

Conducting Risk-Based Inspections

2019 Yankee Conference

Plymouth, MA

FD218 Conducting Risk Based Inspections



Objectives

- Introduction/Definitions
- What is needed to conduct risk-based inspections?
 - FDA resources
 - Regulatory program support
- What can inspectors do in the field?
 - Prioritizing/focusing inspections on risk
 - Assessing Code compliance
- What should food establishment managers do to control risk?
 - Assessing active managerial control (AMC)
- What can regulatory and industry do together?
 - Long-term compliance strategies

What are Risk-Based Inspections?

- Routine, periodic inspection conducted as part of an ongoing regulatory scheme
- Goes beyond mere assessment of Code compliance
- Critical elements include:
 - Information sharing/collaboration between industry & regulators
 - Focus on FBI risk factors & Code interventions
 - Evaluation of Code compliance & AMC
 - Obtaining immediate CA for OOC risk factors
 - Implementation of intervention strategies to achieve long-term compliance



Definition of Terms

- **Active Managerial Control:** The purposeful incorporation of specific actions or procedures by industry management into the operation of their business to attain control over **foodborne illness risk factors**.



Risk Based Inspection Resources

- OTED courses, FD218, Conducting Risk-Based Inspections
- ORAU – Online courses - ComplianceWire
- Food Code Annex 4, Management of Food Safety Practices – Achieving Active Managerial Control
- Food Code Annex 5, Conducting Risk Based Inspections
- FDA's Voluntary National Retail Food Regulatory Program Standards

Risk Based Inspection Resources



Managing Food Safety: A Manual for the Voluntary Use of HACCP Principles for Operators of Food Service and Retail Establishments

Additional copies are available from:

*Office of Food Safety
Retail Food and Cooperative Programs
Coordination Staff/Retail Food Protection Team (HFS-320)
Center for Food Safety and Applied Nutrition
Food and Drug Administration
5100 Paint Branch Parkway
College Park, MD 20740
(Tel) 240-402-2349*

U.S. Department of Health and Human Services
Food and Drug Administration
Center for Food Safety and Applied Nutrition

[April 2006]

OMB Control No. 0910-0578
Expiration Date: 01/31/2013

See additional PRA statement in Annex 5 of this manual



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

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Retail & Food Service HACCP



HACCP & Managerial Control of Risk Factors

Managing retail food safety embodies the principles of HACCP at retail and active managerial control on the part of industry. Regulators also play a role in maintaining a food safety system in retail food establishments. Cooperatively, regulators and industry can work together to understand the perspective of each and account for the variety of food preparation and service needs found in retail food establishments - from the facility with minimal food service to very complex operations that serve hundreds to thousands of meals daily.

Specific information is provided to assist the regulator and industry in meeting the needs for providing safe food to the consumer.

- Managing Food Safety: A Manual for the Voluntary Use of HACCP Principles for Operators of Food Service and Retail Establishments
- 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

<https://www.fda.gov/food/hazard-analysis-critical-control-point-haccp/retail-food-service-haccp>



What is Needed to Conduct Risk-Based Inspections?

- Schedule Inspections Based on Risk (VNRFRPS 3)
- Risk Categorization of Food Establishments
 - History of non-compliance
 - Specialized processes conducted
 - Food preparation a day or more in advance of service
 - Large number of people served
 - History of foodborne illness and/or complaints
 - Highly susceptible population served

