

Chapter 15

MANAGING AND MAINTAINING THE HACCP SYSTEM

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The HACCP system is recognized worldwide as one of the best systems of food safety. However, there are challenges in managing detailed food safety systems. Managing the HACCP system involves effective control of all facility programs.

Once HACCP plans are developed and started, work is still needed to keep them going. To control food safety hazards, the facility's HACCP system must stay 'in good repair'. It must be fine tuned to keep up with what's happening inside and outside the facility. HACCP systems need frequent updates and changes.

Effective HACCP maintenance depends on top management commitment. During HACCP development stages, management needs to show commitment to HACCP by supplying resources, time and money. Once the HACCP system is running, management must show its commitment through regular support of in-house activities (e.g. training, posted policies and continual improvement).

HACCP system maintenance activities include:

- Ongoing verification throughout the life of the HACCP system;
- Validation activities;
- Regular, pre-planned audits of the HACCP system, done by trained in-house or outside (third party) personnel;
- Follow-up and completion of corrective actions noted in earlier audits;
- Updating the HACCP system to deal with changes to the facility, products or processing operations;
- Revising the HACCP system to deal with new scientific information and/or new hazards;
- Keeping a log of all changes within the HACCP system;
- Altering the HACCP system to deal with changing regulations; and
- Ongoing training so that all personnel involved have necessary skills and know-how.

Verification asks: 'Is what should be done, getting done?'

Validation asks: 'Is this the right thing to do? Does it still work?'

Do not confuse verification and validation with routine monitoring activities for critical limits.

The meanings of 'Verification' and 'Validation' often get confused and are used incorrectly.

Verification is the application of methods, tests, procedures and other evaluations to determine CONFORMITY with the HACCP plan. Verification is done in addition to monitoring. (e.g. A HACCP coordinator checks the line supervisor's records to ensure that correct cooking temperatures are being met.)

Validation is obtaining EVIDENCE (e.g. testing, experimenting, or statistical analysis) that prove that the elements of the HACCP plan are WORKING EFFECTIVELY. (e.g. Statistical validation on how often a milk pasteurizer can be used without doing a Clean in Place).

1.0 VALIDATING THE HACCP SYSTEM

It is the responsibility of the manufacturer to validate its activities. Validation helps to confirm that the manufacturer can maintain control of a process. It confirms that the measures being used will control the hazards related to the food product.

Validate the following steps of HACCP plan development:

- CCPs;
- Critical limits;
- Monitoring activities; and
- Corrective actions (frequencies, methods and tasks).

Validation may require hiring people with professional skills or special training (e.g. food safety consultants) and may take time and money.

Do a new hazard analysis each time the system is changed or a new product is developed. It's necessary to check over the results of this new hazard analysis and how well the (new or old) control measures are working. For this reason, validation therefore becomes part of the HACCP maintenance system.

Validation may involve a scientific and technical review of every part of the HACCP plan – from hazard analysis to CCP verification strategies. One of the most important parts of HACCP program development is the original validation of the HACCP plan to make sure it's based on sound science and technology.

There are several ways to validate the HACCP plan. Some examples of validation include:

- Reliance on expert opinion, and scientific facts;
- Statistical evaluation of process parameters;
- Statistical analysis of a cooking step within the process; and
- Analysis of laboratory results (often using statistics) to check if a process is controlled.

Ask the following questions when validating the HACCP plan:

1. Have all hazards been identified?
2. Do the implemented control measures remove significant hazards or reduce them to acceptable levels?
3. Do corrective actions restore control?
4. Are there procedures to ensure unsafe products do not reach consumers?
5. Has there been any new equipment incorporated into the process?
6. Have any new products been developed?
7. Have any new ingredients been sourced?



See Form HACCP Plan Validation Checklist.

How often the facility uses the validation program will depend on:

- Changes to raw materials, packaging materials or suppliers;
- Changes in product or process;
- Changes to the facility or equipment;
- New scientific information on hazards or control measures;
- New practices for handling distribution or consumer practices; and
- The risks associated with the facility's products.

