Applying HACCP: Guidance and Avoiding Gaps A Practical Guide

Part 3 of a 3-Part Series

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CONTENT

INTRODUCTION BY SARA MORTIMORE AND CAROL WALLACE

The identification of critical control points (CCPs) within HACCP shows us the points or places in a process where it is essential to control food safety hazards. This allows businesses to focus efforts on getting control right at all times for the significant hazards of concern to their operation. Setting critical limits that must be achieved at each CCP is the first part of this exercise but businesses need to be able, importantly, to detect whether or not control within critical limits is being achieved and, crucially, to take corrective action if there is deviation from any critical limit. It follows that monitoring and corrective action systems must be carefully designed and fully implemented to be able to detect and correct loss of control at a CCP while effectively dealing with any potentially unsafe product. However, in practice, limitations in monitoring systems mean that they are often incapable of detecting all deviations in a satisfactory manner, and weaknesses in corrective action systems may mean that hazards could slip through the net. As a result, HACCP programs could give a false sense of security to companies in which these elements are not well designed.

Further limitations of HACCP programs are seen in cases in which validation and verification plans are not clearly thought through and implemented and where HACCP documentation is not appropriate, whether over-complicated or too simplistic. HACCP principles 6 (verification) and 7 (documentation) address these issues; however, some companies still struggle with the differences in requirements between validation and verification. Worryingly, inadequacy in the validation requirements results in a weak HACCP program, while limitations in the verification requirements can result in the potentially dangerous situation of not knowing if the program is really under control. This article builds on the previous work of the IAFP HACCP PDG Back to Basics working group on preliminary steps to HACCP development *(3)* and application of HACCP principles 1, 2 and 3 *(1)*. Readers who have not yet seen the first two articles in this series are encouraged to go back and read them to obtain the full benefit of this guidance in sequence. Taking each of the HACCP principles 4–7 *(2)* in turn, this article provides general guidance toward the application of each principle, after which it identifies gaps in current knowledge and practice in their application, along with providing specific guidance to help HACCP teams to overcome these potential problems. Understanding of these areas of potential weakness in HACCP principle application will help food businesses take action to review and design more effective HACCP plans and, for those just starting out, to learn from past mistakes.

STEP 9, PRINCIPLE 4 — ESTABLISH MONITORING ACTIVITIES

Intent

Identification of the appropriate monitoring activity with the associated documentation requirements can serve as evidence that the critical limit (CL) will be met and provide assurance that the food has been rendered safe from a public health standpoint.

General guidance

Monitoring is a planned sequence of observations or measurements taken to assess whether the CCP (Critical

Control Point) is under control and to produce an accurate record for future verification. The established monitoring activities must be able to provide written documentation that the critical limit has been met. As a result, the monitoring procedures developed must take into consideration the nature of the product, the type of processing equipment used and the device/tool used for monitoring the critical limit *(Fig. 1)*. Ideally, monitoring should be continuous to allow for process adjustments when a trend toward loss of control is indicated. The monitoring activity must be "real time" to ensure that corrective actions can immediately be taken to segregate and hold the affected food, should a CCP deviation occur.

Monitoring procedures must define four elements: (a) what is being measured/monitored, (b) how and where the measurements will be taken, or what will be observed, (c) how often the measurements will be collected and (d) who will be taking the measurement.

The monitoring activity must also be compatible with the type of hazard being controlled and the process parameter being measured. The monitoring procedure may need to take into consideration the volume of products that may have to be destroyed or dispositioned in the event a CCP deviation occurs.

The monitoring devices/tools used must be calibrated at a frequency recommended by the manufacturer or whenever