Annex 5, Table 1. Risk Categorization of Food Establishments



RISK CATEGORY	DESCRIPTION	FREQUENCY #/YR
1	<p>Examples include most convenience store operations, hot dog carts, and coffee shops. Establishments that serve or sell only pre-packaged, non- time/temperature control for safety (TCS) foods. Establishments that prepare only non-TCS foods. Establishments that heat only commercially processed, TCS foods for hot holding. No cooling of TCS foods. Establishments that would otherwise be grouped in Category 2 but have shown through historical documentation to have achieved active managerial control of foodborne illness risk factors.</p>	1
2	<p>Examples may include retail food store operations, schools not serving a highly susceptible population, and quick service operations. Limited menu. Most products are prepared/cooked and served immediately. May involve hot and cold holding of TCS foods after preparation or cooking. Complex preparation of TCS foods requiring cooking, cooling, and reheating for hot holding is limited to only a few TCS foods. Establishments that would otherwise be grouped in Category 3 but have shown through historical documentation to have achieved active managerial control of foodborne illness risk factors. Newly permitted establishments that would otherwise be grouped in Category 1 until history of active managerial control of foodborne illness risk factors is achieved and documented.</p>	2
3	<p>An example is a full service restaurant. Extensive menu and handling of raw ingredients. Complex preparation including cooking, cooling, and reheating for hot holding involves many TCS foods. Variety of processes require hot and cold holding of TCS food. Establishments that would otherwise be grouped in Category 4 but have shown through historical documentation to have achieved active managerial control of foodborne illness risk factors. Newly permitted establishments that would otherwise be grouped in Category 2 until history of active managerial control of foodborne illness risk factors is achieved and documented.</p>	3
4	<p>Examples include preschools, hospitals, nursing homes, and establishments conducting processing at retail. Includes establishments serving a highly susceptible population or that conduct specialized processes, e.g., smoking and curing; reduced oxygen packaging for extended shelf-life.</p>	4

What is Needed to Conduct Risk-Based Inspections?

- Have the proper equipment (VNRFRPS 8)
 - Each inspector provided with
 - Thermocouple with the appropriate probes for the food being tested
 - Alcohol swabs or other suitable equipment for sanitizing probe thermometers
 - Chemical test kits for different chemical sanitizer types
 - Heat-sensitive tape or maximum registering thermometer
 - Flashlight
 - Head cover, such as baseball cap, hair net, or equivalent.
 - Other equipment as needed
 - Pressure gauge for determining in-line pressure of hot water at injection point of warewashing machine (5-30 psi)
 - Light meter
 - Measuring device for measuring distances
 - Time/temperature data logger
 - pH meter
 - Water activity meter
 - Camera
 - Computers with or without an electronic inspection system
 - Black light
 - Foodborne illness investigation kits
 - Sample collection kits
 - Cell phones.

What is Needed to Conduct Risk-Based Inspections?

- Provide adequate training (VNRFRPS 2)
 - 1. Classroom training
 - Prevailing statutes, regulations, or ordinances
 - Public health principles
 - Communication skills
 - Epidemiology
 - Microbiology
 - HACCP.
 - 2. Field Training & Experience
 - Interviewing
 - Making observations
 - Measuring conditions (temps., sanitizers, etc.)
 - Assessing AMC over RF
 - Ensuring implementation of Food Code interventions
 - Completing inspection forms, etc.
 - 3. Standardization
 - After classroom and field training
 - 4. Continuing Education



What is Needed to Conduct Risk-Based Inspections?

- Ensure adequate program resources (VNRFRPS 8)
 - Funding
 - Staff
 - Equipment
 - Accredited Laboratory

Risk-Based Inspection Methodology

Focus the Inspection

- The majority of time should be spent on:
 - Assessment of Compliance with Code provisions related to Risk Factors
 - Degree of active managerial control (AMC) over Risk Factors
- Observe behaviors, practices and procedures likely to lead to out of compliance risk factors.
- Ask questions of managers and employees to supplement actual observations

- Risk Factors
 - Food from Unsafe Sources
 - Inadequate Cooking
 - Improper Holding Temperatures
 - Contaminated Equipment
 - Poor Personal Hygiene
- Food Code Interventions
 - Demonstration of Knowledge
 - Implementation of Employee Health Policies
 - Hands as a Vehicle of Contamination
 - Time/Temperature Relationships
 - Consumer Advisory

