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StandardGuide for Conducting Hazard Analysis-Critical Control Point (HACCP) Evaluations[1]

This standard is issued under the fixed designation E2590; the number immediately following the designation indicates the year of original adoption or, in the case of revision, the year of last revision. A number in parentheses indicates the year of last reapproval. A superscript epsilon (ε) indicates an editorial change since the last revision or reapproval.

1. Scope

1.1 This guide describes a stepwise procedure for using existing information, and if available, supporting field and laboratory data concerning a process, materials, or products potentially linked to adverse effects likely to occur in the environment as a result of an event associated with a process such as the dispersal of a potentially invasive species or the release of material (for example, a chemical) or its derivative products to the environment.

1.2 Hazard analysis-critical control point (HACCP) evaluation is a simple linear process or a network of linear processes that represents the structure of any event; the hazard analysis (HA) depends on the data quality and data quantity available for the evaluation process, especially as that relates to critical control points (CCPs) characterized in completing HACCP. Control measures target CCPs and serve as limiting factors or control steps in a process that reduce or eliminate the hazards that initiated the HACCP evaluation. The main reason for implementing HACCP is to prevent problems associated with a specific process, practice, material, or product.

1.3 This guide assumes that the reader is knowledgeable in specific resource management or engineering practices used as part of the HACCP process. A list of general references is provided for HACCP and implementation of HACCP and similar methods, as those apply to environmental hazard evaluation, natural resource management, and environmental engineering practices (**8**, **11-17**, **20**, **21**, **24**, **27**, **28**, **30-32**).[2]

1.4 This guide does not describe or reference detailed procedures for specific applications of HACCP, but describes how existing information or other empirical data should be used when assessing the hazards and identifying CCPs potentially of use in minimizing or eliminating specific hazards. Specific applications of HACCP evaluation are included as annexes to this standard, which include implementation of HACCP in resource management practices related to invasive species control and mitigation.

1.5 HACCP evaluation has a well developed literature in, for example, food science and technology, and in engineering applications (see, for example, **8**, **11**, **12**, **14**, **16**). As a resource management tool, HACCP is relatively recent in application to the analysis of hazards to aquatic, wetland, and terrestrial habitats and the organisms occupying those habitats. Most of the guidance provided herein is qualitative rather than quantitative, although quantitative methods should be applied to any hazard analysis when possible. Uncertainties associated with the analysis should also be characterized and incorporated into the HACCP evaluation when possible (see, for example, **1-10**, **18**, **19**, **29**).

1.6 This standard provides guidance for assessing hazard but does not provide guidance on how to take into account social or political considerations that influence the specification of the acceptability of the hazard. Judgments concerning acceptability are outside the scope of this guide, but available guidance from ASTM is applicable to this process (see E2348 Standard Guide for Framework for a Consensus-based Environmental Decision-making Process).

1.7 This guide is arranged as follows:

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1.8 *This standard does not purport to address all of the safety concerns, if any, associated with its use and the implementation of HACCP. It is the responsibility of the user of this standard to establish appropriate safety and health practices and determine the applicability of regulatory limitations prior to use.*

[1] This guide is under the jurisdiction of ASTM Committee E50 on Environmental Assessment, Risk Management and Corrective Action and is the direct responsibility of Subcommittee E50.47 on Biological Effects and Environmental Fate.

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[2] The boldface numbers in parentheses refer to the list of references at the end of this standard.

2. Referenced Documents

2.1 *ASTM Standards:*[3]

E943 Terminology Relating to Biological Effects and Environmental Fate

E1023 Guide for Assessing the Hazard of a Material to Aquatic Organisms and Their Uses

E1609 Guide for Development and Implementation of a Pollution Prevention Program (Withdrawn 2010)[4]

E2348 Guide for Framework for a Consensus-based Environmental Decision-making Process

3. Terminology

3.1 *Definitions of Terms Specific to This Standard:*

3.1.1 *control, v*—to take all necessary actions to ensure and maintain compliance with criteria established in the HACCP plan.

