argued that contracting for the development of a HACCP plan by a professional consultant could be more efficient and cost effective, especially for many small companies. Related comments pointed out that some of the proposed functions of the trained individual either did not require a person to be onsite continually (e.g., plan development) or required expertise that could not realistically be obtained in a 3-day course (e.g., making decisions about whether product that has been subject to a deviation is safe to release into commerce).

While the agency considers training employees to be preferable to hiring outside consultants in terms of fostering the appropriate corporate culture and commitment to HACCP, FDA recognizes the importance of ensuring the flexibility that firms, especially small businesses, may need to comply with the regulations in a cost-effective manner. The agency also accepts that for some processors, the expertise that may be needed from time to time could best be provided by an expert consultant. Consequently, the agency is modifying § 123.10 to read as follows: ''* * * the following functions shall be performed by an individual who has successfully completed a course of instruction * * *.'' The requirement that processors employ a trained individual has been eliminated. Moreover, FDA has modified § 123.10(c) to state, ''The trained individual need not be an employee of the processor.''

101. A number of comments asked whether the regulations would require a separate trained individual for each processing location of each company or just one per company.

FDA intends that the functions enumerated in § 123.10 be performed by a trained individual. The number of employees a processor must train, or the consultants that must be hired, in order to ensure that trained individuals perform these functions is left to the judgment of the processor. For some firms, one individual will be sufficient. Others will need to secure the services of more than one such individual, either as employees or as consultants. Whether these individuals are located at each facility, at a corporate headquarters, at a consulting firm, or at some combination of these arrangements is to be determined by each individual processor.

102. A few comments were concerned about the logistics of the routine functions that the agency proposed must be performed by someone with HACCP training (i.e., record review and deviation handling). Specifically, they argued that the proposed requirements would actually require each firm to have more than one trained individual because of work weeks that routinely exceed 40 hours, vacations, illnesses, and employee turnover. The consequence, the comments suggested, would drive up the cost of training.

FDA acknowledges that, for certain situations, these comments may be correct. However, the agency has made three changes in the final regulations to minimize this possibility. First, as stated above, a processor may hire trained consultants on an as-needed basis. Second, as discussed in the ''Verification'' section of the preamble, the regulations do not include the proposed requirement that a trained individual review monitoring records before the product to which the records relate is shipped. These final regulations require only a weekly review. As a result, the need to have a trained individual onsite every day has become substantially reduced. Third, as described below, FDA has decided not to require that the trained individual evaluate CL deviations and corrective actions. This modification reduces still further the need to have a trained individual onsite at all times. In addition, as described previously, the agency is allowing processors to employ individuals whose training has been obtained through on-the-job experience. Thus, for example, a processor that needs the services of two trained individuals could satisfy the requirements of these regulations by employing an individual who has been trained in an adequate course and a second individual who has apprenticed sufficiently with the first individual to have mastered the subject.

As a related matter, the provision in the final regulations that provides for the development of corrective action plans (see the ''Corrective Actions'' section of this preamble) could eliminate the need to bring an expert onto the scene in many instances in which corrective action is necessary. The processor may be able to follow the corrective action plan without having to rely on an expert or trained individual. This procedure could permit further savings.

103. Some comments suggested that there should be different categories of trained individuals, with different responsibilities. These comments, from individuals, processors, and trade associations, asserted that a firm should have one HACCP trained person capable of conducting or overseeing the routine operation of the HACCP program, but that this individual should not necessarily be responsible for designing a firm's HACCP plan or making complex scientific evaluations.

Another comment suggested that it was unrealistic to expect that a training program would provide the level of expertise necessary for a person to make a determination on whether a deviation may have rendered a product injurious to health or otherwise adulterated.

FDA generally agrees with these comments. It was never the agency's intent to limit the processor's use of experts to employees whose training included the course prescribed by these regulations, especially in the areas of HACCP plan development and the evaluation of CL deviations and corrective actions (i.e., making evaluations about whether product that has been subject to a deviation is safe to ship). While FDA is convinced that a short course in HACCP principles is important to the success of the overall program, the agency also recognizes that such a course has its limitations.

FDA has deleted the proposed requirement that the HACCP-trained individual be required to evaluate CL deviations and corrective actions to allow for the use of experts in other appropriate scientific disciplines that have not been trained in accordance with these regulations. For example, the agency does not expect that a processor will be able to determine the public health consequences of every possible deviation without the assistance of experts. The kind of expertise necessary would likely involve disciplines other than HACCP. Moreover, the agency agrees that it is unreasonable to expect that successful completion of a 3-day HACCP course alone would qualify an individual to make determinations about the safety of products involved in a CL failure. HACCP training in such a situation could only reasonably be expected to help ensure that appropriate corrective action measures are taken and recorded from a HACCP perspective. Consistent with this change, FDA has modified § 123.7(c)(2) to state that a determination of acceptability for distribution into commerce of products that may have been affected by a deviation must be made by individuals with the expertise to make such a determination, and that such individuals need not be those who meet the requirements of § 123.10.

Nonetheless, FDA expects that, at a minimum, an individual trained in accordance with these regulations will perform the verification function of reviewing records of corrective actions to ensure that they are complete, and that an appropriate corrective action was taken (i.e., one that was predetermined in the HACCP plan, or