Food Code Annex

FORM 3-A Food Establishment Inspection Report



FOODBORNE ILLNESS RISK FACTORS AND PUBLIC HEALTH INTERVENTIONS														
Circle designated compliance status (IN, OUT, N/O, N/A) for each numbered item					Mark "X" in appropriate box for COS and/or R									
IN=in compliance			OUT=not in compliance		N/O=not observed		N/A=not applicable		COS=corrected on-site during inspection		R=repeat violation			
Compliance Status			COS		R		Compliance Status			COS		R		
Supervision														
1	IN	OUT	Person in charge present, demonstrates knowledge, and performs duties											
2	IN	OUT	N/A	Certified Food Protection Manager										
Employee Health														
3	IN	OUT	Management, food employee and conditional employee; knowledge, responsibilities and reporting											
4	IN	OUT	Proper use of restriction and exclusion											
5	IN	OUT	Procedures for responding to vomiting and diarrheal events											
Good Hygienic Practices														
6	IN	OUT	N/O	Proper eating, tasting, drinking, or tobacco use										
7	IN	OUT	N/O	No discharge from eyes, nose, and mouth										
Preventing Contamination by Hands														
8	IN	OUT	N/O	Hands clean & properly washed										
9	IN	OUT	N/A	N/O	No bare hand contact with RTE food or a pre-approved alternative procedure properly allowed									
10	IN	OUT	Adequate handwashing sinks properly supplied and accessible											
Approved Source														
11	IN	OUT	Food obtained from approved source											
12	IN	OUT	N/A	N/O	Food received at proper temperature									
13	IN	OUT	Food in good condition, safe, & unadulterated											
14	IN	OUT	N/A	N/O	Required records available: shellstock tags, parasite destruction									
Protection from Contamination														
15	IN	OUT	N/A	N/O	Food separated and protected									
16	IN	OUT	N/A	Food-contact surfaces; cleaned & sanitized										
Time/Temperature Control for Safety														
17	IN	OUT	Proper disposition of returned, previously served, reconditioned & unsafe food											
18	IN	OUT	N/A	N/O	Proper cooking time & temperatures									
19	IN	OUT	N/A	N/O	Proper reheating procedures for hot holding									
20	IN	OUT	N/A	N/O	Proper cooling time and temperature									
21	IN	OUT	N/A	N/O	Proper hot holding temperatures									
22	IN	OUT	N/A	N/O	Proper cold holding temperatures									
23	IN	OUT	N/A	N/O	Proper date marking and disposition									
24	IN	OUT	N/A	N/O	Time as a Public Health Control; procedures & records									
Consumer Advisory														
25	IN	OUT	N/A	Consumer advisory provided for raw/undercooked food										
Highly Susceptible Populations														
26	IN	OUT	N/A	Pasteurized foods used; prohibited foods not offered										
Food/Color Additives and Toxic Substances														
27	IN	OUT	N/A	Food additives: approved & properly used										
28	IN	OUT	N/A	Toxic substances properly identified, stored, & used										
Conformance with Approved Procedures														
29	IN	OUT	N/A	Compliance with variance/specialized process/HACCP										

Risk factors are important practices or procedures identified as the most prevalent contributing factors of foodborne illness or injury. Public health interventions are control measures to prevent foodborne illness or injury.

Risk-Based Inspection Methodology

- Some examples of good retail practices (GRP) include:
 - Facility and equipment maintenance & storage
 - General cleanliness of the premises
 - Water, plumbing
 - Storage of dry goods
- GRPs are also assessed during a risk-based inspection but consider:
 - GRPs tend to be static, whereas risk factors tend to be more dynamic
 - GRP violations present less of a public health risk than risk factor violations

Risk-Based Inspection Methodology

Lead by Example

- Nonverbal as important as verbal communication
 - Wash hands when appropriate
 - Not working with illness symptoms/illnesses
 - Not contacting RTE with bare hands
 - Cleaning/sanitizing thermocouple probe
 - Use proper hair restraint
 - Not contaminating clean equipment/food contact surfaces with hands/inspection equipment
 - Not chewing gum, drinking beverages

Risk-Based Inspection Methodology

Conduct Inspections at Variable Times

- Conduct inspections during hours of operation/other reasonable times
- Show ID
- Provide written or verbal reason for visit
- Follow procedures in Code/RA policy if access denied & document
- Consider importance of timing
 - Receiving, preparation, cooling, etc., can only be observed at certain times.
 - Allow flexibility to inspect outside of 8:00AM – 5:00 PM Mon-Fri.
 - Dinner only, nightclubs, etc.