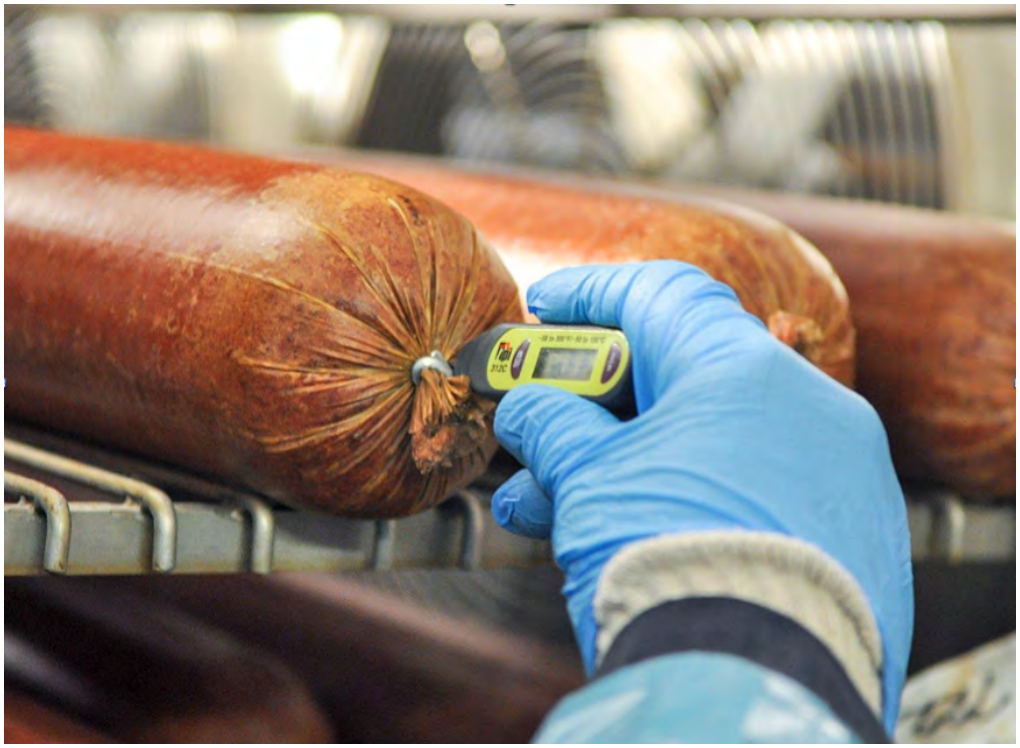

Figure 1. The monitoring procedures developed must take into consideration the nature of the product, type of processing equipment used and the device/tool used for monitoring the critical limit.

observations/experience of trained plant personnel dictate that a more frequent calibration is needed, based on the nature of the product and the limitations of the devices/tools when used under plant operational conditions. Selection of the most appropriate monitoring device should also consider the critical limit value being measured, and personnel with CCP monitoring responsibility must be effectively trained in the monitoring procedure and technique. Records generated as part of the CCP monitoring activity must be accurate and written at the time the measurements are taken or when observations are made.

Industry gaps

Gap A: Failure to identify the appropriate location to monitor the product temperature.

Gap B: Failure to map the temperature profile and set the operating parameters of the processing equipment used at a CCP.

Gap C: Insufficient calibration frequency of monitoring devices.

Gap D: Failure to consider the nature of the product.

Gap E: Failure to collect and document CCP measurements at end of shift and/or between personnel breaks.

Gap A: Failure to identify the appropriate location to monitor the product temperature. The target reduction may not be fully realized in the coldest spot of a non-homogeneous food matrix, which potentially could allow survival of the pathogen of concern. If a critical limit of 165°F must be reached to achieve a 5-log kill in a baked product, the addition of inclusions such as chocolates, dried fruits, cheese, Individually Quick Frozen (IQF) fruits or confectionery ingredients may undermine the adequacy of the thermal process. The target temperature may be readily attained and measured in the slurry/batter where the temperature monitoring device can be inserted. This procedure, however, may fail to measure the interface/core temperature of the inclusion particularly in IQF ingredients. To ensure that the desired lethality is achieved, collect multiple temperature measurements in various sections of the product to establish the coldest spot. Consider measurement of the temperature in the coldest region of the food matrix. If measurement of the cold spot cannot be ascertained, the microbiological quality of these inclusions should be considered as part of the preventive control, if lethality cannot be achieved by the baking process.

Gap B: Failure to establish the temperature profile and set the operating conditions of the processing equipment used at a CCP. Any change to the operating conditions due to process adjustments during production or as a result of diminished performance of the equipment may alter the method by which a CCP would need to be monitored. For example, consider a product baked in a 12-lane oven band where operating parameters are set for only 3 of 5 oven zones. The CCP is measured as the product exits the oven. There could be a temperature gradient through the oven and across the lanes that could introduce measurement variability, if the gradient is not considered during the establishment of the CCP monitoring procedure. The temperature profile of the product across the width of the oven band must be determined during the development of new product or if changes to the operating conditions of the oven occur. Use of data loggers may be considered in establishing the oven/product temperature profile or a pre-established frequency for calibration by the equipment manufacturer.

Gap C: Insufficient calibration of monitoring devices. The safety of the product could be called into question if the calibration of measurement devices used in the monitoring activity fails to demonstrate that the measurements are within specification. For example, the hand-held thermometer used for CCP monitoring generally comes with at least a one-year calibration certificate. Most HACCP programs, however, establish a secondary in-house calibration process. The calibration frequency often varies from daily to weekly or monthly calibration. The adequacy of the CCP measurements could challenge the validity of the CCP measurements if the weekly or monthly calibration measurement fails to perform accurately. Select the most appropriate monitoring device for the intended use and establish the calibration of the monitoring device/tool at a frequency that ensures accurate measurement within a certain degree of error.

Gap D: Failure to consider the nature of the product. For example, fouling of pH electrodes can occur in certain food matrices. If the calibration of the pH meter used to monitor a CCP is performed only at the start of the shift or the day's production, erroneous measurements may be recorded. Consider a shelf-stable cheese type product that is being manufactured with a desired pH between 4.3 – 4.5. The critical limit established is less than 4.6 with the operating limit set to 4.5. The CCP is being measured using a pH meter with a + 0.01 accuracy. The measurements may therefore not be accurate, if the pH meter is calibrated only once, at the start of production. The frequency of calibration and recalibration would need to be pre-established to ensure that accurate measurements can be made.

