

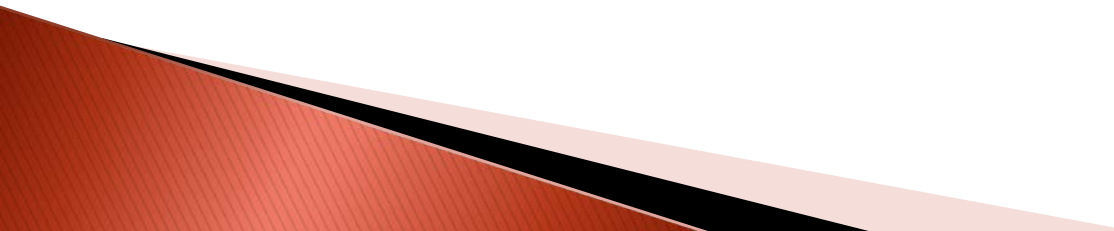
# Process for Getting HACCP and Variance Approval in North Carolina

# Terminology

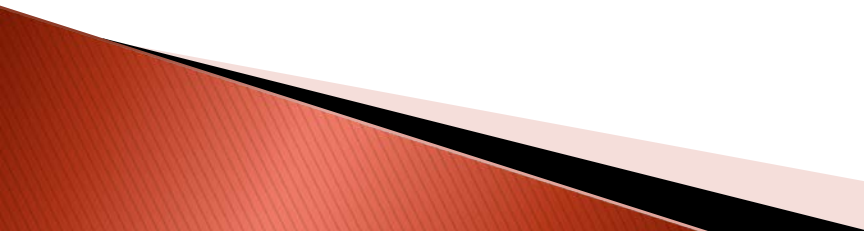
- ▶ Validation
  - “HACCP Purist” meaning
  - Code/”In Practice” meaning
  
- ▶ Verification

Special Process	Variance Required	Variance Exceptions	HACCP Plan Required	HACCP Plan Exceptions
Reduced Oxygen Packaging	YES/NO depends	Methods under 3-502.12 with validated process	YES	
Sprouting	YES		YES	
Custom Processing Meats for Personal Use	YES		YES	
Operating Live Molluscan Shellfish Tank	YES		YES	
Curing, Drying, Smoking of Fish	YES	Smoking for flavor enhancement , color or part of cooking process	YES	Smoking for flavor enhancement, color or part of cooking process
Curing, Smoking of meat/poultry	YES	Smoking for flavor enhancement , color or part of cooking process	YES	Smoking for flavor enhancement, color or part of cooking process
Drying of Meat/Poultry	YES		YES	
Fermentation of Sausages	YES		YES	
Adding Components to Extend Shelf life	YES		YES	
Juice processing and packaging	NO	A performance standard of 5 log reduction required	YES	A warning label can be applied in lieu of HACCP plan

# Why can we do some processes with HACCP Only?

- ▶ 3-502.12
  - ▶ Science is known
  - ▶ Risks have been previously identified
  - ▶ Factors present to inhibit either C. Botulinum or L. monocytogenes
- 

# HACCP Plan – No variance required

- ▶ ROP with two barriers
  - ▶ Fish frozen before, during and after packaging
  - ▶ Hard, semi-soft, or pasteurized cheese products
  - ▶ Cook-chill or sous vide food that follows provisions of 3-502.12 (D) EXACTLY
  - ▶ Unpasteurized packaged juice or unpasteurized eggs serving HSP
- 

# Steps for approving HACCP Plan, no variance required

REHS provides client with specialized process application and templates specific to process. LHD gives deadline for submission



Client submits HACCP plans back to LHD.



REHS reviews and “validates” plan to make sure that all CCPs, CLs, and monitoring are correct



REHS corresponds with client until HACCP plan meets criteria of CODE.

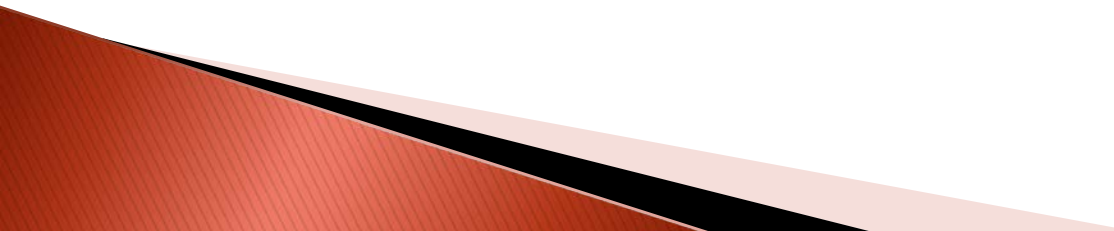


Once HACCP plan contains all elements of CODE, REHS issues HACCP plan review letter to client. Client must retain HACCP docs and final LHD review letter onsite at the establishment for periodic review.



