

# **HACCP Principle 6: Verification**

## **Including Validation and Reassessment**

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# Validation, Verification and Reassessment

- 9 CFR 417.4 a

“Every establishment shall *validate* the HACCP Plan’s adequacy in controlling the food safety hazards identified during the hazard analysis, and shall *verify* that the plan is being effectively implemented.”

# Verify

*“To establish the truth, accuracy, or reality of.”*

- Merriam Webster

# Verification

- **Those Activities other than Monitoring, that Determine the Validity of and Compliance with the HACCP Plan.**

- NACMF

# Purpose of Verification

- **Determine if HACCP Plan is Working.**
  - **Are Hazards Reduced by Plan?**
- **Determine if Operations are in Compliance with HACCP Plan.**
  - **Has HACCP been Implemented Properly?**

# Validate

- **“To Support or Corroborate on a Sound or Authoritative Basis.”**
- **Establish Validity of HACCP Plan by Supplying Factual Proof.**

**- Merriam Webster**

# Validation

- **The *Element of Verification* focused on collecting and Evaluating Scientific and Technical Information to Determine if the HACCP Plan, When Properly Implemented, will Effectively Control the Hazards.**

- NACFMF

# Validation Objective

- **Provide an evaluation of the HACCP plan to determine if the plan will control food safety hazards.**
- **Initial evaluations are needed before implementation of the HACCP plan.**
- **On a periodic basis after implementation of the HACCP plan**
  - **Reassessment**
    - **Once per year**
    - **When Changes are made in the process**



# Initial Validation

- **Conducted during the development of the HACCP plan and the initial implementation of the plan.**
- **Needed to build safeguards into the HACCP plan.**
- **Determine if the plan can be implemented as written.**

# 9 CFR 417.4(1)

**(1) Initial validation. Upon completion of the hazard analysis and development of the HACCP plan, the establishment shall conduct activities designed to determine that the HACCP plan is functioning as intended. During this HACCP plan validation period, the establishment shall repeatedly test the adequacy of the CCP's, critical limits, monitoring and recordkeeping procedures, and corrective actions set forth in the HACCP plan. Validation also encompasses reviews of the records themselves, routinely generated by the HACCP system, in the context of other validation activities.**

# Why Validate?

- **Building Validated Safeguards into the HACCP plan initially will reduce the amount of end product testing.**

# Supporting Documentation Needed to Validate

- **Scientific publications**
- **Regulatory documents**
  - **Regulations**
  - **Guidance documents**
- **Scientific studies**
- **Predictive models**
- **Expert advice**

# Conformation of Validation

- HACCP plan is based on scientific and technical information.
- Demonstration that control parameters can be met during actual production.
  - Review of measurements and records.
  - May include plant studies.

# **What should be Validated by Plant Studies?**

- **CL or CCPs that differ from published scientific journal articles or regulations.**
- **Lethality and Stabilization (Cook and Chill) Processes that Differ from Regulations.**
- **Slaughter interventions similar to but different from published procedures.**
- **Processing room Temperatures that may be too high (above 50 F).**
- **Study may result in changes to CL or CCPs.**

# **Re-Validation or Reassessment**

- **Initial Validation – Does the HACCP Plan Control the Hazards?**
- **Reassessment – Is the HACCP Plan Still Controlling Hazards?**
- **Reassessment is a thorough review of hazard analysis to address specific hazards to determine if they are controlled.**

## **Reasons to Conduct Re-Validation or Reassessment (External Factors)**

- **New safety information becomes Available.**
- **The food Item you produce is linked to an Outbreak.**
- **Regulatory agency alerts related to the product or process.**
- **Recalls or product withdrawals**
- **New scientific or technical literature**



## **Reasons to Conduct Re-Validation or Reassessment (Internal Factors)**

- **Test results on ingredients or products**
- **Modification of production process**
- **Change in product**
  - **Formulation, distribution, consumer use**
- **Consumer complaints**
- **After designated length of time**
  - **Once per year**
  - **Every change in process**

# Phases of Evaluation

- **All CCP Identified**
  - **Is CCP still Necessary?**
  - **Another CCP Needed?**
- **Are Critical Limits Appropriate?**
  - **Review Records of Critical Limits.**
- **Are Corrective Actions Taken?**
- **Are Corrective Actions Effective?**

# Verification

- **Objective:**
  - **Ensure the HACCP plan is being implemented properly.**
- **In broad terms includes:**
  - **Verification of HACCP prerequisite programs.**
  - **Verification of CCPs in the HACCP plan**
  - **Verification of HACCP plan**