Gap E: Failure to collect and document CCP measurements at end of shift and/or between personnel breaks. If CCP measurements, as stated in the HACCP plan, are collected on an hourly basis, a record of the CCP measurement may not be available in less than hourly increments once the production line shuts down. The safety of the products manufactured after the last good check could be called into question if the recalibration of the measuring device during the re-start of production indicate an out-of-specification result *(Fig. 2)*. For example, one of the CCPs of a shelf-stable, fully baked custard-type product is measurement of the pH of the filling. The critical limit of the filling is set at pH less than 4.2, measured after bake and collected every hour, but is not taken at the end of the shift. If the recalibration of the pH meter indicates a drift of +0.1 pH unit on start-up the next day, this potentially challenges the safety of all product since the last good check.

STEP 10, PRINCIPLE 5 — ESTABLISH CORRECTIVE ACTIONS

Intent

Corrective actions that are specific for managing deviations from critical limits that have been defined for those processes deemed critical within the documented HACCP system must be determined. The corrective actions must be sufficient to control and manage all non-conforming product/s and also bring the process step under control.

General guidance

Following the identification of the process steps deemed to be critical, and once specified limits have been set, corrective actions must be developed to ensure product deemed to be non-conforming is effectively controlled. When monitoring activities identify a deviation associated with a CCP, corrective actions must be completed to bring the process back under control.

It is important that any manufactured product, where the safety may be in doubt, is appropriately held from the last successful monitoring check. Actions must be taken to identify and isolate the product when compliance to the specified critical limits is in doubt. Identification of affected product can

Figure 2. The safety of the products manufactured after the last good check could be called into question if the recalibration of the measuring device during the re-start of production indicate an out-of-specification result.

be problematic within a continuous process. In such cases, it is recommended that effort be made to establish the time when the deviation occurred and analysis of CCP records be performed to determine how much product is affected. Once all affected product has been identified and isolated, the subsequent actions that need to be taken would depend on the nature or extent of the deviation identified. Actions may include reassessment of the product from the last effective check, such as using an alternative metal detection unit when the regular metal detection unit malfunctions. It is important to fully document the extent of the deviation that has occurred, as this could indicate an ongoing problem with the process. Where repeated process deviations are identified, it is necessary to reassess the process step not only to ensure the critical limits are accurate but also to determine that the process can effectively control food safety hazards under normal working conditions.

It is important to correct the issue but also to complete a follow-up investigation to identify the root cause of any deviation so that preventive actions can be implemented *(Fig. 3)*.

The actions assigned depend on the extent of the issue identified. Activities may include, but are not limited to,

- Immediate actions taken when failure of critical limit is identified.
- Product disposition (i.e., product either reworked or destroyed).
- Root cause analysis.
- Preventive actions.

Industry gaps

Gap A: Corrective actions address only the immediate issue, and connection to any previous issues is not identified.
Gap B: Assessment of corrective action effectiveness may be incomplete.
Gap C: Weak or absent documentation of issue and corrective actions.
Gap D: Lack of scientific support for corrective actions.
Gap E: Inadequate planning for corrective actions.
Gap F: Discovered deviations or other non-conformances are not closed through effective root cause analysis and implementation of appropriate corrective and preventive actions.

Gap A: Corrective actions address only the immediate issue, and connection to any previous issues is not identified. Failing to establish a potential weakness with a process control through the recognition of repeated issues may cause gaps in the previously completed validation study, which originally set the critical limits, to go unnoticed.

For example, a CCP may be the maximum cooling time established by a validation study for pallets of cream cheese to less than 45°F to prevent outgrowth of *Clostridium botulinum* spores. There may be repeated deviations, in which the time to cool the cheese to < 45°F exceeds the maximum limit. Individual corrective actions that can be taken when

Figure 3. It is important to correct the issue but also to complete a follow-up investigation to identify the root cause of any deviation so that preventive actions can be implemented.

a deviation occurs may include creating smaller pallets to enable faster cooling, changing the format of the pallets to enhance cooling, and increasing the cooling capability of the storage area. These actions taken at different times when the deviations occur may lead to the CCP limit being met, but there is no guarantee that there will be no future deviations after these individual corrective actions are implemented. Repeated failures to meet the CCP limit may indicate a gap in a previous validation study. To address repeated deviations effectively, a re-validation of the cooling process needs to be performed, to establish limits for pallet size, pallet format and cooling capability of the storage area; when these measures are implemented, they will ensure that the maximum cooling time is not exceeded.

Gap B: Assessment of the effectiveness of the corrective action that has been implemented may not be completed. Where deviations have occurred with a CCP, it is important to monitor and assess the level of control to demonstrate that the process step is routinely controlling the specified hazards to an acceptable level. It is also important to update the formats of monitoring, corrective action and record keeping forms to ensure that additional activities to be executed as part of the corrective actions can be documented, so that it can be determined if the CCP is back under control. It is also important to communicate these changes to operators and to perform re-training of the responsible operators/manufacturing functions. Failure to assess the effectiveness of the corrective actions and the lack of associated documentation that indicates that the CCP is back under control may lead to potential gaps in the identification of corrective actions. This can lead to future occurrences of the particular CCP deviation.