REHS conducts field verification of specialized process and HACCP docs (REHS to use field verification templates specific to specialized process).

# Tools available to help you

- ▶ FDA 312 Course Materials
  - ▶ Position Statement released 10/22/15
  - ▶ Chain HACCP Committee
  - ▶ Regional EHS
- 

# Exception to 3-502.12

- ▶ 2013 Food Code extends time/temperature parameters
- ▶ If facility would like to use 2013 Food Code, must send application through Variance Committee
- ▶ ROP of non-TCS foods
  - Jams/jellies of high acid foods
  - Celery, carrots



# What about Chain Facilities?

- ▶ To promote consistency, any facility that has locations in multiple counties will be reviewed by State HACCP Committee
- ▶ HACCP Committee Members:
  - Jennifer E. Moore– Chair
  - Veronica Bryant – Food Protection Branch Regional
  - Jo Hill – Local EHS
  - Felissa Vasquez – Local EHS
  - Katie Delrosario – Local EHS
  - Cathy Burdick – Local EHS

# Variance Committee

# Why??

- ▶ Mandated by 8-103.10
- ▶ The REGULATORY AUTHORITY may grant a VARIANCE by modifying or waiving the requirements of this Code if in the opinion of the REGULATORY AUTHORITY a health HAZARD or nuisance will not result from the VARIANCE. If a VARIANCE is granted, the REGULATORY AUTHORITY shall retain the information specified under § 8-103.11 in its records for the FOOD ESTABLISHMENT.

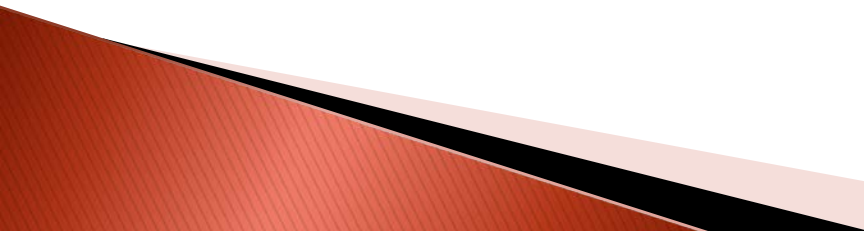
# Additional Relevant Code Sections

## ▶ 8–103.11 Documentation of Proposed Variance and Justification.

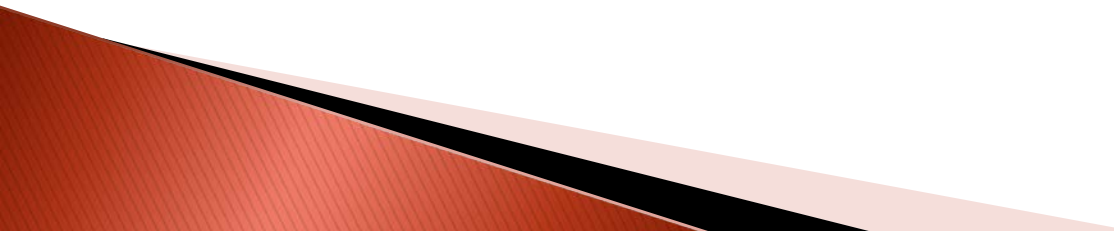
Before a VARIANCE from a requirement of this Code is APPROVED, the information that shall be provided by the PERSON requesting the VARIANCE and retained in the REGULATORY AUTHORITY'S file on the FOOD ESTABLISHMENT includes:

- (A) A statement of the proposed VARIANCE of the Code requirement citing relevant Code section numbers;<sup>Pf</sup>
- (B) An analysis of the rationale for how the potential public health HAZARDS and nuisances addressed by the relevant Code sections will be alternatively addressed by the proposal; <sup>Pf</sup> and
- (C) A HACCP PLAN if required as specified under ¶ 8–201.13(A) that includes the information specified under § 8–201.14 as it is relevant to the VARIANCE requested. <sup>Pf</sup>

