



Variance & HACCP Application Guide

WHAT IS A VARIANCE?

A “**variance**” is defined in **105 CMR 590: Minimum Standards for Food Establishments** as:

“a written document issued by the regulatory authority that authorizes a modification or waiver of one or more requirements in the Code if, in the opinion of the regulatory authority, a hazard or nuisance will not result from the modification or waiver.”

The decision to grant or deny a variance request will be based on the best available science before a final decision is made.

Food operations conducted under a variance will also require submission and approval of a Hazard Analysis Critical Control Point (HACCP) plan; HOWEVER, the Food Code allows some specialized processing methods to be conducted under an approved HACCP plan without need of a variance. See the table on page 3 for more information.

WHAT IS A HACCP PLAN?

A “**HACCP Plan**” is defined in **105 CMR 590: Minimum Standards for Food Establishments** as:

“a written document that delineates the formal procedures following the hazard analysis and critical control point principles developed by The National Advisory Committee on Microbiological Criteria for Foods.”

A properly constructed HACCP Plan will address the following HACCP principles:

1. Conduct a **hazard analysis** to identify potential food safety hazards reasonably likely to occur.
2. Identify **critical control points** (CCP's); which are a point or procedure in a specific food system where loss of control may result in an unacceptable health risk.
3. Establish **critical limits** for each critical control point; which are the maximum or minimum value to which a hazard must be controlled at a CCP to minimize the risk of a potential food hazard.
4. Establish critical control point **monitoring requirements**; these are necessary to ensure that the process is under control at each critical control point.
5. Establish **corrective actions**; which are predetermined actions to be taken when monitoring indicates a deviation from an established critical limit.
6. Establish **record keeping** procedures.
7. Establish **verification procedures** for ensuring the HACCP system is working as intended; these may include such activities as review of HACCP plans, CCP records, critical limits and microbial sampling and analysis.



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WHAT ARE THE CONTENTS OF A HACCP PLAN?

For a retail food establishment that is required to have a HACCP plan, the plan and specifications shall indicate:

- A categorization of the types of **Time/Temperature Control for Safety Foods** that are processed and/or served.
- A flow diagram by specific food or category type identifying critical control points and providing information on the following:
 - Ingredients, materials, and equipment used in the preparation of that food; and
 - Formulations or recipes that delineate methods and procedural control measures that address the food safety concerns involved.
- Food employee and supervisory training plan that addresses the food safety issues of concern.
- A statement of standard operating procedures for the plan under consideration, including and clearly identifying:
 - Each critical control point (CCP);
 - The critical limits for each CCP;
- The method and frequency for monitoring and controlling each CCP by the food employee designated by the person in charge (PIC);
- The method and frequency for the PIC to routinely verify that the food employee is following standard operating procedures and monitoring CCP's;
- Action to be taken by the PIC if critical limits for each CCP are not met;
- Records to be maintained by the PIC to demonstrate that the HACCP plan is properly operated and managed.
- Additional scientific data or other information, as required by the Department, supporting the determination that food safety is not compromised by the proposal.



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WHEN IS A VARIANCE AND/OR HACCP PLAN REQUIRED?

Variance <u>and</u> HACCP Plan	HACCP Plan <u>Only</u> * [◇]
Smoking food for preservation, rather than flavor enhancement	Time/Temperature Control for Safety Foods (TCS Food) packaged under reduced oxygen packaging (ROP), shall be maintained at 41°F or less, AND meets one of the following criteria: • Has a water activity of 0.91 or less; • Has a pH of 4.6 or less; • Is a meat or poultry product cured at a Food Processing Plant regulated by the USDA using substances specified in 9 CFR 424.21, Use of Food Ingredients and Sources or Radiation, and is received in an intake package; or • Is a food with a high level of competing organisms, such as meat, raw poultry, or raw vegetables.
Curing food	
Food additives: • For food preservation rather than flavor enhancement, or • To render the food non-Time/Temperature Control for Safety Food (non-TCS)	
Reduce oxygen packaging (ROP), EXCEPT where otherwise specifically allowed by regulation (3-501.12)	
Operating molluscan shellfish life-support display tank (wet storage of molluscan shellfish)	
Custom processing game animals and deer for personal use, and not for sale or service in the retail establishment	Fish that is frozen before, during, and after packaging using an ROP method
Preparing food by any other method determined by the local health department to require a variance and HACCP plan	Food that is prepared and packaged using a cook-chill or sous vide method
Sprouting seeds or beans	Specific cheeses that are packaged using an ROP method
Certain raw or undercooked foods of animal origin, conducted under an approved HACCP plan	Juice packaged in a retail establishment, which has been treated to attain a 5-log reduction

* Additional regulations for each process as applicable can be found under 3-502.11.

◇ HACCP plan not required for ROP when 1) packaging non-TCS food; or 2) labeled with the production time and date, held at 41°F or less during refrigerated storage, and removed from package within 48 hours. See 3-502.11(F) for more information.



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HOW DO YOU APPLY FOR A VARIANCE?

A Variance Request Application form must be submitted to the local health department for the town in which the food establishment will be operating.

The applicant shall provide the following information with the application:

- A statement of the proposed variance to the Massachusetts Merged Food Code (105 CMR 590) requirement, citing the relevant regulation section(s);
- An analysis of the rationale for how the potential public health hazards and nuisances addressed by the relevant Regulation sections will be alternatively addressed by the proposal; and
- A HACCP Plan as specified by 8-201.14, that includes the information specified in 8-201.13 as it is relevant to the variance request.

VARIANCE AGREEMENT

Once a variance has been granted by the local health department and HACCP plans are accepted, no changes or modifications may occur without prior review by the local health department. It is the responsibility of the establishment to notify the local health department immediately if there are to be any changes made in the authorized process. Variance acceptance applies only to the type of food or food products, and the type of variance requested, specifically listed on the variance application form. That plan also becomes a condition of the food establishment permit. Any adjustment or deviation from the authorization will require resubmission of a new variance request to the local health department.

The local health department will verify the plan is being followed as part of our usual inspection process. If the local health department agent determines that the variance is not being followed, or if recurring deficiencies are observed, a compliance conference may be required. If deficiencies continue to persist, the authorized plan may be revoked by the local Board of Health and all operations associated with the variance shall cease. Upon revocation, and after deficiencies have been corrected, the permit holder may apply for another variance.

Monitoring records must be maintained for a minimum of three years or longer, as specified in the variance acceptance. Monitoring records must be made available upon request from the local health department during routine inspections, or at any other time the request is made by the local health department.

A copy of the variance and HACCP plan must be maintained on site and conveniently located, such that it is available for review by local health department agents at any time the request is made.

The local health department reserves the right to rescind the variance granted, and/or the acceptance of HACCP plans and related documents, at any time. Notification that compliance with the full intent and scope of 8-201.14 will be sent to the Owner and Contact Person as listed on the Variance Request Application form.