For example, an equipment cleaning/product changeover CCP on a line on which multiple allergens are run is modified because operators have noted a trend of product residue being found on particular hard-to-clean spots of the line during pre-op inspections. However, the pre-op inspection form is not modified to direct operators to always inspect those spots, and operators are not retrained on how to inspect these hard-to-reach areas of the line. Because there is no direction on pre-op forms to always inspect the particular hard-to-clean areas of the line and operators have not been re-trained, the operators do not consistently focus on those areas during pre-op inspections. It is discovered a couple of months later that the modification in the cleaning process was not effective in consistently removing product residue from the hard-to-clean spots on the line. In this case, a failure to update documentation to guide the assessment of the effectiveness of the corrective action, and to ensure that there are records to indicate that the CCP was back under control, led to a failure in identifying deficiencies in the implemented corrective action.

Gap C: Absence or weaknesses in documenting the nature of the issue and the corrective actions. Failure to document a CCP deviation or corrective action and/or inadequate documentation of a CCP deviation or

corrective action raises significant doubt as to the safety of the compromised product *(Fig. 4)*. In the event of an audit or inspection, gaps in such documentation may lead to an assumption that corrective and preventive actions did not address the CCP deviation. This may lead to the conclusion that consumers may have been exposed to potentially unsafe food. The consequence of such a conclusion can be disciplinary action against the manufacturer and potentially a recall of affected product.

For example, the CCP limits for a batch cooking process is a minimum cook temperature of 163°F for a minimum hold time of 25 seconds, and these parameters are recorded on a chart recorder. During a review of the temperature and time data at the end of the shift (verification), the data on the chart recorders indicate that for one batch during the shift, the minimum cook temperature and hold time were 157°F for 25 seconds. Product from that batch was put on hold. An investigation was performed and it was determined that the scheduled calibration of the temperature probe had not been performed. All product from the last implemented calibration was put on hold and recalibration of the probe was performed. All product was reprocessed to meet critical limits. In this scenario, if hold records, CCP monitoring records, verification records (including calibration records) and reprocessing records are not kept or are inadequate, an audit or inspection may conclude that consumers were potentially exposed to unsafe food.

Gap D: Lack of scientific support for corrective actions. In some instances, corrective actions will not be deemed effective in the absence of scientific evidence. Scientific support for corrective action validates that the corrective action, when put in place, will be effective. Lack of a scientific basis raises doubt as to whether the corrective action reduced the hazard to an acceptable level, which potentially means that the corrective action taken did not address the CCP deviation.

For example, processing records indicate that the time and temperature critical limits were not met for a 5-log kill of *Salmonella* during steaming of a tote of walnuts. The nuts cannot be resteamed, because that would adversely affect product quality. The plant has a dry roaster that has not been used in a kill step and has not been validated for a 5-log kill of *Salmonella*. It has been used only to lightly roast ready-to-eat (RTE) steam-treated nuts to get a crunchy product. The dry roaster in this case cannot be used to reprocess the tote of walnuts, because it has not been validated for a 5-log kill for *Salmonella* and has been used only to achieve desired product quality. However, if validation of the dry roaster is performed following standard validation guidelines and critical limits to achieve a 5-log kill for *Salmonella* are established, the tote of walnuts can be reprocessed through the dry roaster, because the validation study provides scientific support that an adequate *Salmonella* kill can be achieved by that process.

Figure 4. Failure to document a CCP deviation or corrective action and/or inadequate documentation of a CCP deviation or corrective action raises significant doubt to the safety of the compromised product.

Gap E: Inadequate planning for corrective actions. Corrective actions to address any potential deviations associated with critical limits, monitoring activities and verification activities that are established for a CCP are decided upon by the HACCP team and documented in the HACCP plan. To ensure that corrective actions are effective, the HACCP team is tasked with predicting all potential CCP deviations that can occur and associated corrective actions. Alignment with management may be necessary, especially if capital will be required for the recruitment of additional plant personnel, specialized training of specific personnel, extensive equipment repair, replacement of equipment and equipment parts. For corrective actions to be effective, it is recommended that this alignment occur and an effective plan for the implementation of each corrective action be in place prior to inclusion in the HACCP plan. Failure to plan adequately for corrective actions may lead to ineffective corrective actions that do not address the food safety risk and financial losses due to the inability to execute them.

For example, rerunning product through an off line metal detector is not included in the HACCP plan as a corrective action if a metal detector CCP deviation occurs. In the event that a metal detector CCP deviation occurs and it is found that the inline metal detector is not functioning properly and needs to be replaced/repaired, all product produced after the last good metal detector verification checks is placed on hold. The plant does not have another metal detector, so product will have to be held until another metal detector is brought in or all of the product on hold is inspected and determined to contain no metal. Including the running product through an offline metal detector as part of the corrective actions in the HACCP plan and purchasing another metal detector prior to starting up the line would have facilitated corrective actions in this case.