3.1.2 *control, n*—a state wherein correct procedures are being followed and criteria are being met.

3.1.3 *control measure*—any action and activity that can be used to prevent or eliminate a hazard or reduce it to an acceptable level.

3.1.4 *corrective action*—any action to be taken when the results of monitoring at the CCP indicate a loss of control.

3.1.5 *critical control point (CCP)*—a step at which control can be applied and is essential to prevent or eliminate a hazard or reduce it to an acceptable level.

3.1.6 *critical limit*—a criterion which separates acceptability from unacceptability.

3.1.7 *deviation*—failure to meet a critical limit.

3.1.8 *flow diagram*—a systematic representation of the sequence of steps or operations of a system or process, including the production or manufacture of a materials or products.

3.1.9 *HACCP*—a system which identifies, evaluates, and controls hazards which are significant for a wide range of natural resource management and environmental engineering applications.

3.1.10 *HACCP plan*—a document prepared in accordance with the principles of HACCP to ensure control of hazards.

3.1.11 *hazard*—a biological, chemical or physical agent or condition with the intrinsic capacity to cause an unwanted or adverse effect in an exposed system.

3.1.12 *hazard analysis*—the process of collecting and evaluating data and information on hazards and conditions leading to their presence and necessary to include in a HACCP plan.

3.1.13 *monitor*—the act of conducting a planned sequence of observations or measurements of control parameters to assess whether a critical control point is under control.

3.1.14 *step*—a point, procedure, operation or stage in a process.

3.1.15 *validation*—obtaining evidence that the elements of the HACCP plan are effective.

3.1.16 *verification*—the application of methods, procedures, tests and other evaluations, in addition to monitoring to determine compliance with the HACCP plan.

3.2 For definitions of other terms used in this guide, refer to Terminology E943 and references cited herein.

4. Summary of Guide

4.1 Hazard Analysis-Critical Control Point (HACCP) evaluation has become increasingly applied to natural resource management and environmental engineering problems, particularly as hazards may be managed, for example, with respect to the safety of processes or release of materials or products to the environment. HACCP should be an integral part of management practices focused on engineering or resource management practices used to develop aquatic, wetland, and terrestrial habitats for human use (for example, agriculture or construction activities) or to enhance habitats for fish and wildlife. HACCP is a systematic and preventive approach that addresses biological, chemical and physical hazards through anticipation and prevention, rather than through end-product inspection and testing or retrospective engineering solutions necessitated because of previous undertakings. The HACCP system is intended for assessing and managing risks and safety concerns associated with a wide range of materials, products, and management practices with an emphasis on a total systems approach to improve environmental quality. This standard could be used in conjunction with existing ASTM standards such as Guides E1023, E2348 and E1609. HACCP emphasizes control of a process as far upstream in the processing system as possible by utilizing operator control or continuous monitoring techniques, or a combination of both, at critical control points. The HACCP system uses the approach of controlling critical points in any process to reduce or eliminate risks and prevent safety problems from developing. The identification of specific hazards and measures for their control to ensure the safety of a process, material, or product through prevention and reduces the reliance on end-product inspection and testing (for example, for agrichemicals), remedial measures (for example, related to construction practices), or mitigation measures as part of a control program (for example, quarantine or disinfection for control of invasive species) are integral components of any HACCP system. Any HACCP system should be capable of accommodating change, such as advances in equipment design or developing alternative resource management practices, changes in processing procedures, or technological developments.

4.2 This guide describes an iterative procedure for assessing hazard and characterizing CCPs. Unavailable, yet necessary information concerning the hazard and the process generating that hazard should be identified and characterized through a stepwise evaluation that details the hazard and specifies critical points that may serve to control the process, and minimize or eliminate hazard. At the end of any iteration of the HACCP process, specific CCPs that reduce likelihood of hazard may be identified, or the available data related to the hazard and the

[3] For referenced ASTM standards, visit the ASTM website, www.astm.org, or contact ASTM Customer Service at service@astm.org. For *Annual Book of ASTM Standards* volume information, refer to the standard's Document Summary page on the ASTM website.

