

document the establishment's CCP monitoring, verification activities, and deviation records. FSIS has also concluded that recordkeeping systems are much more effective when they include the actual values obtained, as opposed to terms such as "satisfactory" or "unsatisfactory," which reflect a judgment about the values and do not permit trend analysis.

*Principle No. 7:* Establish procedures to verify that the HACCP system is working correctly.

The NACMCF defines verification as the use of methods, procedures, or tests in addition to those used for monitoring, to determine if the HACCP system is in compliance with the HACCP plan and/or whether the HACCP plan needs modification and revalidation. Four processes are identified as steps in the establishment's verification of its HACCP system.

The first process is the scientific and technical process to verify that all critical limits at CCP's are adequate and sufficient to control hazards that are likely to occur in their specific process(es). This is commonly referred to as "validating" the process.

The second process is to ensure that the HACCP plan functions properly. Establishments should rely on frequent reviews of their HACCP plan, verification that the HACCP plan is being correctly followed, review of CCP records, and determinations that appropriate management decisions and product dispositions are made when deviations occur.

The third process consists of documented periodic reviews to ensure the accuracy of the HACCP plan. Such reviews should include an on-site review and verification of all flow diagrams, CCPs, critical limits, monitoring procedures, corrective actions, and records maintained.

The fourth and final verification process deals with the regulatory agency's responsibility and actions to ensure that the establishment's HACCP system is functioning satisfactorily. This verification can be viewed as an overall process validation and can consist of any and all of the verification activities mentioned above, plus final product testing to demonstrate compliance with regulatory as well as other desired performance standards.

FSIS is proposing to require that the HACCP plan include a set of verification tasks to be performed by establishment personnel. Verification tasks will also be performed by FSIS personnel. However, an important benefit of HACCP is for establishments to take full responsibility for producing a safe product. Thus, it is envisioned that establishments, as well

as the regulatory agency, will undertake final product testing as one of several verification activities. Verification tasks provide an opportunity to demonstrate that a well-functioning HACCP system is in fact controlling a process so that safe product is being produced under conditions that minimize preventable risks.

The verification principle also links HACCP with the key element of the FSIS regulatory strategy for pathogenic microorganisms, which is the establishment of public health-oriented targets, guidelines, or standards. Establishments must meet to engage in commerce. Without some objective measure of what constitutes an acceptable level of food safety performance with respect to pathogenic microorganisms, it would be impossible to determine whether an establishment's HACCP plan is acceptable and functioning effectively. FSIS is taking the first step toward implementation of such objective measures with the proposed interim targets for pathogen reduction, which focus on *Salmonella*. As data become available, these targets will be refined, and possibly expanded in slaughter operations and extended in processing operations, to support the Agency's implementation of HACCP. Verification might well include required microbial testing for all processes and species. Eventually, such testing can be expected to be an integral part of HACCP verification.

#### *FSIS Experience With HACCP*

##### *(1) FSIS HACCP Study, 1990–1992.*

In 1990, FSIS initiated a study of HACCP that focused on how this system of process control could be applied within the meat and poultry industries and what the implications might be for regulatory inspection activities. This study was not designed to establish the efficacy or benefit of the HACCP approach as a process control system. Recognition of HACCP as a proven method for preventing and controlling food safety hazards has been achieved through practical application of the concepts to food production operations since 1971.

Recognizing that acceptance of HACCP within the meat and poultry industries would be dependent on a broad range of constituent support, the FSIS study involved consultations and public hearings; technical workshops with representatives of industry, academia, and trade associations to develop generic HACCP models; and testing and evaluation of in-plant trials through case studies. In-plant testing involved operational application of generic models for refrigerated foods,

cooked sausage, and poultry slaughter in nine volunteer establishments.

The study underscored the significance of the change in roles and responsibilities that use of a HACCP system brings both to the regulated industry and to the inspection service. This finding would later be supported by observations at a Round Table meeting on HACCP in 1994 that successful HACCP implementation will demand a culture change within the inspection service and within the industry. Additionally, the Agency's earlier experiences with HACCP-based regulations, such as those for low-acid canned foods, cooked roast beef, and, more recently, for cooked, uncured patties had demonstrated the advisability of technical collaboration. The study experience confirmed these earlier conclusions that technical collaboration was essential to successful implementation of HACCP.

##### *(2) HACCP Round Table, 1994.*

FSIS was proceeding during 1993 to develop a HACCP regulation when a group of concerned constituent organizations requested greater pre-proposal involvement and public consultations prior to publication of proposed regulations. USDA agreed to have a public event at which the application of HACCP in the meat and poultry industry could be discussed. This event became known as the HACCP Round Table.

On March 30 and March 31, 1994, FSIS held a two-day Round Table meeting in Washington, D.C. Participants in the Round Table were primarily selected by a procedure announced in the **Federal Register** on January 13, 1994. Participants included public health officials, representatives from the meat and poultry industry, consumer groups, scientists and professional scientific organizations, producer and farmer groups, USDA and other Federal, State, and local employees. Prior to the Round Table, a steering committee of nine of the Round Table participants determined the key issues to be addressed during the forum. For each key issue, a particular question was developed to focus the deliberations. Each issue, question, and deliberation is summarized below. FSIS's views on those issues addressed by this regulation are covered under "Discussion of HACCP Proposal" below. A report on the HACCP Round Table has been published and is available from the FSIS Docket Clerk at the address provided under **ADDRESSES**.

*HACCP Plan Approval:* What is the best way to ensure that HACCP plans effectively incorporate the seven HACCP principles?