Gap F: Discovered deviations or other non-conformances are not closed through effective root cause analysis and implementation of appropriate corrective and preventive actions. Root cause analysis identifies all potential causes of a CCP deviation so that effective corrective and preventive actions can be implemented to prevent future deviations from occurring. If corrective actions are implemented without effective root cause analysis, there is a likelihood of reoccurrence of the deviation, since the actual cause(s) of the deviation has/have not been addressed. It is important that root cause analysis be completed and preventive actions implemented before the deviation is closed out. Completing effective root cause analyses and implementing preventive actions saves time and capital in the long run, since recurrences will be less likely.

For example, during a label verification check at the end of the shift, an operator discovers that the label on cheese-stuffed hamburgers does not indicate that it contains milk. Regular hamburgers are also processed on the same line. The labels of the cheese-stuffed hamburgers and the regular hamburgers look very similar in terms of color, graphics and label fonts. Product from the last good label verification check is put on hold. An investigation is conducted and it is discovered that the operator who delivers the labels to the line was new to the facility and the labels for the cheese-stuffed hamburgers and regular hamburgers were stored on the same racks in the same packaging warehouse. All mislabeled product was identified and relabeled with the correct label and, as a corrective action, the employee was retrained on how to read labels and match them to batch sheets to make sure the right labels were delivered to the line. A root cause analysis was not completed, and several months later the same deviation occurred. An effective root cause investigation would have determined that the similarity in the label characteristics and the storage of both labels on the same racks in the packaging warehouse can cause the wrong labels to the delivered to the line. If these root causes were identified, preventive actions such as redesigning of the labels to make them easily distinguishable from each other, the reorganization of the packaging warehouse to store labels separately and labeling of the storage areas for the labels in the warehouse could be implemented, and this will minimize the risk of recurrence of the deviation.

STEP 11, PRINCIPLE 6—ESTABLISH VERIFICATION PROCEDURES

Intent

Verification is used to demonstrate conformance with a validated HACCP system during routine operations. Verification outputs should demonstrate that the control measures in place (including PRPs, OPRPs and CCPs/PCPs) are capable of controlling identified hazards to required levels and that control measures are actively functioning as intended *(Fig. 5)*.

General guidance

Of the seven HACCP principles, the one related to verification procedures may be the one most often misunderstood and most ineffectively implemented, often overlooked or given low priority. The National Advisory Committee on Microbiological Criteria for Food *(4)* defined verification as activity, other than monitoring, that determines that the HACCP plan is valid and that the system is operating according to the plan. Included in verification activities is validation, defined by NACMCF as the element of verification focused on collecting and evaluating scientific and technical information to determine whether the HACCP plan, when properly implemented, will effectively control the defined hazards.

Verification: The HACCP team should define the scope, methods, and approach to verification activities, and the degree of verification will depend on the extent or complexity of the program. The approach and frequency of verification should be defined at the introduction of a new program or when review indicates a change in verification processes is required. Examples of verification activities include:

Figure 5. Verification outputs should demonstrate that the control measures in place are capable of controlling identified hazards to required levels and that control measures are actively functioning as intended.

- Supplier audits
- Environmental monitoring and testing
- Regulatory mandated microbiological testing
- Finished product testing
- Trending of monitoring results
- Internal audits [including applicable prerequisite programs (PRPs)]
- Customer audits
- Third party audits
- Customer complaint and trend analysis
- Review of deviations and corrective actions
- Behavioral observation data

The HACCP team, taking into account regulatory requirements and the effectiveness of the programs, should establish the frequency and scope of verification, but at least once per year the HACCP team should perform a formal scheduled review of the HACCP system. It is the HACCP Team Lead's responsibility to oversee the review of the HACCP system and supporting programs and ensure that the data and evidence obtained during the review is fully documented, appropriately referenced, and entered into the HACCP recordkeeping system. It is essential that review records are accurate and capture compliance as well as non-compliance. The annual review should include an evaluation of the entire HACCP system and include at a minimum:

- Review of the effectiveness of CCPs/PCPs, OPRPs and PRPs
- Evaluation of the accuracy of Process Flow Diagrams and Plant Schematics
- Review of the hazard analysis to determine if it is still accurate
- Review of recorded HACCP deviations and overall performance

Beyond the regular annual review schedule, it is important to consider internal/external factors that might prompt a review of the HACCP system. Potential triggers that could result in a review of either sections or the entire HACCP system might include:

- Change in ingredients/raw materials
- Change of a supplier of raw materials
- Change in product formulation or preparation

- Change in packaging, storage or distribution conditions
- Change in staff or management responsibilities
- Change in consumer use
- Developments in scientific information associated with ingredients, process or product
- New product
- New process step
- New technology or piece of equipment
- Change in production volume that impacts the product flow, sanitation schedule, employee training, etc.
- Failures in the system (e.g., product recall/withdrawal)
- Emergence of foodborne pathogen with public health significance
- Published change in survival characteristics of a foodborne pathogen
- Change made in the application of a CCP (e.g., change in critical limit)
- New regulatory requirements related to food safety
- New HACCP team members

Following completion of the review, the HACCP Team Lead, together with the HACCP team, will ensure that:

- Changes arising from the review are fully incorporated into the HACCP system
- Where further validation activities are required (e.g., changes to the CCP critical limits), the work is completed in a timely and appropriate manner
- Where enhancement to programs is required, actions are completed and their effectiveness reviewed
- Evidence is retained to demonstrate effective communication of any significant changes to the whole HACCP team and senior management (as applicable).

