records it generates are a reflection of what has occurred during processing of products, that deviations have elicited appropriate responses, and that continually complying products have been produced. Whenever any of these conditions are not met, the plan will be judged to need revision and revalidation.

In essence, establishment-specific HACCP plans will be developed, reviewed, and validated at the establishment level on a continuing basis, with activities by both establishment and Program employees. This has emerged as the most viable and efficient approach for both the Agency and industry.

Responding to Deviations From Critical Limits

FSIS is proposing to require that deviations from critical limits trigger a prescribed set of actions by an establishment.

First, under this proposed provision, product affected by the deviation from the critical limit must be segregated and held until the significance of the deviation can be determined. Second, the establishment must make the necessary determination of the effect of the deviation on product safety. This determination must be made in consultation with a HACCP-trained individual and any other subject-matter experts needed to deal with the deviation in question. In consultation with this person or team, the establishment should also determine whether the deviation reveals the need to modify either the process itself or the HACCP plan

Finally, FSIS is proposing to require that establishments record all steps taken in response to a deviation from a critical limit and include that information as part of the HACCP record. Documentation of deviations should be brought to the attention of FSIS personnel.

## HACCP Recordkeeping

Maintenance of accurate HACCP records is fundamental to a HACCP system and is the cornerstone of its usefulness to regulators. Therefore, FSIS is proposing to require that these records contain certain necessary information; that the records be systematically reviewed by the establishment; that the records be maintained for a specific period of time; and that FSIS Program personnel be given access to these records.

First, FSIS is proposing that the records involving measurements during slaughter and processing, corrective actions, verification check results, and

related activities contain the identity of the product, the product code or slaughter production lot, and the date the record was made. The purpose of this proposed requirement is to assure that both the establishment and the regulator can readily link a record to a product and the period during which the product was processed. FSIS is also proposing to require that the information be recorded at the time that it is observed and that the record be signed by the operator or observer.

Second, FSIS is proposing to require that the HACCP records associated with the product to be shipped be reviewed by an establishment employee other than the one who produced the record, before the product is distributed in commerce. The purpose of this review is to verify that the HACCP system has been in operation during the production of the product, that it has functioned as designed, and that the establishment is taking full responsibility for the product meeting applicable food safety regulatory requirements. If a HACCPtrained individual is on-site, that person should be this second reviewer. The reviewer should sign the records. FSIS program personnel will be performing similar reviews of HACCP records on a regular basis, but their oversight cannot be substituted for the establishment's review

Third, FSIS is proposing that HACCP records generated by the establishment be retained on site for at least one year and for an additional two years on-site or at another location. HACCP records will be necessary in the revalidation process. Further, FSIS' experience with other recordkeeping requirements indicates this is a manageable time frame. FSIS invites comments on the appropriateness of these records retention requirements.

Finally, FSIS is proposing to require that HACCP plans and records be available for review and copying by program personnel at reasonable times. Industry records are reviewed by Program personnel as part of their assigned tasks. Comprehensive records access is necessary to permit verification of all aspects of a HACCP system. However, FSIS does not intend to routinely copy or take possession of such records. It is the Agency's intent to generate its own records of its verification tasks and results rather than duplicate the records of the establishment. Data collection instruments for program employee verification tasks are being developed and will become the Agency's verification record that the HACCP system is functioning as intended.

Extensive copying of records is anticipated only in cases where there was evidence of non-compliance with requirements or deviations from critical limits that resulted in product safety problems. In such instances, complete access to all pertinent records would be necessary. FSIS invites comments on this issue.

## Training

There is significant interest by the Agency in HACCP training for Agency and industry personnel. FSIS takes full responsibility for the training of its own personnel within time frames that permit the orderly implementation of HACCP. The Agency's interest in HACCP training for the regulated industry is based on the need to assure that both industry and Agency personnel are receiving training that is founded on a single vision of HACCP and how it is to operate.

Two areas concerning training requirements were considered by the Agency in determining how training for HACCP-trained individuals should be evaluated: The availability of training and whether to require acceptance or accreditation for training programs.

Upon review the Agency determined that there are a number of options for the industry when selecting the appropriate training course for their employee(s). Among these are courses offered by industry trade associations, such as AMI, the National Food Processors' Association, and others. Academia also offers courses in HACCP principles and application. Groups such as the HACCP Alliance, The National Center for Food Safety and Technology, and accredited universities are among the available sources for HACCP training. Private consultants and consulting firms also offer HACCP training. Other available resources include a list of HACCP courses prepared by USDA's Extension Service. These training sources are all available to the regulated industry although the cost, length, and to some extent, the content of these courses differ. Recognizing that there are differing needs for technical knowledge and ability to pay for these courses among the regulated industry, FSIS has determined that each responsible establishment official should be responsible for deciding which provider of training best meets the establishment's needs.

A second concern is whether the Agency should stipulate that the courses taken by a HACCP-trained individual be subject to acceptance or accreditation. This accreditation could be conducted by the Agency, by an outside body (e.g.,