[4] The last approved version of this historical standard is referenced on www.astm.org.

process generating that hazard may be judged as being insufficient to adequately characterize hazard or CCPs. In the latter instance, additional data or information should be identified and obtained, so that HA and CCPs can be reassessed. The process is repeated until the hazard is adequately characterized and CCPs are characterized in order to reduce likelihood that hazard is realized.

5. Significance and Use

5.1 HACCP is a proactive management tool that serves to reduce hazards potentially expressed as adverse biological or environmental effects, for example, associated with chemical releases, changes in natural resource or engineering practices and their related impacts, and accidental or intentional releases of biological stressors such as invasive species.

5.2 Sequential implementation of HACCP and feedback in the iterative HACCP process allows for technically-based judgments concerning, for example, natural resources or the use of natural resources. Implementing the HACCP process serves to reduce adverse effects potentially associated with a particular material or process, and provides guidance for testing and evaluation of products or processes, through a pre-emptive procedure focused on information most pertinent to a system's characterization. For example, identification of CCPs assure that processes and practices can be managed to achieve hazard reduction. For different processes and situations, HA may be based on substantially different amounts and kinds of, for example, biological, chemical, physical, and toxicological data, but the identification of CCPs serving to reduce hazard is key to successful implementation of HACCP.

5.3 HACCP should never be considered complete for all time, and continuing reassessment is a characteristic of HACCP evaluations, especially if there should be changes in, for example, production volumes of a material, or its use or disposal increases, new uses are discovered, or new information on biological, chemical, physical, or toxicological properties becomes available. Similarly, HACCP should be considered an ongoing process serving as a key component in engineering practices, for example, related to construction activities and land-use changes, and natural resource management practices, for example, related to habitat use, enhancement, and species introductions such as fish-stocking programs. Periodic review of a system's performance will help assure that new circumstances and information receive prompt and appropriate attention.

5.4 In many cases, consideration of adverse effects should not end with completion of the HA and identification of CCPs key to the development of control measures. Additional steps may subsequently include risk assessment, and decisions concerning acceptability of identified hazards and risks, and mitigation actions potentially applicable to the process or practice that initially motivated HACCP.

6. Basic Concepts of Hazard Analysis-Critical Control Point (HACCP) Evaluation

6.1 *Overview of HACCP Evaluation*—The basic principle of HACCP relies on system characterization and a repetitive or iterative evaluation of that system and its attendant outcomes. When available data to characterize a system are inadequate and CCPs can not be adequately characterized, data needs are identified and HACCP reiterated. The process is repeated until HA is adequate and CCPs are clearly identified. The HACCP system systematically identifies hazards and measures for their control to ensure the safety of any process, but especially those involving engineering or management practices that manipulate materials, products, or systems potentially associated with adverse effects directly or indirectly associated with those manipulations. HACCP is a tool to assess hazards and establish control systems that focus on prevention rather than relying mainly on end-product testing and inspection. Any HACCP system is capable of accommodating change, such as advances in equipment design, processing procedures or technological developments. This section reviews the 12 tasks in the application of HACCP, including the seven HACCP principles. It emphasizes the importance of standards and guidelines as a basis for developing the HACCP plan.

6.2 *Principles of the HACCP System*—The HACCP system consists of seven principles that guide any evaluation.

6.2.1 Conduct a hazard analysis. Identify the potential hazard(s) associated with at all stages or steps within a system or process of concern within a system. Assess the likelihood of occurrence of the hazard(s) and identify the measures for their control.

6.2.2 Determine the Critical Control Points (CCPs). Determine the points, procedures or operational steps that can be controlled to eliminate the hazard(s) or minimize its (their) likelihood of occurrence. A "step" means any stage in the system, including materials or processes that are part of the system or contribute to the systems form or function, for example, exogenous inputs should have specifications that can be incorporated into HACCP.