Validation: Validation activities are commonly separated into two phases. In the first phase, scientific or technical information is collected that provide evidence a process control is capable of controlling the hazard. The second phase of validation utilizes the information collected in the first phase to design in-plant data collection to prove that a CCP or PCP actually works as it is applied in the process to control hazards.

Validation Phase One: Collection of Scientific Information. The information collected in the initial phase of validation is often in the form of published journal articles, processing guidelines, challenge studies or advice from experts. This phase includes the acquisition and maintenance of material evidence to justify the selection of hazards to be controlled, monitoring activities and their frequencies, corrective actions, verification activities of record, etc. The key to success in this first phase of validation is collecting information that closely replicates and characterizes the process control being validated. In an ideal situation, initial research on a CCP would provide scientific evidence that the hazard is capable of being controlled in the process, as well as guidance on critical parameters that should be applied to assure adequate control. Although this first phase of validation is not likely to provide sufficient evidence to assure the success of a CCP or PCP, it lays the groundwork for a strongly supported validation exercise in the second phase of validation.

Validation Phase Two: Collection of In-plant Data. The second phase of validation utilizes the information collected in the first phase to assist in designing in-plant data collection to prove that a CCP or PCP functions in the actual process to control hazards as claimed. In this phase of validation, process controls are implemented consistent with critical parameters identified in the first phase, and data collection (microbiological, chemical, etc.) is utilized to demonstrate that the HACCP plan or an individual CCP is achieving the desired outcome of controlling identified hazards. The second phase of validation provides opportunities to challenge the validity of original assumptions and expectations, allowing modification and tweaking of the process as needed to produce the desired outcome. Validation should occur:

- During development of the initial HACCP plan
- During annual reassessment
- When there is a process change affecting the CCP/PCP

In addition, when significant changes in the process occur or monitoring activities indicate the HACCP system or process is not under control, validation activities must be completed again to provide assurance that the controls in place are appropriate to address the hazards. Changes that might be significant include those that also may prompt a review of the HACCP system. In most cases, it is expected that initial validation studies would require the greatest effort. Validation activities initiated during an annual reassessment would be expected to take on more of a verification appearance and may only require enough CCP challenging to confirm control still exists as characterized in initial validation studies.

Industry gaps

Verification:

Gap A: Verification is not performed on the entire HACCP system; frequency is not adequate to determine effectiveness; verification is not conducted by others outside the current system.

Gap B: A systematic approach and appropriate records are absent.

Validation:

Gap A: Misunderstanding of the terms verification and validation and their unique importance.

Gap B: Failure to validate.

Gap C: Studies are incorrectly designed or executed.

Gap D: Scientific, fact-based rationale is absent.

Gap E: Validation study is not designed to truly challenge the process control.

Figure 6. It is essential to consider all the programs that impact the HACCP program, including the supporting prerequisite programs that provide the foundation for the formal HACCP Plan.

Verification

Gap A: Verification is not performed on the entire HACCP system; frequency is not adequate to determine effectiveness; verification is not conducted by others outside the current system. The primary purpose of evaluating the HACCP system is not only to identify opportunities for improvement but also to confirm effectiveness. On occasion, the emphasis during verification may focus on those programs that are known to be problematic rather than all the related programs. It is essential to consider all the programs, which can impact the HACCP program, including the supporting prerequisite programs that provide the foundation for the formal HACCP Plan *(Fig. 6)*. There may be a tendency to focus on process steps that have been determined to be critical rather than assessing control methods that are in place to manage generic hazards, such as chemical control and planned maintenance. A balanced approach to verification should be taken to ensure the assessment provides a beneficial overview of the overall effectiveness of the HACCP Plan and related programs. A risk-based approach should to be taken in determining the frequency of verification activities. Various HACCP related programs may be simplistic and not need continual oversight, or perhaps evaluation frequencies can be reduced on those programs that continue to be compliant. With the potential resource commitments required to verify programs, effectively detailed assessment in determining verification frequencies is essential to ensure that allocation of resource is applied appropriately. Remaining independent when completing verification activities can be difficult in a company that has either a small team or personnel with multiple responsibilities. Conflict may occur when evaluating one's own work due to potential bias; this should be avoided wherever possible to ensure an effective verification activities.

