

§ 416.16

therein or appropriate improvements in the execution of the Sanitation SOP's or the procedures specified therein.

[61 FR 38868, July 25, 1996, as amended at 62 FR 26219, May 13, 1997]

§ 416.16 Recordkeeping requirements.

(a) Each official establishment shall maintain daily records sufficient to document the implementation and monitoring of the Sanitation SOP's and any corrective actions taken. The establishment employee(s) specified in the Sanitation SOP's as being responsible for the implementation and monitoring of the procedure(s) specified in 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.

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

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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.