

TEMPLATE FOR CONDUCTING A RISK-BASED INSPECTION

A standardization exercise is intended to be a template for regulatory inspections conducted by federal, state, local, and tribal regulatory officials at the retail level. That is, both a Candidate's standardization and a regulatory inspection should contain education/training components and auditing/evaluating components. The focus of both types of inspections should be on the application of *Food Code* provisions related to Foodborne Illness Risk Factors and *Food Code* Interventions associated with foodborne illness but which does not ignore good retail practices. The template below provides suggested inspection activities for both standardization inspections (Stand.) and regulatory inspections (Reg.) based on the five Performance Areas (PA) identified in Subpart 3-102 of the standardization procedure.

Performance Area A – Foodborne Illness Risk Factors and *Food Code* Interventions

Performance Area B – Good Retail Practices

Performance Area C – Application of HACCP Principles

Performance Area D – Inspection Equipment

Performance Area E – Communication

1. PREPARING FOR AN INSPECTION

Resources and Additional information: Ref. 6,8

Activity

- Contact the agency with jurisdiction in the work area for permission to conduct standardization inspections.
- Be aware of local code requirements (T/T, CA, TPHC, etc.). – Perf. Area A,B
- Calibrate thermocouples and thermometers before the standardization exercise. – Perf. Area D
- Have all essential inspection equipment, appropriate clothing. – Perf. Area D
- Choose facilities that cover risk categories 2-4 as well as food services, food stores and institutions unless exceptions are made for agencies that regulate only one type of facility. – Perf. Area C
- The Standard should explain expectations to the Candidate: scoring to accomplish standardization, conducting risk-based inspections focused on Foodborne Illness Risk Factors and *Food Code* Interventions but knowledge of GRPs, taking cooking temperatures, taking appropriate corrective actions for all OOC Foodborne Illness Risk Factors, doing a Risk Control Plan, doing 3 process flow diagrams, explaining the HACCP principles, identifying the *Food Code* provisions for any OOC Foodborne Illness Risk Factors on the inspection report, using appropriate inspection equipment, communicating effectively and conducting an inspection as closely as possible to a real-time regulatory inspection. – Perf. Area E
- Review establishment files, past inspections, repeat violations, etc. before entering when possible.

2. INTRODUCTION PRIOR TO INSPECTION
Resources and Additional Information: Ref. 8, 10
Activity
<ul style="list-style-type: none"> • Ask to speak to the Person in Charge (PIC) and establish an open dialogue during the inspection. – Perf. Area E • Show identification and give a business card if possible. – Perf. Area E • Introduce yourself and request permission to use the facility for a standardization exercise, explaining the purpose (internal training and auditing, promoting national uniformity) and that the inspection is “off the record” with no written record left behind and no records put into the establishment’s file.- Perf. Area E • Explain that questions will be asked of managers and food employees to better understand the operation’s procedures.- Perf. Area E • Request corrective actions for all OOC Foodborne Illness Risk Factors and Food Code Interventions that contribute to foodborne illness. – Perf. Area C • Invite the PIC to accompany you if they have time. Otherwise, explain that any major problems will be summarized later before you leave. – Perf. Area E • If the PIC refuses entry, thank him/her for his/her attention and leave – do not try to convince the PIC to allow the inspection. Document the refusal for a regulatory inspection.
3. SET A GOOD EXAMPLE
Resources and Additional Information: Ref. 6, 7, 8
Activity
<ul style="list-style-type: none"> • Always wash your hands properly upon entering the work area and anytime when hands may have become contaminated. – Perf. Area E • Do not work if you are ill yourself. – Perf. Area E • Do not touch RTE food with your bare hands. – Perf. Area E • Clean and sanitize your thermocouple probe before taking food temperatures. – Perf. Area D • Make sure your thermometer is accurate. Offer to calibrate your thermometer along with the facility’s thermometer. – Perf. Area D • Wear clean clothes, a lab coat (optional) and effective hair restraint. – Perf. Area D • Do not contaminate food or equipment by setting your clip board down on work surfaces, touching things, etc. – Perf. Area D • Be courteous and respect the food establishment’s need to carry out their job in a timely fashion. – Perf. Area E
4. CONDUCTING A RISK-BASED INSPECTION
Resources and Additional Information: Ref. 3, 5, 6, 8
Activity
<ul style="list-style-type: none"> • Assess the level of risk of foodborne illness to the public presented by the food safety practices of the facility. – Perf. Area A • After identifying which processes are used in the facility (process # 1, 2 &/or 3), focus attention on the CCPs and CLs for that process(s) to reduce the occurrence of Foodborne Illness Risk Factors that contribute to foodborne illness. – Perf. Area C

