cooling process was initiated, may be used to supplement actual observations. The data collector **MUST** make every effort to assess cooling processes in the early part of the data collection. If TCS foods are in the cooling process during the data collection visit, a **MINIMUM** of two food product time and temperature checks are to be obtained and recorded in the temperature chart provided on the data collection form. **Food Cooling Temperature #1** is the initial internal product temperature of a cooked TCS food **OR** TCS food prepared from ambient ingredients that is taken at the beginning, or near the beginning, of the establishment visit. **Food Cooling Temperature #2** is the internal product temperature of the cooked TCS food **OR** TCS food prepared from ambient ingredients that the data collector assessed near the end of the data collection. This second temperature reading is from the same TCS food observed cooling at the beginning of the data collection from which Food Cooling Temperature #1 was obtain. These two temperature measurements provide a method for assessing the cooling rate based on the elapsed time between the first and second temperature measurements.
- **NOTE:** The predictive modeling for cooling rates as presented in FDA’s FD 218 Risk Based Inspection course can be used as a supplemental reference to determine compliance status for cooling observations. The predictive modeling guidance (included as Attachment E) is **NOT** to be used only in conjunction with quantitative temperature measurements but **MUST** be used as part of a holistic assessment of **ALL** information obtained during the data collection regarding the cooling process, equipment, methods, records, etc.

INFO ITEM	MARKING INSTRUCTIONS
	<p style="text-align: center;">FOOD CODE REFERENCE: 3-501.14(B)^P</p> <p>IN – Mark IN when ALL product temperatures taken of TCS food prepared from ambient ingredients that are being cooled meet the <i>Food Code</i> time-temperature critical limits of reaching 41°F or below within 4 hours..</p> <p>OUT – Mark OUT when ONE or MORE product temperatures taken of TCS food prepared from ambient ingredients that are being cooled do NOT meet the <i>Food Code</i> time-temperature critical limits of reaching 41°F or below within 4 hours.</p> <p>NOTE: Quantitative measurements MUST be used in conjunction with an assessment of ALL information obtained during the data collection including cooling methods, equipment, records, and information provided by food management and food employees.</p> <p>NO – Mark NO when the establishment does cool TCS foods prepared from ambient ingredients, but no TCS food prepared from ambient ingredients are being cooled during the data collection. NOTE: Not Observed (NO) can also be marked when the data collector is uncertain, based on the time-temperature assessment conducted during the data collection, whether the TCS food prepared from ambient ingredients will cool within 4 hours.</p> <p>NOTE: An IN or OUT marking of information statements C cooling methods / equipment CAN still be recorded even though quantitative measurements fail to provide definitive information as to the cooling rate of the food.</p> <p>NA – Mark NA when the establishment does not cool TCS foods prepared from ambient ingredients.</p>

(Marking Instructions for information statement 7C continues on the next page)
 (Continued from the previous page – marking instructions for information statement 7C)

7. Foods are cooled properly

IN	OUT	NO	NA	
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	7. Foods are cooled properly
IN	OUT	NO	NA	Description of Cooling Temperature OBSERVATIONS
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	A. Cooked TCS Food is cooled from 135°F (57°C) to 70°F (21°C) within 2 hours and from 135°F (57°C) to 41°F (5°C) or below within 6 hours
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	B. TCS Food (prepared from ingredients at ambient temperature) is cooled to 41°F (5°C) or below within 4 hours
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	C. Proper cooling methods / equipment are used
<input type="checkbox"/>	<input type="checkbox"/>		<input type="checkbox"/>	D. Other (describe in the temperature chart and comments section below)

- Data collectors **CANNOT** select marking option that has been **BLACKED-OUT** for the above information statement.
- **NOTE:** Production documents, as well as statements from managers, the person-in-charge, and food employees regarding the time the cooling process was initiated, may be used to supplement actual observations. The data collector **MUST** make every effort to assess cooling processes in the early part of the data collection. If TCS foods are in the cooling process during the data collection visit, a **MINIMUM** of two food product time and temperature checks are to be obtained and recorded in the temperature chart provided on the data collection form. **Food Cooling Temperature #1** is the initial internal product temperature of a cooked TCS food OR TCS food prepared from ambient ingredients that is taken at the beginning, or near the beginning, of the establishment visit. **Food Cooling Temperature #2** is the internal product temperature of the cooked TCS food OR TCS food prepared from ambient ingredients that the data collector assessed near the end of the data collection. This second temperature reading is from the same TCS food observed cooling at the beginning of the data collection from which Food Cooling Temperature #1 was obtain. These two temperature measurements provide a method for assessing the cooling rate based on the elapsed time between the first and second temperature measurements.
- **NOTE:** The predictive modeling for cooling rates as presented in FDA’s FD 218 Risk Based Inspection course can be used as a supplemental reference to determine compliance status for cooling observations. The predictive modeling guidance (included as Attachment E) is **NOT** to be used only in conjunction with quantitative temperature measurements but **MUST** be used as part of a holistic assessment of ALL information obtained during the data collection regarding the cooling process, equipment, methods, records, etc.

INFO ITEM	MARKING INSTRUCTIONS
C	<p>FOOD CODE REFERENCES: 3-501.15(A)^{Pf}(B)^C; 4-301.11^{Pf}</p> <p>IN – Mark IN when the cooling process IS observed and the METHODS / EQUIPMENT (shallow pans; smaller thinner portions, ice baths, metal containers, ice as an ingredient, pre-chilled ingredients, blast chiller, tumble-chill unit, etc) facilitate the cooling of cooked / reheated foods or cooling TCS foods made from ambient ingredients.</p> <p>OUT – Mark OUT when the cooling process IS observed but the METHODS / EQUIPMENT do NOT facilitate the cooling of cooked / reheated foods or cooling TCS foods made from ambient ingredients.</p> <p>NOTE: An IN or OUT marking of information statement C regarding cooling methods / equipment IS to be recorded when the data collector has an opportunity observe the cooling methodology or process even though quantitative measurements fail to provide definitive information as to the cooling rate of the food. The data collectors may use statements from managers, the person-in-charge and food employees regarding cooling methods / equipment to supplement their actual observations.</p> <p>NO – Mark NO when the establishment does cool cooked / reheated foods or cools TCS foods made from ambient ingredients, but no TCS foods are being cooled during the data collection</p> <p>NA – Mark NA when the establishment does not cool cooked / reheated food or cool TCS food made from ambient ingredients.</p>

(Marking Instructions for information statement 7D continues on the next page)

(Continued from the previous page – marking instructions for information statement 7D)

7. Foods are cooled properly

IN	OUT	NO	NA	
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	7. Foods are cooled properly
IN	OUT	NO	NA	Description of Cooling Temperature OBSERVATIONS
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	A. Cooked TCS Food is cooled from 135°F (57°C) to 70°F (21°C) within 2 hours and from 135°F (57°C) to 41°F (5°C) or below within 6 hours
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	B. TCS Food (prepared from ingredients at ambient temperature) is cooled to 41°F (5°C) or below within 4 hours
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	C. Proper cooling methods / equipment are used
<input type="checkbox"/>	<input type="checkbox"/>		<input type="checkbox"/>	D. Other (describe in the temperature chart and comments section below)

- Data collectors **CANNOT** select marking option that has been **BLACKED-OUT** for the above information statement.
- **NOTE:** Production documents, as well as statements from managers, the person-in-charge, and food employees regarding the time the cooling process was initiated, may be used to supplement actual observations. The data collector **MUST** make every effort to assess cooling processes in the early part of the data collection. If TCS foods are in the cooling process during the data collection visit, a **MINIMUM** of two food product time and temperature checks are to be obtained and recorded in the temperature chart provided on the data collection form. **Food Cooling Temperature #1** is the initial internal product temperature of a cooked TCS food **OR** TCS food prepared from ambient ingredients that is taken at the beginning, or near the beginning, of the establishment visit. **Food Cooling Temperature #2** is the internal product temperature of the cooked TCS food **OR** TCS food prepared from ambient ingredients that the data collector assessed near the end of the data collection. This second temperature reading is from the same TCS food observed cooling at the beginning of the data collection from which Food Cooling Temperature #1 was obtain. These two temperature measurements provide a method for assessing the cooling rate based on the elapsed time between the first and second temperature measurements.
- **NOTE:** The predictive modeling for cooling rates as presented in FDA’s FD 218 Risk Based Inspection course can be used as a supplemental reference to determine compliance status for cooling observations. The predictive modeling guidance (included as Attachment E) is **NOT** to be used only in conjunction with quantitative temperature measurements but **MUST** be used as part of a holistic assessment of ALL information obtained during the data collection regarding the cooling process, equipment, methods, records, etc.

INFO ITEM	MARKING INSTRUCTIONS
D	<p>Mark IN / OUT when a cooling procedure or practice IS observed and not accurately described in the previous information statements for this data item. If the “Other” information statement is marked IN or OUT, the data collector MUST provide a description of the observation in the “Comment” section for the data item.</p> <p>NA – Mark NA when no additional food procedures or practices to the ones presented in the previous information statements for the cooling of TCS foods are observed.</p> <p>The NO marking is NOT used for the “Other” information statement.</p>

8. Refrigerated, ready-to-eat foods are properly date marked and discarded within 7 days of preparation or opening

IN	OUT	NO	NA	
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	8. Refrigerated, ready-to-eat foods are properly date marked and discarded within 7 days of preparation or opening
IN	OUT	NO	NA	Description of Date Marking OBSERVATIONS
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	A. Ready-to-eat, TCS Food (prepared on-site) held for more than 24 hours is date marked as required
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	B. Open commercial containers of prepared ready-to-eat TCS Food held for more than 24 hours are date marked as required
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	C. Ready-to-eat, TCS Food prepared on-site and/or opened commercial container exceeding 7 days at ≤ 41°F is discarded
<input type="checkbox"/>	<input type="checkbox"/>		<input type="checkbox"/>	D. Other (describe in the temperature chart and comments section below)

- Data collectors **CANNOT** select marking option that has been **BLACKED-OUT** for the above information statement.
- **NOTE:** If date marking applies to the establishment, the person-in-charge should be asked to describe the method(s) used to identify product shelf-life or “consume-by” dating. The data collector must be aware of food products that are listed as exempt from date marking.

INFO ITEM	MARKING INSTRUCTIONS
A	FOOD CODE REFERENCE: 3-501.17(A)(C)(D) ^{pf}
	IN – Mark IN when direct observations of food storage and handling practices verifies that there is a system in place for date marking all ready-to-eat TCS foods prepared on-site and held for more than 24 hours as specified in Section 3-501.17 of the <i>Food Code</i>
	OUT – Mark OUT when direct observations of food storage and handling practices indicates that there is NOT a system in place for date marking all ready-to-eat TCS foods prepared on site and held for more than 24 hours as specified in Section 3-501.17 of the <i>Food Code</i> , OR direct observations indicate that ONE or MORE ready-to-eat TCS foods prepared for more than 24 hours are NOT date marked.
	NO – Mark NO when the establishment does prepare ready-to-eat TCS foods that require date marking, but there are no foods requiring date marking being stored or processed at the time of the data collection.
B	FOOD CODE REFERENCE: 3-501.17(B – F) ^{pf}
	IN – Mark IN when direct observations of food storage and handling practices verifies that there is a system in place for date marking all open commercial containers of ready-to-eat TCS foods held for more than 24 hours as specified in Section 3-501.17 of the <i>Food Code</i> .
	OUT – Mark OUT when direct observation of food storage and handling practices indicates that there is NOT a system in place for date marking all open commercial containers of ready-to-eat TCS foods held for more than 24 hours as specified in Section 3-501.17 of the <i>Food Code</i> , OR direct observations indicate that ONE or MORE open commercial containers of ready-to-eat TCS foods held for more than 24 hours are NOT date marked.
	NO – Mark NO when the establishment does serve ready-to-eat TCS foods from commercial containers but no commercial containers of ready-to-eat foods are open and being held for more the 24 hours at the time of the data collection.
	NA – Mark NA when the establishment does not serve ready-to-eat foods from commercial containers.

(Marking Instructions for information statements 8C and 8D continues on the next page)

(Continued from the previous page – marking instructions for information statements 8C and 8D)

8. Refrigerated, ready-to-eat foods are properly date marked and discarded within 7 days of preparation or opening

IN	OUT	NO	NA	
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	8. Refrigerated, ready-to-eat foods are properly date marked and discarded within 7 days of preparation or opening
IN	OUT	NO	NA	Description of Date Marking OBSERVATIONS
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	A. Ready-to-eat, TCS Food (prepared on-site) held for more than 24 hours is date marked as required
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	B. Open commercial containers of prepared ready-to-eat TCS Food held for more than 24 hours are date marked as required
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	C. Ready-to-eat, TCS Food prepared on-site and/or opened commercial container exceeding 7 days at ≤ 41°F is discarded
<input type="checkbox"/>	<input type="checkbox"/>		<input type="checkbox"/>	D. Other (describe in the temperature chart and comments section below)

- Data collectors **CANNOT** select marking option that has been **BLACKED-OUT** for the above information statement.
- **NOTE:** If date marking applies to the establishment, the person-in-charge should be asked to describe the method(s) used to identify product shelf-life or “consume-by” dating. The data collector must be aware of food products that are listed as exempt from date marking.

INFO ITEM	MARKING INSTRUCTIONS
C	<p>FOOD CODE REFERENCES: 3-501.18(A)^P</p> <p>IN – Mark IN when direct observations of food storage and handling practices verify that all ready-to-eat TCS foods or opened containers of RTE TCS Food are date marked as specified in Section 3-501.17 of the <i>Food Code</i> AND/OR are observed being discarded within date marked time limits.</p> <p>OUT – Mark OUT when direct observations of food storage and handling practices indicates that ONE or MORE ready-to-eat TCS foods or open containers of RTE TCS Food EXCEEDS the time limit as specified in Section 3-501.17 of the <i>Food Code</i>.</p> <p>NO – Mark NO when the establishment does serve ready-to-eat TCS food but there are no foods requiring date marking being stored or processed at the time of the data collection.</p> <p>NA – Mark NA when the establishment does not serve ready-to-eat TCS foods that are held for more than 24 hours.</p>
	<p>Marked IN / OUT when a food procedure / practice related to date marking of ready-to-eat TCS foods held for more than 24 hours IS observed and not accurately described in the previous information statements for this data item. If the “Other” information statement is marked IN or OUT, the data collector MUST provide a description of the observation in the “Comment” section for the data item.</p> <p>NA – Mark NA when no additional food storage or handling practices to the ones presented in the previous information statements for date marking ready-to-eat TCS foods held for more than 24 hours are observed.</p> <p>The NO marking is NOT used for the “Other” information statement.</p>

9. Raw animal foods are cooked to required temperatures

I N	O U T	N O	N A	
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	9. Raw animal foods are cooked to required temperatures
IN	OUT	NO	NA	Description of Cooking Temperature OBSERVATIONS
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	A. Raw shell eggs broken for immediate service are cooked to 145°F (63°C) for 15 seconds. Raw shell eggs broken but not prepared for immediate service cooked to 155°F (68°C) for 15 seconds
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	B. Pork; Fish; Beef; Commercially-raised Game Animals are cooked to 145°F (63°C) for 15 seconds
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	C. Comminuted Fish, Meats, Commercially-raised Game Animals are cooked to 155°F (68°C) for 15 seconds
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	D. Poultry; stuffed fish; stuffed meat; stuffed pasta; stuffed poultry; stuffed ratite; or stuffing containing fish, meat, poultry, or ratites; wild game animals are cooked to 165°F (74°C) for 15 seconds
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	E. Roasts, including formed roasts, are cooked to 130°F (54°C) for 112 minutes or as Chart specifies and according to oven parameters per Chart (NOTE: This data item includes beef roasts, corned beef roasts, pork roasts, and cured pork roasts such as ham).
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	F. Other Cooking Observations (describe in the Comment Section and Temperature Chart below)

- Data collectors **CANNOT** select marking option that has been **BLACKED-OUT** for the above information statement.
- **NOTE: ALL** observations **MUST** be based on actual final cook food product temperature measurements using a calibrated food temperature measuring device. **ALL** food product temperatures taken are to be recorded in the cooking temperature chart on the data collection form. If **ONE** product is found to be out of temperature, the information statement is marked **OUT** of Compliance based on the critical limit specified in the *Food Code* regardless of whether the establishment has a consumer advisory that contains both a disclosure and reminder. If the data collector observes an actual food product temperature that does **NOT** meet the specified critical limits in the *Food Code* (served undercooked) but the establishment has developed, and applies correctly, a consumer advisory for that food product, the actual food product temperature is marked **OUT** under this data item **AND** the data collector records the required information for the food product in the cooking temperature chart including checking the **YES** box under the consumer advisory.