6.2.3 Establish critical limit(s). Critical limit(s), also referred to as control limit(s), must be established to ensure the CCP is under control.

6.2.4 Establish a system to monitor control of the CCP. Establish a system to monitor control of the CCP by scheduled testing or observations.

6.2.5 Establish the corrective action to be taken when monitoring indicates that a particular CCP is not under control.

6.2.6 Establish procedures for verification to confirm that the HACCP system is working effectively.

6.2.7 Establish documentation concerning all procedures and records appropriate to these principles and their application.

6.3 *Implementation of the HACCP System*—Management commitment is necessary for implementation of an effective HACCP system. During hazard identification, evaluation, and subsequent operations in designing and applying HACCP systems, consideration must be given to existing technical practices, the role of processes to control hazards, likely end-use of the product (for example, if hazards are associated with manufacturing process), categories of users of concern, and data suggestive of a system being out of control (for example, observation of system failure). The intent of the HACCP system is to focus control at CCPs. Redesign of the operation should be considered if a hazard which must be

controlled is identified but no CCPs are found. In complex systems, HACCP should be applied to each specific operation separately. CCPs identified in any given specific implementation might not be the only ones identified for a specific application or might be of a different nature; hence, HACCP will vary as a function of the system. The HACCP application should be reviewed and necessary changes made when any modification is made in the product, process, or any step. It is important when applying HACCP to be flexible where appropriate, given the context of the application, taking into account the nature and the size of the operation.

6.3.1 *Application of HACCP Principles*—Implementation of HACCP principles is captured in the Logic Sequence for Application of HACCP [Fig. 1].

6.3.1.1 Assemble HACCP team. Appropriate process-specific or material-specific knowledge and expertise must be available for the development of an effective HACCP plan. Optimally, this may be accomplished by assembling a multi-disciplinary team. Where such expertise is not available on site, expert advice should be obtained from other sources. The scope of the HACCP plan should be identified, including the general classes of hazards to be addressed (for example does it cover all classes of hazards or only selected classes).

6.3.1.2 Describe product or process. A full description of the product or process of concern should be developed.

6.3.1.3 Identify intended use. The intended use should be based on the expected uses of the product or services that will result from completion of an engineering project that may variously affect end users or consumers. In specific cases, vulnerable groups should be considered.

6.3.1.4 Construct flow diagram. The flow diagram should be constructed by the HACCP team. The flow diagram should cover all steps in the operation, for example, associated with a product, material, or engineering activity. When applying HACCP to a given operation, consideration should be given to steps preceding and following the specified operation.

6.3.1.5 On-site verification of flow diagram. The HACCP team should confirm the processing operation against the flow diagram during all stages of operation and amend the flow diagram where appropriate.

6.3.1.6 List all potential hazards associated with each step, conduct a hazard analysis, and consider any measures to control identified hazards as supported by Principle 1. The HACCP team should list all hazards that may be expected to occur at each step of the process, for example, from primary production, processing, manufacture, and distribution until the point of use. The HACCP team should next conduct a hazard analysis to identify and describe for the HACCP plan which hazards are of such a nature that their elimination or reduction to acceptable levels is essential to the production of product or to the engineering process. In conducting the hazard analysis, the following should be included whenever possible: the likely occurrence of hazards and severity of their adverse effects; the qualitative and/or quantitative evaluation of the presence of hazards; and conditions leading to the above. The HACCP team must then consider what control measures, if any, exist which can be applied for each hazard. More then one control measure may be required to control a specific hazard(s) and more than one hazard may be controlled by a specified control measure.

