



# BOH Guide: #43 FDA Retail Standard 3 Policies

Board of Health and Local Health Department Standard Operating Procedures (SOP)

This **Checklist** highlights many of the steps needed currently to organize a Massachusetts Board of Health. The checklist is designed to be used in tandem with the **BOH Job Aid #20**. BOXES CAN BE CHECKED WITH the CURSOR.

**Alliance Governing Board approved FDA Voluntary Retail Program Standard Policies**

**Alliance Boards of Health are encouraged to:**

- Become Registered with the FDA Retail Food Program Standards.
- Participate in FDA Standards Assessments every 5 years.
- Adopt Alliance policies that conform to FDA Retail Program Standards as available.
- Promote Alliance education opportunities and trainings to food establishments and the public.
- Actively work towards improving food safety in the county by participating in online permitting and inspector trainings. and inviting the Food Safety Team to present at Board of Health Meetings.
- Follow the Massachusetts Food Code or adopt a more restrictive local regulation.
- Alliance Food Inspectors meet FDA Retail Standard 2 or are in the process of being trained to Standard 2 within 24 mo.
- Support the Alliance Food Safety Program.

**FDA Voluntary Retail Program Standard 3 Policies**

**1. Inspection Form Design**

- a. The Alliance inspection form identifies foodborne illness risk factors and Food Code interventions.
- b. The Alliance inspection form documents actual observations using the convention IN, OUT, NA, and NO.
- c. The Alliance inspection form documents compliance and enforcement activities.

**2. Risk Assessment Categories**

- a. The Alliance uses risk assessments to group food establishments into at least 3 categories based on their potential and inherent food safety risks: low, medium, high

**3. Inspection Frequency**

- a. The Alliance inspection frequency is based on the assigned risk category for each Food Establishment

**4. Written and Implemented Corrective Action Policy**

- a. The Alliance written and implemented policy requires on-site and where possible immediate corrective action for foodborne illness risk factors observed to be out of compliance.
- b. The Alliance has a written and implemented policy that requires discussion for long-term control of foodborne illness risk factors.
- c. The Alliance written and implemented policy requires follow-up activities on foodborne illness risk factor violations.

**5. Variance Requests**

- a. The Alliance has a written and implemented policy on variance requests related to foodborne illness risk factors and Food Code interventions in its Corrective Action Policy

**6. Verification and Validation of HACCP Plans**

- a. The Alliance has a written and implemented policy for the verification and validation of HACCP plans when a HACCP plan is required by the Code in its Corrective Action Policy

**FDA Voluntary Retail Program Standard 3 Corrective Action Policy**

## Alliance Corrective Action Policy: Food Safety Health Inspections

### On-site Corrective Action

Food Inspectors should make corrective actions as quickly as possible for foodborne illness risk factors observed to be out of compliance. Depending on the severity of the violation that is noted, different corrective actions will be required.

### Time Frame for Corrective Action: Priority and Priority Foundation Items

The 2013 FDA Food Code provision 8-405.11 for timely correction of Priority and Priority Foundation items will be followed. A food establishment must correct priority and priority foundation items, HACCP plan provisions (not in compliance with critical limits) at the time of inspection and implement corrective actions. The Board of Health can agree to extend the corrective action depending on the nature of the hazard and complexity of the corrective action. The extension is not to exceed 10 calendar days after the inspection.

**Priority Violations:** Priority violations, described in the 2013 FDA Food Code as a provision in the Code whose application contributes directly to the elimination, prevention, or reduction to an acceptable level, hazards associated with foodborne illness or injury and there is no other provision that more directly controls the hazard. Priority violations require immediate corrective action. The Food Inspector performing the inspection will enforce the immediate corrective action, whether that means shutting down a piece of faulty equipment, a certain process being performed incorrectly, removing expired or improperly received food, etc...

**Priority Foundation Violations:** Priority foundation violations, described in the 2013 FDA Food Code as “including an item that requires the purposeful incorporation of specific actions, equipment, or procedures by industry management to attain control of risk factors that contribute to foodborne illness or injury such as personnel training, infrastructure or necessary equipment, HACCP plans, documentation or record keeping, and labeling. The Environmental Health Specialists will determine whether priority foundation violations need immediate corrective action.