INFO ITEM	MARKING INSTRUCTIONS
A	<p style="text-align: center;">FOOD CODE REFERENCES: 3-401.11(A)(1)(a) and (A)(2)^P</p> <p>IN – Mark IN when ALL product temperatures taken of raw shell eggs broken for immediate service are cooked to 145°F for 15 seconds, AND/OR broken but not prepared for immediate service, are cooked to 155°F for 15 seconds. NOTE: This includes raw shell eggs that are used for baked goods / food products).</p> <p>OUT – Mark OUT when ONE or MORE product temperatures taken of raw shell eggs broken for immediate service AND/OR broken but not prepared for immediate serve, do NOT achieve the final cooking critical limits required in the <i>Food Code</i>. NOTE: This includes raw shell eggs that are used for baked goods / food products).</p> <p>NO – Mark NO when the establishment does cook raw shell eggs but none are cooked during the data collection.</p> <p>NA – Mark NA when the establishment does not cook raw shell eggs.</p>
B	<p style="text-align: center;">FOOD CODE REFERENCE: 3-401.11(A)(1)(b)^P; 3-401.11(C)(3)</p> <p>IN – Mark IN when ALL product temperatures taken of Pork, or Fish, or Beef, or Commercially-raised Game Animals are cooked to the required <i>Food Code</i> critical limit of 145°F for 15 seconds. NOTE: Mark this information statement IN if steaks from whole-muscle, intact beef are cooked on both the top and bottom to a surface temperature of 145°F. or above.</p> <p>OUT – Mark OUT when ONE or MORE product temperatures taken of Pork, or Fish, or Beef, or Commercially-raised Game Animals do NOT achieve the final cooking critical limits of 145°F for 15 seconds. NOTE: Mark this information statement OUT if steaks from whole-muscle, intact beef do NOT achieve the final cooking critical limits on both the top and bottom surfaces of 145°F. or above.</p> <p>NO – Mark NO when the establishment does cook Pork, or Fish, or Beef, or Commercially-raised Game Animals but none are cooked during the data collection.</p> <p>NA – Mark NA when the establishment does not cook Pork, Fish, Beef, or Commercially-raised Game Animals.</p>

(Marking Instructions for information statements 9C, 9D, 9E, and 9F continues on the next page)

(Continued from the previous page – marking instructions for information statements 9C and 9D, 9E, and 9F)

9. Raw animal foods are cooked to required temperatures

I N	OU T	N O	NA	
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	9. Raw animal foods are cooked to required temperatures
IN	OUT	NO	NA	Description of Cooking Temperature OBSERVATIONS
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	A. Raw shell eggs broken for immediate service are cooked to 145°F (63°C) for 15 seconds. Raw shell eggs broken but not prepared for immediate service cooked to 155°F (68°C) for 15 seconds
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	B. Pork; Fish; Beef; Commercially-raised Game Animals are cooked to 145°F (63°C) for 15 seconds
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	C. Comminuted Fish, Meats, Commercially-raised Game Animals are cooked to 155°F (68°C) for 15 seconds
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	D. Poultry; stuffed fish; stuffed meat; stuffed pasta; stuffed poultry; stuffed ratite; or stuffing containing fish, meat, poultry, or ratites; wild game animals are cooked to 165°F (74°C) for 15 seconds
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	E. Roasts, including formed roasts, are cooked to 130°F (54°C) for 112 minutes or as Chart specifies and according to oven parameters per Chart (NOTE: This data item includes beef roasts, corned beef roasts, pork roasts, and cured pork roasts such as ham).
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	F. Other Cooking Observations (describe in the Comment Section and Temperature Chart below)

- Data collectors **CANNOT** select marking option that has been **BLACKED-OUT** for the above information statement.
- **NOTE: ALL** observations **MUST** be based on actual final cook food product temperature measurements using a calibrated food temperature measuring device. **ALL** food product temperatures taken are to be recorded in the cooking temperature chart on the data collection form. If **ONE** product is found to be out of temperature, the information statement is marked **OUT** of Compliance based on the critical limit specified in the *Food Code* regardless of whether the establishment has a consumer advisory that contains both a disclosure and reminder. If the data collector observes an actual food product temperature that does **NOT** meet the specified critical limits in the *Food Code* (served undercooked) but the establishment has developed, and applies correctly, a consumer advisory for that food product, the actual food product temperature is marked **OUT** under this data item **AND** the data collector records the required information for the food product in the cooking temperature chart including checking the **YES** box under the consumer advisory.

INFO ITEM	MARKING INSTRUCTIONS
C	<p>FOOD CODE REFERENCES: 3-401.11(A)(2)^P</p> <p>IN – Mark IN when ALL product temperatures taken of COMMINGUTED fish, or meat, or commercially raised game animals are cooked to the required <i>Food Code</i> critical limit of 155°F for 15 seconds.</p> <p>OUT – Mark OUT when ONE or MORE product temperatures taken of COMMINGUTED fish, or meat, or commercially raised game animals, do NOT achieve the final cooking critical limit of 155°F for 15 seconds.</p> <p>NO – Mark NO when the establishment does cook COMMINGUTED fish, or meat, or commercially raised game animals, but none are cooked during the data collection.</p> <p>NA – Mark NA when the establishment does not cook COMMINGUTED fish, or meat, or commercially raised game animals.</p>

(Marking Instructions for information statements 9D, 9E, and 9F continues on the next page)

(Continued from the previous page – marking instructions for information statements 9D, 9E and 9F)

9. Raw animal foods are cooked to required temperatures

I N	OU T	N O	NA	
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	9. Raw animal foods are cooked to required temperatures
IN	OUT	NO	NA	Description of Cooking Temperature OBSERVATIONS
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	A. Raw shell eggs broken for immediate service are cooked to 145°F (63°C) for 15 seconds. Raw shell eggs broken but not prepared for immediate service cooked to 155°F (68°C) for 15 seconds
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	B. Pork; Fish; Beef; Commercially-raised Game Animals are cooked to 145°F (63°C) for 15 seconds
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	C. Comminuted Fish, Meats, Commercially-raised Game Animals are cooked to 155°F (68°C) for 15 seconds
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	D. Poultry; stuffed fish; stuffed meat; stuffed pasta; stuffed poultry; stuffed ratite; or stuffing containing fish, meat, poultry, or ratites; wild game animals are cooked to 165°F (74°C) for 15 seconds
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	E. Roasts, including formed roasts, are cooked to 130°F (54°C) for 112 minutes or as Chart specifies and according to oven parameters per Chart (NOTE: This data item includes beef roasts, corned beef roasts, pork roasts, and cured pork roasts such as ham).
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	F. Other Cooking Observations (describe in the Comment Section and Temperature Chart below)

- Data collectors **CANNOT** select marking option that has been **BLACKED-OUT** for the above information statement.
- **NOTE: ALL** observations **MUST** be based on actual final cook food product temperature measurements using a calibrated food temperature measuring device. **ALL** food product temperatures taken are to be recorded in the cooking temperature chart on the data collection form. If **ONE** product is found to be out of temperature, the information statement is marked **OUT** of Compliance based on the critical limit specified in the *Food Code* regardless of whether the establishment has a consumer advisory that contains both a disclosure and reminder. If the data collector observes an actual food product temperature that does **NOT** meet the specified critical limits in the *Food Code* (served undercooked) but the establishment has developed, and applies correctly, a consumer advisory for that food product, the actual food product temperature is marked **OUT** under this data item **AND** the data collector records the required information for the food product in the cooking temperature chart including checking the **YES** box under the consumer advisory.

INFO ITEM	MARKING INSTRUCTIONS
D	<p>FOOD CODE REFERENCE: 3-401.11(A)(3)^P</p> <p>IN – Mark IN when ALL product temperatures taken of poultry; stuffed fish; stuffed meat; stuffed pasta; stuffed poultry; stuffed ratites, or <u>stuffing containing</u> (fish; meat; poultry; or ratites), wild game animals are cooked to 165°F for 15 seconds.</p> <p>OUT – Mark OUT when ONE or MORE product temperatures taken of poultry; stuffed fish; stuffed meat; stuffed pasta; stuffed poultry; stuffed ratites; or <u>stuffing containing</u> (fish; meat; poultry; or ratites), wild game animals do NOT achieve the final cooking critical limit of 165°F for 15 seconds</p> <p>NO – Mark NO when the establishment does cook poultry; stuffed fish; stuffed meat; stuffed pasta; stuffed poultry; stuffed ratites, or stuffing containing (fish; meat; poultry; or ratites), or wild game animals but none are cooked during the data collection.</p> <p>NA – Mark NA when the establishment does not cook poultry; stuffed fish; stuffed meat; stuffed pasta; stuffed poultry; stuffed ratites, or <u>stuffing containing</u> (fish; meat; poultry; or ratites) or wild game animals.</p>

(Marking Instructions for information statements 9E, and 9F continues on the next page)

(Continued from the previous page – marking instructions for information statements 9E and 9F)

9. Raw animal foods are cooked to required temperatures

I N	OU T	N O	NA	
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	9. Raw animal foods are cooked to required temperatures
IN	OUT	NO	NA	Description of Cooking Temperature OBSERVATIONS
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	A. Raw shell eggs broken for immediate service are cooked to 145°F (63°C) for 15 seconds. Raw shell eggs broken but not prepared for immediate service cooked to 155°F (68°C) for 15 seconds
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	B. Pork; Fish; Beef; Commercially-raised Game Animals are cooked to 145°F (63°C) for 15 seconds
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	C. Comminuted Fish, Meats, Commercially-raised Game Animals are cooked to 155°F (68°C) for 15 seconds
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	D. Poultry; stuffed fish; stuffed meat; stuffed pasta; stuffed poultry; stuffed ratite; or stuffing containing fish, meat, poultry, or ratites; wild game animals are cooked to 165°F (74°C) for 15 seconds
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	E. Roasts, including formed roasts, are cooked to 130°F (54°C) for 112 minutes or as Chart specifies and according to oven parameters per Chart (NOTE: This data item includes beef roasts, corned beef roasts, pork roasts, and cured pork roasts such as ham).
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	F. Other Cooking Observations (describe in the Comment Section and Temperature Chart below)

- Data collectors **CANNOT** select marking option that has been **BLACKED-OUT** for the above information statement.
- **NOTE: ALL** observations **MUST** be based on actual final cook food product temperature measurements using a calibrated food temperature measuring device. **ALL** food product temperatures taken are to be recorded in the cooking temperature chart on the data collection form. If **ONE** product is found to be out of temperature, the information statement is marked **OUT** of Compliance based on the critical limit specified in the *Food Code* regardless of whether the establishment has a consumer advisory that contains both a disclosure and reminder. If the data collector observes an actual food product temperature that does **NOT** meet the specified critical limits in the *Food Code* (served undercooked) but the establishment has developed, and applies correctly, a consumer advisory for that food product, the actual food product temperature is marked **OUT** under this data item **AND** the data collector records the required information for the food product in the cooking temperature chart including checking the **YES** box under the consumer advisory.

INFO ITEM	MARKING INSTRUCTIONS
E	<p>FOOD CODE REFERENCE: 3-401.11(B)^P</p> <p>IN – Mark IN when ALL product temperatures taken of roasts, including formed roasts, are cooked to 130°F for 112 minutes or as Chart specified and according to oven parameters per Chart contained in the <i>Food Code</i>.</p> <p>OUT – Mark OUT when ONE or MORE product temperatures taken of roasts, including formed roasts, do NOT achieve the final cooking time-temperature critical limits required in the <i>Food Code</i>.</p> <p>NO – Mark NO when the establishment does cook roasts, including formed roasts, but none are cooked during the data collection.</p> <p>NA – Mark NA when the establishment does not cook roasts, including formed roasts.</p>
F	<p>FOOD CODE REFERENCE: 3-401.14(D)^P</p> <p>Marked IN / OUT when a food procedure / practice related to cooking raw animal food IS observed and not accurately described in the previous information statements for this data item. NOTE: <u>Observations of cooking temperature requirements</u> for non-continuous cooking of raw animal foods as specified in Section 3-401.14(D) of the <i>Food Code</i> are marked under the “Other” information statement. NOTE: Change in 2013 Food Code final cook temperatures need to meet critical limits contained in Section 3-401.11 Raw Animal Foods. If the “Other” information statement is marked IN or OUT, the data collector MUST provide a description of the observation in the “Comment” section for the data item.</p> <p>NO – Mark NO when establishment does non-continuous of raw animal foods but it IS not being conducted at the time of the data collection.</p>

<p>NA – Mark NA when no additional food procedures or practices to the ones presented in the previous information statements for the cooking of raw animal foods are observed (including non-continuous cooking processes).</p>
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10. Cooked foods are reheated to required temperatures

I N	O U T	N O	N A	
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	10. Cooked foods are reheated to required temperatures
IN	OUT	NO	NA	Description of Reheating Temperature OBSERVATIONS
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	A. TCS Food that is cooked and cooled on premises is rapidly reheated to 165°F (74°C) for 15 seconds for hot holding
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	B. Commercially-processed ready-to-eat food, reheated to 135°F (57°C) or above for hot holding
<input type="checkbox"/>	<input type="checkbox"/>		<input type="checkbox"/>	C. Other Reheating Observations (describe in the Comments Section and Temperature Chart below)

- Data collectors **CANNOT** select marking option that has been **BLACKED-OUT** for the above information statement.
- **NOTE: ALL** observations **MUST** be based on actual final reheat product temperature measurements using a calibrated food temperature measuring device. **ALL** food product temperatures taken are to be recorded in the reheating temperature chart on the data collection form. If **ONE** product is found to be out of temperature, the information statement is marked **OUT** of Compliance based on the critical limit specified in the *Food Code*.

INFO ITEM	MARKING INSTRUCTIONS
A	<p style="text-align: center;">FOOD CODE REFERENCE: 3-403.11(A)(D)^P</p> <p>IN – Mark IN when ALL product temperatures taken of reheated TCS food that is cooked and cooled on premise achieves 165°F for 15 seconds within 2 hours for hot holding.</p> <p>OUT – Mark OUT when ONE or MORE product temperatures taken of reheated TCS food that is cooked and cooled on premise, do NOT achieve 165°F for 15 seconds within 2 hours for hot holding.</p> <p>NO – Mark NO when the establishment does reheat for hot holding TCS food that is cooked and cooled on premise, but none are reheated during the data collection.</p> <p>NA – Mark NA when the establishment does not reheat for hot holding TCS food that is cooked and cooled on premise.</p>
B	<p style="text-align: center;">FOOD CODE REFERENCE: 3-403.11(C)(D)^P</p> <p>IN – Mark IN when ALL product temperatures taken of reheated commercially processed ready-to-eat foods from intact packaging achieves 135°F for hot holding.</p> <p>OUT – Mark OUT when ONE or MORE product temperatures taken of reheated commercially processed ready-to-eat foods from intact packaging do NOT achieve 135°F for hot holding.</p> <p>NO – Mark NO when the establishment does reheat commercially processed ready-to-eat foods from intact packaging for hot holding, but none are reheated during the data collection.</p> <p>NA – Mark NA when the establishment does not reheat commercially processed ready-to-eat foods from intact packaging for hot holding.</p>
C	<p>Marked IN / OUT when a food procedure / practice related to reheating TCS foods IS observed and not accurately described in the previous information statements for this data item. If the “Other” information statement is marked IN or OUT, the data collector MUST provide a description of the observation in the “Comment” section for the data item.</p> <p>NA – Mark NA when no additional food procedures or practices to the ones presented in the previous information statements for the reheating of TCS foods are observed.</p> <p>The NO marking is NOT used for the “Other” information statement.</p>

Other Areas of Interest (Items 11-19)

NOTE: This section will be used to observe data items that are not part of the primary research area for Retail Food Risk Factor Study but may provide important information related to the primary 10 data items or that will assist other food safety initiatives within the agency

11. Handwashing facilities are accessible and properly maintained

I N	OU T	N O	NA	
<input type="checkbox"/>	<input type="checkbox"/>			11. Handwashing facilities are accessible and properly maintained
IN	OUT	NO	NA	Description of OBSERVATIONS of Handwashing Facilities
<input type="checkbox"/>	<input type="checkbox"/>			A. Handwashing facilities conveniently located and accessible for employees
<input type="checkbox"/>	<input type="checkbox"/>			B. Handwashing facilities supplied with hand cleanser / disposable towels / hand drying devices

- Data collectors **CANNOT** select marking options that have been **BLACKED-OUT** for the above data item and information statements.
- **NOTE:** This data item is specific to **ONLY** handwashing facilities. Observations of food employees’ handwashing practices are to be marked under data item #1 – **Employees practice proper handwashing.**

INFO ITEM	MARKING INSTRUCTIONS
A	<p>FOOD CODE REFERENCE: 5-204.11^{Pf} and 5-205.11(A)^{Pf}</p> <p>IN – Mark IN when handwashing sinks are convenient and accessible for use by food employees.</p> <p>OUT – Mark OUT when ONE or MORE handwashing sinks are NOT convenient and/or accessible for use by food employees. It is also marked OUT if handwashing facilities are blocked by portable equipment, or stacked full of dishes or other items, or the handwashing sink is unavailable for regular employee use.</p> <p>This information statement CANNOT be marked NO or NA.</p>
B	<p>FOOD CODE REFERENCES: 6-301.11^{Pf} and 6-301.12^{Pf}</p> <p>NOTE: The presence of handwashing signage or waste receptacles is NOT part of the assessment of this information statement.</p> <p>IN – Mark IN when handwashing sinks are supplied with hand cleanser and disposable towels or hand drying devices as specified in the <i>Food Code</i>.</p> <p>OUT – Mark OUT when ONE or MORE handwashing sinks are NOT supplied with hand cleanser and/or disposable towels / hand drying devices as specified in the <i>Food Code</i>.</p> <p>This information statement CANNOT be marked NO or NA</p>

12. Employees practice good hygiene

I N	OU T	N O	NA	
<input type="checkbox"/>	<input type="checkbox"/>			12. Employees practice good hygiene
IN	OUT	NO	NA	Description of Good Hygienic Practices OBSERVATIONS
<input type="checkbox"/>	<input type="checkbox"/>			A. Food Employees eat, drink, and use tobacco only in designated areas
<input type="checkbox"/>	<input type="checkbox"/>			B. Food Employees experiencing persistent sneezing, coughing, or runny nose do not work with exposed food, clean equipment, utensils, linens, unwrapped single-service, or single-use articles
<input type="checkbox"/>	<input type="checkbox"/>		<input type="checkbox"/>	C. Other (<i>describe in Comments Section below</i>)

- Data collectors **CANNOT** select marking options that have been **BLACKED-OUT** for the above data item and information statements.