# Variance Committee Members

- ▶ Jennifer Moore – chair
  - ▶ Cindy Callahan – co-chair
  - ▶ Veronica Bryant – Food Protection Branch
  - ▶ Benjamin Chapman, PhD – NCSU
  - ▶ Alyssa Barkley – NCRLA
  - ▶ Jeff Hawley – Harris Teeter
  - ▶ Mary Cashwell – Duplin County
  - ▶ Tammy Rodriguez – Pamlico County
  - ▶ Felissa Vasquez – Buncombe County
  - ▶ Amanda Smith – Pitt County
  - ▶ Alan Wade/Dr. Beth Yongue – NCDA
- 


# Since 2014...

- ▶ Reviewed approximately 100 applications and drafted letters
  - ▶ Updated application to make more user friendly
  - ▶ Approved 1000+ equipment variances
  - ▶ 3 Food Code Variance Trainings
  - ▶ 4 Verification and Validation of HACCP Plan courses with more to come in 2016
- 

# Subcommittees

- ▶ Equipment Subcommittee
    - Carolyn Griffin
    - Kevin Dodge
  - ▶ Sushi Rice Subcommittee
    - Jeff Hawley
    - Veronica Bryant
  - ▶ Education Subcommittee
    - Ben Chapman
    - Alyssa Barkley
    - Carolyn Griffin
- 

# What Requires a Variance

- ▶ Smoking, Curing, Drying of Fish, Meat or Poultry
  - ▶ Additives for food preservation
  - ▶ Extending date marking (rendering TCS food non-TCS)
  - ▶ ROP with one barrier or outside of what is allowable in 3-502.12
  - ▶ Custom Meat Processing
  - ▶ Sprouting
  - ▶ Others?
- 



# Process for Variance Approval

REHS provides client with state variance documents: 1) variance application 2) templates  
REHS gives submission deadline

Client submits HACCP documents and variance application for LHD review.

REHS reviews application to make sure it is complete using supplied checklist and will work with the facility until plan is complete.

Once application and HACCP docs meet all elements of CODE, REHS provides compliance history via space provided on checklist. Application, checklist and completed plan is submitted via mail or email to variance committee

Variance committee will communicate with client and REHS via letter that is copied to LHD

REHS conducts field verification of specialized processes at the establishment (using field verification templates).

# Tools available to help you

- ▶ FDA 312 Course Materials
- ▶ Position Statement released 10/22/2015
- ▶ Regional EHS
- ▶ Variance Committee
- ▶ CFR for curing recipes
- ▶ USDA compliance guide for beef jerky
- ▶ FSIS for charcuterie

<http://www.fsis.usda.gov/wps/portal/fsis/topics/regulatory-compliance/haccp/resources-and-information/haccp-validation/haccp-validation-resources>



# Resources provided by Variance Committee

- ▶ HACCP Plan Review Checklist
- ▶ HACCP Plan requirements document
- ▶ Sushi Rice pH testing protocol information
- ▶ Validation and Verification of HACCP Plans:
  - November 16–17 – Raleigh
  - Next Year: Mecklenburg, Guilford, Buncombe

June 3, 2015

[REDACTED]

RE: Variance Application  
**APPROVED**

Dear [REDACTED]:

Thank you for submitting a request for variance for **Acidified Rice (Sushi Rice)** to the North Carolina Food Code Variance Committee. The Committee has met and reviewed your submitted paperwork and has **APPROVED** your request for variance.

This **VARIANCE APPROVAL** is based on the following criteria:

- The following location(s) in North Carolina:

[REDACTED]

- Cooked sushi rice shall be prepared in accordance to the process described in the documents accompanying the variance application, including a resulting pH of less than 4.2 as a CCP (Critical Control Point).
- All special process employees must be trained on the SSOPs, pH verification procedures, and the sushi rice HACCP (Hazard Analysis Critical Control Point) plan.
- The Department shall be notified of any procedural or process changes in the product manufacturing process that may affect the accuracy of challenge studies or HACCP Plan criteria.
- The Local Health Department will verify the HACCP plan is being properly followed according to the approved written procedures including the required documentation and that the Person-In-Charge is achieving active managerial control and has working knowledge of the processes.

- A copy of this approval letter and the HACCP plan must be kept onsite in the establishment at all times and readily available for review by local or state health department personnel.
- A Certified Food Protection Manager is provided at all times during sushi preparation for this/these location(s) to properly oversee all food safety requirements.
- This variance does not extend to locations not listed above. If new locations are opened, the applicant shall notify the North Carolina Food Code Variance Committee prior to implementing the production of the sushi rice so that the location can be added and the list of approved sites remains current.
- This approval may be revoked for failure to follow the procedures written in the approved HACCP plan or if recurring violations are documented during inspections.

