generic plans will assist in assuring the basic level of uniformity necessary to have inspection activities based on establishment HACCP plans, and that the provision of generic models will help to communicate the level of detail expected in the elements of the plan. FSIS also believes that generic models can help identify the kinds of hazards that should be considered at various CCP's, without interfering with the establishment's hazard analysis.

(b) NACMCF Materials: FŠIS is publishing and will make widely available guidance materials developed by NACMCF describing the optimum steps to be followed in developing HACCP plans. In addition, FSIS is currently exploring the most effective and economical approach to developing a HACCP videotape.

(c) Computer Packages: FSIS is aware of commercially available software programs that might assist food processors in developing HACCP plans. FSIS has made a commitment to work with companies developing these programs to make them more applicable to meat and poultry processes.

2. Discussion of HACCP Proposal Regulatory Considerations

Process control is neither FSIS's responsibility nor a shared responsibility between the Agency and industry. Each USDA inspected establishment must assume full responsibility for making safe and wholesome products. FSIS is responsible for assuring that products in marketplace distribution are unadulterated, wholesome, and accurately labeled. From a public health perspective, the more that industry process controls anticipate and prevent problems, the less likely products produced under such systems are to become adulterated.

HACCP is not an inspection system; it is an industry process control system that provides opportunities to make inspection more effective. Currently, FSIS performs inspection by having inspectors generate information about the establishment's production process and environment to evaluate the conditions under which meat and poultry products are being produced. This activity permits oversight of establishment efforts at the time of inspection. In contrast to this relatively small amount of information, HACCP records will enable inspectors to see how the establishment's processes have operated on a continuing basis over time. The Program employee will be able to determine whether problems have occurred and, if so, how they were addressed.

In addition to providing a greater quantity of information and in effect extending the scope of regulatory observations, the presence of functional HACCP plans for all products and processes will also produce more relevant data. This is because the monitoring and recordkeeping requirements of a HACCP plan are organized around identified hazards, CCP's, critical limits, and the actions taken to ensure that defects are corrected before they become a risk. Finally, HACCP systems will yield data that are more objective and more scientific.

(1) Definitions

For the purposes of this discussion and within this proposed rule, FSIS has adopted some definitions of terms related to HACCP and HACCP systems from the NACMCF in the publication titled "Hazard Analysis and Critical Control Point System," dated March 20, 1992; these definitions are noted by "*" Other definitions are specific to FSIS and its activities.

Corrective action. Procedures to be followed when a deviation occurs.*

Criterion. A requirement on which a judgment or decision can be based.*

Critical Control Point (CCP). A point, step, or procedure at which control can be applied and a food safety hazard can be prevented, eliminated, or reduced to acceptable levels.*

Critical Control Point (CCP) failure. Inadequate control at a CCP resulting in an unacceptable risk of a hazard.

Critical limit. A criterion that must be met for each preventive measure associated with a CCP.*

Deviation. Failure to meet a critical imit.*

HACCP. A hazard analysis and critical control point system (HACCP) that identifies specific hazards and preventive measures for their control to ensure the safety of food.

HACCP plan. The written document which is based upon the principles of HACCP and which delineates the procedures to be followed to assure the control of a specific process or procedure.*

HACCP-trained individual. A person who has successfully completed a recognized HACCP course in the application of HACCP principles to meat and poultry processing operations, and who is employed by the establishment. A HACCP-trained individual must have sufficient experience and training in the technical aspects of food processing and the principles of HACCP to determine whether a specific HACCP plan is appropriate to the process in question.

HACCP system. The result of the implementation of the HACCP plan.*

Hazard. A biological, chemical, or physical property that may cause a food to be unsafe for consumption.*

Hazard Analysis. The identification of any biological, chemical, or physical properties in raw materials and processing steps and an assessment of their likely occurrence and seriousness to cause the food to be unsafe for consumption.

Monitor. To conduct a planned sequence of observations or measurements to assess whether a CCP is under control and to produce an accurate record for future use in verification.*

Preventive measures. Physical, chemical, or other factors that can be used to control an identified health hazard.*

Process. A procedure consisting of any number of separate, distinct, and ordered operations that are directly under the control of the establishment employed in the manufacture of a specific product, or a group of two or more products wherein all CCP's are identical, except that optional operations or CCP's, such as packaging, may be applied to one or more of those products within the group.

Product. Any carcass, meat, meat byproduct, or meat food product, poultry, or poultry food product capable of use as human food.

Recognized HACCP course. A HACCP course available to meat and poultry industry employees, which satisfies the following: consists of at least three days, one day devoted to understanding the seven principles of HACCP, one day devoted to applying these concepts to this and other regulatory requirements of FSIS, and one day devoted to beginning development of a HACCP plan for a specified process.

Responsible Establishment Official. The management official located on-site at the establishment who is responsible for the establishment's compliance with this part.

Validation. An analysis of verification procedures, HACCP plan components, and an evaluation of records associated with the HACCP system to determine its efficacy for the production of wholesome product for which the process was designed.

Verification. The use of methods, procedures, or tests in addition to those used in monitoring to determine if the HACCP system is in compliance with the HACCP plan and/or whether the HACCP plan needs modification and revalidation.*