One of the most important parts of HACCP program development is the original validation of the HACCP plan.

2.0 VERIFICATION

Verification activities should cover all parts of the HACCP system including prerequisite programs. Examples of verification include:

- Watching employees to ensure that they are doing their job effectively, and comparing these findings to the written SOPs;
- Checking if records have been filled out accurately;
- Random tests to make sure that equipment is functioning as intended;
- Microbial or allergen testing to make sure cleaning and sanitation have been done correctly;
- Calibration or checking of monitoring devices;
- Checking for trends by reviewing calibration and other prerequisite program records;
- Targeted sampling and testing;
- Review of CCP (critical control point) records; and
- Audits or inspections by a regulatory agency.

Important factors to consider when developing the verification program:

- Verification processes need to be developed as a part of the HACCP plan. Write the verification processes, including how often they're done and who performs the activities, in a format similar to the rest of the HACCP plan.
- If the facility plans to do only in-house audits, using its own staff, ensure the personnel have the skills and knowledge needed. Make sure they can assess and understand the results and can perform the activities.
- Verifiers or auditors must be objective (unbiased). *Do not use the same people who developed the HACCP system to verify and audit that system.* Separating HACCP development from HACCP verification and auditing will prevent bias. It also helps in finding inconsistencies or problems within the programs.
- The same person cannot verify and monitor the same activity. To ensure that verification procedures are objective (unbiased) and credible (reliable), never have the same person who monitors a process or maintenance activity, also verify that same activity.

- Management must ensure that failures found in the system are dealt with. They must make sure the necessary corrective actions are taken. Management must continue to show commitment to the HACCP system.

Figure 1: Direct and Indirect Ways to Verify the Effectiveness of Food Safety Controls

What is Evaluated		Methods Used?
Producer	Knowledge Attitudes Behaviour Ownership Training	Of Operators and Managers Questionnaires, Attitude, Scales, Audit, Observations
HACCP Plans And GMPs	Quality of Plans	Design and Implementation Audit, Inspections
Surfaces Equipment Plant	Design Construction Cleanliness Cleaning Programs	Audit, Observation ATP Bioluminescence Microbiological Testing
Food Produced	Microbiological & Chemical Quality	Microbiological and Chemical Testing, APC Indicator Organisms Presence of Pathogens or Chemical Contaminants
Health of the Public	Foodborne Illness Trends And Risks	Epidemiological Surveillance

2.1 HACCP Verification

Four methods most commonly used for HACCP verification are:

1. Equipment calibration;
2. Calibration record review;
3. Targeted sampling and testing; and
4. CCP record review.

If a monitoring procedure is not as strict as it needs to be, combine it with a strong verification strategy.

Verification reports should include:

- Mention of related HACCP plans;
- Direct monitoring of the CCPs (on-site observations);
- Direct monitoring of operators responsible for the CCP (where appropriate);
- valuation of records related to CCP monitoring;
- Certification that monitoring equipment is calibrated accurately;
- Deviations and corrective actions; and
- Modifications to the HACCP plan.

Equipment Calibration

Although this part of the HACCP system is covered in the equipment prerequisite program, it's also an important part of HACCP verification. Calibration of CCP monitoring devices helps to confirm the accuracy of measurements taken at each CCP.

If equipment is out of calibration, the CCP is considered to be out of control since the last time it was calibrated. How often calibration is done depends on the sensitivity of the equipment. It also depends on the risks related to loss of control.

Calibration Record Review

Calibration review involves going over equipment calibration records to check dates, methods and results of recent calibration activities. This is generally done as part of an internal (in-house) audit of the HACCP system, or as part of annual HACCP system maintenance.

Calibrations are performed:

- *On equipment and instruments used in monitoring or verification;*
- *Often enough to ensure accuracy of measurements; and*
- *By checking the accuracy against a recognized standard (at or near the equipment's normal functioning condition).*



For more information on equipment calibrations see Chapter 6: Developing An Equipment Program.