If you have any questions, please contact your local Health Department's Environmental Health Section for assistance. You may also contact me via email at [ncvariancecommittee@dhhs.nc.gov](mailto:ncvariancecommittee@dhhs.nc.gov).

Sincerely,

A handwritten signature in black ink, reading "Cindy R. Callahan". The signature is written in a cursive, flowing style.

Cindy Callahan

May 5, 2015



RE: Request for Variance  
**MORE INFORMATION REQUIRED**

Dear [Redacted Name]:

Thank you for submitting a request for variance for acidification of rice to the North Carolina Variance Committee. The Committee has reviewed your documents and has determined that additional information is needed before your request can be approved. Please re-submit the attached application with the following documentation:

- Provide corrected language regarding target pH of acidified rice. The required pH for rice to be considered a non-time/temperature control for safety (TCS) food is less than 4.2. There are various pH values listed throughout the document, including some areas where conflicting information about pH for quality and pH for safety. Please correct this critical limit in each part of the document as needed.
- Provide corrected frequency of calibration of thermometers. Page XI-1 and VI-6 refer to thermometer calibration and accuracy tested weekly. Thermometers must be calibrated daily and procedures must reflect this.
- Provide clarification on how long sushi rice will be held. Procedure states that “the optimum quality of sushi rice is just one day.” More detailed procedure regarding how long sushi rice will be held and how this will be monitored is needed.
- Provide corrected frequency of calibration of pH meter. Page VI-6 part 2 refers to pH meter calibration and occurring “regularly”. The pH meter must be calibrated daily and procedures must reflect this.

Please contact me if you have any questions or you may contact your local Health Department’s Environmental Health Section. Please submit the additional information to the Variance Committee at [ncvariancecommittee@dhhs.nc.gov](mailto:ncvariancecommittee@dhhs.nc.gov).

Sincerely,

A handwritten signature in cursive script that reads "Cindy R. Callahan".

Cindy Callahan, REHS

November 7, 2014



RE: Variance Request  
**DENIED**

Dear Mr. Bremer:

Thank you for submitting a request for variance to the North Carolina Variance Committee. The Committee has reviewed the submitted documents and has made the decision to **DENY** [REDACTED] request for variance from North Carolina Food Code Manual Subparagraph **3-602.11(B)(5)** for the following reason(s):

- **The methods for notifying the consumer do not present an acceptable alternative to labeling requirements in 3-602.11, specifically Subparagraph (B)(5) labeling the package with the name of the food source for each major food allergen contained in the food.**
- **The Committee cannot in good faith approve a methodology which, in its opinion, will not provide an acceptable alternative to allergen labeling for notification to the consumer.**

Should you have any questions concerning the Committee's decision for this variance request, please contact the Committee at [ncvariancecommittee@dhhs.nc.gov](mailto:ncvariancecommittee@dhhs.nc.gov). You may also contact me at the telephone number listed in the signature below.

Sincerely,

A handwritten signature in black ink that reads "Gregory J. Yankee".

Gregory Yankee, REHS

RE: Request for Variance  
NO VARIANCE REQUIRED

Dear:

Thank you for submitting a request for variance for reduced oxygen packaging (ROP) to the North Carolina Variance Committee. The Committee has reviewed your documents and has determined that a variance is not required for the ROP of pizzas. Section 3-502.12 of the North Carolina Food Code Manual, allows a food establishment to package food using ROP without a variance, with a HACCP plan only, for packaged food that is maintained at 41°F or less and meet at least 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,
- Is a food with a high level of competing organisms such as raw meat, raw poultry, or raw vegetables, or
- Is a cheese manufactured in a food processing plant that meets the standard of identity of Hard Cheeses, Pasteurized Process cheese, or Semi-soft cheese.

According to the HACCP Plan that was submitted, all pizza ingredients fall into one of these categories and can be packaged using ROP without a variance provided Section 3-502.12 is followed. However, MORE INFORMATION IS NEEDED for the canned artichokes and peppidew peppers that are being added to the pizza. These products are heat treated plant food, and therefore would need to meet the pH or water activity requirements in order to be able to be packaged using ROP. If you wish to continue using these ingredients on the pizza, please provide this additional information to ensure the products can be safely packaged using ROP.

