compliance with the process schedule. These observations should be made and recorded at intervals not exceeding 30 minutes of continuous retort operation. Functioning of the condensate bleeder(s) shall be observed and recorded at the time the first container enters the retort and thereafter as specified in §318.305(b)(3)(v).

(4) *Hydrostatic retorts.* Record the retort system number, the approximate total number of containers retorted, product initial temperature, time steam on, the time and temperature vent(s) closed, time process temperature reached, time first containers enter the retort, time last containers exit the retort, and, if specified in the process schedule, measurements of temperatures in the hydrostatic water legs. Readings of the temperature indicating device, which is located in the steam/water interface, and the temperature recording device shall be observed and the temperatures recorded at the time the first containers enter the steam dome. Thereafter, these instruments shall be read and the temperatures recorded with sufficient frequency to ensure compliance with the temperature specified in the process schedule and should be made at least every hour of continuous retort operation. Container conveyor speed, and for agitating hydrostatic retorts, the rotative chain speed, shall be determined and recorded at intervals of sufficient frequency to ensure compliance with the process schedule and should be performed at least every 4 hours.

(b) *Processing in water*—(1) *Batch still retorts.* For each retort batch, record the retort number or other designation, the approximate number of containers or number of retort crates per retort load, product initial temperature, time steam on, the start of process timing, water level, water recirculation rate (if critical), overriding pressure maintained, time steam off, and actual processing time. The indicating temperature device and the temperature recorder shall be read at the same time at least once during process timing and the observed temperatures recorded.

(2) *Batch agitating retorts.* In addition to recording the information required in paragraph (b)(1) of this section, record the retort or reel speed.

(c) *Processing in steam/air mixtures.* For each retort batch, record the retort number or other designation, the approximate number of containers or number of retort crates per retort load, product initial temperature, time steam on, venting procedure, if applicable, the start of process timing, maintenance of circulation of the steam/air mixture, air flow rate or forced recirculation flow rate (if critical), overriding pressure maintained, time steam off, and actual processing time. The indicating temperature device and the temperature recorder shall be read at the same time at least once during process timing and the observed temperatures recorded.

(d) *Atmospheric cookers*—(1) *Batch-type systems.* For each cooker batch, record the cooker number or other designation and the approximate number of containers. In addition, record all critical factors of the process schedule such as cooker temperature, initial temperature, the time the thermal process cycle begins and ends, hold time, and the final internal product temperature.

(2) *Continuous-type systems.* Record the cooker number or other designation, the time the first containers enter and the last containers exit a cooker, and the approximate total number of containers processed. In addition, record all critical factors of the process schedule such as the initial temperature, cooker speed, and final internal product temperature.

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§318.307 Record review and maintenance.

(a) *Process records.* Charts from temperature/time recording devices shall be identified by production date, container code, processing vessel number or other designation, and other data as necessary to enable correlation with the records required in §318.306. Each entry on a record shall be made at the time the specific event occurs, and the recording individual shall sign or initial each record form. No later than 1 working day after the actual process, the establishment shall review all

processing and production records to ensure completeness and to determine if all product received the process schedule. All records, including the temperature/time recorder charts and critical factor control records, shall be signed or initialed and dated by the person conducting the review. All processing and production records required in this subpart shall be made available to Program employees for review.

(b) *Automated process monitoring and recordkeeping.* Automated process monitoring and recordkeeping systems shall be designed and operated in a manner that will ensure compliance with the applicable requirements of § 318.306.

(c) *Container closure records.* Written records of all container closure examinations shall specify the container code, the date and time of container closure examination, the measurement(s) obtained, and any corrective actions taken. Records shall be signed or initialed by the container closure technician and shall be reviewed and signed by the establishment within 1 working day after the actual production to ensure that the records are complete and that the closing operations have been properly controlled. All container closure examination records required in this subpart shall be made available to Program employees for review.

(d) *Distribution of product.* Records shall be maintained by the establishment identifying initial distribution of the finished product to facilitate, if necessary, the segregation of specific production lots that may have been contaminated or are otherwise unsound for their intended use.

(e) *Retention of records.* Copies of all processing and production records required in § 318.306 shall be retained for no less than 1 year at the establishment, and for an additional 2 years at the establishment or other location from which the records can be made available to Program employees within 3 working days.

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§ 318.308 Deviations in processing.

(a) Whenever the actual process is less than the process schedule or when any critical factor does not comply with the requirements for that factor as specified in the process schedule, it shall be considered a deviation in processing.

(b) Deviations in processing (or process deviations) must be handled according to:

(1)(i) A HACCP plan for canned product that addresses hazards associated with microbial contamination, or,

(ii) Alternative documented procedures that will ensure that only safe and stable product is shipped in commerce; or

(iii) Paragraph (d) of this section.

(c) [Reserved]

(d) Procedures for handling process deviations where the HACCP plan for thermally processed/commercially sterile product does not address food safety hazards associated with microbial contamination, where there is no approved total quality control system, or where the establishment has no alternative documented procedures for handling process deviations.

(1) *Deviations identified in-process.* If a deviation is noted at any time before the completion of the intended process schedule, the establishment shall:

(i) Immediately reprocess the product using the full process schedule; or

(ii) Use an appropriate alternate process schedule provided such a process schedule has been established in accordance with § 318.302 (a) and (b) and is filed with the inspector in accordance with § 318.302(c); or

(iii) Hold the product involved and have the deviation evaluated by a processing authority to assess the safety and stability of the product. Upon completion of the evaluation, the establishment shall provide the inspector the following:

(*a*) A complete description of the deviation along with all necessary supporting documentation;

(*b*) A copy of the evaluation report; and

(*c*) A description of any product disposition actions, either taken or proposed.

(iv) Product handled in accordance with paragraph (d)(1)(iii) of this section