Gap B: Absences of systematic approach and appropriate records. When setting up the HACCP system, the scope and processes to be implemented to verify the effectiveness of the programs should also be considered, although initially it may be difficult to determine frequencies and the activities required to verify the effectiveness of the HACCP plan and related programs. The framework for some fundamental assessment approaches and some suggested timelines for review should be defined and then modified as required, depending on program performance. Considerations should include:

- The scope of the verification activities or work to be completed
- Defining who will be completing the work (considering ability and independence)
- Suggested timelines for frequency
- Review of the findings from verification activities

Table 1. Components of a Validation Study

Component	Points for consideration
Introduction (or problem statement)	What is the purpose of the validation study? Why is this relevant to the HACCP system? Is there an issue or problem with a particular hazard in the process? What has occurred to prompt the validation? Are there any limitations to the study?
Method	What activities must be undertaken to complete the validation study? What information will be collected and reviewed? What resources will be required — people, equipment, time, etc.? When and how will the validation be completed? Who is accountable and for which activities? Appropriate sampling plan has been defined? Is there a need to consider seasonal or shift variations?
Component	**Points for consideration**
Results	Assemble plant observational information, test results, analytical data and any other information deemed applicable for review and interpretation by the HACCP team.
Conclusion	Did the validation study confirm that the control measures that are in place are effective and capable of producing safe food? Is there a need for further work? Has a frequency or indicator been set for re-validation? Do monitoring frequencies require adjustment due to the findings? Do the results indicate that some other systems or processes also need to be re-validated?

Validation

Gap A: Misunderstanding of the terms verification and validation and their unique importance. According to the National Advisory Committee on Microbiological Criteria for Food *(4)*, verification is defined as activity, other than monitoring, that determines the validity of the HACCP plan and ensures that the system is operating according to the plan. Included in verification activities is validation, defined by NACMCF as the element of verification focused on collecting and evaluating scientific and technical information to determine whether the HACCP plan, when properly implemented, will effectively control the defined hazards.

Gap B: Failure to validate. Before a HACCP plan or system can function with assured control, it must be determined that all hazards have been identified and that the plan to control them is scientifically sound and will be effective. Validation, both of individual CCPs as well as the entire HACCP plan and system, is integral to determining the reliability of a HACCP plan or system. Validation is an activity that ultimately provides evidence that the HACCP system and its controls, as designed and implemented, can adequately control hazards to an acceptable level or endpoint.

Gap C: Incorrectly designed or executed validation studies. The second phase of validation is typically a scientific study, and all design features, assessments, reviews and completed work must be documented with clarity to enable external third parties to clearly understand the scope and conclusions of the work. The HACCP Team Lead must ensure the full documentation of validation activities undertaken. The validation study *(Table 1)* must, at a minimum, incorporate four components:

Gap D: Absence of scientific, fact-based rationale. Validation is integral to determining the reliability of a HACCP plan or system, so the inclusion of accurate scientific information is essential to an effective validation. Initial validation of the HACCP plan or system can be based upon various types of information, but most often utilizes scientific studies and advice of experts, as well as data collection and observations in the processing facility. For example, to validate a cooking process as a CCP within a HACCP plan, times and temperatures shown in the scientific literature to be capable of destroying the pathogen of concern should be considered. Studies may be conducted to make certain that the actual

processing conditions of cooking will provide the necessary temperature for the required length of time. Additionally, inoculated packs (usually containing indicator bacteria or surrogates) may be exposed to processing steps to collect data validating expected bacterial reductions. Validation may be conducted at numerous times, especially subsequent to identification of additional hazards, a change in the process, or a HACCP system failure.

Gap E: Validation study is not designed to truly challenge the process control. Validation studies must be documented and should test potential "worst case scenario" situations rather than optimal conditions. In addition, a validation study should indicate the capability of a process when stressed by less than optimal conditions and the impact of process and product variation must also be considered. The goal is to learn what the process is capable of controlling. In some cases, the second phase of validation may demonstrate that the expected control cannot be achieved at a particular point of control. While not the desired outcome of challenging process control, this situation provides an opportunity to improve the overall process. Learning that a process control does not provide the control needed prevents operation in an environment of unknown, but assumed, control.

STEP 12, PRINCIPLE 7 — ESTABLISH DOCUMENTATION AND RECORDKEEPING

Intent

Information pertinent to the HACCP Plan and associated programs needs to be appropriate and managed effectively to be of value in supporting the HACCP system. The information maintained must be such that it is able to demonstrate that the Principles of HACCP have been correctly applied through detailed documentation and suitable recordkeeping.

General guidance

Maintaining detailed and comprehensive information concerning the HACCP plan is essential to demonstrating the original framework of the HACCP system, how it was developed and how the system works in practice. Records and information maintained should be sufficiently detailed to provide clarity as to how all the HACCP Principles and Steps were established and how the system links together. This includes information on the HACCP Team, product description, HACCP flow diagrams, identification of hazards, hazard analysis, control measures, critical limits, corrective actions, validation activities and, potentially, numerous records that demonstrate how the HACCP system works in practice.

The structure of the documented system and associated records should be such that it not only is appropriate to the size and complexity of the HACCP system but also can be easily followed and intuitive for a reader external to the HACCP team to fully understand. Documented systems should provide value to the plan and be easy to understand by regulators, auditors and individuals who were not part of the development and management of the documented program.

Document and record management system

Whether the information related to the HACCP system is to be captured in either paper format or electronically, the information must be retained accurately and be relevant. Defining the structure and the rules of the document management system is essential to ensure that programs are controlled effectively and remain current.