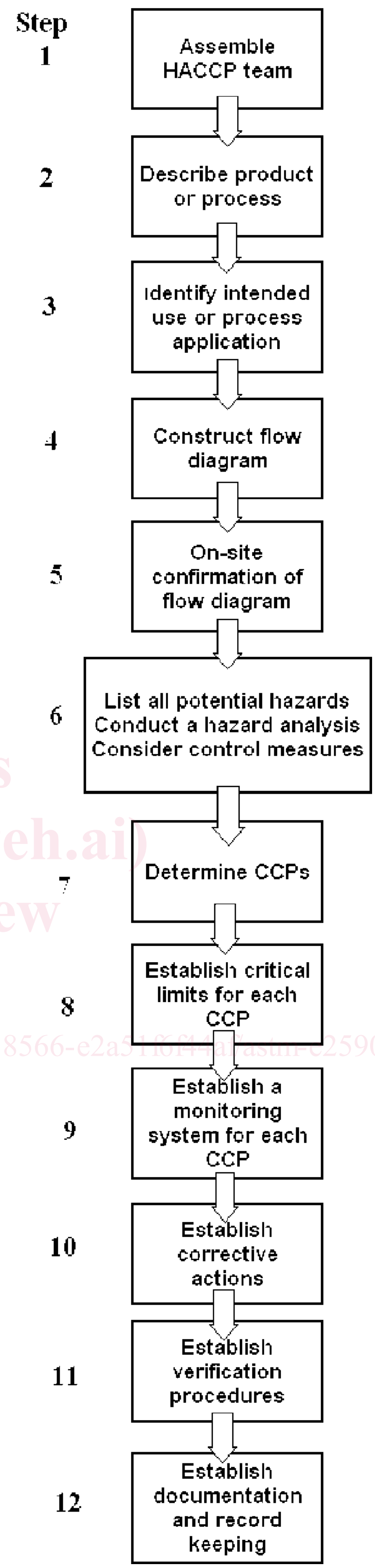

FIG. 1 Overview of HACCP Process

6.3.1.7 Determine Critical Control Points (CCP). There may be more than one CCP at which control is applied to address the same hazard. The determination of a CCP in the HACCP system can be facilitated by the application of a decision tree which indicates a logic reasoning approach, as illustrated in Annex 1. Application of a decision tree should be flexible, given whether the operation production or outcomes of the process being evaluated. The decision tree could be used for guidance when determining CCPs, although a decision tree may not be applicable to all situations. Other approaches may be used, and training in the application of the decision tree is recommended, if that approach to HACCP is pursued. If a hazard has been identified at a step where control is necessary for safety, and no control measure exists at that step, or any other, then the product or process should be modified at that step, or at any earlier or later stage, to include a control measure.

6.3.1.8 Establish critical limits for each CCP. Limits must be specified and validated if possible for each CCP. In some cases more than one critical limit will be elaborated at a particular step. Criteria may capture upper and/or lower bounds of acceptable performance, and may be specified by indicators benchmarked on past performance.

6.3.1.9 Establish a monitoring system for each CCP. Monitoring is the scheduled measurement or observation of a CCP relative to its critical limits. The monitoring procedures must be able to detect loss of control at the CCP. Further, monitoring should ideally provide data in real-time to make adjustments to ensure control of the process to prevent violating the critical limits. Where possible, process adjustments should be made when monitoring results indicate a trend towards loss of control at a CCP. The adjustments should be taken before a deviation occurs. Data derived from monitoring must be evaluated by a designated person with knowledge and authority to carry out corrective actions when indicated. If monitoring is not continuous, then the amount or frequency of monitoring must be sufficient to guarantee the CCP d in control. Most monitoring procedures for CCPs will need to be done rapidly because they relate to on-line processes or real-time activities that may not allow for lengthy analytical testing. All records and documents associated with monitoring CCPs must be signed by the person(s) doing the monitoring and by a responsible reviewing official(s).

6.3.1.10 Establish corrective actions. Specific corrective actions must be developed for each CCP in the HACCP system in order to deal with deviations when they occur. The actions must ensure that the CCP has been brought under control, including actions that must be taken for proper disposition of the affected product, for example, in the food industry. Deviation and product disposition procedures must be documented in the HACCP record keeping similar in practice to establishing risk management practices wherein acceptable risk is characterized.

