

Chapter 10: Principle 6: Verification Procedures

Overhead 1

Objective:

In this module, you will learn:

- How to define verification.
- What functions are part of HACCP plan verification.
- What functions are part of validation.

Overhead 2

Principle 6:

Establish verification procedures.

Overhead 3

Definition:

Verification: Those activities, other than monitoring, that determine the validity of the HACCP plan and that verify the system is operating according to the plan.

Verification

One of the more complex HACCP principles is verification. Although it is complex, the proper development and implementation of the verification principle is fundamental to the successful execution of the HACCP plan. HACCP has spawned the use of a new adage — “trust what you verify,” which speaks to the heart of the verification principle. The purpose of the HACCP plan is to prevent food-safety hazards, and the purpose of verification is to provide a level of confidence that the plan is based on solid scientific principles, is adequate to control the hazards associated with the product and process, and is being followed.

Explanatory Note:

Routine monitoring activities for critical limits should not be confused with verification methods, procedures or activities. This could be a point of confusion, and the instructor should keep this in mind while addressing this chapter.

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“Trust What You Verify”

Verification provides a level of confidence that the HACCP plan is based on solid scientific principles, is adequate to control the hazards associated with the product and process, and is being followed.

Perhaps one of the reasons verification has been difficult to understand is because there are several elements associated with this principle, including validation and reviews. Confusion also arises because the HACCP plan must include verification procedures for individual CCPs and for the overall plan. To facilitate understanding, each of these elements will be discussed.

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Elements of Verification:

- Validation
- CCP verification activities
 - Calibration of monitoring devices
 - Calibration record review
 - Targeted sampling and testing
 - CCP record review
- HACCP system verification
 - Observations and reviews
 - Microbiological end-product testing
- Regulatory agencies

- *Validation*

Overhead 6

Definition:

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.

Validation is an essential component of verification and requires substantiation that the HACCP plan, if implemented effectively, is sufficient to control the food-safety hazards that are likely to occur. Validation of the plan occurs before the plan is actually implemented. The purpose of

validation is to provide objective evidence that all essential elements of the plan have a scientific basis and represent a “valid” approach to controlling the food-safety hazards associated with the specific product and process. There are several approaches to validating the HACCP plan, among them are: incorporation of fundamental scientific principles, use of scientific data, reliance on expert opinion or conducting in-plant observations or tests.

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Validation of the HACCP plan, who does it?

- HACCP team
- Individual qualified by training or experience

What does validation involve?

- A scientific and technical review of the rationale behind each part of the HACCP plan from hazard analysis through each CCP verification strategy.

Validation can be performed by the HACCP team or by an individual qualified by training or experience. Validation activities may be similar in scope and time commitment to the original HACCP plan development. An in-plant validation should be performed initially before actual reliance on the HACCP plan and when factors warrant. These factors could include: changes to the raw materials, product or process; adverse review findings; recurring deviations; new scientific information about potential hazards or control measures; on-line observations; or new distribution or consumer-handling practices. Validation involves a scientific and technical review of the rationale behind each part of the HACCP plan from hazard analysis through each CCP verification strategy.

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Validation Frequency:

- Initially
- When factors warrant. The following may warrant validation of the plan:
 - changes in raw materials,
 - changes in product or process,
 - adverse review findings,
 - recurring deviations,
 - new information on hazards or control measures,
 - on-line observations, and
 - new distribution or consumer handling practices.

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Examples of Validation Activities:

1. One approach to controlling vegetative pathogens as a hazard in cooked hamburgers is to ensure that the hamburgers are cooked to an internal temperature that destroys pathogens. In the HACCP plan, parameters for maximum patty thickness, maximum belt speed and minimum oven temperature could be the critical limits to ensure that an adequate temperature is reached at the cook step. These criteria would be established after collecting enough data on-line to ensure that controlling those points would also control the minimum internal temperature of every hamburger patty as it is cooked.
2. An internal temperature of 145 F was determined as critical to destroy pathogens in cooked shrimp. The firm uses a process of 212 F for three minutes to provide an internal temperature of at least 145 F. The ability of the process time and temperature to achieve the internal temperature of the cooked shrimp should be validated by measuring the center temperature of a representative number of cooked shrimp. The cooking equipment should also be validated using temperature distribution tests to determine that adequate temperatures are delivered throughout the cooker during processing.

