Section 3-9: Principle 7: Record-Keeping Procedures

Asia-Pacific Economic Cooperation
FSCF Food Safety Cooperation Forum
PTIN Partnership Training Institute Network
THE WORLD BANK
MICHIGAN STATE UNIVERSITY

Principle 7: Record-Keeping Procedures

Section Overview

The seventh and final principle of HACCP is to establish effective record-keeping procedures that document the HACCP system. Maintaining complete and accurate records is essential to ensure effective monitoring of the HACCP system and demonstration of compliance with food safety requirements.

The following topics will be discussed in this section:

- Preliminary considerations
- Types of HACCP records
- Control of documents
- Retention of records
- Electronic records
- Review of records
- Records – other considerations
- HACCP plan form
- Final considerations on HACCP systems

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Learning Objectives

At the conclusion of this section, the learner will be able to:

- discuss reasons why HACCP record-keeping is important,
- list different types of required HACCP records,
- list examples of HACCP system support documents that are important records,
- describe the information required in routine HACCP system monitoring records,
- discuss examples of relevant records concerning corrective actions and verification activities,
- describe appropriate procedures for control of HACCP documents,
- discuss requirements for HACCP record retention,
- describe general considerations regarding review of HACCP records, and
- list the required elements of a HACCP plan form.

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Preliminary Considerations

Efficient and accurate record keeping is essential to the application of a HACCP system. According to the Codex guidelines, "documentation and record keeping should be appropriate to the nature and size of the operation and sufficient to assist the business to verify that the HACCP controls are in place and being maintained."

Although it requires considerable effort, the record-keeping program should be viewed as a benefit rather than a burden for the following reasons.

- Records are the only references available to trace the production history of a finished product.
- Records can be used as a tool to alert the operator to potential problems before they lead to the violation of a critical limit.
- Records can serve as evidence that proper procedures are being followed.

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Types of HACCP Records

Several different types of records are required to properly document the HACCP system. These include:

- Support documentation for developing the HACCP plan
- Records generated by the HACCP system
- Documentation of methods and procedures used
- Records of employee training programs

These types of records will be discussed in the following sections.

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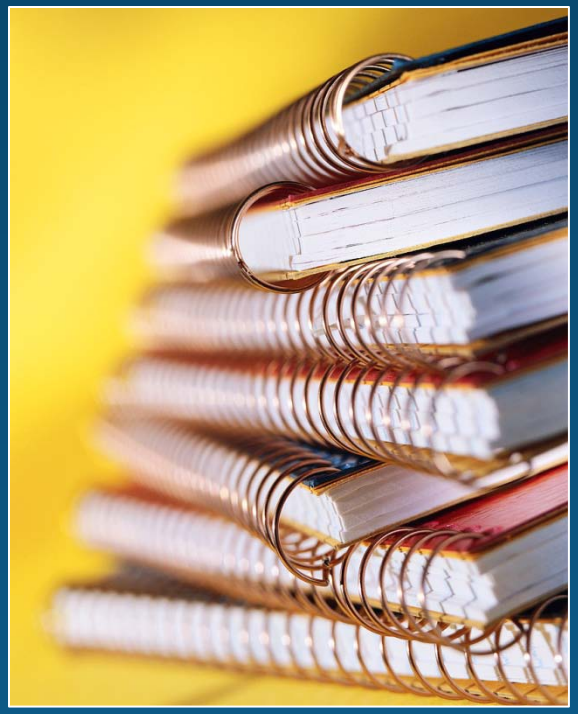
HACCP System Support Documents

The HACCP plan support documents include information and supporting data used to establish the HACCP plan such as the hazard analysis and records documenting the scientific basis for establishing the CCPs and critical limits. Examples include:

- A summary of the hazard analysis, including the rationale for determining hazards and control measures.
- Data used to establish the control measures to prevent microbiological growth.
- Data used to establish the shelf-life of the product (if age of the product can affect safety).
- Data used to establish the adequacy of critical limits in ensuring the safety of the product.



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HACCP System Support Documents

The HACCP plan support documents should also include the written HACCP plan and systems which support its implementation. Examples of these records include:

- Listing of the HACCP team and assigned responsibilities.
- Description of the food, its distribution, intended use, and consumers.
- Verified flow diagram.
- HACCP Plan Summary Table that includes information for:
  - Steps in the process that are CCPs
  - The hazard(s) of concern
  - Critical limits
  - Monitoring procedures
  - Corrective actions
  - Verification procedures and schedule
  - Record-keeping procedures

Support documents may also include correspondence with consultants and other documents detailing how the HACCP plan was developed.

Records Generated by the HACCP System

The records generated by the HACCP system include all activities and documentation required by the plan, including:

- monitoring records for all CCPs,
- deviation and corrective action records, and
- verification/validation records.