INFO ITEM	MARKING INSTRUCTIONS
A	<p style="text-align: center;">FOOD CODE REFERENCE: 2-401.11^c</p> <p>IN – Mark IN when food employees eat, drink, and use tobacco ONLY in designated areas.</p> <p>OUT – Mark OUT when ONE or MORE food employees are observed improperly tasting food; eating, drinking, or smoking, or there is supporting evidence of these activities taking place in non-designated areas of the establishment. NOTE: An open container of liquid in the kitchen preparation area does not necessarily result in an OUT marking for this information statement. The data collector should have further discussion with food employees or the person-in-charge to determine what the liquid is and its intended use.</p> <p>This information statement CANNOT be marked NO or NA.</p>
B	<p style="text-align: center;">FOOD CODE REFERENCE: 2-401.12^c</p> <p>IN – Mark IN when no food employees are observed experiencing persistent sneezing, coughing, runny nose, or watery eyes working with, or handling exposed food, clean equipment, utensils, linens, unwrapped single-service or single-use articles.</p> <p>OUT – Mark OUT when ONE or MORE food employees are observed having persistent sneezing, coughing, runny nose, or watery eyes and are working with, or handling exposed food, clean equipment, utensils, linens, unwrapped single-service or single-use articles.</p> <p>This information statement CANNOT be marked NO or NA.</p>
C	<p>Marked IN / OUT when an observation pertaining to a food employee hygienic practice IS not accurately described in the previous information statements for this data item. If the “Other” information statement is marked IN or OUT, the data collector MUST provide a description of the observation in the “Comment” section.</p> <p>NA – Mark NA when no additional food procedures or practices to the ones presented in the previous information statements for employee hygienic practices are observed.</p> <p>The NO marking is NOT used for the “Other” information statement.</p>

13. Consumers are properly advised of risk of consuming raw or undercooked animal foods

I N	OU T	N O	NA	
<input type="checkbox"/>	<input type="checkbox"/>		<input type="checkbox"/>	13. Consumers are properly advised of risks of consuming raw or undercooked animal foods

- Data item 13 does not contain any information statements. The language in the data item is intended to be all encompassing of observations related to consumer advisories for animal foods that are served raw or undercooked
- Data collectors **CANNOT** select marking options that have been **BLACKED-OUT** for the above data item.

FOOD CODE REFERENCE: **3-603.11^{Pf}**

IN – Mark IN when the establishment provides a consumer advisory that meets the disclosure and reminder requirements as specified in Section 3-603.11 of the *Food Code* for **ALL** animal foods, such as untreated eggs, beef,, meats, fish, lamb, milk, or poultry, or shellfish that are served raw or undercooked without otherwise being processed to eliminate pathogens either in ready-to-eat form or as an ingredient in ready-to-eat food.

OUT – Mark OUT when the establishment does **NOT** provide a consumer advisory **OR** provides a consumer advisory that does **NOT** meet the disclosure and reminder requirements as specified in Section 3-603.11 of the *Food Code* for **ONE or MORE** animal foods, such as eggs, beef,, fish, lamb, milk, poultry, or shellfish that are served raw, undercooked, or without otherwise being processed to eliminate pathogens either in ready-to-eat form or as an ingredient in ready-to-eat food.

NO – This information statement **CANNOT** be marked NO.

NA – Mark NA when the establishment does **NOT** serve raw animal food or animal food that is **PARTIALLY COOKED or UNDERCOOKED**.

14. Time alone is properly used as a public health control

I N	OU T	N O	NA	
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	14. Time alone is properly used as a public health control
IN	OUT	NO	NA	Description of Time as a public health control OBSERVATIONS
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	A. When time only is used as a public health control for 4 HOURS , the food establishment follows procedures to serve or discard food as specified in Section 3-501.19 of the <i>Food Code</i>
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	B. When time only is used as a public health control for 6 HOURS , the food establishment follows procedures to serve or discard food as specified in Section 3-501.19 of the <i>Food Code</i>
<input type="checkbox"/>	<input type="checkbox"/>		<input type="checkbox"/>	C. Other (describe in the comments section below)

- Data collectors **CANNOT** select marking option that has been **BLACKED-OUT** for the above information statement.
- **NOTE:** Marking this item **MUST** be based on direct observations, record review, discussion with food employee, and review of any standard operating procedures. This data item is only applicable if it is the actual intention or conscious decision by the person-in-charge / food employees to store TCS Food out of temperature control using time as a public health control, otherwise it should be addressed as a hot or cold holding observation.

INFO ITEM	MARKING INSTRUCTIONS
A	<p style="text-align: center;">FOOD CODE REFERENCES: 3-501.19(A)^{Pf}(B)^P</p> <p>IN – Mark IN when there is a WRITTEN procedure at the food establishment that identifies the types of food products that will be held using time only, describes the procedure for how time as a public health control will be implemented, and ALL food items marked or identified for time as a public health control DO NOT EXCEED the 4-HOUR limit.</p> <p>OUT – Mark OUT when ONE or MORE food items marked or identified for time as a public health control EXCEED the 4-HOUR limit. In addition, this information statement is marked OUT if the food is not marked or identified. This information statement is also marked OUT when ALL food items marked or identified for time as a public health control DO NOT EXCEED the 4-HOUR limit BUT there is NO written procedure <u>OR</u> the written procedure for using time only does NOT meet the requirements specified in Section 3-501.19 of the <i>Food Code</i>.</p> <p>NO – Mark NO when the establishment uses a 4-HOUR time only critical limit as a public health control, but time as a public health control is not used during the data collection.</p> <p>NA – Mark NA when the establishment does not use a 4-HOUR time only critical limit as a public health control.</p>
B	<p style="text-align: center;">FOOD CODE REFERENCES: 3-501.19(A)^{Pf}(C)(1)^P(2)^{Pf}(3)^{Pf}(4)^P(5)^P</p> <p>IN – Mark IN when there is a WRITTEN procedure at the food establishment that identifies the types of food products that will be held using time only, describes the procedure for how time as a public health control will be implemented, and ALL food items marked or identified for time as a public health control DO NOT EXCEED the 6-HOUR limit.</p> <p>OUT – Mark OUT when ONE or MORE food items marked or identified for time as a public health control EXCEED the 6-HOUR limit. In addition, this information statement is marked OUT if the food is not marked or identified. This information statement is also marked OUT when ALL food items marked or identified for time as a public health control DO NOT EXCEED the 6-HOUR limit BUT there is NO written procedure <u>OR</u> the written procedure for using time only does NOT meet the requirements specified in Section 3-501.19 of the <i>Food Code</i>.</p> <p>NO – Mark NO when the establishment uses a 6-HOUR time only critical limit as a public health control, but time as a public health control is not used during the data collection.</p> <p>NA – Mark NA when the establishment does not use a 6-HOUR time only critical limit as a public health control.</p>
C	<p>Marked IN / OUT when an observation pertaining to the use of time only as a public health control IS not accurately described in the previous information statements for this data item. If the “Other” information statement is marked IN or OUT, the data collector MUST provide a description of the observation in the Comment section.</p> <p>NA – Mark NA when no additional food procedures or practices to the ones presented in the previous information statements for time only as a public health control are observed.</p>

	The NO marking is NOT used for the “Other” information statement.
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15. Facilities have adequate equipment and tools for ensuring food temperature control and sanitization of food contact surfaces

I N	OU T	N O	NA	
<input type="checkbox"/>	<input type="checkbox"/>			15. Facilities have adequate equipment and tools for ensuring food temperature control and sanitization of food contact surfaces
IN	OUT	NO	NA	Description of OBSERVATIONS for temperature control
<input type="checkbox"/>	<input type="checkbox"/>			A. Refrigeration / cold holding units have sufficient capacity to maintain TCS Foods at 41°F (5°C) or below
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	B. Hot holding units have sufficient capacity to maintain TCS Foods at 135°F (57°C) or above
<input type="checkbox"/>	<input type="checkbox"/>			C. Refrigeration and hot storage units are equipped with accurate ambient air temperature measuring device
<input type="checkbox"/>	<input type="checkbox"/>			D. Accurate temperature measuring device, with appropriate probe, is provided and accessible for use to measure internal food temperatures
<input type="checkbox"/>	<input type="checkbox"/>			E. Accurate temperature measuring devices and/or test kits provided and accessible for use to measure sanitization rinse temperatures and/or sanitization concentrations
<input type="checkbox"/>	<input type="checkbox"/>		<input type="checkbox"/>	F. Other (describe in the comments section below)

- Data collectors **CANNOT** select marking options that have been **BLACKED-OUT** for the above data item and information statements.

INFO ITEM	MARKING INSTRUCTIONS
A	<p style="text-align: center;">FOOD CODE REFERENCE: 4-301.11^{Pf}</p> <p>IN – Mark IN when enough refrigeration / cold holding EQUIPMENT with sufficient capacity is available to maintain TCS Food at 41°F or below.</p> <p>OUT – Mark OUT when there is NOT enough refrigeration / cold holding EQUIPMENT with sufficient capacity to maintain TCS Food at 41°F or below.</p> <p>This information statement CANNOT be marked NO or NA.</p>
B	<p style="text-align: center;">FOOD CODE REFERENCE: 4-301.11^{Pf}</p> <p>IN – Mark IN when enough hot holding EQUIPMENT with sufficient capacity is available to maintain TCS Food at 135°F or above.</p> <p>OUT – Mark OUT when there is NOT enough hot holding EQUIPMENT with sufficient capacity to maintain TCS Food at 135°F or above.</p> <p>NO – Mark NO when the establishment does hot hold foods, but no foods are being held hot during the data collection.</p> <p>NA – Mark NA when the establishment does NOT hot hold food.</p>
C	<p style="text-align: center;">FOOD CODE REFERENCES: 4-203.12^{Pf}; 4-204.112^C</p> <p>IN – Mark IN when refrigeration and / or hot storage units are equipped with accurate AMBIENT AIR TEMPERATURE MEASURING devices.</p> <p>OUT – Mark OUT when refrigeration and / or hot storage unit are NOT equipped with accurate AMBIENT AIR TEMPERATURE MEASURING devices.</p> <p>This information statement CANNOT be marked NO or NA.</p>

(Marking Instructions for information statements 15D, 15F, and 15E continues on the next page)

(Continued from the previous page – marking instructions for information statements 15D, 15F, and 15E)

15. Facilities have adequate equipment and tools for ensuring food temperature control and sanitization of food contact surfaces

IN	OUT	NO	NA	
<input type="checkbox"/>	<input type="checkbox"/>			15. Facilities have adequate equipment and tools for ensuring food temperature control and sanitization of food contact surfaces
IN	OUT	NO	NA	Description of OBSERVATIONS for temperature control
<input type="checkbox"/>	<input type="checkbox"/>			A. Refrigeration / cold holding units have sufficient capacity to maintain TCS Foods at 41°F (5°C) or below
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	B. Hot holding units have sufficient capacity to maintain TCS Foods at 135°F (57°C) or above
<input type="checkbox"/>	<input type="checkbox"/>			C. Refrigeration and hot storage units are equipped with accurate ambient air temperature measuring device
<input type="checkbox"/>	<input type="checkbox"/>			D. Accurate temperature measuring device, with appropriate probe, is provided and accessible for use to measure internal food temperatures
<input type="checkbox"/>	<input type="checkbox"/>			E. Accurate temperature measuring devices and/or test kits provided and accessible for use to measure sanitization rinse temperatures and/or sanitization concentrations
<input type="checkbox"/>	<input type="checkbox"/>		<input type="checkbox"/>	F. Other (describe in the comments section below)

- Data collectors **CANNOT** select marking options that have been **BLACKED-OUT** for the above data item and information statements.

INFO ITEM	MARKING INSTRUCTIONS
D	<p>FOOD CODE REFERENCES: 4-203.11^{Pf}; 4-302.12(A)^{Pf}(B)^{Pf}; 4-502.11(B)^{Pf}</p> <p>IN – Mark IN when an ACCURATE TEMPERATURE MEASURING DEVICE, with appropriate probe IS provided and accessible for use to measure INTERNAL FOOD TEMPERATURES.</p> <p>OUT – Mark OUT when an ACCURATE TEMPERATURE MEASURING DEVICE, with appropriate probe IS NOT provided and accessible to measure INTERNAL FOOD TEMPERATURES.</p> <p>This information statement CANNOT be marked NO or NA.</p>
E	<p>FOOD CODE REFERENCES: 4-302.13^C 4-301.14^{Pf}; 4-703.11(B)^{Pf}</p> <p>IN – Mark IN when an ACCURATE TEMPERATURE MEASURING DEVICE and/or TEST KITS are provided and accessible to measure SANITIZING RINSE TEMPERATURES or SANITIZING CONCENTRATIONS.</p> <p>OUT – Mark OUT when an ACCURATE TEMPERATURE MEASURING DEVICE and/or TEST KITS are NOT provided and accessible to measure SANITIZING RINSE TEMPERATURES or SANITIZING CONCENTRATIONS.</p> <p>This information statement CANNOT be marked NO or NA.</p>
F	<p>Marked IN / OUT when an observation pertaining to equipment and tools for maintaining and measuring proper temperature IS not accurately described in the previous information statements for this data item. If the “Other” information statement is marked IN or OUT, the data collector MUST provide a description of the observation in the “Comment” section.</p> <p>NA – Mark NA when no additional observations to the ones presented in the previous information statements are noted for equipment and tools for maintaining and measuring proper temperature.</p> <p>The NO marking is NOT used for the “Other” information statement.</p>

16. Special processes are conducted in compliance with issued variance / HACCP Plan, when required

I N	OU T	N O	NA	
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	16. Special processes are conducted in compliance with issued variance / HACCP Plan, when required
IN	OUT	NO	NA	Description of OBSERVATIONS of Specialized Processes
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	A. Food establishment conducts reduced oxygen packaging without a variance as specified in Section 3-502.12 of the <i>Food Code</i>
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	B. Food establishment performs specialized process in accordance with approved variance and HACCP Plan when required
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	C. Juice packaged in the food establishment is treated under a HACCP Plan to reduce pathogens or labeled as specified in Section 3-404.11 of the <i>Food Code</i>
<input type="checkbox"/>	<input type="checkbox"/>		<input type="checkbox"/>	D. Other (describe in the comments section below)

- Data collectors **CANNOT** select marking option that has been **BLACKED-OUT** for the above information statement.

INFO ITEM	MARKING INSTRUCTIONS
A	<p style="text-align: center;">FOOD CODE REFERENCES: 3-502.12^{P,Pf}; 8-201.13(B)^C; 8-201.14(A-D)^{Pf}</p> <p>IN – Mark IN when direct observations of REDUCED OXYGEN PACKAGING processes permitted WITHOUT a VARIANCE (including cook chill, sous vide, or vacuum packaging) indicate they are conducted in accordance with the required HACCP Plan and MEET the specific critical limits required in Section 3-502.12 of the <i>Food Code</i>. NOTE: This includes observations of ROP foods being held under refrigeration AND labeling and record information associated with those refrigerated ROP foods.</p> <p>OUT – Mark OUT when direct observations of REDUCED OXYGEN PACKAGING processes permitted WITHOUT A VARIANCE (including cook chill, sous vide, or vacuum packaging) indicate they are NOT conducted in accordance with the required HACCP Plan <u>or</u> DO NOT MEET the specific critical limits required in Section 3-502.12 of the <i>Food Code</i>. NOTE: This includes observations of ROP foods being held under refrigeration AND labeling and record information associated with those refrigerated ROP foods.</p> <p>NO – Mark NO when the establishment does reduced oxygen packaging without a variance, but no ROP foods are being processed <u>OR</u> observed at the time of the data collection and no ROP products are available.</p> <p>NA – Mark NA when the establishment does not conduct reduced oxygen packaging <u>OR</u> only conducts ROP processes that require a variance.</p>
B	<p style="text-align: center;">FOOD CODE REFERENCES: 3-502.11^{Pf}; 8-103.12^{P,Pf}; 8-201.14(A-D)^{Pf}</p> <p>IN – Mark IN when direct observations of SPECIAL PROCESSES (including smoking food, curing food, using food additives to render a food so it is not a TCS Food, and reduced oxygen packaging processes that REQUIRE A VARIANCE) indicate they are CONDUCTED IN ACCORDANCE with the approved variance and required HACCP Plan (including adherence to all critical limits, product labeling, and record keeping requirements). NOTE: Special Processes for this information statement DOES NOT include juice packaged in a food establishment which is addressed in information statement 16C.</p> <p>OUT – Mark OUT when direct observations of SPECIAL PROCESSES (including smoking food, curing food, using food additives to render a food so it is not a TCS Food, and reduced oxygen packaging processes that REQUIRE A VARIANCE) indicate they ARE NOT CONDUCTED IN ACCORDANCE with the approved variance and required HACCP Plan (including adherence to all critical limits, product labeling, and record keeping requirements). NOTE: Special Processes for this information statement DOES NOT include juice packaged in a food establishment which is addressed in information statement 16C.</p>

NO – Mark NO when the establishment does special processes as described under this information statement, but no specialized processes are being conducted OR no foods prepare using a special process are observed at the time of the data collection and no special process products are available.