Please be advised that although a variance may not be required, the HACCP Plan must be approved by the local Health Department's Environmental Health Section. Also, because this food is being sold packaged, all applicable labeling requirements in the law must be followed, including, but not limited to, 21 CFR 101 FOOD Labeling, 9 CFR 317 Labeling, Marking Devices, and Containers, and 9 CFR 381 Subpart N Labeling and Containers, and as specified under §§ 3-202.17 and 3-202.18.

Please contact me if you have any questions or your local Health Department's Environmental Health Section for assistance. You may also contact the Variance Committee at [ncvariancecommittee@dhhs.nc.gov](mailto:ncvariancecommittee@dhhs.nc.gov).

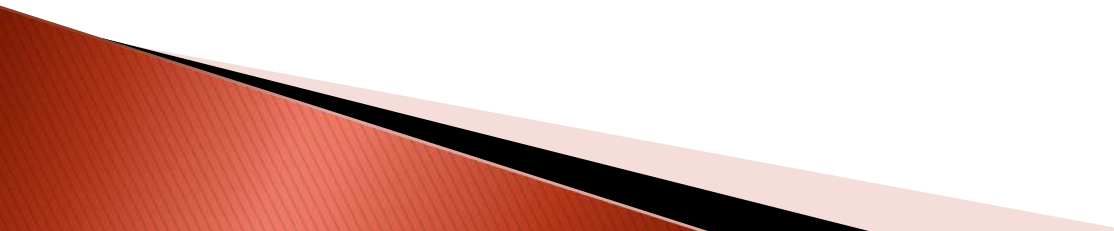
Sincerely,

Cindy Callahan, REHS

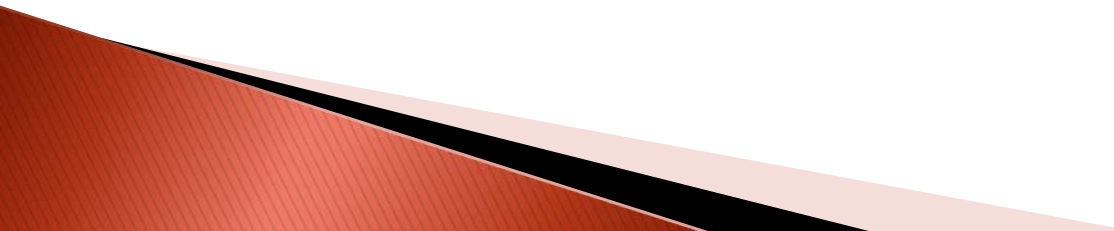


# Field Guidance for REHS

# Issues addressed in Position Statement

- ▶ 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.
- 

# Response/Interpretation

- ▶ Section is committed to education and training
  - ▶ EHS is responsible to supplying resources such as application, HACCP guidance
  - ▶ Use website for fillable pdf
- 

## Request for Variance and HACCP Plan Checklist for Local EHS

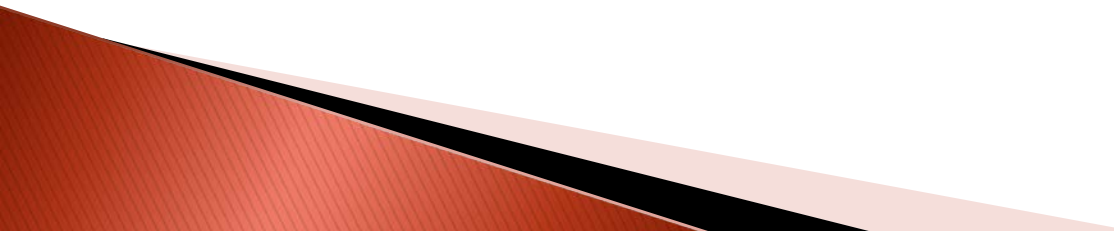
Please complete this checklist and submit to Variance Committee with completed Request for Variance/HACCP Plan from establishment to [NCVarianceCommittee@dhhs.nc.gov](mailto:NCVarianceCommittee@dhhs.nc.gov)