Risk-Based Inspection Methodology

Establish inspection priorities/use time wisely

- Complete four activities early in inspection process
 - 1. Establish an open dialogue with PIC
 - 2. Review previous inspection records
 - 3. Conduct a menu or food list review
 - 4. Conduct a quick walk-through



Risk-Based Inspection Methodology

- 1. Establish an open dialogue with PIC
 - The tone of inspection is usually set in first few minutes
 - Be professional but personable
 - Genuine interest in establishment and staff = good relations/open dialogue
 - Open dialogue facilitates learning strengths & weaknesses of food safety system. Focus on weaknesses
 - Open dialogue  Honest answers questions about FBI Risk Factors, Interventions, Employee health, etc.
 - Encourage PIC to accompany inspectors during inspection
 - Violations can be corrected immediately – still document with CA
 - Share knowledge discuss AMC, etc.
 - Beware of one-way communication, listen



Risk-Based Inspection Methodology



- 2. Review Previous Inspection Reports
 - Detect trends in OOC risk factors
 - Develop intervention strategy
 - Opportunity to provide positive feedback when previous observations have been corrected
 - Especially important when inspectors rotate through establishments/geographical areas.



Risk-Based Inspection Methodology

- **3. Conduct Menu/Food List Review**

- Can be done simultaneously during walk-through
- Doesn't have to be done on every inspection. If recently inspected:
 - Ask about new items
 - Seasonal Items
 - Raw oysters
 - Changes in preparation techniques/equipment
 - Consumer advisory?

- Mentally group foods by process
 - No cook, same day, complex
- Establish inspection priorities by identifying:
 - High-risk foods/preparation processes
 - Operational steps requiring further inquiry
 - Ask questions about operational steps that can't be observed (receiving, cooling, etc.)

Risk-Based Inspection Methodology

- **4. Conduct an Initial Quick Walk-through**

- Meant to be QUICK – 2-3 minute in duration
- Purpose: Determine the critical processes being conducted at the time of the inspection
- Normally, you would not stop and address issues that you see