NA – Mark NA when the establishment does not conduct special processes as described under this information statement.

(Marking Instructions for information statements 16C and 16D continues on the next page)

(Continued from the previous page – marking instructions for information statements 16C and 16D)

16. Special processes are conducted in compliance with issued variance / HACCP Plan, when required

I N	OU T	N O	NA	
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	16. Special processes are conducted in compliance with issued variance / HACCP Plan, when required
IN	OUT	NO	NA	Description of OBSERVATIONS of Specialized Processes
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	A. Food establishment conducts reduced oxygen packaging without a variance as specified in Section 3-502.12 of the <i>Food Code</i>
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	B. Food establishment performs specialized process in accordance with approved variance and HACCP Plan when required
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	C. Juice packaged in the food establishment is treated under a HACCP Plan to reduce pathogens or labeled as specified in Section 3-404.11 of the <i>Food Code</i>
<input type="checkbox"/>	<input type="checkbox"/>		<input type="checkbox"/>	D. Other (describe in the comments section below)

- Data collectors **CANNOT** select marking option that has been **BLACKED-OUT** for the above information statement.

INFO ITEM	MARKING INSTRUCTIONS
C	<p style="text-align: center;">FOOD CODE REFERENCE: 3-404.11^{P, Pf}; 8-201.14(A-D)^{Pf}</p> <p>IN – Mark IN when direct observations of JUICE BEING PACKAGED <u>OR</u> that HAS BEEN PACKAGED in the food establishment indicate the process IS conducted in accordance with a HACCP Plan that attains a 5-log reduction of the most resistant pathogen <u>OR IS</u> labeled as required in Section 3-404.11 of the <i>Food Code</i>.</p> <p>OUT – Mark OUT when direct observations of JUICE BEING PACKAGED <u>OR</u> that HAS BEEN PACKAGED in the food establishment indicate the process IS NOT conducted in accordance with a HACCP Plan that attains a 5-log reduction of the most resistant pathogen <u>OR IS NOT</u> labeled as required in Section 3-404.11 of the <i>Food Code</i>.</p> <p>NO – Mark NO when the establishment does PACKAGE JUICE, but no juice is being packaged OR no juice that has been packaged in the establishment is present at the time of the data collection.</p> <p>NA – Mark NA when the establishment does not package juice.</p>
D	<p>Marked IN / OUT when an observation pertaining to reduced oxygen packaging or special processes or juice packaging IS NOT accurately described in the previous information statements for this data item. If the “Other” information statement is marked IN or OUT, the data collector MUST provide a description of the observation in the “Comment” section, such as a Molluscan Shellfish Tank used to store or display shellfish for human consumption.</p> <p>NA – Mark NA when no additional observations to the ones presented in the previous information statements are noted for reduced oxygen packaging or special processes or juice packaging.</p> <p>The NO marking is NOT used for the “Other” information statement.</p>

17. Food is received from safe sources

I N	OU T	N O	NA	
<input type="checkbox"/>	<input type="checkbox"/>			17. Food is received from safe sources
IN	OUT	NO	NA	Description of FOOD SOURCE OBSERVATIONS
<input type="checkbox"/>	<input type="checkbox"/>			A. All food is from regulated food processing plants / No home prepared/canned foods
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	B. Shellfish are from NSSP-listed sources. No recreationally caught shellfish are received/sold
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		C. Food is protected from contamination during transportation/receiving
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		D. TCS Food is received at a temperature of 41°F (5°C) or below OR according to Law
<input type="checkbox"/>	<input type="checkbox"/>			E. Food is safe and unadulterated
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	F. Shellstock tags/labels are retained for 90 days and filed in chronological order from the date the container is emptied
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	G. Written documentation of parasite destruction is maintained for 90 days for fish products
<input type="checkbox"/>	<input type="checkbox"/>		<input type="checkbox"/>	H. Other (<i>describe in Comments Section below</i>)

- Data collectors **CANNOT** select marking options that have been **BLACKED-OUT** for the above data item and information statements.

INFO ITEM	MARKING INSTRUCTIONS
A	<p style="text-align: center;">FOOD CODE REFERENCES: 3-201.11^{P,Pf}; 3-201.12^P; 3-201.13^P; 3-201.14^P; 3-202.12^P; 3-202.13^P; 3-202.14^P; 3-202.110^{P, Pf}; 5-101.13^P</p> <p>IN – Mark IN when direct observations determine that food is obtained from approved food sources. A review of supplier names, shipment invoices, buyer specifications, proof of regulatory permit/licensure of food source, etc., can be used to document approved food sources. Milk and milk products comply with Grade A Standards.</p> <p>OUT – Mark OUT when direct observations determine that food is NOT obtained from approved food sources <u>OR</u> milk and milk products do NOT comply with Grade A Standards.</p> <p>This information statement CANNOT be marked NO or NA.</p>
B	<p style="text-align: center;">FOOD CODE REFERENCE: 3-201.15^P</p> <p>IN – Mark IN when direct observations determine that molluscan shellfish are obtained from approved food sources. A review of the ICSSL listed sources, molluscan shellfish tags, supplier’s names, shipment invoices, proof of regulatory permit/licensure of food source, buyer specification, etc., can be used to determine approved food source.</p> <p>OUT – Mark OUT when direct observations determine that molluscan shellfish are NOT obtained from approved food sources.</p> <p>NO – Mark NO when molluscan shellfish are sold periodically in the establishment but are not being sold at the time of the data collection.</p> <p>NA – Mark NA when molluscan shellfish are not used/offered as a menu item within the establishment.</p>
C	<p style="text-align: center;">FOOD CODE REFERENCES: 3-101.11^P; 3-202.15^{Pf}</p> <p>NOTE: This information statement is specific to observations made of food as it is received from the supplier</p> <p>IN – Mark IN when direct observations determine that food is protected from environmental contamination during transport and receiving. Observations can be based on the integrity of product packaging and/or an assessment of the environmental conditions within transportation vehicles at the time of receipt.</p> <p>OUT – Mark OUT when direct observations determine that food is NOT protected from environmental contamination during transport and receiving.</p> <p>NO – Mark NO when food is not received by the establishment during the data collection</p> <p>This information statement CANNOT be marked NA</p>

(Marking Instructions for information statements 17D, 17E, 17F, 17G, and 17H continues on the next page)

(Continued from the previous page – marking instructions for information statements 17D, 17E, 17F, 17G, and 17H)

17. Food is received from safe sources

I N	OU T	N O	NA	
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	17. Food is received from safe sources
IN	OUT	NO	NA	Description of FOOD SOURCE OBSERVATIONS
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	A. All food is from regulated food processing plants / No home prepared/canned foods
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	B. Shellfish are from NSSP-listed sources. No recreationally caught shellfish are received/sold
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	C. Food is protected from contamination during transportation/receiving
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	D. TCS Food is received at a temperature of 41°F (5°C) or below OR according to Law
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	E. Food is safe and unadulterated
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	F. Shellstock tags/labels are retained for 90 days and filed in chronological order from the date the container is emptied
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	G. Written documentation of parasite destruction is maintained for 90 days for fish products
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	H. Other (<i>describe in Comments Section below</i>)

- Data collectors **CANNOT** select marking options that have been **BLACKED-OUT** for the above data item and information statements.

INFO ITEM	MARKING INSTRUCTIONS
D	<p style="text-align: center;">FOOD CODE REFERENCE: 3-202.11^{P, Pf}</p> <p>NOTE: This information statement MUST be based on actual food product temperature measurements of TCS food being RECEIVED.</p> <p>IN – Mark IN when direct observations of actual food product temperature measurements determine that food is RECEIVED at proper temperatures during the data collection.</p> <p>OUT – Mark OUT when direct observations of actual food product temperature measurements determine that ONE or MORE food products are NOT RECEIVED at proper temperature.</p> <p>NO – Mark NO if food is not received during the data collection.</p> <p>This information statement CANNOT be marked NA</p>
E	<p style="text-align: center;">FOOD CODE REFERENCE: 3-101.11^P</p> <p>NOTE: This information statement applies to observations of the wholesomeness of food from receiving through service and is NOT restricted to only receiving of foods.</p> <p>IN – Mark IN when direct observations determine that all food products are wholesome <u>AND/OR</u> show no signs of adulteration.</p> <p>OUT – Mark OUT when direct observations determine that food products are NOT wholesome <u>AND/OR</u> indicate signs of adulteration.</p> <p>This information statement CANNOT be marked NO or NA.</p>

(Marking Instructions for information statements 17F, 17G, and 17H continues on the next page)

(Continued from the previous page – marking instructions for information statements 17F, 17G, and 17H)

17. Food is received from safe sources

I N	OU T	N O	NA	
<input type="checkbox"/>	<input type="checkbox"/>			17. Food is received from safe sources
IN	OUT	NO	NA	Description of FOOD SOURCE OBSERVATIONS
<input type="checkbox"/>	<input type="checkbox"/>			A. All food is from regulated food processing plants / No home prepared/canned foods
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	B. Shellfish are from NSSP-listed sources. No recreationally caught shellfish are received/sold
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		C. Food is protected from contamination during transportation/receiving
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		D. TCS Food is received at a temperature of 41°F (5°C) or below OR according to Law
<input type="checkbox"/>	<input type="checkbox"/>			E. Food is safe and unadulterated
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	F. Shellstock tags/labels are retained for 90 days and filed in chronological order from the date the container is emptied
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	G. Written documentation of parasite destruction is maintained for 90 days for fish products
<input type="checkbox"/>	<input type="checkbox"/>		<input type="checkbox"/>	H. Other (<i>describe in Comments Section below</i>)

- Data collectors **CANNOT** select marking options that have been **BLACKED-OUT** for the above data item and information statements.

INFO ITEM	MARKING INSTRUCTIONS
F	<p style="text-align: center;">FOOD CODE REFERENCES: 3-202.18(A)^{Pf}; 3-203.12^{Pf}</p> <p>IN – Mark IN when direct observations of shellstock tags indicates that ALL required information as specified in Section 3-202.18 of the <i>Food Code</i> is present and shellstock tags are retained for 90 days and filed in chronological order and in conformance with Section 3-203.12 of the <i>Food Code</i>.</p> <p>OUT – Mark OUT when no shellstock tags are available for shellfish used or sold in the establishment within the past 90 days <u>AND/OR</u> the information on the shellstock tags does NOT contain the required information as specified in Section 3-202.18 of the <i>Food Code</i>. In addition, the information statement is marked OUT if the establishment is not in compliance with Section 3-203.12 of the <i>Food Code</i> OR there is evidence indicates commingling of shellstock.</p> <p>NO – Mark NO when shellstock are sold periodically in the establishment but are not being sold at the time of the data collection and have not been sold or used within the establishment within the past 90 days.</p> <p>NA – Mark NA when shellstock are not used/sold in the establishment.</p>

(Marking Instructions for information statements 17G, and 17H continues on the next page)

(Continued from the previous page – marking instructions for information statements 17G, and 17H)

17. Food is received from safe sources

I N	OU T	N O	NA	
<input type="checkbox"/>	<input type="checkbox"/>			17. Food is received from safe sources
IN	OUT	NO	NA	Description of FOOD SOURCE OBSERVATIONS
<input type="checkbox"/>	<input type="checkbox"/>			A. All food is from regulated food processing plants / No home prepared/canned foods
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	B. Shellfish are from NSSP-listed sources. No recreationally caught shellfish are received/sold
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		C. Food is protected from contamination during transportation/receiving
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		D. TCS Food is received at a temperature of 41°F (5°C) or below OR according to Law
<input type="checkbox"/>	<input type="checkbox"/>			E. Food is safe and unadulterated
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	F. Shellstock tags/labels are retained for 90 days and filed in chronological order from the date the container is emptied
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	G. Written documentation of parasite destruction is maintained for 90 days for fish products
<input type="checkbox"/>	<input type="checkbox"/>		<input type="checkbox"/>	H. Other (<i>describe in Comments Section below</i>)

- Data collectors **CANNOT** select marking options that have been **BLACKED-OUT** for the above data item and information statements.
- **NOTE:** Data collectors should be aware of exemptions to the freezing for parasite destruction. Such exemptions include molluscan shellfish, Tuna species *Thunnus alalunga*, *Thunnus albacares* (Yellowfin tuna), *Thunnus atlanticus*, *Thunnus maccoyli* (Bluefin tuna, Southern), *Thunnus obesus* (Bigeye tuna), or *Thunnus thynnus* (Bluefin tuna, Northern), and aquacultured fish such as salmon that are pen-raised and are fed formulated feed.

INFO ITEM	MARKING INSTRUCTIONS
	<p style="text-align: center;">FOOD CODE REFERENCES: 3-402.11^P; 3-402.12^{Pf}</p> <p>IN – Mark IN when direct observations determine that fish products intended for raw or undercooked consumption have been frozen in accordance with the time and temperature requirements specified in Section 3-402.11 of the <i>Food Code</i>. Observations are to be supported by documentation from the supplier identifying that fish sold as raw, raw marinated, or undercooked is frozen by the supplier for parasite destruction <u>AND/OR</u> there are records maintained by the permit holder documenting the time and temperature critical limits when fish are frozen at the establishment.</p> <p>G OUT – Mark OUT when direct observations determine that ONE or MORE fish products intended for raw or undercooked consumption have NOT been frozen in accordance with the time and temperature requirement specified in Section 3-402.11 of the <i>Food Code</i> <u>OR</u> no documentation is available at the time of the data collection verifying that fish sold as raw, raw marinated, or undercooked has been frozen for parasite destruction.</p> <p>NO – Mark NO if fish products intended for raw or undercooked consumption are sold periodically in the establishment, but are not being sold or used at the time of the data collection.</p> <p>NA – Mark NA if fish products intended for raw or undercooked consumption are not sold or used in the establishment.</p>
H	<p>Marked IN / OUT when an observation pertaining to an approved food source IS NOT accurately described in the previous information statements for this data item. If the “Other” information statement is marked IN or OUT, the data collector MUST provide a description of the observation in the “Comment” section.</p> <p>NA – Mark NA when no additional observations to the ones presented in the previous information statements are noted for approved food sources.</p> <p>The NO marking is NOT used for the “Other” information statement.</p>

18. Toxic materials are identified, used, and stored properly

I N	OU T	N O	NA	
<input type="checkbox"/>	<input type="checkbox"/>			18. Toxic materials are identified, used, and stored properly
IN	OUT	NO	NA	Description of Toxic Materials OBSERVATIONS
<input type="checkbox"/>	<input type="checkbox"/>			A. Poisonous or toxic materials, chemicals, lubricants, pesticides, medicines, first aid supplies, and other personal care items are properly identified, stored, and used
<input type="checkbox"/>	<input type="checkbox"/>		<input type="checkbox"/>	B. Other (<i>describe in the comments section below</i>)

- Data collectors **CANNOT** select marking options that have been **BLACKED-OUT** for the above data item and information statements.
- **NOTE:** This item will require some judgment to be used when marking the information statements IN or OUT of compliance. The information statement should be marked OUT of compliance if observations are made that **support a pattern** of non-compliance with the procedure or practice. One unlabeled cleaning agent bottle would not necessarily support an OUT of Compliance marking. The data collector **MUST** complete the comment section when an OUT of Compliance marking is documented for one or more of the information statements.

INFO ITEM	MARKING INSTRUCTIONS
A	<p>FOOD CODE REFERENCES: 7-101.11^{Pf}; 7-102.11^{Pf}; 7-201.11^P; 7-202.11^{Pf}; 7-202.12^{P,Pf}; 7-203.11^P; 7-204.11^P; 7-204.12^{P,C}; 7-204.13^P; 7-204.14^P; 7-205.11^P; 7-206.11^P; 7-206.12^P; 7-206.13^{P,C}; 7-207.11^{P,Pf}; 7-207.12^P; 7-208.11^{P,Pf}; 7-209.11^C</p> <p>IN – Mark IN when direct observations determine that bulk and working containers of cleaning agents and sanitizers are labeled; sanitizing solutions are NOT exceeding the maximum concentrations; personal care items, first aid supplies, medicines, and chemicals are stored separate from and NOT above food, equipment, utensils, linens, and single-use articles; and restricted use pesticides are applied only by or under the supervision of a certified applicator.</p> <p>OUT – Based on an overall assessment of the establishment’s operation, mark OUT when direct observations indicate a substantive pattern of unlabeled containers of cleaning agents and/or sanitizers. In addition, this information statement is marked out if there is NOT adequate separation of chemicals and medicines from food, equipment, utensils, linens and single-use articles. Mark Out when sanitizer solution exceeds maximum concentration or if medicines and first aid kits are improperly label and/or stored.</p> <p>This information statement CANNOT be marked NO or NA</p>
B	<p>Marked IN / OUT when an observation pertaining to the labeling, use, or storage of toxic materials IS NOT accurately described in the previous information statements for this data item. If the “Other” information statement is marked IN or OUT, the data collector MUST provide a description of the observation in the “Comment” section.</p> <p>NA – Mark NA when no additional observations to the ones presented in the previous information statements are noted for the labeling, use, or storage of toxic materials.</p> <p>The NO marking is NOT used for the “Other” information statement.</p>

19. Management and food employees are trained in food allergy awareness as it relates to their assigned duties

I N	OU T	N O	NA	
<input type="checkbox"/>	<input type="checkbox"/>			19. Management and food employees are trained in food allergy awareness as it relates to their assigned duties
IN	OUT	NO	NA	Description of Allergen Awareness OBSERVATIONS
<input type="checkbox"/>	<input type="checkbox"/>			A. The person in charge accurately describes foods identified as major food allergens and the symptoms associated with major food allergens
<input type="checkbox"/>	<input type="checkbox"/>			B. Food employees are trained in food allergy awareness as it relates to their assigned duties
<input type="checkbox"/>	<input type="checkbox"/>		<input type="checkbox"/>	C. Other (describe in the comments section below)

- Data collectors **CANNOT** select marking options that have been **BLACKED-OUT** for the above data item and information statements.
- **NOTE:** Data collector should be aware of the 8 major food allergens including : Milk; Egg; Fish (such as bass, flounder, or cod); Crustacean shellfish (such as crab, lobster, or shrimp); Tree nuts (such as almonds, pecans, or walnuts); Wheat; Peanuts; and Soybeans
- **NOTE:** Data collector should be aware of the symptoms associated with a food allergic response including: hives or other itchy rashes; nausea; abdominal pain; vomiting and/or diarrhea; wheezing; shortness of breath; and swelling of various parts of the body. In severe cases, anaphylactic shock and death may result.

