

§416.17

the Sanitation SOP's shall authenticate these records with his or her initials and the date.

(b) Records required by this part may be maintained on computers provided the establishment implements appropriate controls to ensure the integrity of the electronic data.

(c) Records required by this part shall be maintained for at least 6 months and made accesable available to FSIS. All such records shall be maintained at the official establishment for 48 hours following completion, after which they may be maintained off-site provided such records can be made available to FSIS within 24 hours of request.

§416.17 Agency verification.

FSIS shall verify the adequacy and effectiveness of the Sanitation SOP's and the procedures specified therein by determining that they meet the requirements of this part. Such verification may include:

- (a) Reviewing the Sanitation SOP's;
(b) Reviewing the daily records documenting the implementation of the Sanitation SOP's and the procedures specified therein and any corrective actions taken or required to be taken;
(c) Direct observation of the implementation of the Sanitation SOP's and the procedures specified therein and any corrective actions taken or required to be taken; and
(d) Direct observation or testing to assess the sanitary conditions in the establishment.

PART 417—HAZARD ANALYSIS AND CRITICAL CONTROL POINT (HACCP) SYSTEMS

- Sec.
417.1 Definitions.
417.2 Hazard Analysis and HACCP plan.
417.3 Corrective actions.
417.4 Validation, Verification, Reassessment.
417.5 Records.
417.6 Inadequate HACCP Systems.
417.7 Training.
417.8 Agency verification.

AUTHORITY: 7 U.S.C. 450; 21 U.S.C. 451-470, 601-695; 7 U.S.C. 1901-1906; 7 CFR 2.18, 2.53.

SOURCE: 61 FR 38868, July 25, 1996, unless otherwise noted.

§417.1 Definitions.

For purposes of this part, the following definitions shall apply:

Corrective action. Procedures to be followed when a deviation occurs.

Critical control point. A point, step, or procedure in a food process at which control can be applied and, as a result, a food safety hazard can be prevented, eliminated, or reduced to acceptable levels.

Critical limit. The maximum or minimum value to which a physical, biological, or chemical hazard must be controlled at a critical control point to prevent, eliminate, or reduce to an acceptable level the occurrence of the identified food safety hazard.

Food safety hazard. Any biological, chemical, or physical property that may cause a food to be unsafe for human consumption.

HACCP System. The HACCP plan in operation, including the HACCP plan itself.

Hazard. SEE Food Safety Hazard.

Preventive measure. Physical, chemical, or other means that can be used to control an identified food safety hazard.

Process-monitoring instrument. An instrument or device used to indicate conditions during processing at a critical control point.

Responsible establishment official. The individual with overall authority on-site or a higher level official of the establishment.

§417.2 Hazard Analysis and HACCP Plan.

(a) Hazard analysis. (1) Every official establishment shall conduct, or have conducted for it, a hazard analysis to determine the food safety hazards reasonably likely to occur in the production process and identify the preventive measures the establishment can apply to control those hazards. The hazard analysis shall include food safety hazards that can occur before, during, and after entry into the establishment. A food safety hazard that is reasonably likely to occur is one for which a prudent establishment would establish controls because it historically has occurred, or because there is a reasonable possibility that it will occur in the