# Verification of Prerequisite Programs

- **Periodic review of the records**
- **Review of the written procedures**
- **Assurance that programs are working and are appropriate for the Hazard Analysis in the HACCP plan.**
  - **SSOP**
  - **Receiving**

# Ongoing Verification of CCPs

- **Calibration of process control equipment.**
- **Review of monitoring records.**
- **Independent checks of CCP monitoring and corrective actions.**
  - **Direct observation**
  - **Duplicate monitoring**

# **Elements of CCP Verification in the written HACCP plan**

- **Determine the frequency for the verification.**
- **Set up a verification schedule / calendar**
- **Identify who will conduct the verification.**
- **Describe the verification activity.**
  - **May include reference to a SOP.**

## 9 CFR 417.4 (2)

(2) *Ongoing verification activities.* Ongoing verification activities include, but are not limited to:

- (i) The calibration of process-monitoring instruments;
- (ii) Direct observations of monitoring activities and corrective actions; and
- (iii) The review of records generated and maintained in accordance with § 417.5(a)(3) of this part.

# Verification of HACCP Plan

- **HACCP Records**
  - **Flow Diagram**
  - **Deviations from Critical Limits**
  - **Calibration Records**
  - **Corrective Actions**
- **Initial Records after Review**



# **Regulatory Verification Activities**

- **HACCP plans comply with regulations.**
- **Review the HACCP plan.**
- **Determine the adequacy of corrective actions.**
- **Record Review.**
- **Direct observation of CCP monitoring.**
- **Sampling activities.**

# **Pre-Shipment Review**

**(meat and poultry processors only)**

- **Review Records Associated with the Production of that Product BEFORE it has Been Shipped to Ensure Completeness.**
  - **All CCP's Met**
  - **Corrective Actions Taken (if applicable)**

# Verification Group Activity

- **Always include**
  - **Review of records.**
  - **Calibration of Equipment**
  - **Direct observation of monitoring**



# **Group Activity Items to Include**

- **Verification will focus on the ongoing activities for the HACCP plan. This includes**
  1. **Review of records**
  2. **Direct observation of monitoring of Critical Limits and the Corrective Actions taken for a deviation.**
  3. **Calibration of Process Equipment**

# **Description of Verification Process**

- **The verification activity should include**
  1. **The personnel responsible for the verification.**
  2. **The frequency of the verification activity.**
  3. **A description of the procedures or a reference to a standard operating procedure.**

# Example Frequencies for Verification

Activity	Frequency	Responsibility	Reviewer
Verification Activities Scheduling	Yearly or Upon HACCP System Change	HACCP Coordinator	Plant Manager
Initial Validation of HACCP Plan	Prior to and During Initial Implementation of Plan	Independent Expert(s) <sup>a</sup>	HACCP Team
Subsequent validation of HACCP Plan	When Critical Limits Changed, Significant Changes in Process, Equipment Changed, After System Failure, etc.	Independent Expert(s) <sup>a</sup>	HACCP Team
Verification of CCP Monitoring as Described in the Plan (e.g., monitoring of patty cooking temperature)	According to HACCP Plan (e.g., once per shift)	According to HACCP Plan (e.g., Line Supervisor)	According to HACCP Plan (e.g., Quality Control)
Review of Monitoring, Corrective Action Records to Show Compliance with the Plan	Monthly	Quality Assurance	HACCP Team
Comprehensive HACCP System Verification	Yearly	Independent Expert(s) <sup>a</sup>	Plant Manager

# Examples

## Principles 6 and 7 Record Keeping and Verification

**Product:**

Process Step/CCP	Verification Procedures	HACCP Records
Fermentation CCP 1B, pH <5.0	<ol style="list-style-type: none"><li data-bbox="764 820 1285 1084">1. The smokehouse operator will calibrate the pH meter according to manufactures recommendations using the standard two point calibration between pH 4.0 and 7.0. The meter will be calibrated for the measurement of each batch of sausage.</li><li data-bbox="764 1101 1285 1198">2. The HACCP coordinator will review the CCP and Corrective action records for pH daily.</li><li data-bbox="764 1214 1285 1403">3. A member of the HACCP team will directly observe the CCP monitoring procedures once per month and will observe corrective actions once per month or when a corrective action occurs.</li></ol>	

## **Verification activities not written in an ongoing HACCP plan**

- **Initial verification is not usually indicated on the form for Principle 6.**
- **Validation studies or supporting documents are not usually indicated on the Principle 6 form.**
- **Re-Validation or Reassessment**