complete and that these activities occurred in accordance with the processor’s written procedures. These reviews shall occur within a reasonable time after the records are made; and

(v) The following of procedures in §120.10 whenever any verification procedure, including the review of consumer complaints, establishes the need to take a corrective action; and

(vi) Additional process verification if required by §120.25.

(2) Records that document the calibration of process monitoring instruments, in accordance with paragraph (a)(1)(iv)(B) of this section, and the performance of any periodic end-product and in-process testing, in accordance with paragraph (a)(1)(iv)(C) of this section, are subject to the recordkeeping requirements of §120.12.

(b) Validation of the HACCP plan. Each processor shall validate that the HACCP plan is adequate to control food hazards that are reasonably likely to occur; this validation shall occur at least once within 12 months after implementation and at least annually thereafter or whenever any changes in the process occur that could affect the hazard analysis or alter the HACCP plan in any way. Such changes may include changes in the following: Raw materials or source of raw materials; product formulation; processing methods or systems, including computers and their software; packaging; finished product distribution systems; or the intended use or intended consumers of the finished product. The validation shall be performed by an individual or individuals who have been trained in accordance with §120.13, and, records documenting the validation shall be subject to the recordkeeping requirements of §120.12.

§ 120.12 Records.

(a) Required records. Each processor shall maintain the following records documenting the processor’s Hazard Analysis and Critical Control Point (HACCP) system:

(1) Records documenting the implementation of the sanitation standard operating procedures (SSOP’s) (see §120.6);

(2) The written hazard analysis required by §120.7;

(3) The written HACCP plan required by §120.8;

(4) Records documenting the ongoing application of the HACCP plan that include:

(i) Monitoring of critical control points and their critical limits, including the recording of actual times, temperatures, or other measurements, as prescribed in the HACCP plan; and

(ii) Corrective actions, including all actions taken in response to a deviation; and

(5) Records documenting verification of the HACCP system and validation of the HACCP plan or hazard analysis, as appropriate.

(b) General requirements. All records required by this part shall include:

(1) The name of the processor or importer and the location of the processor or importer, if the processor or importer has more than one location;

(2) The date and time of the activity that the record reflects, except that records required by paragraphs (a)(2), (a)(3), and (a)(5) of this section need not include the time;

(3) The signature or initials of the person performing the operation or creating the record; and
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§ 120.13

(a) Only an individual who has met the requirements of paragraph (b) of this section shall be responsible for the following functions:

(1) Developing the hazard analysis, including delineating control measures, as required by §120.7.

(2) Developing a Hazard Analysis and Critical Control Point (HACCP) plan that is appropriate for a specific processor, in order to meet the requirements of §120.8.

(3) Verifying and modifying the HACCP plan in accordance with the corrective action procedures specified in §120.10(b)(5) and the validation activities specified in §§120.11(b) and (c); and §120.7.

(4) Performing the record review required by §120.11(a)(1)(iv).

(b) The individual performing the functions listed in paragraph (a) of this section shall have successfully completed training in the application of HACCP principles to juice processing at least equivalent to that received under standardized curriculum recognized as adequate by the Food and Drug Administration, or shall be otherwise qualified through job experience to perform these functions. Job experience may qualify an individual to perform these functions if such experience

§ 120.13 Training.

(a) Only an individual who has met the requirements of paragraph (b) of this section shall be responsible for:

(1) Developing the hazard analysis, including delineating control measures, as required by §120.7.

(2) Developing a Hazard Analysis and Critical Control Point (HACCP) plan that is appropriate for a specific processor, in order to meet the requirements of §120.8.

(3) Verifying and modifying the HACCP plan in accordance with the corrective action procedures specified in §120.10(b)(5) and the validation activities specified in §§120.11(b) and (c); and §120.7.

(4) Performing the record review required by §120.11(a)(1)(iv).

(b) The individual performing the functions listed in paragraph (a) of this section shall have successfully completed training in the application of HACCP principles to juice processing at least equivalent to that received under standardized curriculum recognized as adequate by the Food and Drug Administration, or shall be otherwise qualified through job experience to perform these functions. Job experience may qualify an individual to perform these functions if such experience