• *Verification of CCPs*

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CCP Verification Activities:

- Calibration
- Calibration record review
- Targeted sampling and testing
- CCP record review

Verification activities developed for CCPs are essential to ensure that the control procedures used are properly functioning and that they are operating and calibrated within appropriate ranges for food-safety control. Additionally, CCP verification includes supervisory review of CCP calibration, monitoring and corrective action records to confirm compliance with the HACCP plan. CCP verification may also include targeted sampling and testing.

• *Calibration*

Verification activities at CCPs include calibration of monitoring devices to assure the accuracy of the measurements taken. Calibration is conducted to verify that monitoring results are accurate.

Calibration of CCP monitoring equipment is fundamental to the successful implementation and operation of the HACCP plan. If the equipment is out of calibration, then monitoring results will be unreliable. If this happens, the CCP should be considered out of control since the last documented acceptable calibration. This situation should be given ample consideration when establishing the frequency of calibration. Frequency of calibration should also be influenced by equipment sensitivity.

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Calibrations are performed:

- On equipment and instruments used in monitoring or verification.
- At a frequency to ensure accuracy of measurements.
- By checking accuracy against a recognized standard at or near the condition that the instrument or equipment will be used.

Examples of calibration activities:

1. A thermometer used to monitor temperature at a cook CCP may be checked for accuracy by comparing it against a certified thermometer in a hot-water bath.
2. The continuous temperature chart recorder on a pasteurizer may be compared during each batch against a certified accurate thermometer.
3. A pH meter is calibrated against pH buffer standards of 7.0 and 4.0 when it is used to test products with a final pH of 3.8 to 4.2.

• ***Calibration Record Review***

Reviewing the equipment calibration records involves checking the dates and methods of calibration and the test results (e.g., equipment passing or failing). Calibration records are kept and reviewed. This review may be conducted as part of an audit (audits are discussed later in this chapter).

Example of calibration record review:

1. A review of the thermometer records indicates that the thermometer was checked for accuracy against a certified thermometer at a frequency specified in the HACCP plan. The records also indicate that the thermometer performed within established limits and did not need adjustment. This review disclosed no problems in the MIG calibrations.

• ***Targeted Sampling and Testing***

Verification may also include targeted sampling, testing and other periodic activities. Vendor compliance may be checked by targeted sampling when receipt of material is a CCP and purchase specifications are relied

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on as critical limits. Typically, when a monitoring procedure is not as stringent as desired, it should be coupled with a strong verification strategy.

Examples of targeted sampling and testing:

1. In the cooked-shrimp example, the firm may purchase frozen shrimp under a supplier's guarantee for a sulfite-free product. A quarterly sample is collected for laboratory analysis to verify that the product being tested is sulfite-free.
2. In the cooked-shrimp example, verification of sulfite residual control at receiving of fresh shrimp may involve quarterly analysis of samples to ensure that the results obtained through the original monitoring procedure are accurate. Records should indicate any deviations.
3. Egg white is used as an ingredient in meringue-pie topping. Historically, egg whites have been associated with a risk of *Salmonella*. Since the meringue is not cooked or otherwise treated to kill *Salmonella*, the preventive measure could be to ensure that all egg whites received are *Salmonella*-free. The CCP would be egg-white receiving, and the critical limit would be "every lot has a guarantee ensuring it is pasteurized and *Salmonella*-free." The adequacy of the supplier's certificate could be periodically verified by collecting samples from a lot and testing for *Salmonella*.

When critical limits are set for equipment operation, product samples may be taken to ensure that the equipment settings are appropriate for product safety. For example, the firm processing cooked shrimp may collect in-line samples of selected product after cooking to measure internal temperature.

• *CCP Record Review*

At least two types of records are generated at each CCP: monitoring and corrective action. These records are valuable management tools, providing documentation that CCPs are operating within established safety parameters and that deviations are handled in a safe and appropriate manner. However, records alone are meaningless unless someone in a supervisory capacity reviews them on a periodic basis to "verify" that the HACCP plan is being followed. Current seafood HACCP regulations mandate a second review of monitoring records within one week after the initial records were taken.