**Core Violations:** Core violations are described in the 2013 FDA Food Code as an item that usually relates to general sanitation, operational controls, sanitation standard operating procedures (SSOP’s), facilities or structures, equipment design, or general maintenance. The Environmental Health Specialists will determine whether Core violations need immediate corrective action.

The Alliance follows the Massachusetts 2018 Food Code based on the 2013 FDA Food Code 8-406.11 when proceeding with correcting Core violations. The regulatory authority can enforce the food establishment to correct Core items by the agreed timeline but no later than 90 calendar days after the inspection. The timeframe can extend beyond 90 days if a written schedule of compliance is submitted by the permit holder and no health hazard exists or will result from extending the re-inspection.

- a. Destruction of foods that have experienced extreme temperature abuse;
- b. Embargo or destruction of foods from unapproved sources;
- c. Accelerated cooling of foods when cooling time limits can still be met;
- d. Reheating when small deviations from hot holding have occurred;
- e. Continued cooking when proper cooking temperatures have not been met;
- f. Initiated use of gloves, tongs or utensils to prevent hand contact with ready to eat foods; or
- g. Required handwashing when potential contamination is observed.

### **Resumption of Operations**

The Alliance refers to the 2018 Mass State Code and 2013 FDA Food Code 8-404.12 and 8-404.11. Food establishments will discontinue operations and notify the regulatory authority if an imminent health hazard exists due to an emergency such as: fire, flood, extended interruption of utilities, sewage backup, misuse of poisonous/toxic material, onset of foodborne illness outbreak, gross unsanitary conditions, or any other public health dangers. If the violation occurs in an unaffected area of the food establishment, they need not cease operations but need approval of the regulatory authority before resuming operations.

### **Conditions Warranting Action**

The Alliance follows the Mass 2018 State Food Code and the 2013 FDA Food Code 8-904.10 for conditions warranting action. The regulatory authority can suspend a permit if an imminent health hazard exists.

## **Risk Control Plan**

### **Long Term Control of Risk Factors**

The Alliance provides a Risk Control Plan form (Appendix A) to the food establishments. The Risk Control Plan will be given to food establishments that are marked for Priority violations as the inspector sees fit. Some violations that will require a risk control plan are: temperature control issues, cross-contamination, cooling, reheating, handwashing, and other processes.

The Alliance takes a two-pronged approach at long term control of risk factors contributing to foodborne illness. The environmental health inspectors reach out to the restaurant community in an effort to work together with them on food safety. This partnership is essential to encourage good food safety

techniques and result in reduced risk factors in Alliance restaurants. The inspectors also have a responsibility to enforce the Food Code and require risk control plans in food establishments with special processes (HACCP).

## Hearings

In order to maintain long term control of risk factors, the Alliance requires hearings for certain circumstances including acquiring a certain number of violations at a given inspection (earning a 'Fail' grade, or 'Fair' grade with a poor inspection history). The Alliance enforces the Mass 2018 State Food Code and the 2013 FDA Food Code 8-905.10- Response to Notice of Hearing or Request for Hearing, Basis and Time Frame.

The Alliance internal policies and procedures for hearings are the following:

Restaurants receiving the following grades:

"Failing" (179 and below)- A food establishment that receives a Failing grade will be immediately closed and will be their responsibility to request a hearing. The food establishment will not be allowed to open unless they have a hearing. The hearing will determine whether the food establishment is allowed to open. If it is allowed to open, the food establishment will be required to work with a consultant.

"Unacceptable" (180-209)- A hearing may be required for food establishments that receive an Unacceptable grade. Inspectors will look at the food establishment's prior history to determine whether a hearing is necessary. If a food establishment has had 2 or more prior inspections that resulted in 3 or more Priority violations, or have been closed because of an imminent health hazard, the food establishment will require a hearing. The hearing will determine whether or not the Commissioner will order the food establishment to work with a consultant. If the food establishment's history indicates that prior inspections were 2 or less Priority violations, they will not require a hearing.

### *Administrative Hearing*

- A) A person who receives a notice of hearing for an administrative remedy as specified in Part 8-8 (8-901.10 or 8-905.30A) and elects to respond to the notice shall file a response to notice as specified in 8-905.20 within 7 calendar days after service.
- B) A permit applicant may request a hearing regarding the disposition of an application for a new or revised permit if the regulatory authority does not issue or deny the permit within the time frame specified in law.
- C) A permit holder may request a hearing to address concerns about the regulatory authority's denial of application for a permit or request for a variance or compliance actions, except that a hearing request does not say the regulatory authority's restriction or exclusion of employees specified in 8-501.10-8-501.40, a hold order specified in 8-903.10, or the imposition of a summary suspension specified in 8-904.10
- D) A person desiring a hearing in response to a denial of application for permit or an adverse administrative determination shall submit a hearing request to the regulatory authority within 10 calendar days of the date of the denial, inspection or compliance action, unless the regulatory authority specifies in certain situations that the request shall be submitted within a shorter period of time.