6.3.1.11 Establish verification procedures. Establish procedures for verification. Verification and auditing methods, procedures and tests, including random sampling and analysis, can be used to determine if the HACCP system is working correctly. The frequency of verification should be sufficient to confirm that the HACCP system is working effectively. Examples of verification activities include: review of the HACCP system and its records; review of deviations and product dispositions; confirmation that CCPs are kept under control. Where possible, validation activities should include actions to confirm the efficacy of all elements of the HACCP plan.

6.3.1.12 Establish documentation and record keeping. Efficient and accurate record keeping is essential to the application of an HACCP system. HACCP procedures should be documented. Documentation and record keeping should be appropriate to the nature and size of the operation. Documentation examples are hazard analysis; CCP determination; Critical limit determination. Record examples are: CCP monitoring activities; Deviations and associated corrective actions; Modifications to the HACCP system.

6.4 *Expanded Characterization of HACCP Process*—The first task in the application of HACCP is to assemble a team having the knowledge and expertise to develop an HACCP plan. The team should be multidisciplinary and should represent a blend of expertise and experience. The assembled team will collect, collate and evaluate technical data and identify hazards and critical control points. One person may fulfill several roles or even constitute the whole team, in which case the use of external consultants or advice may be necessary. The team should include personnel who are directly involved in daily activities related to the hazards of concern, since these individuals will be more familiar with the specific variability and limitations of the operation or materials in question. The HACCP team may require independent outside experts to advise on identified issues or problem areas; however, complete reliance on outside sources is not recommended in developing the HACCP plan. Ideally the team should not be larger than six, although for some implementations of HACCP, it may be necessary to develop larger teams.

6.4.1 *Team Composition*—When selecting the team, the coordinator should focus on those who will be involved in hazard identification, those who will be involved in determination of critical control points, those who will monitor critical control points, those who will verify operations at critical control points, those who will examine samples and perform verification procedures.

6.4.2 *Knowledge Required*—In addition to knowledge of HACCP principles and techniques, personnel participating as part of the HACCP team should have a basic understanding of technology and procedures characteristic of the process or material that initiated the HACCP evaluation, as well as a basic understanding of the particular hazard(s) that the plan will address.

6.4.3 *Scope*—One of the first tasks of the HACCP team should be to identify the scope of the HACCP plan. The team should limit the study to a specific material and process, define the type(s) of hazards to be included (for example biological, chemical, physical), define the system or part of the system to be studied.

6.4.4 *Coordinator*—The team must include a coordinator (chairperson) whose role is to ensure that the composition of the team meets the needs of the study, suggest changes to the team if necessary, coordinate the team's work, ensure that the

agreed established plan is followed, share the work and responsibilities, ensure that a systematic approach is used, ensure that the scope of the study is met, chair meetings so that team members can freely express their ideas, represent the team before management, provide management with an estimate of the time, money and labor required for the study.

6.4.5 *Develop a Flow Diagram*—It is easier to identify hazards and CCPs to suggest methods of control and to discuss these among the HACCP team if there is a flow diagram of the system linked to the hazard of interest. The review of the flow of materials or the process in the system from the beginning to end is the feature that makes HACCP a specific and important tool for the identification and control of potential hazards. A process flow diagram should be constructed following interviews, observation of operations and other sources of information, for example, such as engineering design or field operations manuals. The process flow diagram will identify the important process steps used in the production of the specific material or specific operation being assessed. There should be enough detail to be useful in hazard identification, but not so much as to overburden the plan with less important points.

6.4.6 *Hazard Analysis*—Hazard analysis is the first HACCP principle, and is one of the most important tasks of HACCP. An inaccurate hazard analysis would inevitably lead to the development of an inadequate HACCP plan. Hazard analysis requires technical expertise and scientific background in various domains for proper identification of all potential hazards.