INFO ITEM	MARKING INSTRUCTIONS
A	<p style="text-align: center;">FOOD CODE REFERENCE: 2-102.11(C)(9)^{Pf}</p> <p>IN – Mark IN when the person-in-charge provides responses to questions that demonstrate knowledge of the 8 major food allergens and symptoms associated with the major food allergens.</p> <p>OUT – Mark OUT when the person-in-charge does NOT provide responses to questions that demonstrate knowledge of the 8 major food allergens and symptoms associated with the major food allergens</p> <p>This information statement CANNOT be marked NO or NA.</p>
B	<p style="text-align: center;">FOOD CODE REFERENCE: 2-103.11(N)^{Pf}</p> <p>IN – Mark IN when the person-in-charge provides a description of the food employee allergen training program that covers the 8 major allergens as they related to the employees assigned duties and symptoms associated with the major food allergens. The training program can be verbal or written. The person-in-charge is able to describe how the training is provided to front line employees and whether menu items containing one or more of the major food allergens are covered in the training.</p> <p>OUT – Mark OUT when a food employee allergen training program is NOT provided or does NOT address food allergy awareness as it related to food employees assigned duties. In addition, this information statement is marked OUT if a menu item containing one or more of the major food allergens is offered but is NOT included as part of the food employee allergen training program.</p> <p>This information statement CANNOT be marked NO or NA.</p>
C	<p>Marked IN / OUT when an observation pertaining to food allergy awareness IS NOT accurately described in the previous information statements for this data item. If the “Other” information statement is marked IN or OUT, the data collector MUST provide a description of the observation in the “Comment” section.</p> <p>NA – Mark NA when no additional observations to the ones presented in the previous information statements are noted for food allergy awareness.</p> <p>The NO marking is NOT used for the “Other” information statement.</p>

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DATA COLLECTION FORM**

Food Code Reference Sheet

1. Employees practice proper handwashing (Deleted Reference to Info Statement 1C)	
Info Statement	Food Code Reference(s)
A	2-301.12 ^P – Cleaning Procedure
B	2-301.14(A-I) ^P – When to Wash
2. Employees do not contact ready-to-eat foods with bare hands	
Food Code Reference(s)	
3-301.11(B) ^P – Preventing Contamination from Hands	
3. Food is protected from cross-contamination during storage, preparation, and display	
Info Statement	Food Code Reference(s)
A	3-302.11(A)(1) ^P – Packaged and Unpackaged Food – Separation, Packaging, and Segregation
B	3-302.11(A)(2) ^P – Packaged and Unpackaged Food – Separation, Packaging, and Segregation
C	3-302.11(A)(4-8) ^C – Packaged and Unpackaged Food – Separation, Packaging, and Segregation 3-304.11(B) ^P – Food Contact with Equipment and Utensils 3-304.15(A) ^P – Gloves, Use Limitation 3-306.13(A) ^P – Consumer Self-Service Operations
D	3-302.11(A)(4-8) ^C – Packaged and Unpackaged Food – Separation, Packaging, and Segregation 3-304.11(B) ^P – Food Contact with Equipment and Utensils 3-304.15(A) ^P – Gloves, Use Limitation 3-306.11 ^P – Food Display 3-306.12(A) ^C – Condiments, Protection 3-306.13(A) ^P – Consumer Self-Service Operations
E	<i>Other Priority Item as Identified by Data Collector</i>

**FDA RETAIL FOOD PROGRAM – FOODBORNE ILLNESS RISK FACTOR STUDY
DATA COLLECTION FORM**

Food Code Reference Sheet

4. Food contact surfaces are properly cleaned and sanitized	
Info Statement	Food Code Reference(s)
A	<p>NOTE: Specific to observations of cleaned and sanitized food contact dishware, utensils, cookware that have been stored and that are considered ready-for-use.</p> <p>4-601.11(A)^{Pf}(B)^C – Equipment, Food-Contact Surfaces, Nonfood-Contact Surfaces, and Utensils 4-602.11^{P&C} – Equipment Food-Contact Surfaces and Utensils 4-602.12^C – Cooking and Baking Equipment 4-702.11^P – Before Use After Cleaning</p>
B	<p>NOTE: Specific to observations of food contact surfaces and utensils as part of a manual warewashing or clean-in-place procedure</p> <p>4-303.11^{Pf} – Cleaning Agents and Sanitizers, Availability (<i>as it applies to observations of manual warewashing or clean-in-place procedures</i>) 4-501.111^P – Manual Warewashing Equipment, Hot Water Sanitization Temperatures 4-501.114^P – Manual and Mechanical Warewashing Equipment, Chemical Sanitization – Temperature, pH, Concentration, and Hardness 4-501.115^C – Manual Warewashing Equipment, Chemical Sanitization Using Detergent-Sanitizers 4-703.11(A), (B), and (C)^P – Hot Water and Chemical</p>
C	<p>NOTE: Specific to observations of food contact surfaces and utensils as part of a mechanical warewashing procedure</p> <p>4-303.11^{Pf} – Cleaning Agents and Sanitizers, Availability (<i>as it applies to observations of mechanical warewashing or procedures</i>) 4-501.113^C – Mechanical Warewashing Equipment, Sanitization Pressure 4-501.114^P – Manual and Mechanical Warewashing Equipment, Chemical Sanitization – Temperature, pH, Concentration, and Hardness 4-703.11(B) and (C)^P – Hot Water and Chemical</p>
D	<i>Other Priority Item as Identified by Data Collector</i>
5. Foods requiring refrigeration are held at the proper temperature	
Info Statement	Food Code Reference(s)
A	3-501.16(A)(2) ^P – Potentially Hazardous Food (Time/Temperature Control for Safety Food), Hot and Cold Holding
B	3-501.16(B) ^P – Potentially Hazardous Food (Time/Temperature Control for Safety Food), Hot and Cold Holding
C	<i>Other Priority Item as Identified by Data Collector</i>
6. Foods displayed or stored hot are held at the proper temperature	
Info Statement	Food Code Reference(s)
A	3-501.16(A)(1) ^P – Potentially Hazardous Food (Time/Temperature Control for Safety Food), Hot and Cold Holding
B	3-501.16(A)(1) ^P – Potentially Hazardous Food (Time/Temperature Control for Safety Food), Hot and Cold Holding
C	<i>Other Priority Item as Identified by Data Collector</i>

FDA RETAIL FOOD PROGRAM – FOODBORNE ILLNESS RISK FACTOR STUDY
DATA COLLECTION FORM
Food Code Reference Sheet

7. Foods are cooled properly	
Info Statement	Food Code Reference(s)
A	3-501.14(A) ^P – Cooling
B	3-501.14(B) ^P – Cooling
C	3-501.15(A) ^{PF} and (B) ^C – Cooling Methods; 4-301.11 ^{PF} – Cooling, Heating, and Holding Capacities
D	<i>Other Priority Item as Identified by Data Collector</i>
8. Refrigerated, ready-to-eat foods are properly date marked and discarded within 7 days of preparation or opening	
Info Statement	Food Code Reference(s)
A	3-501.17(A)(C)(D)(E) ^{PF} – Ready-to-Eat, Potentially Hazardous Food (Time/Temperature Control for Safety Food), Date Marking
B	3-501.17(A – F) ^{PF} – Ready-to-Eat, Potentially Hazardous Food (Time/Temperature Control for Safety Food), Date Marking
C	3-501.18(A) ^P – Ready-to-Eat, Potentially Hazardous Food (Time/Temperature Control for Safety Food), Disposition
D	<i>Other Priority Item as Identified by Data Collector</i>
9. Raw animal foods are cooked to required temperatures	
Info Statement	Food Code Reference(s)
A	3-401.11(A)(1)(a) and (A)(2) ^P – Raw Animal Foods
B	3-401.11(A)(1)(b) ^P and 3-401.11(C)(3) – Raw Animal Foods
C	3-401.11(A)(2) ^P – Raw Animal Foods
D	3-401.11(A)(3) ^P – Raw Animal Foods
E	3-401.11(B) ^P – Raw Animal Foods
F	<i>Other Priority Item as Identified by Data Collector</i> NOTE: Observations of actual final temperatures pertaining to non-continuous cooking of raw animal foods as specified in Section 3-401.14(D) of the Food Code are recorded as part of the “Other” information statement.
10. Cooked foods are reheated to required temperatures	
Info Statement	Food Code Reference(s)
A	3-403.11(A)(D) ^P – Reheating for Hot Holding
B	3-403.11(C)(D) ^P – Reheating for Hot Holding
C	<i>Other Priority Item as Identified by Data Collector</i>

**FDA RETAIL FOOD PROGRAM – FOODBORNE ILLNESS RISK FACTOR STUDY
DATA COLLECTION FORM
Food Code Reference Sheet**

11. Handwashing facilities are accessible and properly maintained	
Info Statement	Food Code Reference(s)
A	5-204.11 ^{Pf} – Handwashing Sinks 5-205.11(A) ^{Pf} – Using a Handwashing Sink
B	6-301.11 ^{Pf} – Handwashing Cleanser, Availability 6-301.12 ^{Pf} – Hand Drying Provision
12. Employees practice good hygiene	
Info Statement	Food Code Reference(s)
A	2-401.11 ^C – Eating, Drinking, or Using Tobacco
B	2-401.12 ^C – Discharges from the Eyes, Nose, and Mouth
C	<i>Other Priority Item as Identified by Data Collector</i>
13. Consumers are properly advised of risks of consuming raw or undercooked animal foods	
Food Code Reference(s)	
3-603.11 ^{Pf} – Consumption of Animal Food that are Raw, Undercooked, or Not Otherwise Processed to Eliminate Pathogens	
14. Time alone is properly used as a public health control	
Info Statement	Food Code Reference(s)
A	3-501.19(A) ^{Pf} (B) ^P – Time as a Public Health Control
B	3-501.19(A) ^{Pf} (C)(1) ^P (2) ^{Pf} (3) ^{Pf} (4) ^P (5) ^P – Time as a Public Health Control
C	<i>Other Priority Item as Identified by Data Collector</i>
15. Facilities have adequate equipment and tools for ensuring food temperature control and sanitization of food contact surfaces	
Info Statement	Food Code Reference(s)
A	4-301.11 ^{Pf} – Cooling, Heating, and Holding Capacities
B	4-301.11 ^{Pf} – Cooling, Heating, and Holding Capacities
C	4-203.12 ^{Pf} – Temperature Measuring Devices, Ambient Air and Water 4-204.112 ^C – Temperature Measuring Devices
D	4-203.11 ^{Pf} – Temperature Measuring Devices, Food 4-302.12(A) ^{Pf} (B) ^{Pf} – Food Temperature Measuring Devices 4-502.11(B) ^{Pf} – Good Repair and Calibration
E	4-302.13 ^C – Temperature Measuring Devices, Manual Warewashing 4-302.14 ^{Pf} – Sanitizing Solutions, Testing Devices 4-703.11(B) ^P – Hot Water and Chemical
F	<i>Other Priority Item as Identified by Data Collector</i>

**FDA RETAIL FOOD PROGRAM – FOODBORNE ILLNESS RISK FACTOR STUDY
DATA COLLECTION FORM
Food Code Reference Sheet**

16. Special processes are conducted in compliance with issued variance / HACCP Plan when required	
Info Statement	Food Code Reference(s)
A	3-502.12 ^{P,Pf} – Reduced Oxygen Packaging Without a Variance 8-201.13(B) ^C – When a HACCP Plan is Required 8-201.14(A-D) ^{Pf} – Contents of a HACCP Plan
B	3-502.11 ^{Pf} – Variance Requirement 8-103.12 ^{P,Pf} – Conformance with Approved Procedures 8-201.14(A-D) ^{Pf} – Contents of a HACCP Plan
C	3-404.11 ^{P,Pf} – Treating Juice 8-201.14(A-D) ^{Pf} – Contents of a HACCP Plan
D	<i>Other Priority Item as Identified by Data Collector</i>
17. Food is received from safe sources	
Info Statement	Food Code Reference(s)
A	3-201.11 ^{P,Pf} – Compliance with Food Law 3-201.12 ^P – Food in Hermetically Sealed Container 3-201.13 ^P – Fluid Milk and Milk Products 3-201.14 ^P – Fish 3-202.12 ^P – Additives 3-202.13 ^P – Eggs 3-202.14 ^P – Eggs and Milk Products, Pasteurized 3-202.110 ^{P,Pf} – Juice Treated 5-101.11 ^P – Approved System 5-101.13 ^P – Bottled Drinking Water
B	3-201.15 ^P – Molluscan Shellfish
C	3-101.11 ^P – Safe, Unadulterated, and Honestly Presented 3-202.15 ^{Pf} – Package Integrity
D	3-202.11 ^{P,Pf} – Temperature
E	3-101.11 ^P – Safe, Unadulterated and Honestly Presented
F	3-202.18(A) ^{Pf} – Shellstock Identification 3-203.12 ^{Pf} – Shellstock, Maintaining Identification
G	3-402.11 ^P – Parasite Destruction 3-402.12 ^{Pf} – Records, Creation and Retention
H	<i>Other Priority Item as Identified by Data Collector</i>

**FDA RETAIL FOOD PROGRAM – FOODBORNE ILLNESS RISK FACTOR STUDY
DATA COLLECTION FORM
Food Code Reference Sheet**

18. Toxic materials are identified, used, and stored properly	
Info Statement	Food Code Reference(s)
A	7-101.11 ^{Pf} – Identifying Information, Prominence 7-102.11 ^{Pf} – Common Name 7-201.11 ^{Pf} – Separation 7-202.11 ^{Pf} – Restriction 7-202.12 ^{P,Pf} – Conditions of Use 7-203.11 ^P – Poisonous or Toxic Material Containers 7-204.11 ^P – Sanitizers, Criteria 7-204.12 ^{P,C} – Chemicals for Washing, Treatment, Storage and Processing Fruits and Vegetables, Criteria 7-204.13 ^P – Boiler Water Additives, Criteria 7-204.14 ^P – Drying Agents, Criteria 7-205.11 ^P – Incidental Food Contact, Criteria 7-206.11 ^P – Restricted Use Pesticides, Criteria 7-206.12 ^P – Rodent Bait Stations 7-206.13 ^{P,C} – Tracking Powders, Pest Control and Monitoring 7-207.11 ^{P,Pf} – Restriction and Storage 7-207.12 ^P – Refrigerated Medicines, Storage 7-208.11 ^{P,Pf} – Storage 7-209.11 ^C – Storage
B	<i>Other Priority Item as Identified by Data Collector</i>
19. Management and food employees are trained in food allergy awareness as it relates to their assigned duties	
Info Statement	Food Code Reference(s)
A	2-102.11(C)(9) ^{Pf} – Demonstration
B	2-103.11(N) ^{Pf} – Person in Charge
C	<i>Other Priority Item as Identified by Data Collector</i>

FDA FOODBORNE ILLNESS RISK FACTOR STUDY

Instructions for Conducting the Food Safety Management System Assessment

Food Safety Management System Assessment – Poor Personal Hygiene Risk Factor

If the Poor Personal Hygiene risk factor has been randomly selected within a facility for conducting a food safety management system assessment, the data collector will complete a separate Procedure; Training; and Monitoring (PTM) assessment for the following two data items from the data collection form:

Poor Personal Hygiene Risk Factor

#1 – Employees practice proper handwashing

#2 – Food employees do not contact ready-to-eat foods with bare hands

The data collector should complete the assessment tools provided at the end of these instructions prior to marking the rating scale 1 – 4 on the data collection form for each of three food safety management system assessment areas (Procedures; Training; Monitoring).

Using the Food Safety Management System Assessment Tool

For each of the two data items listed above, the data collector will individually assess each of the three food safety management system elements (Procedures, Training, and Monitoring).

Using an effective interview process the data collector will solicit sufficient information from the PIC to respond “YES” or “NO” to the four statements listed under each of the PTM elements.

NOTE: *Data collectors are strongly encouraged to use a conversational approach to obtain information from the person in charge on their food safety management system rather than using the tool to drive questions in the order the statements appear.*

Using the information gathered from the interview, the data collector will answer each of the first three statements under the food safety management system element (PTM) either “YES” or “NO”. Each of the three statements is to be answered independently of one another.

For example, the person in charge describes handwashing procedures that include critical limits that do not meet minimum requirements for controlling hazards of concern. However, the PIC is able to provide a sound management structure for how and when handwashing is done in the facility and who is responsible for following the procedures. Under the procedures section, therefore, the data collector would record NO for statement #1 related to critical limits but YES to statements #2 (how and when) and #3 (who is assigned to correctly perform the procedure).