The Alliance also refers to 8-303.30 for the Denial of Application for Permit, Notice

- A) The specific reasons and Code citations for the permit denial
- B) The actions, if any that the applicant must take to qualify for a permit and
- C) Advisement of the applicant's right of appeal and the process and time frames for appeal that are provided in law

### *Requested Hearings*

The Alliance follows the Mass 2018 State Food Code and the FDA 2013 Food Code for Conditions Warranting Remedy or 8-901.10. The regulatory authority may seek an administrative or judicial remedy to

achieve compliance with the provisions of the 2013 FDA Food Code if a person operating a food establishment or an employee:

- A) Fails to have a valid permit to operate a food establishment as specified under 8-301.11
- B) Violated any term of condition of a permit as specified under 8-304.11- the permit must be posted, the food establishment must comply with the 2013 FDA Food Code including granted variances and approved plans
- C) Allows serious or repeated code violations to remain uncorrected beyond time frames for correction approved, directed or ordered by the regulatory authority under 8-405.11(A) (operations must be discontinued and regulatory authority must be notified if an imminent health hazard may exist because of an emergency such as a fire, flood extended interruption of utilities, sewage backup, misuse of poisonous materials, onset of foodborne illness outbreak, gross unsanitary occurrence or condition, or other circumstance that may endanger public health) and (B) and 8-406.11(A) (food establishment must correct core items by a certain time identified by the regulatory authority or by 90 days and (B) (the regulatory authority may approve compliance schedule that extends beyond the time limits specified in 8-406.11A if a written schedule of compliance is submitted by the permit holder and no health hazard exists or will result from allowing an extended schedule for compliance.
- D) Fails to comply with a hold order as specified in 8-903.10- Regulatory authority may place a hold order on food from an unapproved source, unsafe, adulterated or not honestly presented, is not labeled according to law, is otherwise not in compliance with the 2013 Code. The regulatory authority may remove this food and order to a place of safekeeping.
- E) Fails to comply with an order issued as a result of a hearing for an administrative remedy as specified in 8-801.20 (Restriction or exclusion order, hold order or summary suspension- An employee restriction or exclusion order, an order to hold and not distribute food, such as hold, detention, embargo, or seizure order which is referred to as a hold order or a summary extension order shall be served as specified in the Code – 8-801.10A or clearly posted by the regulatory authority at a public entrance to the food establishment and a copy of the notice sent by first class mail to the permit holder or the owner or custodian of the food establishment as appropriate and 8-904.10 (The regulatory authority may suspend a person’s permit as specified by the code by providing written notice (8-801.20) of the summary suspension to the permit holder or person in charge without prior warning, notice of a hearing, or a hearing.
- F) Fails to comply with an order issued as a result of a hearing for an administrative remedy as specified in 8-906.40 (powers of the hearing official) or
- G) Fails to comply with a summary suspension order issued by the regulatory authority as specified in 8-801.20 (holding/food embargoes) and 8-904.10 (suspending a permit because an imminent health hazard exists)

### **Community Outreach**

In order to address long-term control of foodborne illness risk factors, in addition to the risk control plan, the Alliance along with their Boards of Health will reach out to the food establishment community and created a training program to educate the owners, managers, and employees of Alliance communities’ food establishments. The health inspectors have a monthly training for this group to accommodate frequent restaurant turnover. The training focuses mainly on priority and priority foundation violations. In educating the restaurant community, the environmental health inspectors hope to reduce risk factors that contribute to foodborne illness.

As per guidelines of the 2013 FDA Food Code, regardless of the severity of the violation, the Environmental Health Specialists will make the decision whether or not the food establishment needs to immediately correct the problem. All violations are recorded in the electronic inspection form and provided to the food establishment for their review. The electronic inspection form contains an area where the

Environmental Health Specialist can write a corrective action to ameliorate the priority, priority foundation, or core violation in question. The Alliance focuses on the HACCP principles during inspections.