- Supplement observations by asking questions of the PIC and employees to fully understand food preparation, storage and serving/selling procedures used and the management systems in place to monitor and control the CCPs. – Perf. Area E
- Initiate corrective actions for all “out of compliance” Foodborne Illness Risk Factors identified during the inspection to signal their importance. Short term (immediate correction) and long term (changes in procedures, practices, behaviors, monitoring, record keeping, etc.) should be considered and discussed with the responsible party or PIC. – Perf. Area A
- Minimize but do not ignore time and attention spent on facilities, general sanitation, good retail practices, etc. – Perf. Area A, E
- Conduct a menu or food list review. – Perf. Area A, E
- Focus on verification of Foodborne Illness Risk Factors control measures implemented by the establishment. – Perf. Area A

5. INITIAL WALK THROUGH

Resources and Additional Information: Ref. 3, 5, 6, 8

Activity

- Ask the PIC what is occurring now – prep, set up, cooling, reheating, cooking, etc.
- Do an initial walk through to familiarize yourself with the layout of the facility (prep area, cook and serve areas, walk-in-coolers, dishwashing areas, storage, etc.) and the activities that are currently occurring. This helps you set priorities and focus the inspection. Do not begin the inspection unless you have an opportunity to record or observe something that may not be present later (i.e., get a final cooking or reheating temperature). – Perf. Area A, B, C
- Identify and prioritize activities that you want to investigate in more detail (deliveries if present, preparation, cooling, reheating, cooking, etc.). – Perf. Area A, B, C
- Ask employees to call you if you are not there when they finish cooking a food product, reheating before hot holding, etc. – Perf. Area E
- Determine which processes (Process HACCP #1, #2 &/or #3) occur in the facility to help you determine which critical control points (and risk factors) should receive focused attention. – Perf. Area C
- Do not be distracted by the PIC trying to “lead” the inspection or by out of compliance GRPs, although notes can be taken as you do the walk through. – Perf. Area B, E

6. OBSERVATIONS

Resources and Additional Information: Ref. 3, 5, 6, 8

Activity

- Focus on procedural and behavioral aspects of the operation that contribute to foodborne illness. Structures, equipment and utensils, plumbing, repairs and maintenance, cleaning, etc. can easily be observed later in the inspections. – Perf. Area A, C
- Observe when and how handwashing is done. Before starting work? Before donning gloves? After using the restroom? After touching raw meat? After handling dirty dishes before handling clean dishes? – Perf. Area A
- Observe situations where bare hand contact with RTE food may occur such as plating food at the grill or serving line or making sandwiches. – Perf. Area A
- Ask employees who are engaged in food preparation if you can see their hands. Then ask them if they know why you are asking (teaching moment – no infected lesions or uncovered bandages,

- short, clean nails, no excess jewelry, etc.). – Perf. Area A, E
- Observe products and employees behavior when deliveries are made at the time you are present. – Perf. Area A
- Take final cook temperatures of all raw animal foods served/sold. – Perf. Area A
- Observe or question cooling practices for all intended/unintended leftover PHF (TCS Food). – Perf. Area A, E
- Determine reheating practices if any (method, equipment, T/T), if any for cooled products and commercially prepared products. – Perf. Area A
- Observe product temperatures for hot and cold holding and required criteria for Time as a Public Health Control. – Perf. Area A
- Verify that *Food Code* Interventions are implemented. – Perf. Area A
- Use majority of inspection time observing practices, behaviors and procedures that contribute to Out of Compliance Foodborne Illness Risk Factors. – Perf. Area A

7. CORRECTIVE ACTIONS

Resources and Additional Information: Ref. 5, 7, 8

Activity

- Request corrective actions for all OOC Foodborne Illness Risk Factors identified during the inspection to reinforce their importance. – Perf. Area A, E
- Explain why the corrective action is needed. – Perf. Area E
- Solicit ideas from the PIC as to how to accomplish the correction and/or offer alternative solutions to the OOC Foodborne Illness Risk Factors . – Perf. Area C, E
- Consider whether this may be an opportunity to do a Risk Control Plan for long term correction. – Perf. Area C
- Verify that each identified corrective action for an OOC risk factor has been accomplished (or initiated if it involves repairs, etc.) before you leave the facility. – Perf. Area C

8. COMMUNICATION

Resources and Additional Information: Ref. 1, 3, 8, 10

Activity

- Questions, observations, attention will signal inspection priorities to the PIC and management. Focusing on control of Foodborne Illness Risk Factors instead of GRPs will establish this priority in their mind instead of “floors, walls and ceilings.” – Perf. Area A, E
- Communicate non-verbally as well as verbally. Set a good example with your own behavior and actions. – Perf. Area E
- “Teaching Moments” by the Standard or Regulatory Inspector can add substance and value to an inspection. When requesting a corrective action for an OOC Foodborne Illness Risk Factors , the Candidate or Inspector should explain the public health reason and offer alternatives where appropriate for the needed correction. New equipment, procedures, code provisions and interpretations can be explained as they are encountered during a standardization inspection. – Perf. Area E
- To be most effective, short and long term corrective actions should be the operator’s/employee’s idea. When their ideas are inappropriate or they have no ideas, offer options for correction.- Perf. Area A, E
- Provide helpful information to the PIC related to their operation or OOC Foodborne Illness Risk