Targeted Sampling and Testing

An internal supplier compliance assessment (checking to see that suppliers are following food safety procedures) is a good example of verification using targeted sampling and testing. Supplier compliance is most often checked by taking a sample of the material being supplied. These test results are then compared with the safety specifications for that material.



For more information on supplier compliance see Chapter 12: Supplier Food Safety Assurance Program.

CCP Record Review

For each CCP, at least two kinds of records are produced. They are monitoring and corrective action records. (These may be separate documents, or combined into one.) Records alone are meaningless unless someone in a supervisory, quality assurance or management role reviews them. They must check that the HACCP plan is being followed. These records are very helpful for showing that CCPs are operating within safe limits. They also show whether all deviations or unusual situations are handled safely and effectively.

At set times the verifier will review, sign and date all records to confirm that they are complete and accurate. Write down any deviations found during the verification. Also write down what corrective actions were taken.

2.2 Verification Records

Create and keep records of all verification activities. The following table shows how to simplify verification recording activities.

WHAT	WHY	WHEN	HOW	WHO	RECORD
Product Test for Coliforms	Assess product cook-kill step.	End of each batch	Lab – instructions	Lab Tech	Finished Product Testing
Monitoring Trends	Implement improvements and catch deviations	End of each month	Review of documents – Graphs	QA Manager	Document Trend Review

3.0 AUDITS

Audits compare the actual practices and procedures of the HACCP system with what is written in the prerequisite programs and HACCP plans.

Audits:

- Are systematic, organized, and independent examinations that may involve both paper reviews and on-site checking;
- Check into whether an operation is conforming to, or following, the rules of the food safety system; and
- Are a way to reinforce strengths and find weaknesses in the food safety system.

Unlike traditional inspections, audits are more than just a snapshot of one point in time. They review everything from management commitment to employee practices.

Figure 2: The following charts describe some ways to develop an Auditing System.

Prerequisite Program Audit		HACCP Plan Procedures	
Program Audited	Methodology	Program Audited	Methodology
Are prerequisite programs being carried out as defined by the plan?	Visual Observation	Have CCPs been consistently documented within the critical limits and the monitoring frequencies required by the HACCP plan?	Record Review
Have all procedures been carried out consistently since the last audit?	Record Review	Have deviations and corrective actions been noted accurately? Was the product and the process corrected prior to further manufacturing?	Record Review
Are staff members aware of the requirements?	Discussion / Interviews with new and existing employees	Have verification procedures on CCPs been carried out consistently?	Record Review
Are the prerequisite programs effective?	Review of consumer complaints, facility problems attributable to prerequisite programs <ul style="list-style-type: none"> • Record Review Waste, rework, or returns associated with GMP issues <ul style="list-style-type: none"> • Record Review 	Are CCPs managed properly on the floor today?	Visual Observation
		Are line operators aware of the HACCP plan's requirements?	Discussion / Interviews with new and existing employees
		Has the HACCP plan been effective?	Review of deviation records. Was effective corrective action taken? Are there repeat problem areas? Is deviation frequency increasing or decreasing?
		Is there any new information or evidence from scientific journals or other sources that suggest the plan should be modified?	Literature search and review

3.1 Setting Up Audit Systems

Checklists are very helpful in keeping the audit process consistent. These checklists may be based on standards from which the food safety system was developed. Some food processors prefer that audit checklists suit their own facility and special concerns. To make customers more confident, some facilities use the same audit checklists as their customers.

Whatever method is used, keep the following in mind when developing the audit checklist:

- **Scope of the audit**
Will the entire system be assessed or just parts of it?
- **Use written procedures to gather objective evidence**
As with any part of a food safety system, set down the requirements of the auditing plan to ensure consistency.
- **An annual auditing timetable**
Develop a yearly plan for when each audit is to be done and who does it. Modify the auditing schedule when it makes sense.
- **Follow-up and corrective actions**
Create a procedure that not only allows for follow-up on corrective actions, but also shows the results of those actions.
- **Reporting procedures**
The watchwords for HACCP are 'document, document, and document'. Find the best way to report auditing activities.