Considerations for setting up a documentation and record system include some basic governance of the system:

- Document and record identification methods
- Version control and indexing
- Frequency of review
- Access and restrictions
- Retention and storage
- Process for rescinding and destroying

These fundamental requirements should be considered not only for the HACCP Plan itself but also for all the monitoring records and other related information that has been used to support the construction and maintenance of the food safety management system.

Once the process for the management of documentation and records has been established, consideration of the scope of the information specifically related to the HACCP plan and supporting programs should be clearly defined.

Specific information might include:

- HACCP team member information (qualification and relevant experience)
- Scope of HACCP plan
- Product description
- Intended use
- Process flow diagram information
- Hazard identification, hazard analysis and control measures
- Determination of the critical control points
- Information relating to establishing critical limits and related validation
- Monitoring systems and records
- Corrective action plans
- Verification procedures
- Prerequisite information
- HACCP review information
- HACCP plan amendment log
- Record templates

Figure 7. Overall the amount of information, documentation and records that are developed and implemented can often be significant and potentially confusing to anyone external to the decision making HACCP team.

Industry gaps

Gap A: The documented HACCP Plan is overdesigned and cumbersome, making it difficult to communicate and manage effectively.

Gap B: Weaknesses exist in the overall management and review of documentation systems and records.

Gap C: The technical content and rationale for decisions made within supporting HACCP documentation lacks clarity.

Gap D: Data captured in monitoring records is not utilized to improve performance.

Gap A: The documented HACCP Plan is overdesigned and cumbersome, making it difficult to communicate and manage effectively. Simplicity is key; detailed information should be reflective of the practices and processes being undertaken by the manufacturing plant, using terminology that is easily understandable not just by the food safety and quality personnel but also by individuals outside the HACCP team. Often HACCP Plans are written without specific thought as to their true purpose and also with an external reviewer in mind. Overall, the amount of information, documentation and records developed and implemented to address the requirements of a HACCP system can often be significant and potentially confusing to anyone external to the decision-making HACCP team *(Fig. 7)*. Adding documents and information without appropriate consideration of existing information, potentially to address non-conformances from audits or due to recommendations from regulators, may significantly increase the scope of the HACCP Plan. Adding more requirements and expectations may sometimes appear to be enhancing the HACCP Plan; however, the work needed to carry out the related activities, such as extra monitoring and management of extra records and programs, can ultimately be detrimental to the effectiveness of the program as it becomes more cumbersome and requires more resources to manage.

The target audience needs to be considered when developing procedural guidance and templates for records. Information and records should be sufficient to inform the practitioner on what they should do and not be created to appease those external to the manufacturing processes. Overcomplicating record templates may cause numerous issues due to a lack of understanding of expectations for completing the documentation.

Gap B: Weaknesses exist in the overall management and review of documentation systems and records. In a simplistic HACCP system, the management of the related documentation and records to demonstrate a compliant system can take a considerable amount of time. The more complicated the program, the more time and effort are required to monitor compliance. The number of records that often need to be completed, reviewed and verified can often be significant. Truly educating those responsible for the completion of records as to why the information is important and why it needs to be accurate is often overlooked, resulting in a lack of engagement with the HACCP program.

The governance of the documented program, including the rescinding of obsolete documents and record templates, is important to ensuring correlation between the information being either provided or captured and the formalized HACCP program requirements. The advance issue of record templates can often become a problem when requirements change and pre-printed templates are being stored. Control and access to records need to be stringently enforced to prevent unauthorized revisions or changes to documentation and records.

Gap C: The technical content and rationale for decisions made within supporting HACCP documentation lacks clarity. It is important that terminology and information contained within the HACCP decision-making documentation is not ambiguous, as this could lead to confusion, misinterpretation or a lack of comprehension by individuals who may not have been involved in the original decision-making. Using historical or "tribal" knowledge without referencing appropriate or technically relevant information weakens the quality and accuracy of the assessments that are made. For example, personnel working in a particular role or function may have been performing a task or activity for many years, such as a particular equipment sanitation activity, because "we've always done it this way," while independent review of the task may determine the work is being completed appropriately, which when documented could provide a good basis to demonstrate a program is working effectively. Alternatively, review could also indicate that some simple changes may make the task more effective (different tooling, more concentrated sanitizers, etc.), or the review may establish that the work is being completed inappropriately and is the actual cause of some issues further along the manufacturing process flow.

Without being involved in the development and decision-making process and without clarity in documenting decisions that are made it can be difficult for anyone not involved to determine why certain decisions may have been made. While it is certainly sometimes difficult to describe technical decisions, the content needs to stand alone to inform the reader.

Gap D: Data captured in monitoring records is not utilized to improve performance. Built-in recording systems for demonstrating the verification checks and recording programs can be resource intensive to manage. Copious amounts of information may be captured routinely through day-to-day monitoring activities in order to demonstrate compliance and to serve as a reference point if any issues occur. Frequently, nothing is actually done with the data being obtained, when analysis of the information might indicate process changes that could improve efficiency or reduce the number of checks or assessments taking place. The resources required to complete, authorize and verify monitoring checks can be significant; to ensure business value, an evaluation of the data should be completed not only to check on compliance but to drive operational improvements.

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