Factors that were observed during the inspection – new code requirements, current food safety issues (allergens, produce safety, employee health, food defense, etc.), websites, health department training, etc.).- Perf. Area A, E

- Share “Best Practices” or good examples of solutions to similar problems you observed elsewhere. – Perf. Area E

9. USE OF INSPECTION EQUIPMENT

Resources and Additional Information: Ref. 5, 7, 8

Activity

- Have all essential inspection equipment with you including the correct probes for your thermocouple, enough alcohol swabs, appropriate head gear, inspection forms, etc. – Perf. Area D
- Calibrate your thermocouple/thermometers before arriving and beginning the exercise. Then you are confident of your readings and can offer to calibrate yours along with the operator’s during the inspection. – Perf. Area D
- Carefully clean and sanitize your thermocouple probe before use and when changing from raw to RTE foods or from one type of animal food to another. – Perf. Area D
- If you use an IR thermometer, understand its limitations (surface temperatures only, reflections can interfere, etc.) – Perf. Area D
- Do you have a way to verify the effective sanitization of hot water and chemical sanitizing warewashing machines and manual hot water and chemical warewashing equipment (160°F temperature sensitive tapes, maximum-minimum registering thermometers [glass/mercury or digital “lollipop” type], thermocouple thermometer, appropriate chemical test strips for chlorine, iodine and quaternary ammonium sanitizers). – Perf. Area D
- If you use a pH meter or water activity meter, have the appropriate buffer solutions and calibration solutions available to check your own equipment, understand how to use it, how frequently to calibrate it, etc. – Perf. Area D
- Laboratory grade pH strips are available (4 color match) but still give only an approximate pH reading (e.g., 4.0, 5.0, etc.) – Perf. Area D

10. HACCP AND RECORD KEEPING

Resources and Additional Information: Ref. 2, 3, 4, 5, 6, 7, 9

Activity

- HACCP concepts are used in several different ways during a standardization inspection. The Candidate is expected to know the seven principles of HACCP and be able to complete an exercise involving the evaluation of a HACCP plan. HACCP concepts are also addressed in other ways. – Perf. Area C
- Three flow charts for Process #1 (no cook step), Process #2 (preparation for same day service) and Process #3 (complex food preparation) are to be completed for foods identified during the Standardization exercise with hazard, CCPs and CLs shown. – Perf. Area C
- If the operator has an approved variance (e.g., sushi, curing, smoking (not cooking), use of preservatives, live shellfish tanks, custom animal processing, sprouting seeds, or other preparation method deemed by the regulatory authority to require a variance), review the HACCP plan and records. – Perf. Area A, C
- If ROP is conducted on-site, verify that the necessary records and HACCP plan are available and maintained for 6 months. – Perf. Area A, C

- If freezing for parasite destruction in fish is done, a letter of guaranty that is company and product-specific should be available from the processor or records to show time and temperature used for freezing if done internally should be reviewed. – Perf. Area A, C
- If searing steaks for surface coloration without a consumer advisory, labeling on the container or letter of guaranty from the processor should be available for review. – Perf. Area C
- If Molluscan shellstock are served, review shellfish tags for 90 day retention, chronological order and date last sold marked on the tag. – Perf. Area B

11. GENERAL ASPECTS OF AN INSPECTION

Resources and Additional Information: Ref. 3, 4, 6, 7, 8

Activity

- Ask the PIC if the operator has a variance for any code provision along with a HACCP plan to support the approved variance request. – Perf. Area C, E
- Ask the PIC questions to determine whether the facility is in compliance with employee health requirements. If they do not appear to be in compliance, use this opportunity to raise their awareness about employee health issues (symptoms, diagnosis, exposure, training, conditional employees, reporting, connection between employee health, handwashing and no bare hand contact with RTE food) and provide resources or sources of information. – Perf. Area A, E
- Ask whether the facility has “specials” not listed on the menu, holiday meals, catering, parties. Also note if they use procedures or equipment not typically used. – Perf. Area E
- Note if there are management systems in place for monitoring and verifying time/temperature control, date marking, hand washing, no bare hand contact with ready-to-eat foods, time as a public health control (if used), recalls, foodborne illness outbreaks, orientation and refresher training, etc. – Perf. Area A, C, E
- Review the menu or menu board before leaving to determine if you saw all necessary operations or asked questions in cases where you were unable to observe the actual preparation. – Perf. Area A, E
- Determine if PIC is familiar with eight major allergens, their symptoms in sensitive individuals and labeling requirements for allergens. – Perf. Area A, B, E
- Observe the general level of sanitation and compliance with GRPs. – Perf. Area B