	Completed application with code section cited
	All locations listed or attached that will be using specialized process
	Food involved in HACCP plan, with all ingredients identified
	Type of specialized process being used (ROP, curing, smoking, acidification, etc.)
	Equipment and materials involved
	Flow diagram of food from receiving through service
	Critical control points (CCP) identified on the flow diagram
	Hazard analysis with hazards identified at each step
	HACCP worksheet with CCP's identified
	Critical limits, monitoring, and corrective action listed for each CCP
	Blank copies of any log sheets
	All applicable SOP's included (handwashing, calibration of thermometers, employee health policy, sanitization of equipment/utensils, etc.)
	Copy of training program
	Comments/Field Observations for Committee Consideration:

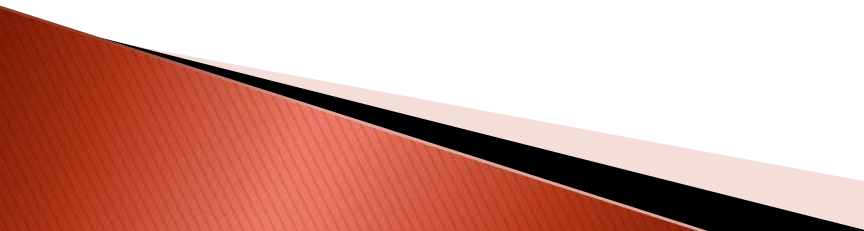
This Request for Variance is supported: \_\_\_\_ Yes \_\_\_\_ No

REHS Signature: \_\_\_\_\_ Date: \_\_\_\_\_

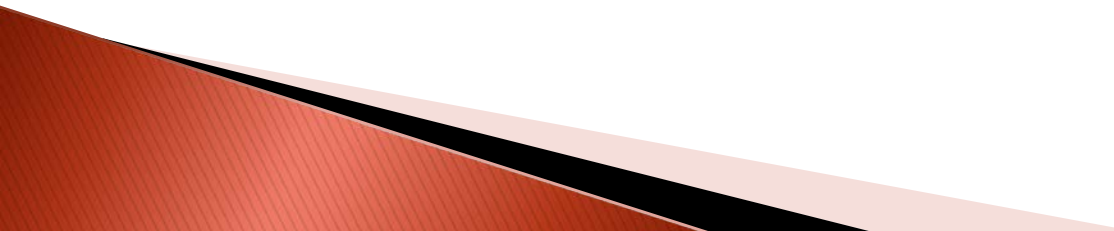
# Response/Interpretation cont.

- ▶ HACCP Plans without a variance compliant with 3–502.12 are reviewed and approved at the COUNTY LEVEL
  - ▶ Use Variance Committee as a template for process
  - ▶ Ask for State assistance if you have questions or need help on review.
- 

# Response/Interpretation cont.

- ▶ HACCP and variance approval can be revoked
  - ▶ DOCUMENTATION
  - ▶ HACCP writers vs. trained HACCP personnel within facility
  - ▶ For chain facilities, single locations can be revoked
  - ▶ Revoked variance and HACCP Plans will have to re-apply
- 

# Verification Visits

- ▶ Ideally, done within a few weeks of approval
  - ▶ Full verification done once per year or when changes occur
  - ▶ Details are important
  - ▶ Anything written is fair game
  - ▶ DOCUMENTATION, specific examples of non compliance
  - ▶ Assess the severity of the violation when determining discarding of food
- 

# Updated marking instructions

- ▶ If Item #30 is OUT, Item #27 is OUT. Item #30 refers only to **variance approval**. The EHS must determine which approval is required for the specialized food process.
- ▶ Item #27 is IN if the facility is complying with procedures
- ▶ Item #27 could be out for many reasons.
  - No HACCP
  - Not following procedure



# Updated marking instructions

If facility does not have an approved HACCP Plan:

- ▶ First offense:
  - Zero points
  - Must get immediate correction
  - Follow-up, don't wait until next quarter
  - Do not allow dangerous food to stay in commerce
- ▶ Second offense:
  - Two strike system
  - Permit action (ITS)
  - Food embargo
  - Do not allow dangerous food to stay in commerce

# Updated Marking Instructions

If facility has an approved plan, but is not following it:

- ▶ First Offense

- Zero points
- Stop process to assess severity, immediate correction
- Follow-up before next quarter

- ▶ Second Offense

- Half points
- Continual non compliance, move forward for revocation

# Testing for Special Processes

- ▶ Product needed for challenge study/validation
  - ▶ Can be done under conditional/test variance
  - ▶ No HACCP Plan submitted
  - ▶ Food cannot be sold
  - ▶ Separated by time/space
  - ▶ Plan review may be required
  - ▶ Do not change or amend permit
- 