a HACCP plan for a specified process. As discussed below, the Agency expects that many organizations will be knowledgeable about such courses and may serve as legitimate sources of such training. It is the responsibility of the establishment sending its employee(s) to a particular training course to ascertain that the course meets the minimum requirements described above.

FSIS is aware that, through industrysponsored training courses, several hundred industry employees have already received the necessary training. It is not expected that such training needs to be repeated. Individuals who previously received HACCP training should be able to supplement their knowledge through guidelines and informational materials made available by FSIS, NACMCF, professional associations, and trade associations. FSIS invites comments on this approach for supplementing knowledge levels of previously trained individuals. In cases where a consulting expert serves as the HACCP-trained individual for an establishment, it is the responsibility of the establishment to assure that this individual has the requisite training.

FSIS is also proposing that the HACCP-trained individual participate in the hazard analysis and subsequent development of the HACCP plans, and assist in addressing product safety in situations where there have been deviations from critical limits and judgment is needed to determine the adequacy of the response. HACCPtrained individuals must also be available to establishments to participate in plan modification and revalidation. FSIS does not believe it needs to prescribe details about the hours or days on which the HACCPtrained individual is to be on establishment premises, or what should be done in establishments having multishift operations, other than to require that the HACCP-trained individual be available to the establishment to accomplish the prescribed role. FSIS is proposing that the establishment have on file the name and a brief resume of the HACCP-trained individual on whom it is relying.

The Ågency has determined that a HACCP-trained individual must be employed by each establishment. This individual will be responsible for addressing and performing functions related to hazard analysis, plan development, plan validation, review and assessment of critical limits, and responses to deviations. The HACCP trained individual will be pivotal in an establishment's ability to successfully assure process control in an operational HACCP system. The Agency recognizes that employment of a HACCP trained individual could also be accomplished through acquisition of the services of a HACCP consultant. The Agency does not intend to be overly prescriptive by specifying the conditions of employment between the establishment and the HACCP trained individual. It is, however, the determination of the Agency that the services of a HACCPtrained individual able to carry out the activities described above is essential to successful operation of a HACCP system. Comments are invited on this approach.

This proposed requirement for involvement by a HACCP-trained individual is an alternative to requiring that there be such an individual in each establishment. FSIS recognizes that, for many establishments, securing HACCP expertise by training one employee in a recognized HACCP course is the best means to meet this requirement. Comments are invited on this approach.

(6) Hazard Analysis

FSIS believes that success in HACCP plan development is founded on a hazard analysis that is thorough and forces the establishment to critically think about and analyze its processes. Guidance materials prepared by the NACMCF for carrying out Principle 1 address this issue. Especially for establishments without HACCP experience, this is a critical and challenging first step. Because FSIS is concerned that each establishment properly begin its application of the concepts of HACCP, the Agency is proposing to specify a time frame prior to the due date for any HACCP plan, during which hazard analysis should be conducted.

The proposed time frame is six months; this means that six months before any HACCP plan is required to be completed, establishments should begin the hazard analysis process. Activities constituting the hazard analysis include: accurately and completely describing product composition, developing a flow diagram, listing of all hazards associated with each processing step, and collecting of necessary scientific data to assess and validate the effectiveness and variability of process controls. During the six-month hazard analysis period, there should be regular meetings between inspection personnel and the establishment HACCP team on the subject of the hazard analysis.

Once the hazard analysis has been completed, it is expected that identification of CCP's will begin and the activities related to the remaining principles will be carried out so that the plan can be ready and validated by the due date.

In only one circumstance will Program employees be expected to report on the progress of these establishment activities with respect to plan development; that is, if there has been no effort to initiate hazard analysis, and the subsequent application of remaining HACCP principles, at least one month prior to the due date for the HACCP plan. FSIS believes that, in such a circumstance, there is a considerable likelihood that the plan will be insufficient and that regulatory action will be necessary. Therefore, Program employees will report such a situation through their supervisory channels. FSIS invites comment on this particular feature of the proposed implementation schedule.

(7) Establishment-Specific HACCP Plan Acceptance

The question of HACCP plan acceptance has been long and thoroughly considered by the Agency. In reviewing various options, the Agency has maintained several objectives:

• Any acceptance system should not include a requirement that HACCP plans be physically forwarded to the Agency and remain in its possession at one or a few central locations.

• The acceptance system must accommodate varying establishmentspecific HACCP plans for similar products, but maintain uniformity on basic standards.

• The acceptance system should involve Agency in-plant Program employees to the maximum extent possible, after they have been provided the requisite education and training in HACCP.

The Agency gave serious consideration to requiring formal plan acceptance prior to full plan operation, either by formal FSIS approval or by an "expert" computer system. However, advice from colleagues at FDA suggested that any system of acceptance prior to operational validation was likely to be administratively complex and irrelevant to successful implementation. Therefore, the Agency has decided that plan acceptance will not be a one-time administrative event but a process. Successful process control, as evidenced by the existence of a plan having all the features required by the seven principles plus the capacity of the plan to result in production of complying products, will mean that the plan is acceptable.

Inspection activities will be designed to verify that the plan has all the required features, that the plan and the