



North Carolina Department of Health and Human Services
Division of Public Health

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October 22, 2015

POSITION STATEMENT: HACCP/Variance Verification and Enforcement Guidance

PURSUANT TO: North Carolina Food Code Manual, Sections 3-502.11, 3-502.12, 8-103.11, 8-103.12, 8-201.13, and 8-201.14

SOURCE: Cindy Callahan, REHS
Food Protection and Facilities Branch Head, Environmental Health Section

ISSUE(S): Training on specialized processes and HACCP plans.
Guidance on verification of HACCP plans during an inspection.
How to assess violations during inspections when a special process is being conducted and is not approved.
Enforcement action when an approved variance or HACCP plan is not being followed.

DISCUSSION AND RATIONALE:

The North Carolina Food Code Manual, Section 8-103.12, states: "If the REGULATORY AUTHORITY grants a VARIANCE as specified in § 8-103.10, or a HACCP plan is otherwise required as specified under § 8-201.13, the PERMIT HOLDER shall:

- (A) Comply with the HACCP plans and procedures that are submitted as specified under § 8-201.14 and APPROVED as a basis for the modification or waiver; ^P and
- (B) Maintain and provide to the REGULATORY AUTHORITY, upon request, records specified under §§ 8-201.14(D) and (E) that demonstrate that the following are routinely employed;
 - (1) Procedures for monitoring the CRITICAL CONTROL POINTS,
 - (2) Monitoring of the CRITICAL CONTROL POINTS, ^{Pf}
 - (3) Verification of the effectiveness of the operation or process, ^{Pf} and
 - (4) Necessary corrective actions if there is failure at a CRITICAL CONTROL POINT.

RESPONSE / INTERPRETATION:

The Section is committed to continuing education and training for environmental health specialists (EHS) on HACCP plan verification and how to interpret specialized process HACCP plans. The following items are for guidance:

1. If an operator needs to submit a HACCP plan (for franchise or chain establishments) or a "Request for Variance", the operator should be provided with the necessary applications or directed to the Sections' website <http://ehs.ncpublichealth.com/faf/food/correspondence.htm> and email address ncvariancecommittee@dhhs.nc.gov.
2. The Section requests the regulatory authority to review the "Request for Variance" and "HACCP Plan Application" packets for completeness prior to submission to the appropriate committee. This review will be solely to confirm the permit holder has compiled all the necessary components of the HACCP plan. This will ensure completed applications and packets are submitted to the variance committee or the HACCP committee and will reduce the review time and approval process. A checklist to assist this process is attached.

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3. Reduced oxygen packaging (ROP) without a variance requires HACCP plan approval (Section 3-502.12). This approval may be granted by the regulatory authority. If a county does not have trained staff or experience with HACCP plan review, contact your Regional Specialist for guidance and assistance.
4. Verification is a critical component of any approved HACCP plan. This step will require following the specialized process from start to finish. The EHS must review documentation and records on file at the food establishment, as well as observe the food going through the process. Verification may require more than one visit to capture the entire process. When the regulatory authority must conduct a HACCP plan verification visit, contact the Regional Specialist if guidance and/or assistance is needed. Guidance documents will be provided for verification of HACCP plans.
5. It is the goal of the Section to seek a rule change to allow one (annual) inspection of these food establishments to become a verification of HACCP plan. Any food establishment using a specialized process should be a Risk Category IV and would require four inspections per year. Currently, permission to replace one of four inspections with a verification of a HACCP plan has not been granted.
6. If a variance has been granted by the variance committee or a HACCP plan approved by the regulatory authority and is not being followed in accordance with approved procedures, the EHS should take the appropriate actions provided in the revised marking instructions. The action taken depends on the specialized process as well as the violation.
7. If a specialized process must be tested, for product validation purposes, in a permitted establishment prior to the variance being granted; then, the following items must be addressed in the food establishment:
 - A "Request for Variance" must be submitted and approved prior to testing the product
 - A time limit for the testing must be specified
 - Product cannot be sold
 - Plan review may be required if a new space is added or an existing space will be modified
 - There can be no co-mingling with regulated food items
 - If cross contamination occurs the food shall be discarded
 - Designate a separate area for storage of tested product to prevent cross-contamination

Any questions or concerns that are not addressed by this document can be directed to your Regional Specialist.

This position statement supersedes information provided in the memo released on May 24, 2013, *Variance Compliance*.

REFERENCES:

Rules Governing the Food Protection and Sanitation of Food Establishments, 15A NCAC 18A .2600

North Carolina Food Code Manual

Enforcement Strategies for Environmental Health Programs

<http://ehs.ncpublichealth.com/faf/food/fd/docs/EnforcementManual/EnforcementStrategiesManual-fulldocument.pdf>

NOTE: Position statements are policy documents to clarify how to interpret or enforce a law or rule. They are not enforceable on their own, but are intended to promote uniform interpretation and enforcement of the underlying law or rule.