Routine CCP monitoring records should include the following information:

1. Form title
2. Firm name and location
3. Time and date
4. Product identification (including product type, package size, processing line and product code, where applicable)
5. Actual observation or measurement
6. Critical limits
7. Corrective action taken, where applicable
8. Operator's signature or initials
9. Reviewer's signature or initials
10. Date of review

Records Generated by the HACCP System

Deviation and corrective action records should include:

- identification of the deviant lot/product,
- amount of affected product in the deviant lot,
- nature of the deviation,
- information on the disposition of the lot, and
- description of the corrective action.

Examples of verification and validation records include:

- in-house on-site inspection,
- equipment testing and evaluation,
- accuracy and calibration of monitoring equipment, and
- results of verification activities, including methods, date, individuals and/or organizations responsible, results or findings and action taken.

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Documentation of Methods and Procedures

Methods and procedures used in implementing the HACCP system also must be documented. Examples include:

- Description of procedures used to implement key prerequisite programs, such as employee hygiene and sanitation of equipment and facilities. In certain cases, records of these procedures are required by regulation (e.g. as in certain U.S. HACCP regulations).
- Description of the monitoring system for the critical limits of each CCP, including the methods and equipment used for monitoring, the frequency of monitoring and the person performing the monitoring.
- Plans for corrective actions for critical limit violations or situations resulting in potential hazards.
- Description of record keeping procedures, including copies of all record forms.
- Description of verification and validation procedures.

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Employee Training Programs and Other Records

Records should be kept to document all all training activities for employees. Employee training is particularly important for employees involved with:

- monitoring critical limits for CCPs, and
- deviation review, corrective actions and verification

Employees must be trained to understand the appropriate procedures and actions to be taken regarding control of CCPs.

Other types of records may also be appropriate for inclusion in the record-keeping system. For example, records of customer complaints can be very useful to determine the likelihood of occurrence of product contamination with foreign materials and other potential physical hazards.

Minutes of HACCP team meetings and management review meetings also should be maintained.

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Control of Documents

Proper control and maintenance of documentation procedures is an often overlooked aspect of HACCP system maintenance.

Standardized record-keeping forms must be established and utilized. Procedures need to be in place to ensure that:

1. documents are adequate for use,
2. relevant documents are available at points of use,
3. documents are legible and readily identifiable,
4. completed documents are filed appropriately,
5. documents are reviewed and updated as necessary, and
6. obsolete documents are not used.

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Retention of Records

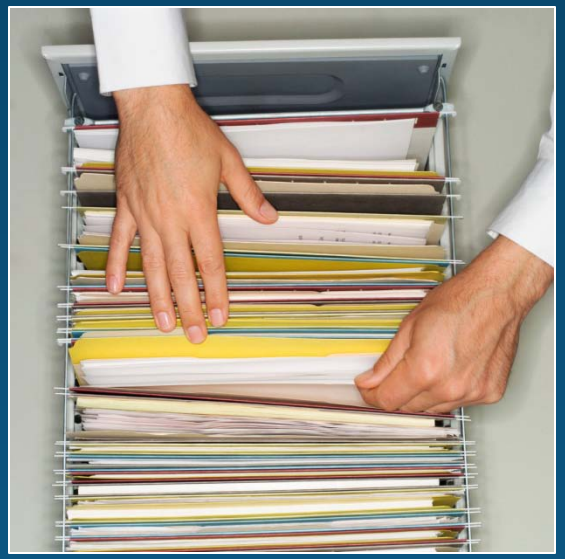
Records documenting the HACCP system should be stored for a predefined period. The duration of record retention is generally linked to the anticipated shelf life of the product.

The HACCP team must familiarize themselves with the legal and/or customer requirements for maintenance and retention of records in the countries where they operate and where their products are sold.

For example, regulatory agencies in the United States require that HACCP records be retained for at least the following durations:

- One year, for perishable or refrigerated products.
- Two years (or shelf life of the product, if longer), for frozen, preserved, or shelf-stable products.

Records must be readily accessible. Off-site storage is often permitted by regulatory authorities provided that records can be retrieved within a reasonable period of time (e.g. 24 hours).



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Electronic Records

Electronic, or computerized, records are an increasingly common option to traditional written record keeping on printed forms. When using computerized records, it is important to include controls to ensure that records are :

- authentic,
- accurate, and
- protected from unauthorized changes.

The HACCP team should ensure that any electronic record-keeping procedures used in their system comply with the regulatory requirements in the jurisdictions where they operate.

