

## Regulatory References for Verifying the Five HACCP Requirements

### Monitoring

417.2(c)(4) - List the procedures, and the frequency with which those procedures will be performed, that will be used to monitor each of the critical control points to ensure compliance with the critical limits.

### Verification

417.2(c)(7) - List the verification procedures, and the frequency with which those procedures will be performed, that the establishment will use in accordance with Sec. 417.4 of this part.

417.4(a)2(i)(ii)(iii) - Ongoing verification activities - Ongoing verification activities include, but are not limited to:

- (i) The calibration of process-monitoring instruments;
- (ii) Direct observations of monitoring activities and corrective actions; and
- (iii) The review of records generated and maintained in accordance with Sec. 417.5(a)(3) of this part.

### Recordkeeping

417.2(c)(6) Recordkeeping System - Provide for a recordkeeping system that documents the monitoring of the critical control points. The records shall contain the actual values and observations obtained during monitoring.

417.5(a)(1)(2) Supporting Documentation - (a) The establishment shall maintain the following records documenting the establishment's HACCP plan:

- (1) The written hazard analysis prescribed in Sec. 417.2(a) of this part, including all supporting documentation;
- (2) The written HACCP plan, including decision-making documents associated with the selection and development of CCPs and critical limits, and documents supporting both the monitoring and verification procedures selected and the frequency of those procedures.

417.5(a)(3) HACCP Records - Records documenting the monitoring of CCPs and their critical limits, including the recording of actual times, temperatures, or other quantifiable values, as prescribed in the establishment's HACCP plan; the calibration of process-monitoring instruments; corrective actions, including all actions taken in response to a deviation; verification procedures and results; product code(s), product name or identity, or slaughter production lot. Each of these records shall include the date the record was made.

417.5(b) Records Authenticity - Each entry on a record maintained under the HACCP plan shall be made at the time the specific event occurs and include the date and time recorded, and shall be signed or initialed by the establishment employee making the entry.

417.5(d) Computerized Records - Records maintained on computers. The use of records maintained on computers is acceptable, provided that appropriate controls are implemented to ensure the integrity of the electronic data and signatures.

417.5(e)(1)(2) Record Retention and Availability - (1) Establishments shall retain all records required by paragraph (a)(3) of this section as follows: for slaughter activities for at least one year; for refrigerated product, for at least one year; for frozen, preserved, or shelf-stable products, for at least two years. (2) Off-site storage of records required by paragraph (a)(3) of this section is permitted after six months, if such records can be retrieved and provided, on-site, within 24 hours of an FSIS employee's request.

417.5(c) Preshipment Review - Prior to shipping product, the establishment shall review the records associated with the production of that product, documented in accordance with this section, to ensure completeness, including the determination that all critical limits were met and, if appropriate, corrective actions were taken, including the proper disposition of product. Where practicable, this review shall be conducted, dated, and signed by an individual who did not produce the record(s), preferably by someone trained in accordance with Sec. 417.7 of this part, or the responsible establishment official.

### **Corrective Actions**

417.3(a) - The written HACCP plan shall identify the corrective action to be followed in response to a deviation from a critical limit. The HACCP plan shall describe the corrective action to be taken, and assign responsibility for taking corrective action, to ensure: (1) The cause of the deviation is identified and eliminated; (2) The CCP will be under control after the corrective action is taken; (3) Measures to prevent recurrence are established; and (4) No product that is injurious to health or otherwise adulterated as a result of the deviation enters commerce.

417.3(b) - If a deviation not covered by a specified corrective action occurs, or if another unforeseen hazard arises, the establishment shall:

(1) Segregate and hold the affected product, at least until the requirements of paragraphs (b)(2) and (b)(3) of this section are met;

(2) Perform a review to determine the acceptability of the affected product for distribution;

(3) Take action, when necessary, with respect to the affected product to ensure that no product that is injurious to health or otherwise adulterated, as a result of the deviation, enters commerce;

(4) Perform or obtain reassessment by an individual trained in accordance with Sec. 417.7 of this part, to determine whether the newly identified deviation or other unforeseen hazard should be incorporated into the HACCP plan.

### **Reassessment**

417.4(a)(3) Reassessment of the HACCP plan - Every establishment shall reassess the adequacy of the HACCP plan at least annually and whenever any changes occur that could affect the hazard analysis or alter the HACCP plan. Such changes may include, but are not limited to, changes in: raw materials or source of raw materials; product formulation; slaughter or processing methods or systems; production volume; personnel; packaging; finished product distribution systems; or, the intended use or consumers of the finished product. The reassessment shall be performed by an individual trained in accordance with Sec. 417.7 of this part. The HACCP plan shall be modified immediately whenever a reassessment reveals that the plan no longer meets the requirements of Sec. 417.2(c) of this part.

417.4(b) Reassessment of the hazard analysis - Any establishment that does not have a HACCP plan because a hazard analysis has revealed no food safety hazards that are reasonably likely to occur shall reassess the adequacy of the hazard analysis whenever a change occurs that could reasonably affect whether a food safety hazard exists. Such changes may include, but are not limited to, changes in: raw materials or source of raw materials; product formulation; slaughter or processing methods or systems; production volume; packaging; finished product distribution systems; or, the intended use or consumers of the finished product.

## Verifying the Five HACCP Requirements

<b>Requirement</b>	<b>Regulatory References</b>	<b>Procedure</b>	<b>Component</b>
Monitoring	417.2(c)(4) <u>Monitoring Requirement</u>	01 or 02	Rk R&O
Verification	417.2(c)(7) <u>Verification Requirement</u> 417.4(a)(2)(i)(ii)(iii) <u>Verification Activities</u>	01 or 02	Rk R&O
Recordkeeping	417.2(c)(6) <u>Recordkeeping System</u>	01 or 02	Rk
	417.5(a)(1)(2) <u>Supporting Documentation</u>	01 (02 <sup>2</sup> )	Rk
	417.5(a)(3) <u>HACCP Records</u>	01 or 02	Rk
	417.5(b) <u>Records Authenticity</u>	01 or 02	Rk R&O
	417.5(d) <u>Computerized Records</u>	01 or 02	Rk
	417.5(e)(1)(2) <u>Record Retention and Availability</u>	01 or 02	Rk
	417.5(c) <u>Pre-shipment Review</u>	02	Rk R&O (on occasion)
Corrective Action	417.3(a) Deviation from a critical limit  417.3(b) Deviation not covered by a specified corrective action/unforeseen hazard	01 <sup>3</sup> or 02	Rk R&O
Reassessment	417.4(a)(3) Annual Reassessment <sup>4</sup> or Changes in Establishment Processes  417.4(b) Hazard Analysis Reassessment	01 or 02	Rk

<sup>2</sup> Product acceptability or disposition could be verified using the 02 procedure.

<sup>3</sup> Corrective actions and reassessment can be verified through 01 but not randomly.

<sup>4</sup> Annual Reassessment will be verified with the 03A01 procedure.