12. EXIT INTERVIEW

Resources and Additional Information: Ref. 6, 7, 8

Activity

- If the PIC accompanied you throughout the inspection, there is no need to review the entire inspection again before leaving. A very short review of the OOC Foodborne Illness Risk Factors and corrective actions taken or needed will be sufficient. – Perf. Area C, E
- Discussion of individual GRPs is not usually necessary unless extremely blatant. – Perf. Area B, E
- Have a list of resources available that you can provide to the PIC based on situations and questions encountered during the inspection (websites for the *Food Code*, Operator’s Manual, EEOC Restaurant Guide, Employee Health Handbook (soon to be completed), Bad Bug Book, Seafood Hazards Guide, ICSSL, Risk Factor Study, etc.). You can also offer to send them information later. – Perf. Area E
- Provide positive reinforce to the PIC for active managerial control, “Best Practices”, innovative methods, etc. that you observed during the inspection. – Perf. Area E

- Ask the PIC if there are any questions he/she would like to ask. – Perf. Area E
- Thank the PIC for his/her assistance and cooperation in the standardization exercise. – Perf. Area E

13. “Real Time” Inspection

Resources and Additional Information: Ref. 5, 6, 7, 8

Activity

- Inspectors doing regulatory inspections often have to work under time and resource constraints that are not considered during a standardization inspection. In order to help the Candidate better understand this transition, one or more standardization inspections should be conducted as closely as possible to a “real time” inspection. – Perf. Area A, B
- The time should be limited to the average time for the type of facility in the jurisdiction, including inspection, write up and exit interview with the emphasis on a risk based inspection and identification and correction of Foodborne Illness Risk Factors. – Perf. Area A, B
- Passing the “Foodborne Illness Risk Factors and Food Code Interventions” portion of the Inspection Report, as noted in 3-302(A) of the Standardization Procedure. – Perf. Area A
- Passing the “Good Retail Practices” portion of the Inspection Report, as noted in 3-302(A) of the Standardization Procedure. – Perf. Area B

Resources and Additional Information:

1. EEOC “How to Comply with the Americans with Disabilities Act: A Guide for Restaurant and Other Food Service Employers. Available at http://www.eeoc.gov/facts/restaurant_guide.html.
2. FDA Fish and Fisheries Products Hazards and Control Guide, Third Ed. Available at <http://www.fda.gov/Food/GuidanceComplianceRegulatoryInformation/GuidanceDocuments/Seafood/FishandFisheriesProductsHazardsandControlsGuide/default.htm>.
3. FDA Food Code. Available at <http://www.fda.gov/Food/FoodSafety/RetailFoodProtection/FoodCode/FoodCode2005/default.htm>.
4. FDA Food Code, Annex 3 – Public Health Reasons/Administrative Guidelines. Available at <http://www.fda.gov/Food/FoodSafety/RetailFoodProtection/FoodCode/FoodCode2005/default.htm>.
5. FDA Food Code, Annex 4 – Management of Food Safety Practices Achieving Active Managerial Control of Foodborne Illness Risk Factors. Available at <http://www.fda.gov/Food/FoodSafety/RetailFoodProtection/FoodCode/FoodCode2005/default.htm>.
6. FDA Food Code, Annex 5 – Conducting Risk-Based Inspections. Available at <http://www.fda.gov/Food/FoodSafety/RetailFoodProtection/FoodCode/FoodCode2005/default.htm>.
7. FDA Managing Food Safety: A Regulator’s Manual for Applying HACCP Principles to Risk-based Retail and Food Service Inspections and Evaluating Voluntary Food Safety Management Systems. Available at <http://www.fda.gov/downloads/Food/FoodSafety/RetailFoodProtection/ManagingFoodSafetyHACCPPrinciples/Regulators/UCM078159.pdf>.
8. FDA Procedures for Standardization of Retail Food Safety Inspection Officers. Available at <http://www.fda.gov/Food/FoodSafety/RetailFoodProtection/InspectionsQualityAssurance/Standardization/default.htm>.
9. National Advisory Committee on Microbiological Criteria for Foods (NACMCF). 1997. Hazard Analysis and Critical Control Point Principles and Application Guidelines. Available at <http://www.fda.gov/Food/FoodSafety/HazardAnalysisCriticalControlPointsHACCP/ucm114868.htm>.
10. FDA ORA-U Communications Course. Available at <http://www.fda.gov/Training/ForStateLocalTribalRegulators/default.htm>.