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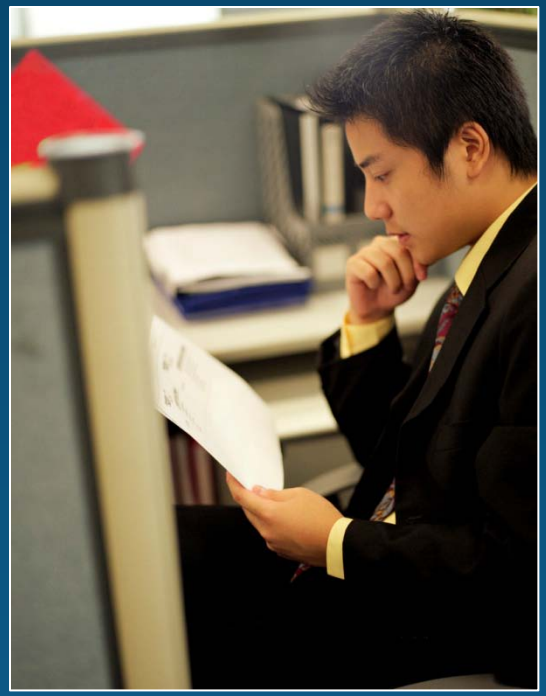
Review of Records

Routine HACCP records, such as daily operation records for CCP monitoring, corrective action records, and records of verification activities, must be reviewed on a routine basis. The HACCP team must be familiar with and comply with regulatory or customer requirements for review of HACCP records.

For example, the following are the current regulations regarding review of HACCP records in the United States:

- The U.S. Food and Drug Administration requires that HACCP records be reviewed within 7 days of generation of the original record.
- The U.S. Department of Agriculture requires a review of HACCP records prior to shipment of any finished products. This is often referred to as the "pre-shipment review."

The record review must be conducted by a trained, responsible individual. At the completion of the review and reconciliation of any deficiencies, this person signs or initials the HACCP record.



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Records – Other Considerations

Employees with record-keeping responsibilities must be trained on the importance of accurate and timely record-keeping.

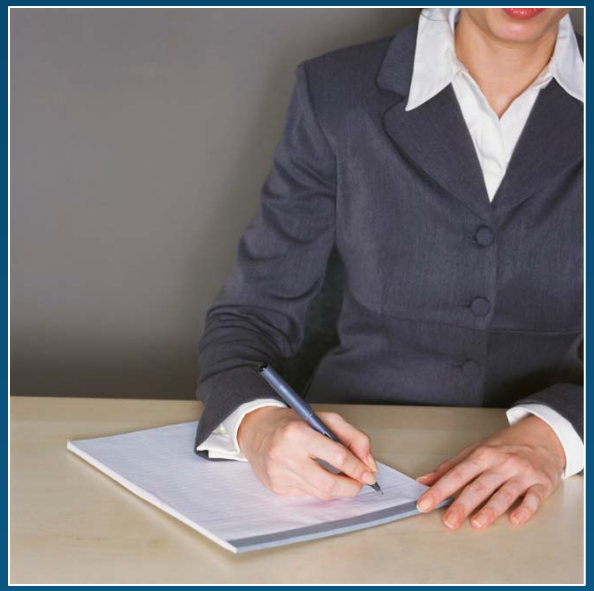
Records must be taken at the times and frequencies stipulated in the HACCP plan. They should never be completed prior to or long after the scheduled frequency.

The employee must record the actual measurement or observation, not the critical limit specified in the HACCP plan.

Written records typically must be recorded in ink, not pencil.

Corrections to written records should be completed by crossing out the mistaken reading with a single line and replacing it with the correct reading. It is good practice to have these edits approved and initialed by supervisory personnel.

Records must be readily accessible and maintained in a secure location.



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HACCP Plan Form

Below is an example of a blank standard HACCP plan summary table. The purpose of the summary table is to aggregate all of the key information regarding implementation of the HACCP plan in a single document. The completed summary table should be supported by a variety of other records, including records of the hazard analysis, determination of CCPs, maintenance of prerequisite programs, methods and procedures, daily operational records, corrective action records, verification and validation records and other supporting documentation.

1. CCP	2. Hazards	3. Critical limits	Monitoring				8. Corrective actions	9. Verifica-tion	10. Record keeping
			4. What	5. How	6. Frequency	7. Who			

Final Considerations

Design and maintenance of a valid and effective HACCP system requires a significant and lasting commitment by the establishment. Management support is essential.

The HACCP team should be multidisciplinary and have a complete understanding of the firm's products and processes, as well as the likely hazards in these products and methods for controlling these hazards.

HACCP systems are dynamic. At a minimum, HACCP plans must be revalidated annually. Revalidation is also triggered by a host of other factors, including changes in product formulation, processing steps, understanding of potential hazards in the products, recalls or other food safety incidents, or other information that may impact food safety hazard incidence or severity.

Finally, once written and validated the establishment must treat the HACCP system as the "law" in their establishment. Once implemented, all operations must be in accord with the plan.

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