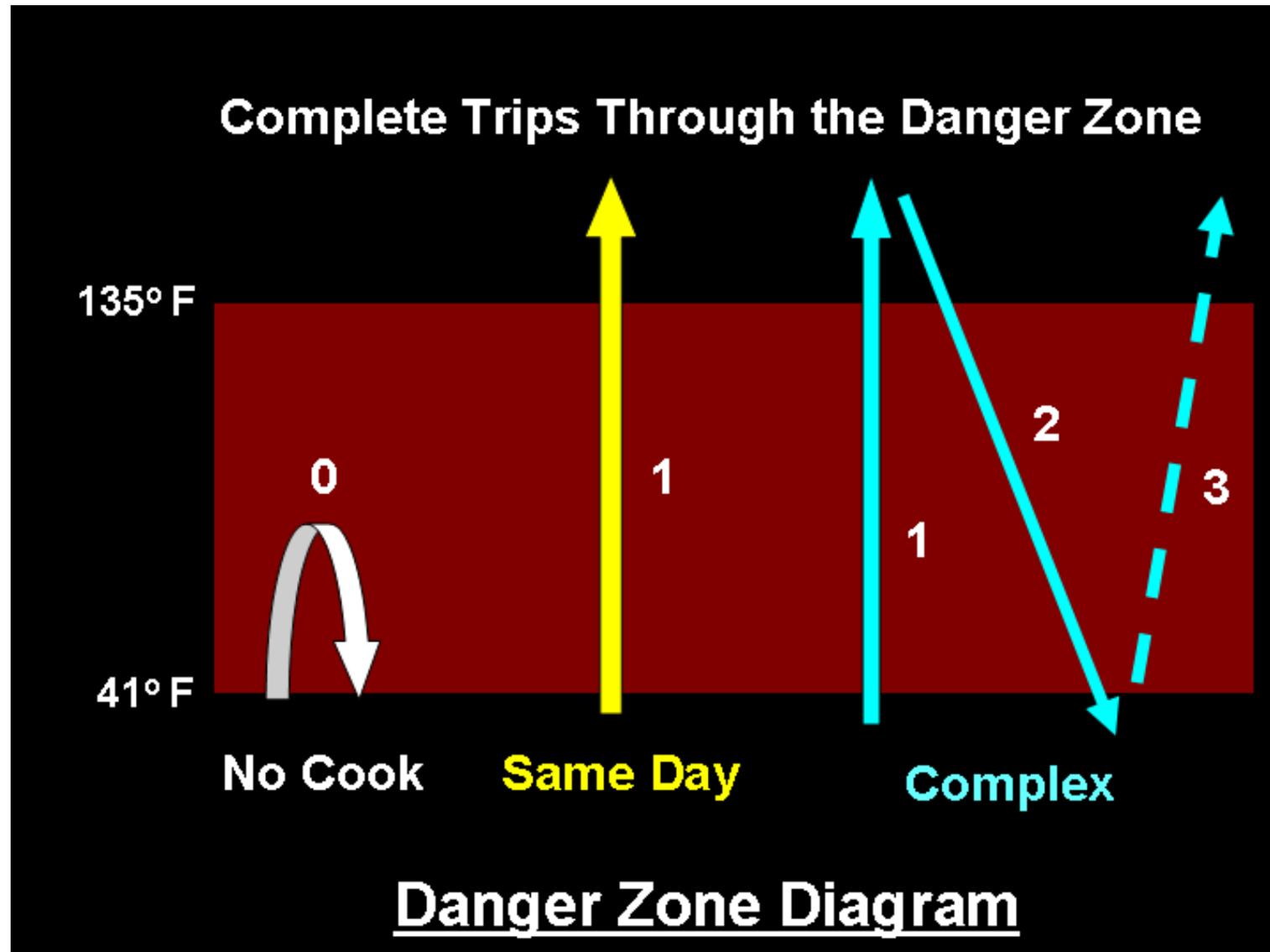
- **Consider:**

- Relative risk
- Whether the activity is static or dynamic
- The data you will need to accurately assess the activity

Risk-Based Inspection Methodology

- During the quick walk-through or before, ask specific questions to determine if the following are being conducted:
 - **Cooking/Preparation**
 - **Cooling**
 - **Reheating**
 - **Receiving**
- Don't hesitate to ask to be notified when dynamic activities are completed.

Determine Process Flow



Process 1: Food Preparation with No Cook Step



Receive → Store → Prepare → Hold → Serve

***Examples:* Tuna Salad, Raw Oysters,
Sashimi, Cold Cut
Sandwiches**



Inspection Priorities Associated with Process 1



- Cold Holding or Time as a Public Health Control
- Food Source (Shellfish; Sashimi)
- Receiving Temperatures (Tuna; Species of Finfish)
- Freezing
- Cooling from Ambient Temp



Process 2: Food Preparation for Same Day Service



Receive → Store → Prepare → Cook → Hold → Serve

***Examples:* Fried Shrimp and Baked Fish**



Inspection Priorities Associated with Process 2



- Cooking
- Hot Holding
- Time as a Public Health Control



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Process 3: Complex Food Preparation



Receive → Store → Prepare → Cook

Cool → Reheat → Hot Hold → Serve

***Examples:* Beef Stew, Soups, Gravy, Chili**



Inspection Priorities Associated with Process 3



- Cooking
- Hot Holding
- Time as a Public Health Control
- Cooling
- Cold Holding
- Reheating



Inspection Priorities Regardless of Food Prep Process



- **Cleaning and Sanitization of Food Contact Surfaces**
- **Cross-Contamination Related to Storage and Preparation**
- **Date Marking RTE, PHFs (TCS Foods)**
- **Calibration of Thermometers**