**Corrective Action**

- Destruction of foods that have been subjected to extreme temperature abuse (taken from the Emergency

Time (Hours)	42°-45°F	46°-50°F	51°F or above
0-2	TCS Foods can be used	Immediately cool TCS to 41°F or below within 2 hours	Dispose TCS foods
2-3	TCS can be sold but must be cooled to 41°F or below within 2 hours	Immediately cool TCS food to 41°F or below within 1 hour	Dispose of TCS foods
4	Immediately cool TCS foods to 41°F or below within 1 hour	Dispose TCS foods	Dispose of TCS foods
5+	Dispose TCS foods	Dispose of TCS foods	Dispose of TCS foods

- Embargo or destruction of foods from unapproved sources: The Alliance has a procedure for dealing with embargoed foods outlined in the Foodborne Illness Standard Operating Procedures, page 5 and Appendix G. The standard operating procedures will be attached as their own Appendix B. The corrective action that must be taken in order to address the violation that the inspectors find is outlined below:

- **590.016: Examination and Embargo of Food**

- (A) Examination and Sampling. Food may be examined or sampled by the board of health pursuant to
- M.G.L. c. 94, §§ 146 and 189 for the purpose of determining compliance with 105 CMR 590.000.
- (B) Embargo Notice. The board of health may place an embargo on any food, which it knows, or has
- probable cause to believe is adulterated or misbranded provided that:
- (1) A written notice is issued to the holder of the permit to operate the food establishment or to the person in charge; and
- (2) The notice specifies in detail the reason(s) for the embargo order.
- (C) Embargo Tag. The board of health shall tag, label, or otherwise identify any food subject to the embargo
- order. The tag or label shall state that the food:
- (1) Is believed to be adulterated or misbranded;
- (2) Has been embargoed for ten days; and
- (3) Cannot be removed, used, sold or disposed of without permission of the board of health.
- (D) Storage or Destruction of Embargoed Food. The board of health shall permit storage of food under
- conditions specified in the embargo order, unless storage is not possible without risk to the public health, in
- which case immediate destruction shall be ordered and accomplished.
- (E) Condemnation, Disposal or Reconditioning. If the food subject to embargo is found to be adulterated or
- misbranded, the board of health shall take such steps as are necessary, pursuant to M.G.L. c. 94, §§ 146 or



- 189A, to effect the condemnation and disposal or reconditioning of the food.
- (F) Embargo Release. If the food subject to embargo is not found to be adulterated or misbranded it shall be
- released.

The Alliance also has an Embargo Notice Form to go with these standard procedures (Appendix G&H of Foodborne Illness SOP's)

- Accelerated cooling of foods when cooling time limits can still be met:
  - o Place foods in shallow pans (four inches or less)
  - o Separate foods in smaller or thinner portions
  - o Use rapid cooling equipment such as blast chillers, ice wands, cold master pans
  - o Use ice baths- stir foods frequently, ice water depth should be equal or greater than food depth. Replace ice when it melts.
  - o Use containers that facilitate the transfer of heat- avoid plastic containers
  - o Stir products frequently
  - o Add ice as an ingredient
  - o Use walk-ins (refrigerator/freezers)- top shelves
  - o Keep foods uncovered until properly cooled
  - o Use cooling racks in walk-ins- Be sure to rotate cooled foods with recently cooked foods
  - o Pre-chill ingredients
  - o Use combination of all (or some) of the above
- Reheating when small deviations from hot holding time/temperature have occurred:
  - o Reheat cooked hot food to at least 165°F for 15 seconds and start the cooling process again using one of the above methods when:
    - Cooling foods are above 70°F and two hours or less into the cooling process and
    - Above 41°F and 6 hours or less into the cooling process
  - o Discard cooked, hot foods when reheated once already:
    - Above 70°F and more than 2 hours into the cooling process or
    - Above 41°F and more than 6 hours into the cooling process
  - o Use a different cooling method for prepared TCS foods when the food is above 41°F and less than 4 hours into the cooling process.
    - If TCS foods are held below 135°F for a maximum of 4 hours, reheat foods to at least 165°F for 15 seconds and hot hold at 135°F and above.
    - If TCS foods are held below 135°F for over 4 hours, and already reheated once, discard foods
  - o Discard prepared TCS foods when foods are above 41°F and more than 4 hours into the cooling process.
- Continued cooking when proper cooking temperatures have not been met
- Initiated use of gloves, tongs, or utensils to prevent bare hand contact with RTE foods:
- Required hand washing when potential contamination is observed:

The corrective action that is taken for these items is written on the inspection form in the “notes” section. Appendix C is a copy of a blank inspection report. The inspection report shows each item that is covered in an inspection.

