

§ 417.5

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§ 417.5 Records.

(a) The establishment shall maintain the following records documenting the establishment's HACCP plan:

(1) The written hazard analysis prescribed in § 417.2(a) of this part, including all supporting documentation;

(2) The written HACCP plan, including decisionmaking documents associated with the selection and development of CCP's and critical limits, and documents supporting both the monitoring and verification procedures selected and the frequency of those procedures.

(3) Records documenting the monitoring of CCP's 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.

(b) 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.

(c) 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 § 417.7 of this part, or the responsible establishment official.

(d) *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.

(e) *Record retention.* (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.

(f) *Official review.* All records required by this part and all plans and procedures required by this part shall be available for official review and copying.

§ 417.6 Inadequate HACCP Systems.

A HACCP system may be found to be inadequate if:

(a) The HACCP plan in operation does not meet the requirements set forth in this part;

(b) Establishment personnel are not performing tasks specified in the HACCP plan;

(c) The establishment fails to take corrective actions, as required by § 417.3 of this part;

(d) HACCP records are not being maintained as required in § 417.5 of this part; or

(e) Adulterated product is produced or shipped.

§ 417.7 Training.

(a) Only an individual who has met the requirements of paragraph (b) of this section, but who need not be an employee of the establishment, shall be permitted to perform the following functions:

(1) Development of the HACCP plan, in accordance with § 417.2(b) of this part, which could include adapting a generic model that is appropriate for the specific product; and

(2) Reassessment and modification of the HACCP plan, in accordance with § 417.3 of this part.

(b) The individual performing the functions listed in paragraph (a) of this