Inspection Priorities Regardless of Food Prep Process

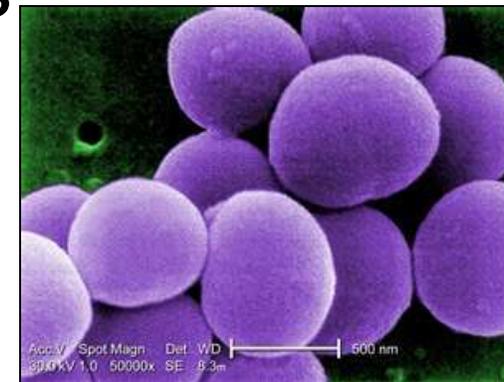


- Employee Health Policy
- Personal Hygiene Program (Handwashing/No Bare Hand Contact)
- Food source



Top 5 Pathogens Causing Domestically Acquired FBI (91% Total)

- Norovirus
 - 5,461,731 (58%)
- Salmonella (non-Typhi)
 - 1,027,561 (11%)
- Clostridium perfringens
 - 965,958 (10%)
- Campylobacter spp.
 - 845,024 (9%)
- Staphylococcus aureus
 - 241,148 (3%)



Why Norovirus and Other Viruses are so Hard to Control

- 1,000,000,000,000 - # of viral particles you start with in 1 ml of feces*
- 10,000,000,000 - # left after properly washing your hands (2 log reduction) (Ayliffe et al., 1978)
- 1,000,000,000 - # transferred from an ungloved hand to food (10%) (Montville, 2001)
- In contrast, it takes 1-10 virus particles to make you sick*

*Teunis & Moe, 2008



Prevention of Contamination from Hands



- Prevention of fecal-oral route transmission is key

- Exclusion/restriction of ill food employees
- Proper handwashing
- No bare hand contact with ready-to-eat food

Assessing Active Managerial Control

- Steps for assessing Code Compliance
 - Make accurate observations
 - Ask open-ended questions
 - Determine code critical limits (CLs)
 - Compare observations with CLs
- Assessing AMC
 - Involves more than just assessing code compliance
 - Helps you know what happens at times when you are not there
 - Requires asking a lot of open-ended questions to supplement quantitative measurements or observations

Assessing Active Managerial Control

- An establishment may be IN COMPLIANCE at the time of inspection but lack AMC
- Why assess AMC:
 - Strengthens the food safety management system in place
 - May lead to better long-term compliance
 - Consistent, comprehensive control over the risk factors = reduction in the chance of foodborne illness outbreaks
- Elements of a food safety management system designed to achieve AMC:
 - Food Safety Procedures/Policies
 - Monitoring Procedures
 - Corrective Action Procedures
 - Management Oversight (Verification)
 - Training
 - Periodic Re-evaluation of Procedures/Policies

Incorporating Assessment of AMC into an Inspection Program



- Duties of the Person in Charge – *2017 FDA Food Code*, Section 2-103.11
 - Routine monitoring and daily oversight of critical processes are required
- 8-201.12(E)
 - Content of Plans and Specifications: Evidence that standard procedures that ensure compliance with the requirements of this Code are developed or are being developed. (New, remodeled or change of facility type)
- 8-203.10
 - Conduct preop. Inspections to verify construction and SOP established