After marking the first three statements, the data collector will review the responses. If ALL three statements are marked “YES”, the data collector will then mark a response “YES” or “NO” to the last question in the shaded row. The fourth question in the shaded row is designed to assess whether there are written materials available to support the PTM element.

If any of the first three statements have been marked “NO” the data collector does not enter a response for the shaded statement. The first three statements **MUST** be marked “YES” for the data collector to enter a response for the fourth statement.

Using the Results of the Assessment Tool to Rate PTM on the Data Collection Form

Using the Assessment Tool, the data collector will add up the total number of YES responses for each of the management system elements (PTM). The number of “YES” responses on the assessment tool will determine how to mark the Procedures, Training, and Monitoring sections for the data item on the data collection form.

- If the number of **“YES” responses is “0” or “1”**, mark the **data collection form “1”** for that management system (PTM) element;
- If the number of **“YES” responses is “2”**, mark the data collection form **“2”** for that management system (PTM) element;
- If the number of **“YES” responses is “3”**, mark the data collection form **“3”** for that management system (PTM) element; and
- IF the number of **“YES” responses is “4”**, mark the data collection form **“4”** for that management System (PTM) element.

In the “COMMENT” section of the data collection form, provide a description of any scenarios that presented some challenges to assigning a 1-4 marking for a management system (PTM) element.

FDA Foodborne Illness Risk Factor Study
FOOD SAFETY MANAGEMENT SYSTEM ASSESSMENT
Poor Personal Hygiene Risk Factor

HANDWASHING

PROCEDURES	YES	NO
Management is able to describe the critical limits for handwashing as they apply to their establishment.	<input type="checkbox"/>	<input type="checkbox"/>
Management is able to describe the steps / tasks (how and when) that are performed to ensure that the identified critical limits for handwashing are achieved.	<input type="checkbox"/>	<input type="checkbox"/>
Management is able to identify specific employees that have been assigned the responsibility to correctly perform the handwashing procedure (for handwashing – reference to a system-wide policy for all employees is acceptable).	<input type="checkbox"/>	<input type="checkbox"/>
Management is able to produce written materials (SOPs; posters; wall charts; wallet cards; etc.) that support the implementation of their handwashing procedure within their establishment.	<input type="checkbox"/>	<input type="checkbox"/>
DATA COLLECTION NOTES:		
TRAINING	YES	NO
Management is able to confirm that the critical limits for handwashing are included in the establishment’s food employee training program.	<input type="checkbox"/>	<input type="checkbox"/>
Management is able to describe the methods/process (how and when) for providing training to front line employees on the critical limits and procedures for proper handwashing.	<input type="checkbox"/>	<input type="checkbox"/>
Management is able to identify specific employees that are assigned the responsibility to train front line food employees to wash their hands properly and when appropriate.	<input type="checkbox"/>	<input type="checkbox"/>
Management is able to produce written materials (PP Presentations; handouts; course books or policy manuals; reminder cards; wall charts, etc.) that are used to support their food safety training for handwashing within their establishment.	<input type="checkbox"/>	<input type="checkbox"/>
DATA COLLECTION NOTES:		

FDA Foodborne Illness Risk Factor Study
FOOD SAFETY MANAGEMENT SYSTEM ASSESSMENT
Poor Personal Hygiene Risk Factor

HANDWASHING

MONITORING	YES	NO
Management is able to confirm that the critical limits for handwashing are included in the establishment's monitoring program.	<input type="checkbox"/>	<input type="checkbox"/>
Management is able to describe the methods / process (how and when) monitoring of handwashing procedures is conducted to confirm whether food employees are washing their hands properly and when they should.	<input type="checkbox"/>	<input type="checkbox"/>
Management is able to identify specific employees that are assigned the responsibility to monitor handwashing within the facility. In addition, management is able to describe the corrective actions food employees will take when handwashing is not conducted when it should or when hands are not washed properly.	<input type="checkbox"/>	<input type="checkbox"/>
Management is able to produce written forms / records / logs / checklists / etc., used to document the findings from monitoring food employee's handwashing within their establishment.	<input type="checkbox"/>	<input type="checkbox"/>
DATA COLLECTION NOTES:		

FDA Foodborne Illness Risk Factor Study
FOOD SAFETY MANAGEMENT SYSTEM ASSESSMENT
Poor Personal Hygiene Risk Factor

NO BARE HAND CONTACT WITH RTE FOOD

PROCEDURES	YES	NO
Management is able to describe the critical limits for no bare hand contact with ready-to-eat food that apply to their food establishment.	<input type="checkbox"/>	<input type="checkbox"/>
Management is able to describe the steps / tasks (how and when) that are performed by food employees to ensure that the identified critical limits for no bare hand contact with ready-to-eat food are achieved	<input type="checkbox"/>	<input type="checkbox"/>
Management is able to identify specific employees that have been assigned the responsibility to correctly perform the procedures to ensure no bare hand contact with ready-to-eat food (for no bare hand contact with ready-to-eat food – reference to a system-wide policy for all employees is acceptable)	<input type="checkbox"/>	<input type="checkbox"/>
Management is able to produce written materials (SOPs; posters; wall charts; wallet cards, etc.) that support the implementation of their policy for no bare hand contact with ready-to-eat within their establishment,	<input type="checkbox"/>	<input type="checkbox"/>
DATA COLLECTION NOTES:		
TRAINING	YES	NO
Management is able to confirm that the critical limits for no bare hand contact with ready-to-eat food are included in the establishment’s food employee training program.	<input type="checkbox"/>	<input type="checkbox"/>
Management is able to describe the methods/process (how and when) for providing training to front line employees on the critical limits and procedures specific to no bare hand contact with ready-to-eat food.	<input type="checkbox"/>	<input type="checkbox"/>
Management is able to identify specific employees that are assigned the responsibility to train front line food employees on procedures for no bare hand contact with ready-to-eat food.	<input type="checkbox"/>	<input type="checkbox"/>
Management is able to produce written materials (PP Presentations; handouts; course books or policy manuals; reminder cards; wall charts, etc.) that are used to support their food safety training for no bare hand contact with ready-to-eat food within their establishment.	<input type="checkbox"/>	<input type="checkbox"/>
DATA COLLECTION NOTES:		

FDA Foodborne Illness Risk Factor Study
FOOD SAFETY MANAGEMENT SYSTEM ASSESSMENT
Poor Personal Hygiene Risk Factor

NO BARE HAND CONTACT WITH RTE FOOD

MONITORING	YES	NO
Management is able to confirm that the critical limits for no bare hand contact with ready-to-eat food are included in the establishment’s monitoring program.	<input type="checkbox"/>	<input type="checkbox"/>
Management is able to describe the methods / process (how and when) for monitoring procedure for no bare hand contact with ready-to-eat food to confirm whether food employees are following the establishment’s procedures.	<input type="checkbox"/>	<input type="checkbox"/>
Management is able to identify specific employees that are assigned the responsibility to monitor no bare hand contact with ready-to-eat food within the facility. In addition, management is able to describe the corrective actions food employees will take when bare hand contact with ready-to-eat food is observed.	<input type="checkbox"/>	<input type="checkbox"/>
Management is able to produce written forms / records / logs /checklists / etc., used to document the findings from monitoring procedure for no bare hand contact with ready-to-eat food within their establishment.	<input type="checkbox"/>	<input type="checkbox"/>
DATA COLLECTION NOTES:		

FDA FOODBORNE ILLNESS RISK FACTOR STUDY

Instructions for Conducting the Food Safety Management System Assessment

Food Safety Management System Assessment – Contaminated Equipment / Protection From Contamination Risk Factor If the Contaminated Equipment / Protecting From Contamination risk factor has been randomly selected within a facility for conducting a food safety management system assessment, the data collector will complete a separate Procedure; Training; and Monitoring (PTM) assessment for the following two data items from the data collection form:

Contaminated Equipment / Protection From Contamination Risk Factor

#3 – Food is protected from cross-contamination during storage, preparation, and display

#4 – Food contact surfaces are properly cleaned and sanitized

The data collector should complete the assessment tools provided at the end of these instructions prior to marking the rating scale 1 – 4 on the data collection form for each of three food safety management system assessment areas (Procedures; Training; Monitoring).

Using the Food Safety Management System Assessment Tool

For each of the two data items listed above, the data collector will individually assess each of the three food safety management system elements (Procedures, Training, and Monitoring).

Using an effective interview process the data collector will solicit sufficient information from the PIC to respond “YES” or “NO” to the four statements listed under each of the PTM elements.

NOTE: *Data collectors are strongly encouraged to use a conversational approach to obtain information from the person in charge on their food safety management system rather than using the tool to drive questions in the order the statements appear.*

Using the information gathered from the interview, the data collector will answer each of the first three statements under the food safety management system element (PTM) either “YES” or “NO”. Each of the three statements is to be answered independently of one another.

For example, the person in charge describes cleaning and sanitizing procedures that include sanitizer concentrations (critical limits) that do not meet minimum requirements for controlling hazards of concern. However, the PIC is able to provide a sound management structure for how and when food contact surfaces are cleaned and sanitized in the facility and who is responsible for following the procedures. Under the procedures section, therefore, the data collector would record NO for statement #1 related to critical limits but YES to statements #2 (how and when) and #3 (who is assigned to correctly perform the procedure).

After marking the first three statements, the data collector will review the responses. If ALL three statements are marked “YES”, the data collector will then mark a response “YES” or “NO” to the last question in the shaded row. The fourth question in the shaded row is designed to assess whether there are written materials available to support the PTM element.

If any of the first three statements have been marked “NO” the data collector does not enter a response for the shaded statement. The first three statements MUST be marked “YES” for the data collector to enter a response for the fourth statement.

Using the Results of the Assessment Tool to Rate PTM on the Data Collection Form

Using the Assessment Tool, the data collector will add up the total number of YES responses for each of the management system elements (PTM). The number of “YES” responses on the assessment tool will determine how to mark the Procedures, Training, and Monitoring sections for the data item on the data collection form.

- If the number of “YES” responses is “0” or “1”, mark the **data collection form “1”** for that management system (PTM) element;
- If the number of “YES” responses is “2”, mark the data collection form “2” for that management system (PTM) element;
- If the number of “YES” responses is “3”, mark the data collection form “3” for that management system (PTM) element; and
- IF the number of “YES” responses is “4”, mark the data collection form “4” for that management System (PTM) element.

In the “COMMENT” section of the data collection form, provide a description of any scenarios that presented some challenges to assigning a 1-4 marking for a management system (PTM) element.

FDA Foodborne Illness Risk Factor Study

**FOOD SAFETY MANAGEMENT SYSTEM ASSESSMENT
Contaminated Equipment / Protection from Contamination Risk Factor**

FOOD IS PROTECTED FROM CROSS CONTAMINATION

PROCEDURES	YES	NO
Management is able to describe the critical limits for protecting food from contamination that apply to their food establishment.	<input type="checkbox"/>	<input type="checkbox"/>
Management is able to describe the steps / tasks (how and when) that food employees perform to ensure that the identified critical limits for protecting food from contamination are achieved.	<input type="checkbox"/>	<input type="checkbox"/>
Management is able to identify specific employees that have been assigned the responsibility to correctly perform procedures to ensure food is protected from contamination.	<input type="checkbox"/>	<input type="checkbox"/>
Management is able to produce written materials (SOPs; posters; wall charts; wallet cards; etc.) that support the implementation of their procedure for ensuring food is protected from contamination within their establishment.	<input type="checkbox"/>	<input type="checkbox"/>
DATA COLLECTION NOTES:		
TRAINING	YES	NO
Management is able to confirm that the critical limits for protecting food from contamination are included in the establishment’s food employee training program.	<input type="checkbox"/>	<input type="checkbox"/>
Management is able to describe the methods/process (how and when) for providing training to front line employees on the critical limits and procedures for protecting food from contamination.	<input type="checkbox"/>	<input type="checkbox"/>
Management is able to identify specific employees that are assigned the responsibility to train front line food employees on how to protect food from contamination.	<input type="checkbox"/>	<input type="checkbox"/>
Management is able to produce written materials (PP presentations; handouts; course books or policy manuals; reminder cards; wall charts, etc.) that are used to support their food safety training for protecting food from contamination within their establishment.	<input type="checkbox"/>	<input type="checkbox"/>
DATA COLLECTION NOTES:		

FDA Foodborne Illness Risk Factor Study
FOOD SAFETY MANAGEMENT SYSTEM ASSESSMENT
Contamination Equipment/Protection from Contamination Risk Factor

FOOD IS PROTECTED FROM CROSS CONTAMINATION

MONITORING	YES	NO
Management is able to confirm that the critical limits for protection food from contamination are included in the establishment’s monitoring program.	<input type="checkbox"/>	<input type="checkbox"/>
Management is able to describe the methods / process (how and when) for monitoring food to ensure it is protected from contamination to confirm that food employees are following the establishment’s procedures.	<input type="checkbox"/>	<input type="checkbox"/>
Management is able to identify specific employees that are assigned the responsibility to monitor procedures for protecting food from contamination within the facility. In addition, management is able to describe the corrective actions food employees will take when food is not properly protected from contamination.	<input type="checkbox"/>	<input type="checkbox"/>
Management is able to produce written forms / records / logs / checklists / etc., used to document findings from monitoring procedures for protection food from contamination within their establishment.	<input type="checkbox"/>	<input type="checkbox"/>
DATA COLLECTION NOTES:		

FDA Foodborne Illness Risk Factor Study

**FOOD SAFETY MANAGEMENT SYSTEM ASSESSMENT
Contaminated Equipment/Protection From Contamination Risk Factor**

FOOD CONTACT SURFACES – CLEANED & SANITIZED

PROCEDURES	YES	NO
Management is able to describe the critical limits for cleaning and sanitizing food contact surfaces that apply to their food establishment.	<input type="checkbox"/>	<input type="checkbox"/>
Management is able to describe the steps / tasks (how and when) that food employees perform to ensure that the identified critical limits for cleaning and sanitizing food contact surfaces are achieved.	<input type="checkbox"/>	<input type="checkbox"/>
Management is able to identify specific employees that have been assigned the responsibility to correctly perform cleaning and sanitizing procedures for food contact surfaces.	<input type="checkbox"/>	<input type="checkbox"/>
Management is able to produce written materials (SOPs; posters; wall charts; wallet cards; etc.) that support the implementation of cleaning and sanitizing procedures for food contact surfaces within their establishment.	<input type="checkbox"/>	<input type="checkbox"/>
DATA COLLECTION NOTES:		
TRAINING	YES	NO
Management is able to confirm that the critical limits for cleaning and sanitizing food contact surfaces are included in the establishment’s food employee training program.	<input type="checkbox"/>	<input type="checkbox"/>
Management is able to describe the methods/process (how and when) for providing training to front line employees on the critical limits and procedures for cleaning and sanitizing food contact surfaces.	<input type="checkbox"/>	<input type="checkbox"/>
Management is able to identify specific employees that are assigned the responsibility to train front line food employees on how to clean and sanitize food contact surfaces.	<input type="checkbox"/>	<input type="checkbox"/>
Management is able to produce written materials (PP presentations; handouts; course books or policy manuals; reminder cards; wall charts; etc.) that are used to support their food safety training for cleaning and sanitizing food contact surfaces within their establishment.	<input type="checkbox"/>	<input type="checkbox"/>
DATA COLLECTION NOTES:		

FDA Foodborne Illness Risk Factor Study

**FOOD SAFETY MANAGEMENT SYSTEM ASSESSMENT
Contaminated Equipment/Protection from Contamination Risk Factor**

FOOD CONTACT SURFACES – CLEANED & SANITIZED

MONITORING	YES	NO
Management is able to confirm that the critical limits for cleaning and sanitizing food contact surfaces are included in the establishment’s monitoring program.	<input type="checkbox"/>	<input type="checkbox"/>
Management is able to describe the methods / process (how and when) for monitoring cleaning and sanitizing procedures for food contact surfaces to confirm that employees are following the establishment’s procedures.	<input type="checkbox"/>	<input type="checkbox"/>
Management is able to identify specific employees that are assigned the responsibility to monitor cleaning and sanitizing procedures for food contact surfaces within the facility. In addition, management is able to describe the corrective actions food employees will take when food contact surfaces are not cleaned and sanitized properly.	<input type="checkbox"/>	<input type="checkbox"/>
Management is able to produce written forms / records / logs / checklists / etc., used to document the findings from monitoring procedures for cleaning and sanitizing food contact surfaces within their establishment.	<input type="checkbox"/>	<input type="checkbox"/>
DATA COLLECTION NOTES:		

FDA FOODBORNE ILLNESS RISK FACTOR STUDY

Instructions for Conducting the Food Safety Management System Assessment

Food Safety Management System Assessment – Improper Holding / Time & Temperature Risk Factor If the Improper Holding / Time & Temperature risk factor has been randomly selected within a facility for conducting a food safety management system assessment, the data collector will complete a separate Procedure; Training; and Monitoring (PTM) assessment for the following four data items from the data collection form:

Improper Holding / Time & Temperature Risk Factor

- #5 – Foods requiring refrigeration are held at the proper temperature
- #6 – Foods displayed or stored hot are held at the proper temperature
- #7 – Foods are cooled properly
- #8 – Refrigerated, ready-to-eat foods are properly date marked and discarded within 7 days of preparation or opening

The data collector should complete the assessment tools provided at the end of these instructions prior to marking the rating scale 1 – 4 on the data collection form for each of three food safety management system assessment areas (Procedures; Training; Monitoring).

