Examples of CCP's may include, but are not limited to: cooking, chilling, specific sanitation procedures, product formulation controls, prevention of cross contamination, and certain aspects of employee and environmental hygiene. All CCP's must be carefully developed and documented.

Consistent with the principles of the NACMCF, FSIS is proposing to require that establishments identify CCP's for food safety hazards in their HACCP plans. All three types of hazards (physical, chemical and biological, including microbiological) must be addressed and controlled.

FSIS believes that implementation of mandatory HACCP, in conjunction with related changes described elsewhere in this document, will result in less risk of foodborne illness being associated with these products. Therefore, identification of CCP's throughout the production process for controlling microbial hazards is particularly important.

Principle No. 3: Establish critical limits for preventive measures associated with each identified CCP.

A critical limit is defined as a criterion that must be met for each preventive measure associated with a CCP. Another way of considering critical limits is that they serve as boundaries of safety for each CCP.

Critical limits are most often based on process parameters, such as temperature, time, physical dimensions, humidity, moisture level, water activity, pH, titratable acidity, salt concentration, available chlorine, viscosity, preservatives, or sensory information, such as texture, aroma, or visual appearance in relation to the growth or survival of target pathogens or chemical or physical hazards. Establishment of critical limits should be justifiable in relation to knowledge available from such sources as the meat and poultry regulations or guidelines, literature, surveys, experimental studies, or from recognized experts in the industry, academia, or trade associations.

In accordance with the principles set forth by NACMCF, FSIS is proposing that processors identify critical limits in their HACCP plans that must be met at each CCP to be certain that the hazard is controlled. Critical limits must reflect relevant FSIS regulations, FDA tolerances, and action levels where appropriate. Processing establishments are encouraged to establish critical limits more stringent than those now in FSIS regulations or related documents to ensure that regulatory requirements are routinely met even when deviations occur. If critical limits more stringent than regulatory limits or requirements are set, then the establishment must meet those more stringent limits.

Principle No. 4: Establish CCP monitoring requirements. Establish procedures for using the results of monitoring to adjust the process and maintain control.

Monitoring is observations or measurements taken to assess whether a CCP is under control. Monitoring is used to determine when a deviation occurs at a CCP; therefore, monitoring procedures must be effective. There are many ways to monitor CCP critical limits on a continuous or batch basis; however, continuous monitoring is always preferred. When continuous monitoring is not feasible, frequencies must be sufficient to ensure that the CCP is under control. Statistically designed data collection or sampling plans need to be developed in such instances.

Assignment of the responsibility for monitoring is an important consideration for each CCP. Personnel assigned the monitoring activities must be properly trained to report all results, including any unusual occurrences, so that adjustments can be made and any processes or products that do not meet critical limits are identified so that immediate corrective actions may be taken.

Monitoring activities are necessary to assure that the process is in fact under control at each critical control point. Some monitoring procedures could be accomplished by automatic instruments and devices such as time/temperature recording devices. Some monitoring procedures could consist of checks performed, with outcomes recorded. Other monitoring procedures might involve rapid testing technologies that provide feedback within appropriate time frames, for example, the use of quick tests to verify levels of chlorine in poultry chillers.

HACCP requires establishments to systematically monitor, control, and, where necessary, adjust their production processes to meet a specified standard. Process monitoring may necessitate materials or devices to measure, test, or otherwise evaluate the process at critical control points. Examples would be such items as thermometers and test kits.

FSIS is proposing to require that procedures for monitoring each CCP be identified in the HACCP plan. These monitoring procedures should assure that the monitoring systems are capable of detecting process deviations, including product segregation and holding procedures, effect of deviations on product safety, indicators for modification of the HACCP plan, and the establishment employee responsible for monitoring activities.

Principle No. 5: Establish corrective action to be taken when monitoring indicates that there is a deviation from an established critical limit.

A HACCP system is designed to identify potential health hazards and to establish strategies to prevent their occurrence. However, ideal circumstances will not always prevail in a processing operation and deviations will occur. In such instances, the NACMCF points out that corrective action plans must be in place to: (1) determine the disposition of the non-compliant product and (2) identify and correct the cause of the deviation to regain control of the CCP. Individuals who have a thorough understanding of the process, product, and HACCP plan should be identified and assigned responsibility for making decisions. When appropriate, scientific experts must be consulted to determine disposition of the product.

FSIS is proposing to require that establishments describe in their HACCP plans the corrective actions that will be taken if a critical limit is not met. Corrective actions must be specified in sufficient detail to ensure that no public health hazard exists after these actions have been taken. Although the process of developing a HACCP plan emphasizes organized and preventive thinking about what is occurring as the meat or poultry product is being manufactured, the existence of a HACCP plan does not guarantee that problems will not arise. For this reason, the identification of a planned set of activities to address deviations is an important part of a HACCP plan.

Principle No. 6: Establish effective recordkeeping procedures that document the HACCP system.

The NACMCF points out that an establishment's HACCP plan and all associated records must be maintained on file at the establishment, and provides several examples of records that could be maintained, such as those relating to incoming ingredients, product safety, processing, packaging, storage, and distribution, deviations and corrective actions, and employee training.

A HACCP system will not work unless records are generated during the operation of the plan, and those records are maintained and available for review. One of the principal benefits of a HACCP process control system to both industry and regulatory officials is the availability of objective, relevant data. Thus, FSIS is proposing to require that the HACCP plan provide for a recordkeeping system that will