HACCP System Verification

In addition to the verification activities for CCPs, strategies should be developed for scheduled verification of the complete HACCP system. The frequency of the system-wide verification should be yearly (at a mini-

mum) or whenever there is a system failure or a significant change in the product or process. The HACCP team is responsible for ensuring that this verification function is performed. Often, the HACCP team will contract an independent third party to conduct the system-wide verification activities.

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HACCP System Verification Frequency:

- Annually
- Occurrence of a system failure or significant change in product or process

• *System Verification Activities*

Systematic verification activities include on-site observations and record reviews. Reviews are usually performed by an unbiased person who is not responsible for performing the monitoring activities.

System verification should occur at a frequency that ensures the HACCP plan is being followed continuously. This frequency depends on a number of conditions, such as the variability of the process and product.

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Verification Activities of the HACCP System:

- Check the accuracy of the product description and flow chart.
- Check that CCPs are monitored as required by the HACCP plan.
- Check that processes are operating within established critical limits.
- Check that records are completed accurately and at the time intervals required.

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Record Review:

- Monitoring activities have been performed at the locations specified in the HACCP plan.
- Monitoring activities have been performed at the frequencies specified in the HACCP plan.
- Corrective actions have been performed whenever monitoring indicated deviation from critical limits.
- Equipment has been calibrated at the frequencies specified in the HACCP plan.

Explanatory Note:

The frequency of verification activities will likely change over time. A history of review findings that indicate that the processes are consistently in control may justify safely reducing the frequency. On the other hand, adverse findings, such as inconsistent monitoring activities, inconsistent record keeping and improper corrective actions warrant correcting the problems and more frequent verification reviews. Adverse findings may indicate a need for subsequent validation of the HACCP plan. FDA's seafood HACCP regulation requires "reassessment" of the HACCP plan on an annual basis. This is a process that includes a technical review of the hazard analysis and each element of the HACCP plan as well as on-site review of all flow diagrams and appropriate records from the operation of the plan. The purpose of the reassessment is to ensure that the HACCP plan accurately identifies and controls relevant hazards.

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• *End-Product Microbiological Testing in HACCP Verification*

As explained in Chapter 2, microbiological testing is ineffective for routine monitoring but can be used as a verification tool. Microbiological testing can be used to determine (e.g., during verification audits or on periodic basis that the overall operation is under control.

Example of microbiological testing:

1. Several years ago, NACMCF recommended a microbiological criteria for *Staphylococcus aureus* in cooked, ready-to-eat crabmeat. The recommended criteria for plants operating under a HACCP plan and following GMPs are as follows: for every five sample units (n=5), no more than two units (c = 2) can exceed 100 organisms per gram (m = 100/g), and no unit can exceed 1,000 organisms per gram (M = 1,000/g). Obviously, analysis for this organism would not be useful for routine CCP monitoring. However, it may be useful for periodically verifying the effectiveness of the HACCP system.

• *Company Verification Schedule*

Table 1 is an example of company-established HACCP verification schedule.

Table 1 and Overhead 14

Example of a Company-Established HACCP Verification Schedule	
<i>Activity</i>	<i>Frequency</i>
Initial validation of HACCP plan	Prior to and during initial implementation of plan
Subsequent validation of HACCP plan	When critical limits changed, significant changes in process occurred, equipment failed, system failed, etc.
Verification of CCP monitoring as described in the plan (e.g., monitoring of shrimp cook time and temperature)	According to HACCP plan (e.g., daily record review)
Review of monitoring and corrective action records to show compliance with the plan	Weekly
Reassessment of HACCP plan	Yearly

**The Role of Regulatory Agencies
in HACCP Plan Verification**

The major role of regulatory agencies in a HACCP system is to verify that HACCP plans are effective and are being followed. Verification normally will occur at the inspected facility; however, some aspects of verification may be conducted at other appropriate locations.

HACCP plans are unique documents prepared by a processor to ensure the control of a specific process or procedure. The plans may contain proprietary information and must be appropriately protected by the regulatory agency. Agency personnel must have access to records that pertain to CCPs, deviations, corrective actions and other information pertinent to the HACCP plan that may be required for verification.