Incorporating Assessment of AMC into an Inspection Program



Credit: Olmsted County, MN Public Health Services

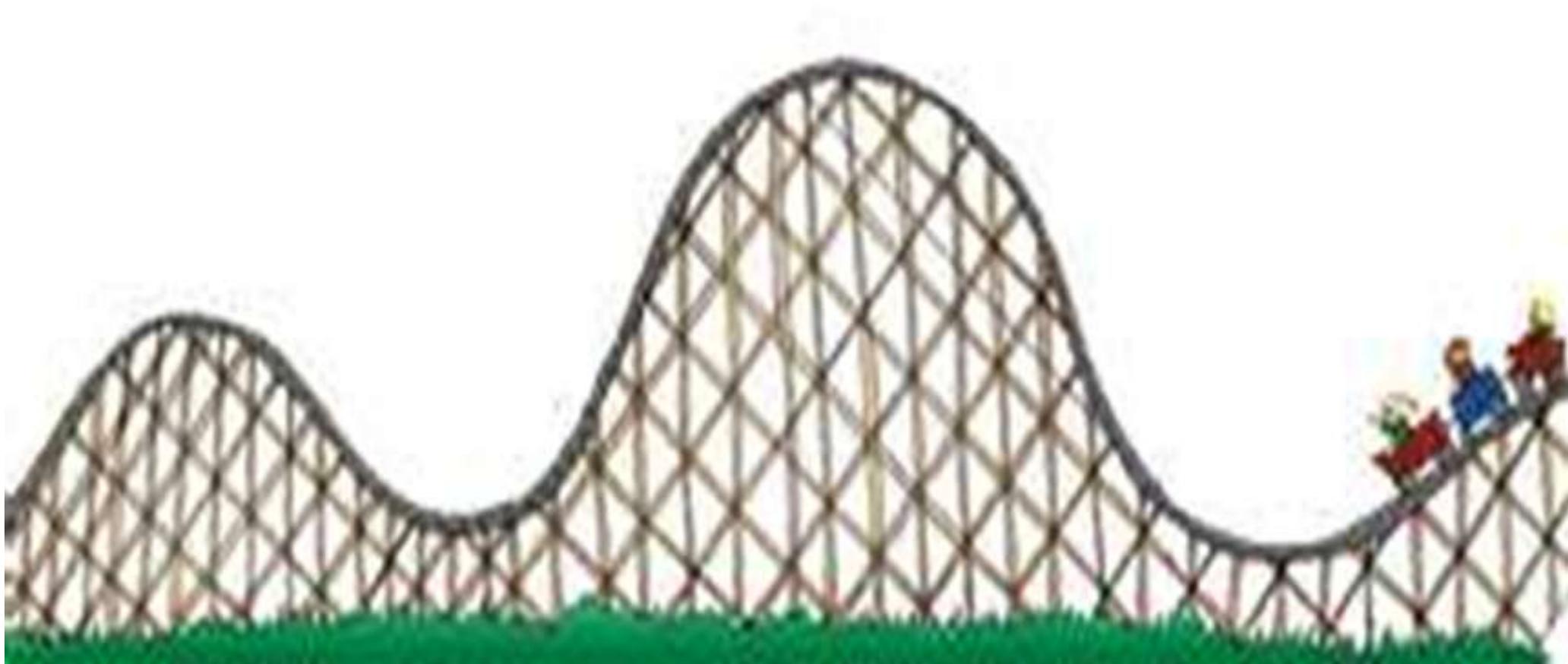
- Assess code compliance (IN, OUT, NO, NA) plus AMC
- By evaluating PTV for each risk factor:
 - Procedures, Training, & Verification
- “PTV” evaluation based on:
 - Discussion w/CFM-PIC and food employees
 - Observations
 - Reviewing logs, etc.

Incorporating Assessment of AMC into an Inspection Program

- **Procedures** - Defined set of actions set in place based on developed policies that minimize food safety risks (written – ideally; verbal OK, esp. for smaller operations).
- **Training** - Conveyance of food safety and procedure knowledge to the appropriate staff.
- **Verification** - The periodic validation of food safety procedures

- 1- **Non-existent**
- 2- **Under developed**
- 3- **Basic**
- 4- **Well developed**
- 5- **Proactive**

Long-term Intervention Strategies



Examples of Long-term Intervention Strategies

- Change Equipment or Layout
- Change Buyer Specifications
- Develop Recipe/Process Instructions
- Implement First-In-First-Out (FIFO)
- Implement Standard Operating Procedures (SOPs)
- Implement Risk Control Plans (RCPs)
- Develop Food Safety Management Systems based on HACCP Principles



CONDUCTING A RISK-BASED INSPECTION

- Assess the level of risk of foodborne illness in the facility
- Focus attention on CCPs and CLs
- Focus majority of attention on Risk Factors & Interventions
- Observe and ask questions to understand procedures/systems
- Focus on procedural and behavioral aspects of operation
 - Pay special attention to handwashing, bare hand contact with RTE food, temperature control
- Set a good example with your own behavior
- Establish open communication
- Initiate corrective action for all OUT of Compliance Risk Factors
 - Signal their importance
 - Change short term behavior (immediate correction)
 - Change long term behavior (Risk Control Plans, change procedure, monitor & keep records, etc.)



Questions?

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