There is also a section in the inspection form that an inspector can take notes during the inspection if there are observations that do not coincide with a particular item.

The inspector can then take notes on the particular violation in the box above, or type in next to the violation that was selected. Any inspection report can be pulled up on our electronic inspection software and can show the inspectors notes about the corrective action that took place for any given inspection.

**Re-inspections:** Upon inspection of food establishments, if the Alliance environmental health inspectors find priority violations that need to be corrected immediately, they will instruct the manager or PIC to correct the violation. If the violation cannot be corrected immediately, the inspector will come back in a reasonable amount of time for the establishment to correct the violation (1-2 weeks) and document that the violation has been corrected. There is a specific area on the inspection form to indicate that the inspection is a re-inspection. If a certain violation has not been corrected, or has not been corrected properly, the environmental health inspectors reserve the right to close down the establishment until the correction is made.

### **Verification and Validation of HACCP Plans**

There are few establishments in Alliance communities that require formal HACCP plans and approvals. During an inspection environmental health inspectors encourage food establishment managers and owners to have plans in place that outline the proper procedures when working with potentially hazardous foods going in and out of the temperature “danger zone”. The environmental health inspectors also will cite the FDA created manual “Managing Food Safety: A Manual for the Voluntary Use of HACCP Principles for Operators of Food Service and Retail Establishments”. This manual outlines how to apply HACCP principles to a daily routine in a restaurant and different procedures that managers and owners of food establishments can adopt to maintain safe food.

Food establishments that require HACCP plans must fill out and have their plans reviewed by the environmental health inspectors prior to opening or starting a process that requires HACCP. The process of obtaining a license to have a food establishment in Alliance communities also includes validation of HACCP plans by the environmental health inspectors if they are necessary. The HACCP Plan Review Application is attached as (Appendix D). The plan includes a checklist of items that must be in place in order for the environmental health inspector to sign off on the plan. If the HACCP plan does not meet the requirements specified in the 2013 FDA Food Code, Annex 4, and the requirements outlined in the HACCP Plan Review Application, the food establishment will not be able to perform said process and will have to make adjustments or additions until the plan is acceptable. The establishment’s HACCP plans will be approved or rejected and they will be given the “Food Establishment Plan/Special Processes Review Approval/Disapproval Form” (Appendix E) indicating such decision. An ‘approval’ marking on this form indicates that the HACCP procedures for the food establishment have been validated by the environmental health staff.

In addition to having the HACCP plans reviewed, the environmental health inspectors are required to fill out the “HACCP Field Verification Report Form” when they inspect an establishment that requires special processes. Appendix F describes the items necessary for the establishment to meet in order to be in compliance. The “HACCP Field Verification Report Form” indicates that their HACCP plan has been validated, the prerequisites are met and coincide with the Massachusetts regulations and the FDA 2013 Food Code regulations. The form also indicates that the HACCP process(es) have been checked by the inspector, there are monitoring procedures in place that the inspector has seen, there are viewable records available to address Critical Limits at each critical control point and employees have been trained on the HACCP procedure(s). There is also a section of the form that indicates whether corrective action has been taken if the food establishment is not in compliance. It is required that a description of the corrective action is documented in order to complete the form. After completion of the form, the inspectors will verify that the HACCP procedures of a given food establishment are acceptable or unacceptable.

### **Variance Requirements**

The requirements of food establishments requesting a variance is shown in the document ‘Request for Variance to Use Time as a Public Health Control’ (Appendix G). The items contained in this document require the food establishment to indicate the type of food, how the food will be marked or identified to indicate that after 4 hours the food is removed from temperature control, and how the food will be discarded if the time exceeds 4 hours. There is also a place on the form indicating that the food establishment is keeping

records of the time and temperature of the food in question. Examples of when this document has been used are attached with the original document. There is one additional form for variances 'Time as a Public Health Control Variance' (Appendix H) that is used to indicate whether or not the variance has been approved. The food establishment that is requesting the variance must fill out this form and have it approved by the health inspector and the Commissioner of Health prior to conducting the special food process.