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Verification procedures by an agency include:

- Review of the HACCP plan and any modification.
- Review of CCP monitoring records.
- Review of corrective action records.
- Review of the verification records.
- Visual inspections of operations to determine if the HACCP plan is followed and records are properly maintained.
- Random sample collection and analysis.

Notes:

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EXAMPLE: For Illustrative Purposes Only - HACCP Plan Form
ABC Shrimp Co.
Cooked Shrimp

(1) Critical Control Point (CCP)	(2) Significant Hazards	(3) Critical Limits for each Control Measure	(4)		(5) Monitoring		(6)		(7)		(8) Corrective Action(s)	(9) Verification	(10) Records
			What		How	Frequency	Who						
Cooker	Survival of bacterial pathogens	Cook at 212 F for 15 minutes (to achieve minimum internal temperature of 145 F for 15 seconds)	Cook temperature		<ul style="list-style-type: none"> Monitor temperature with a continuous temperature recorder Monitor cook time by timing the movement of a block placed on belt through cooker. 	<ul style="list-style-type: none"> Temperature monitored continuously with hourly visual checks. Cook time monitored hourly. 	<ul style="list-style-type: none"> Quality-control supervisor will program the continuous-recording thermometer. Cook will perform the hourly checks. 	If temperature or time parameters are not met, then processing line will be stopped and required adjustments made. All product produced during the deviation will be recooked or destroyed.	<ul style="list-style-type: none"> Daily record review Quarterly calibration of thermometer Semi-annual finished-product microbial testing Process validation study of time and temperature of cook and its effect on the final internal temperature of various sizes of shrimp and initial temperature (on file) Cooking equipment validation study (on file) 				
<p><i>Note: In this example, results from product screening at the receiving step are a portion of the monitoring necessary to assure compliance with weight/pack/label critical limits.</i></p>													
Firm Name: <u>ABC Shrimp Co.</u> Firm Address: <u>Anywhere, USA</u> _____ _____ Signature: _____ Date: _____													
Product Description: <u>Cooked and frozen, headless, peeled and deveined shrimp</u> Method of Storage and Distribution: <u>Frozen</u> Intended Use and Consumer: <u>Thaw and serve</u>													

**Models may not be fully consistent with guidance contained in FDA's Fish and Fishery Products Hazards and Control Guide.*

EXAMPLE: For Illustrative Purposes Only - HACCP Plan Form
ABC Shrimp Co.
Cooked Shrimp

(1) Critical Control Point (CCP)	(2) Significant Hazards	(3) Critical Limits for each Control Measure	(4) Monitoring			(7) Who	(8) Corrective Action(s)	(9) Verification	(10) Records
			(4) What	(5) How	(6) Frequency				
Weigh/Pack Label	Allergic-type reaction from undeclared sulfiting agent	All product containing residual sulfiting agent must declare presence	<ul style="list-style-type: none"> At weigh/pack/label stage, check for "contains sulfite" declaration. 	<ul style="list-style-type: none"> Examine all labels issued at packing line and match declaration with product identity. 	<ul style="list-style-type: none"> One label each time a label roll is replaced 	<ul style="list-style-type: none"> Packing supervisor 	If this product is mislabeled, then appropriately label.	<ul style="list-style-type: none"> Daily record review Daily record review Quarterly lab report for sulfite (fresh shrimp) Daily record review Quarterly lab report for sulfite (frozen shrimp) 	
			<ul style="list-style-type: none"> At receiving, sample each vessel of fresh shrimp to test for presence of sulfites. 	<ul style="list-style-type: none"> Rapid sulfite test 	<ul style="list-style-type: none"> Fresh shrimp, three-grab samples per vessel 	<ul style="list-style-type: none"> Dock master 			
			<ul style="list-style-type: none"> At receiving, supplier declaration for absence of sulfites for frozen shrimp. 	<ul style="list-style-type: none"> Observation of supplier declaration 	<ul style="list-style-type: none"> Frozen shrimp, check every shipment 	<ul style="list-style-type: none"> Dock master 			
<p>Note: In this example, results from product screening at the receiving step are a portion of the monitoring necessary to assure compliance with weigh/pack/label critical limits.</p>									

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