Many believe that for a HACCP system to be credible, or trustworthy, an independent review or audit is needed. Independent reviews can offer unbiased opinions. Some customers and regulatory agencies require confirmation that the HACCP system works well. They want to see documented activities showing that a facility's food safety hazards are being dealt with effectively.

Independent audits or assessments can be done by third parties. When selecting someone to assess the facility, make sure they are honest, reliable and skilled in auditing and inspection of the products being produced.

The frequency for auditing prerequisite programs and HACCP plans will depend on the special features of the facility. Record any changes to the annual audit schedule and the reasons for them in the HACCP log. When repeated compliance is confirmed, it may be possible to audit less often.

Here are some examples of when to modify or increase auditing schedules:

- When the process changes (new equipment, new products);
- Research indicates a new hazard;
- Customers have new requirements; and/or
- An unusual number of non-conformities or corrective actions are noticed.

3.2 Audit Records

Use audit results as a tool to encourage communication between facility staff – from management to floor workers. Many facilities use an easy-to-read, shortened audit report that can be posted in the employee lunchroom. It can also be reviewed at management meetings.

4.0 HACCP TRAINING

Employee buy-in is the key to maintaining a good HACCP system. Management support is also of key importance. Many facilities that have used HACCP consultants may forget this. They may also overlook the need for both initial and ongoing HACCP training.

Maintenance of the HACCP system should include ensuring that employees are well trained. Make sure they can carry out their tasks well. Training needs will differ throughout an organization. Keep staff motivated by developing their technical knowledge and expertise. This helps ensure that the HACCP system is successful.

Whether the facility is just beginning employee training, or adding to it, a good HACCP training program should include:

- Explanation of the importance of food safety to the facility, the consumer, and even the employees involved;
- Visual demonstrations of all steps and procedures;
- Chances for employees to practice;
- Opportunities for employees to provide feedback;
- Tests to reinforce the information being taught;
- Making the training and learning appealing for all employees;
- Setting down how often (at least yearly) to do reviews or refresher training with employees; and
- Follow-up on the training to ensure that it is effective.



For more information on employee training see Chapter 7: Developing a Personnel Training Program.

5.0 CORRECTIVE ACTION FOLLOW-UP

During HACCP audits or internal verification activities, non-conformances or shortcomings that require corrective action, may be noticed. A corrective action plan must be developed to deal with all issues. It should explain the action to be taken and a set time for doing it. Record all deviations and corrective actions. Include them as part of the HACCP documents.

6.0 DOCUMENTATION

As with every part of the HACCP system, HACCP maintenance is a documented process. There must be a plan that describes who is responsible for maintenance of the system.

Record all changes to the HACCP system. The easiest way to do this is with a HACCP system logbook. It provides an ongoing history of the facility's HACCP system. The logbook may be as simple as a coil-bound booklet with headings. It may also be a more advanced computerized HACCP database.

All entries should include:

- The program or part of the system that was changed;
- Why it was changed;
- What change was made;
- Who made the change; and
- Initials of the employee making the change.

There should also be a column to mark verification or validation of the change. For example, if changes are made to a CCP, it may be necessary to re-validate the effectiveness of that CCP.

Example of HACCP System Logbook Entry:

Date	Prerequisite Program or HACCP Plan	Change Made	Verification or Validation Activities	Initials
May 23, 2006	E1 – Sanitation	Restroom re-stocking schedule increased to twice per day.	Records check shows a decrease in necessary corrective actions associated with this activity.	RB

Note: The above change is very simple and does not indicate all the records involved. Any changes to prerequisite programs or HACCP plans that are recorded in the logbook should also be noted in the written control program. These changes should also be recorded in any documents where monitoring and corrective actions are tracked.

7.0 HACCP MANAGEMENT AND MAINTENANCE FORMS

- HACCP Revision Log
- HACCP Plan Validation Checklist
- HACCP Plan Internal Audit Report

8.0 SOURCES OF INFORMATION

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