Using the Food Safety Management System Assessment Tool

For each of the two data items listed above, the data collector will individually assess each of the three food safety management system elements (Procedures, Training, and Monitoring).

Using an effective interview process the data collector will solicit sufficient information from the PIC to respond “YES” or “NO” to the four statements listed under each of the PTM elements.

NOTE: *Data collectors are strongly encouraged to use a conversational approach to obtain information from the person in charge on their food safety management system rather than using the tool to drive questions in the order the statements appear.*

Using the information gathered from the interview, the data collector will answer each of the first three statements under the food safety management system element (PTM) either “YES” or “NO”. Each of the three statements is to be answered independently of one another.

For example, the person in charge describes cooling procedures that include critical limits that do not meet minimum requirements for controlling hazards of concern. However, the PIC is able to provide a sound management structure for how and when cooling is done in the facility and who is responsible for following the procedures. Under the procedures section, therefore, the data collector would record NO for statement #1 related to critical limits but YES to statements #2 (how and when) and #3 (who is assigned to correctly perform the procedure).

After marking the first three statements, the data collector will review the responses. If ALL three statements are marked “YES”, the data collector will then mark a response “YES” or “NO” to the last question in the shaded row. The fourth question in the shaded row is designed to assess whether there are written materials available to support the PTM element.

If any of the first three statements have been marked “NO” the data collector does not enter a response for the shaded statement. The first three statements MUST be marked “YES” for the data collector to enter a response for the fourth statement.

Using the Results of the Assessment Tool to Rate PTM on the Data Collection Form

Using the Assessment Tool, the data collector will add up the total number of YES responses for each of the management system elements (PTM). The number of “YES” responses on the assessment tool will determine how to mark the Procedures, Training, and Monitoring sections for the data item on the data collection form.

- If the number of “YES” responses is “0” or “1”, mark the **data collection form “1”** for that management system (PTM) element;
- If the number of “YES” responses is “2”, mark the data collection form “2” for that management system (PTM) element;
- If the number of “YES” responses is “3”, mark the data collection form “3” for that management system (PTM) element; and
- IF the number of “YES” responses is “4”, mark the data collection form “4” for that management System (PTM) element.

In the “COMMENT” section of the data collection form, provide a description of any scenarios that presented some challenges to assigning a 1-4 marking for a management system (PTM) element.

FDA Foodborne Illness Risk Factor Study

**FOOD SAFETY MANAGEMENT SYSTEM ASSESSMENT
Improper Holding/Time and Temperature Risk Factor**

FOODS REQUIRING REFRIGERATION – PROPER TEMP.

PROCEDURES	YES	NO
Management is able to describe the critical limits for holding foods requiring refrigeration at proper temperature that apply to their food establishment.	<input type="checkbox"/>	<input type="checkbox"/>
Management is able to describe the steps / tasks (how and when) that food employees perform to ensure that the identified critical limits for holding foods requiring refrigeration at proper temperature are achieved.	<input type="checkbox"/>	<input type="checkbox"/>
Management is able to identify specific employees that have been assigned the responsibility to correctly perform procedures for holding foods requiring refrigeration at proper temperature.	<input type="checkbox"/>	<input type="checkbox"/>
Management is able to produce written materials (SOPs; posters; wall charts; wallet cards; etc.) that support the implementation of procedures for holding food requiring refrigeration at proper temperature within their establishment.	<input type="checkbox"/>	<input type="checkbox"/>
DATA COLLECTION NOTES:		
TRAINING	YES	NO
Management is able to confirm that the critical limits for holding foods requiring refrigeration at proper temperature are included in the establishment’s food employee training program.	<input type="checkbox"/>	<input type="checkbox"/>
Management is able to describe the methods/process (how and when) for providing training to front line employees on the critical limits and procedures for holding food requiring refrigeration at proper temperature.	<input type="checkbox"/>	<input type="checkbox"/>
Management is able to identify specific employees that are assigned the responsibility to train front line food employees on holding food requiring refrigeration at proper temperature.	<input type="checkbox"/>	<input type="checkbox"/>
Management is able to provide written materials (PP presentations; handouts; course books or policy manuals; reminder cards; wall charts; etc.) that are used to support their food safety training for holding food requiring refrigeration at proper temperature within their establishment.	<input type="checkbox"/>	<input type="checkbox"/>
DATA COLLECTION NOTES:		

FDA Foodborne Illness Risk Factor Study
FOOD SAFETY MANAGEMENT SYSTEM ASSESSMENT
Improper Holding/Time and Temperature Risk Factor
FOODS REQUIRING REFRIGERATION – PROPER TEMP.

MONITORING	YES	NO
Management is able to confirm that the critical limits for holding foods requiring refrigeration at proper temperature are included in the establishment’s monitoring program.	<input type="checkbox"/>	<input type="checkbox"/>
Management is able to describe the methods / process (how and when) for monitoring procedures for holding foods requiring refrigeration at proper temperature to confirm that employees are following the establishment’s procedures.	<input type="checkbox"/>	<input type="checkbox"/>
Management is able to identify specific employees that are assigned the responsibility to monitor procedures for holding foods requiring refrigeration at proper temperature. In addition, management is able to describe the corrective actions food employees will take when food is not maintained at proper refrigeration temperatures.	<input type="checkbox"/>	<input type="checkbox"/>
Management is able to produce written forms / records / logs / checklists / calibration records / etc., used to document the findings from monitoring procedure for holding foods requiring refrigeration at proper temperature within the establishment.	<input type="checkbox"/>	<input type="checkbox"/>
DATA COLLECTION NOTES:		

FDA Foodborne Illness Risk Factor Study
FOOD SAFETY MANAGEMENT SYSTEM ASSESSMENT
Improper Holding/Time and Temperature

FOODS DISPLAYED OR STORED HOT – PROPER TEMP.

PROCEDURES	YES	NO
Management is able to describe the critical limits for holding foods displayed or stored hot at proper temperature that apply to their food establishment.	<input type="checkbox"/>	<input type="checkbox"/>
Management is able to describe the steps / tasks (how and when) that food employees perform to ensure that the identified critical limits for holding foods displayed or stored hot at proper temperature are achieved.	<input type="checkbox"/>	<input type="checkbox"/>
Management is able to identify specific employees that have been assigned the responsibility to correctly perform procedures for holding foods displayed or stored hot at proper temperature.	<input type="checkbox"/>	<input type="checkbox"/>
Management is able to produce written materials (SOPs; posters; wall charts; wallet cards; etc.) that support the implementation of procedures for holding foods displayed or stored hot at proper temperature within their establishment.	<input type="checkbox"/>	<input type="checkbox"/>
DATA COLLECTION NOTES:		
TRAINING	YES	NO
Management is able to confirm that the critical limits for holding foods displayed or stored hot at proper temperature are included in the establishment’s food employee training program.	<input type="checkbox"/>	<input type="checkbox"/>
Management is able to describe the methods/process (how and when) for providing training to front line employees on the critical limits and procedures for holding foods displayed or stored hot at proper temperature.	<input type="checkbox"/>	<input type="checkbox"/>
Management is able to identify specific employees that are assigned the responsibility to train front line food employees on how to hold foods displayed or stored hot at proper temperature.	<input type="checkbox"/>	<input type="checkbox"/>
Management is able to produce written materials (PP presentations; handouts; course books or policy manuals; reminder cards; wall charts; etc.) that are used to support their food safety training for holding foods displayed or stored hot at proper temperature within their establishment.	<input type="checkbox"/>	<input type="checkbox"/>
DATA COLLECTION NOTES:		

FDA Foodborne Illness Risk Factor Study
FOOD SAFETY MANAGEMENT SYSTEM ASSESSMENT
Improper Holding/Time and Temperature Risk Factor
FOODS DISPLAYED OR STORED HOT – PROPER TEMP.

MONITORING	YES	NO
Management is able to confirm that the critical limits for holding foods displayed or stored hot at proper temperature are included in the establishment’s monitoring program.	<input type="checkbox"/>	<input type="checkbox"/>
Management is able to describe the methods / process (how and when) for monitoring procedure for holding foods displayed or stored hot at proper temperature to confirm that employees are following the establishment’s procedures.	<input type="checkbox"/>	<input type="checkbox"/>
Management is able to identify specific employees that are assigned the responsibility to monitor procedures for holding foods displayed or stored hot at proper temperature within the facility. In addition, management is able to describe the corrective actions food employees will take when food is not displayed or stored at proper hot holding temperature.	<input type="checkbox"/>	<input type="checkbox"/>
Management is able to produce written forms / records / logs / checklists / calibration records / etc., used to document the findings from monitoring procedures for holding foods displayed or stored hot to ensure proper temperature is maintained within their establishment.	<input type="checkbox"/>	<input type="checkbox"/>
DATA COLLECTION NOTES:		

FDA Foodborne Illness Risk Factor Study
FOOD SAFETY MANAGEMENT SYSTEM ASSESSMENT
Improper Holding/Time and Temperature
FOODS ARE COOLED PROPERLY

PROCEDURES	YES	NO
Management is able to describe the critical limits for cooling foods to proper temperature that apply to their food establishment.	<input type="checkbox"/>	<input type="checkbox"/>
Management is able to describe the steps / tasks (when and how) that food employees perform to ensure that the identified critical limits for cooling foods to proper temperature are achieved.	<input type="checkbox"/>	<input type="checkbox"/>
Management is able to identify specific employees that have been assigned the responsibility to correctly perform procedures for cooling foods to proper temperature.	<input type="checkbox"/>	<input type="checkbox"/>
Management is able to produce written materials (SOPs; posters; wall charts; wallet cards; etc.) that support the implementation of procedures for cooling foods to proper temperature within their establishment.	<input type="checkbox"/>	<input type="checkbox"/>
DATA COLLECTION NOTES:		
TRAINING	YES	NO
Management is able to confirm that the critical limits for cooling foods to proper temperature are included in the establishment’s food employee training program.	<input type="checkbox"/>	<input type="checkbox"/>
Management is able to describe the methods/process (how and when) for providing training to front line employees on the critical limits and procedure(s) for cooling foods to proper temperature.	<input type="checkbox"/>	<input type="checkbox"/>
Management is able to identify specific employees that are assigned the responsibility to train front line food employees on how to cool foods to proper temperature.	<input type="checkbox"/>	<input type="checkbox"/>
Management is able to produce written materials (PP presentations; handouts; course books or policy manuals; reminder cards; wall charts; etc.) that are used to support their food safety training for cooling foods to proper temperature within their establishment.	<input type="checkbox"/>	<input type="checkbox"/>
DATA COLLECTION NOTES:		

FDA Foodborne Illness Risk Factor Study
FOOD SAFETY MANAGEMENT SYSTEM ASSESSMENT
Improper Holding/Time and Temperature
FOODS ARE COOLED PROPERLY

MONITORING	YES	NO
Management is able to confirm that the critical limits for cooling foods to proper temperature are included in the establishment’s monitoring program.	<input type="checkbox"/>	<input type="checkbox"/>
Management is able to describe the methods / process (how and when) for monitoring procedures for cooling foods to proper temperature to confirm that employees are following the establishment’s procedures.	<input type="checkbox"/>	<input type="checkbox"/>
Management is able to identify specific employees that are assigned the responsibility to monitor procedures for cooling foods to proper temperatures within the facility. In addition, management is able to describe the corrective actions food employees will take when food is not cooled to proper temperature within the required time frame.	<input type="checkbox"/>	<input type="checkbox"/>
Management is able to provide written forms / records / logs / checklists / calibration records / etc., used to document the findings from monitoring procedures used to cool foods to proper temperature within their establishment.	<input type="checkbox"/>	<input type="checkbox"/>
DATA COLLECTION NOTES:		

FDA Foodborne Illness Risk Factor Study
FOOD SAFETY MANAGEMENT SYSTEM ASSESSMENT
Improper Holding/Time and Temperature Risk Factor
REFRIGERATED, RTE FOODS – DATE MARKED

PROCEDURES	YES	NO
Management is able to describe the critical limits for date marking refrigerated, ready-to-eat foods that apply to their food establishment.	<input type="checkbox"/>	<input type="checkbox"/>
Management is able to describe the steps / tasks (how and when) that food employees perform to ensure that the identified critical limits for date marking refrigerated, ready-to-eat foods are achieved.	<input type="checkbox"/>	<input type="checkbox"/>
Management is able to identify specific employees that have been assigned the responsibility to correctly perform procedures for date marking refrigerated, ready-to-eat foods.	<input type="checkbox"/>	<input type="checkbox"/>
Management is able to produce written materials (SOPs; posters; wall charts; wallet cards; etc.) that support the implementation of their procedures for date marking refrigerated, ready-to-eat foods within their establishment.	<input type="checkbox"/>	<input type="checkbox"/>
DATA COLLECTION NOTES:		
TRAINING	YES	NO
Management is able to confirm that the critical limits for date marking refrigerated, ready-to-eat foods are included in the establishment’s food employee training program.	<input type="checkbox"/>	<input type="checkbox"/>
Management is able to describe the methods/process (how and when) for providing training to front line employees on the critical limits and procedure(s) for date marking refrigerated, ready-to-eat foods.	<input type="checkbox"/>	<input type="checkbox"/>
Management is able to identify specific employees that are assigned the responsibility to train front line food employees on how to date mark refrigerated, ready-to-eat foods.	<input type="checkbox"/>	<input type="checkbox"/>
Management is able to produce written materials (PP presentations; handouts; course books or policy manuals; reminder cards; wall charts, etc.) that are used to support their food safety training for date marking refrigerated ready-to-eat foods within their establishment.	<input type="checkbox"/>	<input type="checkbox"/>
DATA COLLECTION NOTES:		

FOOD SAFETY MANAGEMENT SYSTEM ASSESSMENT
Improper Holding/Time and Temperature Risk Factor
REFRIGERATED, RTE FOODS – DATE MARKED

MONITORING	YES	NO
Management is able to confirm that the critical limits for date marking refrigerated, ready-to-eat foods are included in the establishment’s monitoring program.	<input type="checkbox"/>	<input type="checkbox"/>
Management is able to describe the methods / process (how and when) for monitoring procedures for date marking refrigerated, ready-to-eat foods to confirm that employees are following the establishment’s procedures.	<input type="checkbox"/>	<input type="checkbox"/>
Management is able to identify specific employees that are assigned the responsibility to monitor date marking of refrigerated, ready-to-eat foods. In addition, management is able to describe the corrective actions food employees will take when refrigerated ready-to-eat food is not properly date marked.	<input type="checkbox"/>	<input type="checkbox"/>
Management is able to provide written forms / records / logs / checklists / calibration records / etc., used to document findings from monitoring procedures for date marking refrigerated, ready-to-eat foods within their establishment.	<input type="checkbox"/>	<input type="checkbox"/>
DATA COLLECTION NOTES:		

FDA FOODBORNE ILLNESS RISK FACTOR STUDY

Instructions for Conducting the Food Safety Management System Assessment

Food Safety Management System Assessment – Inadequate Cooking Risk Factor

If the Inadequate Cooking risk factor has been randomly selected within a facility for conducting a food safety management system assessment, the data collector will complete a separate Procedure; Training; and Monitoring (PTM) assessment for the following two data items from the data collection form:

Inadequate Cooking Risk Factor

#9 – Raw animal foods cooked to required temperatures

#10 – Cooked foods reheated to required temperatures

The data collector should complete the assessment tools provided at the end of these instructions prior to marking the rating scale 1 – 4 on the data collection form for each of three food safety management system assessment areas (Procedures; Training; Monitoring).

Using the Food Safety Management System Assessment Tool

For each of the two data items listed above, the data collector will individually assess each of the three food safety management system elements (Procedures, Training, and Monitoring).

Using an effective interview process the data collector will solicit sufficient information from the PIC to respond “YES” or “NO” to the four statements listed under each of the PTM elements.

NOTE: *Data collectors are strongly encouraged to use a conversational approach to obtain information from the person in charge on their food safety management system rather than using the tool to drive questions in the order the statements appear.*

Using the information gathered from the interview, the data collector will answer each of the first three statements under the food safety management system element (PTM) either “YES” or “NO”. Each of the three statements is to be answered independently of one another.

For example, the person in charge describes procedures that include final cooking temperatures (critical limits) that do not meet minimum requirements for controlling hazards of concern. However, the PIC is able to provide a sound management structure for how and when cooking is done in the facility and who is responsible for following the procedures. Under the procedures section, therefore, the data collector would record NO for statement #1 related to critical limits but YES to statements #2 (how and when) and #3 (who is assigned to correctly perform the procedure).

After marking the first three statements, the data collector will review the responses. If ALL three statements are marked “YES”, the data collector will then mark a response “YES” or “NO” to the last question in the shaded row. The fourth question in the shaded row is designed to assess whether there are written materials available to support the PTM element.

If any of the first three statements have been marked “NO” the data collector does not enter a response for the shaded statement. The first three statements MUST be marked “YES” for the data collector to enter a response for the fourth statement.

Using the Results of the Assessment Tool to Rate PTM on the Data Collection Form

Using the Assessment Tool, the data collector will add up the total number of YES responses for each of the management system elements (PTM). The number of “YES” responses on the assessment tool will determine how to mark the Procedures, Training, and Monitoring sections for the data item on the data collection form.

- If the number of “YES” responses is “0” or “1”, mark the **data collection form “1”** for that management system (PTM) element;
- If the number of “YES” responses is “2”, mark the data collection form “2” for that management system (PTM) element;
- If the number of “YES” responses is “3”, mark the data collection form “3” for that management system (PTM) element; and
- IF the number of “YES” responses is “4”, mark the data collection form “4” for that management System (PTM) element.