6.4.7 *Critical Control Points and Critical Limits*—At each CCP critical limits are established and specified. Critical limits are defined as criteria that separate acceptability from unacceptability. A critical limit represents the boundaries that are used to judge whether a process is producing materials or conducting specific operations in a safe manner. Critical limits may be set for factors, for example, such as temperature, time (minimum time exposure), physical dimensions, as these attributes affect system performance. These parameters, if maintained within boundaries, will confirm the safety of the system of interest.

6.4.8 *Monitoring*—Monitoring is the process that users rely upon to show that the HACCP plan is being followed. It provides the user with accurate records that demonstrate that the conditions of system are in compliance with the HACCP plan. Ideally, monitoring should provide information in time to allow any adjustments to the process, thus preventing loss of control of the process and critical limits being exceeded. In practice, operating limits are often used to provide a safety margin which allows extra time to adjust the process before the critical limit is exceeded. There are many ways to monitor the critical limits of a CCP. Monitoring can be done on a continuous (100 percent) or batch basis. When feasible, continuous monitoring is preferred, since it is more reliable. Continuous monitoring is designed to detect shifts around target levels, thus allowing correction of these shifts and preventing deviation beyond the critical limits. When monitoring is not continuous, the amount and frequency of monitoring should be sufficient to provide an acceptable level of assurance that the CCP is under control. The higher the frequency of monitoring (i.e. the less time between each instance of monitoring), the less system performance will be affected when there is a loss of control at the CCP. A further consideration when establishing a monitoring system is the time taken to achieve a result from the monitoring procedure. Most monitoring procedures will need to be rapid, since time for lengthy analytical testing may not be practical. For this reason physical and chemical measurements or visual observations, which may be done rapidly, are often preferred as monitoring tools. If analytical instrumentation is used in a monitoring program, it is essential that all monitoring equipment be properly calibrated for accuracy. Monitoring procedures performed during the operation should result in written documentation which will serve as an accurate record of the operating conditions. Monitoring records provide information on conditions during the operation and allow for action to be taken in the event of a loss of control or for a process adjustment to be made if there is a trend towards a loss of control. Accurate monitoring procedures and associated records provide information to the operator and allow for decisions to be made on the acceptability of the lot at a particular stage in the process. To complete the monitoring process, data derived from monitoring should be reviewed and evaluated by a designated person or persons with knowledge and authority to carry out corrective actions when indicated. The worst scenario is that in which monitoring procedures indicate that any one of the critical limits is exceeded, which indicates loss of control of a CCP. This lack of control is considered to be a deviation resulting in the production of a hazardous or unsafe product. The situation requires immediate identification and control of the affected product and corrective action. Responsibility for monitoring should be clearly defined, and individuals must be adequately trained in the monitoring procedures for the CCP for which they are responsible. They must also fully understand the purpose and importance of monitoring. The individual should have ready access to the monitoring activity, must be unbiased in monitoring and must accurately report the monitoring activity.

6.4.9 *Design of a Monitoring System and Establishing Corrective Actions*—Loss of control is considered as a deviation from a critical limit for a CCP. Deviation procedures are a predetermined and documented set of actions to be implemented when a deviation occurs. All deviations must be controlled by taking action(s) to control the non-compliant product or process and to correct the cause of non-compliance. Product or process control includes proper identification, control and disposition of the variance. The control and disposition of the variance and the corrective action(s) taken must be recorded and filed. The diversity of possible deviations at each CCP means that more than one corrective action may be necessary at each CCP. When a deviation occurs, it will most likely be noticed during the routine monitoring of the CCP. Deviation and corrective action procedures are prescribed so that employees responsible for CCP monitoring understand and are able to perform the appropriate corrective action(s) in the event of a deviation. Process adjustments should also be made when monitoring results indicate a trend towards loss of control at a CCP. Action should be taken to bring the process