In the “COMMENT” section of the data collection form, provide a description of any scenarios that presented some challenges to assigning a 1-4 marking for a management system (PTM) element.

FDA Foodborne Illness Risk Factor Study
FOOD SAFETY MANAGEMENT SYSTEM ASSESSMENT
Inadequate Cooking Risk Factor

RAW ANIMAL FOODS – COOKED TO REQUIRED TEMP.

PROCEDURES	YES	NO
Management is able to describe the critical limits for cooking raw animal foods that apply to their food establishment.	<input type="checkbox"/>	<input type="checkbox"/>
Management is able to describe the steps / tasks (how and when) that food employees perform to ensure that the identified critical limits for cooking raw animal foods are achieved.	<input type="checkbox"/>	<input type="checkbox"/>
Management is able to identify specific employees that have been assigned the responsibility to correctly perform procedures for cooking raw animal foods to proper temperatures.	<input type="checkbox"/>	<input type="checkbox"/>
Management is able to produce written materials (SOPs; posters; wall charts; wallet cards; etc.) that support the implementation of their procedure for cooking raw animal foods to proper temperature within their establishment.	<input type="checkbox"/>	<input type="checkbox"/>
DATA COLLECTION NOTES:		
TRAINING	YES	NO
Management is able to confirm that the critical limits for cooking raw animal foods to proper temperatures are included in the establishment’s food employee training program.	<input type="checkbox"/>	<input type="checkbox"/>
Management is able to describe the methods/process (how and when) for providing training to front line employees on the critical limits and procedures for cooking raw animal foods to proper temperatures.	<input type="checkbox"/>	<input type="checkbox"/>
Management is able to identify specific employees that are assigned the responsibility to train front line food employees on cooking raw animal foods to proper temperatures.	<input type="checkbox"/>	<input type="checkbox"/>
Management is able to produce written materials (PP presentations; handouts; course books or policy manuals; reminder cards; wall charts; etc.) that are used to support their food safety training for cooking raw animal foods to proper temperatures within their establishment.	<input type="checkbox"/>	<input type="checkbox"/>
DATA COLLECTION NOTES:		

FDA Foodborne Illness Risk Factor Study
FOOD SAFETY MANAGEMENT SYSTEM ASSESSMENT
Inadequate Cooking Risk Factor

RAW ANIMAL FOODS – COOKED TO REQUIRED TEMP.

MONITORING	YES	NO
Management is able to confirm that the critical limits for cooking raw animal foods to proper temperature are included in the establishment’s monitoring program.	<input type="checkbox"/>	<input type="checkbox"/>
Management is able to describe the methods / process (how and when) for monitoring procedures for cooking of raw animal foods to confirm employees are following the establishment’s procedures.	<input type="checkbox"/>	<input type="checkbox"/>
Management is able to identify specific employees that are assigned the responsibility to monitor procedures for cooking raw animal foods to proper temperatures. In addition, management is able to describe the corrective actions food employees will take when raw animal food is not cooked to proper temperatures.	<input type="checkbox"/>	<input type="checkbox"/>
Management is able to produce written forms / records / logs / checklists / calibration records / etc., used to document findings from monitoring procedures for cooking raw animal to proper temperature within their establishment.	<input type="checkbox"/>	<input type="checkbox"/>
DATA COLLECTION NOTES:		

FDA Foodborne Illness Risk Factor Study
FOOD SAFETY MANAGEMENT SYSTEM ASSESSMENT
Inadequate Cooking Risk Factor

COOKED FOODS REHEATED TO REQUIRED TEMP.

PROCEDURES	YES	NO
Management is able to describe the critical limits for reheated cooked foods that apply to their food establishment.	<input type="checkbox"/>	<input type="checkbox"/>
Management is able to describe the steps / tasks (how and when) that food employees perform to ensure that the identified critical limits for reheating cooked foods are achieved.	<input type="checkbox"/>	<input type="checkbox"/>
Management is able to identify specific employees that have been assigned the responsibility to correctly perform procedures for reheating cooked foods to proper temperatures.	<input type="checkbox"/>	<input type="checkbox"/>
Management is able to produce written materials (SOPs; posters; wall charts; wallet cards; etc.) that support the implementation of their procedure for reheating cooked foods to proper temperature within their establishment.	<input type="checkbox"/>	<input type="checkbox"/>
DATA COLLECTION NOTES:		
TRAINING	YES	NO
Management is able to confirm that the critical limits for reheating cooked foods to proper temperatures are included in the establishment’s food employee training program.	<input type="checkbox"/>	<input type="checkbox"/>
Management is able to describe the methods/process (how and when) for providing training to front line employees on the critical limits and procedures for reheating cooked foods to proper temperatures.	<input type="checkbox"/>	<input type="checkbox"/>
Management is able to identify specific employees that are assigned the responsibility to train front line food employees on reheating cooked foods to proper temperatures.	<input type="checkbox"/>	<input type="checkbox"/>
Management is able to produce written materials (PP presentations; handouts; course books or policy manuals’ reminder cards; wall charts; etc.) that are used to support their food safety training for reheating cooked foods to proper temperatures within their establishment.	<input type="checkbox"/>	<input type="checkbox"/>
DATA COLLECTION NOTES:		

FDA Foodborne Illness Risk Factor Study
FOOD SAFETY MANAGEMENT SYSTEM ASSESSMENT
Inadequate Cooking Risk Factor

COOKED FOODS REHEATED TO REQUIRED TEMP.

MONITORING	YES	NO
Management is able to confirm that the critical limits for reheating cooked foods to proper temperature are included in the establishment's monitoring program.	<input type="checkbox"/>	<input type="checkbox"/>
Management is able to describe the methods / process (how and when) for monitoring procedures for reheating cooked foods to proper temperature to confirm that food employees are following the establishment's procedures.	<input type="checkbox"/>	<input type="checkbox"/>
Management is able to identify specific employees that are assigned the responsibility to monitor procedures for reheating cooked foods to proper temperatures. In addition, management is able to describe the corrective actions food employees will take when cooked food is not reheated to proper temperatures.	<input type="checkbox"/>	<input type="checkbox"/>
Management is able to produce written forms / records / logs / checklists / calibration records / etc., used to document findings from monitoring procedures for reheating cooked foods to proper temperature within their establishment.	<input type="checkbox"/>	<input type="checkbox"/>
DATA COLLECTION NOTES:		

ELEMENTS TO CONSIDER WHEN CONDUCTING COOLING ASSESSMENTS AND USING PREDICTIVE MODELING TO SUPPLEMENT ACTUAL OBSERVATIONS

OVERVIEW

Assessing cooling of cooked foods or foods prepared from ambient ingredients can pose challenges to the data collector due to the significant period of time needed to determine compliance with *Food Code* time/temperature critical limits. In addition, all or a significant portion of the cooling process may occur outside the tradition work hours during which the data collections are conducted. .

An evaluation of cooling methods, processes, equipment, production documents / records, as well as statements from managers, the person-in-charge, and food employees regarding the time the cooling process was initiated, may be used to supplement quantitative temperature measurements used to determine cooling rates. The data collection has been designed so that it provides an opportunity to collect information specific to quantitative cooling temperature measures (information statements A and B in the table below), and/or cooling methods / equipment (information statement C in the table below).

IN	OUT	NO	NA	
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	7. Foods are cooled properly
IN	OUT	NO	NA	Description of Cooling Temperature OBSERVATIONS
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	A. Cooked TCS Food is cooled from 135°F (57°C) to 70°F (21°C) within 2 hours and from 135°F (57°C) to 41°F (5°C) or below within 6 hours
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	B. TCS Food (prepared from ingredients at ambient temperature) is cooled to 41°F (5°C) or below within 4 hours
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	C. Proper cooling methods / equipment are used
<input type="checkbox"/>	<input type="checkbox"/>		<input type="checkbox"/>	D. Other (describe in the temperature chart and comments section below)

DETERMINING COOLING PROCESSES

The data collector **MUST** make every effort to assess cooling processes in the early part of the data collection. Always ask the question at the beginning of every data collection, “Do you have any leftovers from last night (if an AM inspection) or are you cooling anything that was prepared this morning (if a PM inspection)?”

During your quick walk-through, open the walk-in coolers and reach-in units and note large deep containers of TCS foods. Note the size, depth, and type (metal/plastic) of containers being used for cooling. Note the consistency of the product (i.e., broth vs. thick stew/chili).

After your quick walk through, during which you have determined what is going on in this facility and set your priorities for the data collection, go to the walk-in cooler (or other equipment) where the foods are being held. Before taking any temperatures ask the manager when the containers were placed in the cooler.

ASSESSING COOLING METHODS / EQUIPMENT

In the ideal world, a data collector would be able to correlate observations of cooling methods / equipment with actual quantitative temperature measurements of the foods being cooled. This may not always be the case. Situations may arise when the establishment initiates a cooling process late in the data collection visit so that obtaining temperature measurements over a period of time to assess cooling rates is not feasible. Another

example may be an observation of a food product that has just completed a cooling process but the operator maintains and has documented by cooling times / temperatures in a log.

Ask the operator to explain the cooling process used for the products. This will tell you whether they in fact added ice or used chill sticks, a blast chiller, or ice bath in the cooling process. In situations where obtaining quantitative measurements of the cooling process is not feasible, the data collector is to assess the cooling methods / equipment and make a determination as to whether they are in keeping with best practices that are generally known to facilitate a cooling process. While the information statements 7A and 7B noted in the table on the previous page would be marked not observed because no quantitative measurements were taken, the data collector can mark information statement 7C (IN or OUT), based on observations made and information obtained regarding cooling methods / equipment used.

QUANTITATIVE TEMPERATURE ASSESSMENTS OF COOLING RATES

If TCS foods are in the cooling process during the data collection visit, a **MINIMUM** of two food product time and temperature checks are to be obtained and recorded in the temperature chart provided on the data collection form for data item 7 – **Foods are cooled properly**. **Food Cooling Temperature #1** is the initial internal product temperature of a cooked TCS food or TCS food prepared from ambient ingredients that is taken at the beginning, or near the beginning of the data collection. **Food Cooling Temperature #2** is the internal product temperature of the cooked TCS food or TCS food prepared from ambient ingredients that the data collector assessed near the end of the data collection. This second temperature reading is from the same TCS food observed cooling at the beginning of the data collection from which Food Cooling Temperature #1 was obtained. These two temperature measurements provide a method for assessing the cooling rate based on the elapsed time between the first and second temperature measurements. The data collector can use predictive modeling as described in the next section as a tool to assist with making a determination as to whether the cooling process is IN or OUT of compliance.

USE OF PREDICTIVE MODELING AS A TOOL TO ASSESS COOLING RATES

For the purposes of the Study, the data collector can use predictive modeling as presented in this section as a tool for determining whether a cooling process that can not be completed during the data collection visit will achieve the prescribed *Food Code* critical limits. The application of predictive modeling to actual quantitative measurements should be used to determine both cooling procedures that are IN compliance as well as those that are OUT of compliance.

The data collector is expected to use predictive modeling as only one of the elements in their holistic approach to determining the compliance status for cooling. It should be placed in the context with all other observations and information received pertaining to cooling methods, procedures, equipment, and quantitative temperature measurements.

The use of predictive modeling requires that the data collector take actual temperature and time measurements of the TCS food product being cooled. Statements from the food employees as to time and/or temperatures of the product when it began the cooling process should not be used for predictive modeling if they were not verified by the data collector.

TCS food must be cooled from 135 to 41°F in 6 hours and from 135 to 70°F within the first 2 hours. The estimates that follow assume the worse-case IN compliance scenario, a full 2 hours to cool from 135 to 70°F and the remaining 4 hours to cool to 41°F. Use of rapid chill techniques (like chill sticks, ice baths, pre-chilled ingredients) can accelerate the rate of cooling.

To successfully cool from 135 to 70°F within two hours, the food must be cooled at a rate of approximately 0.54°F per minute ($135 - 70 = 65^\circ\text{F}$ total divided by 120 minutes = 0.54°F per minute) or ~32°F per hour. To successfully cool from 70 to 41°F within the remaining four hours, the food must be cooled at a rate to approximately 0.12°F per minute ($70 - 41 = 29^\circ\text{F}$ total divided by 240 minutes = 0.12°F per minute) or ~7°F per hour. Depicted graphically, the cooling curve would normally produce a quick drop in temperature from 135 to 70°F and a more gradual, extended loss of temperature as the core food temperature approaches the temperature of the cold holding / cold equipment.

Example of IN Compliance Determination Using Predictive Modeling

Early in the data collection vegetable beef soup is observed stored to a depth of two inches in a shallow pan in the walk-in cooler. The walk-in cooler is maintaining an ambient air temperature of 36°F and there is decent air flow being produced by the compressor unit. The person-in-charge indicates that the soup was put in the cooler 30 minutes ago after being cooked in the kettle along the production line. At 11:00AM the internal temperature of the soup is taken while it is cooling in the walk-in cooler and the warmest part is reading 128°F. Later in the data collection, 12:30PM, a second temperature is taken of the soup and the internal temperature is recorded at 76°F.

In this example, the vegetable beef soup is cooling at a rate of 0.58°F per minute ($128 - 76 = 52 \div 90 = 0.577$). This cooling rate is faster than the 0.54°F per minute rate required for cooling a product from 135 - 70°F in the 2 hours presented in our conservative predictive model. Though the data collector does not know the exact time the vegetable soup reached 135°F, using a holistic approach to assessing cooling along with the use of predictive modeling provides a solid foundation for marking information statement 7A IN compliance with the Food Code critical limit of 135 - 70°F in 2 hours.

Example of OUT of Compliance Determination Using Predictive Modeling

Early in the data collection chili is observed stored to a depth of three inches in shallow pan in the walk-in cooler. The walk-in cooler is maintaining an ambient air temperature of 41°F and there is decent air flow being produced by the compressor unit. The person-in-charge indicates that the chili was put in the cooler 30 minutes ago after being cooked in the kettle along the production line. At 11:00AM the internal temperature of the chili is taken while cooling in the walk-in cooler and the warmest part is reading 132°F. Later in the data collection, 12:30 PM, a second temperature is taken of the chili and the internal temperature is recorded at 100°F.

In this example, the chili is cooling at a rate of ~0.35°F per minute ($132 - 100 = 32 \div 90 = 0.355$). This cooling rate is significantly slower than the 0.54°F per minute rate required for cooling a product from 135 - 70°F in the 2 hours presented in our conservative predictive model. The chili would have to cool another 30 degrees in 30 minutes (1°F per minute). The 1°F per minute cooling rate is significantly faster than the 0.54°F per minute rate used in our predictive modeling. Cooling rates that strictly rely on the ambient temperature and air flow within a refrigeration unit will slow down, not increase, as the food product proceeds through the cooling process. Though the data collector does not know the exact time the vegetable soup reached 135°F, using a holistic approach to assessing cooling along with the use of predictive modeling, a solid foundation of information has been obtained for marking information statement 7A OUT of compliance with the *Food Code* critical limit of 135 - 70°F in 2 hours

ASSESSING COOLING OF LEFTOVERS/PREPARED PRODUCTS FROM THE PREVIOUS DAY

During the data collection, the person-in-charge or other food employees may indicate that some food product requiring cooling were placed in one or more refrigeration units earlier in the day or the night before. After your quick walk-through, go to the walk-in cooler (or other equipment) where the foods are being held. Have the manager/food employee point out the foods he/she was referring to. Before taking any temperatures,

determine whether the foods in question are TCS foods and ask the manager/food employee when the containers were placed in the cooler. As with the previous cooling assessment guidance, note the size, depth and type (metal/plastic) of the containers being used for cooling and note the consistency of the product (broth versus thick stew/chili).

Take the temperature of the product by inserting your thermocouple probe in the four corners and center of the product. Note the temperatures and time on your list of observations. Especially note any differences of temperature. Food that is in the process of cooling will usually be cooler around the edges and warmer in the middle. This is an indication that the food is still cooling rather than being cold held.

Note the ambient temperature of the unit and take some temperatures of food products (TCS or not) that you know have been in the unit for a few days. This will provide an indication of the refrigeration unit's capabilities, as well as provide additional confirmation that certain products are being cooled versus being cold held. For example, if the temperature of a product is around 44°F, yet all the other products in the unit are 39°F and the unit itself is 39°F, then the product found at 44°F is probably being cooled especially if there are temperature difference in the container (as described in the previous paragraph).

Once it has been determined that products are in the process of cooling, ask the manager/food employee to explain the cooling process/methods for these products. This will provide information as to whether a rapid cooling technique such as, adding ice to the product, using an ice bath, placing the product in a blast chiller, etc., was an integral part of the cooling process. In some cases, when one of these rapid chill techniques is used, proper cooling may not be achieved if the product has been placed in deep containers before it has attained an internal product temperature of 41°F.

The data collector is to use all the information obtained from the manager / food employees to supplement their observations of cooling methods and quantitative temperature measurements to determine IN and OUT markings. In many cases, food placed in the walk-in from the night before will still provide an opportunity to assess cooling rates based on predictive modeling. For example, if the temperature of the food is taken at the beginning of the inspection and it is 52°F and two hours later it is 50°F, the food is cooling at a rate of .022 / per minute which is significantly slower than 0.12 cooling rate (70°F - 41°F in 4hours) used in the predictive modeling. Based on all the information obtained regarding the cooling method, this type of quantitative assessment adds important confirmation to the cooling assessment. Information statement 7A would be marked OUT in this scenario.