

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 which will ensure compliance with the applicable requirements of § 381.306.

(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 § 381.306 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.

(Approved by the Office of Management and Budget under control number 0583-0015)

[51 FR 45634, Dec. 19, 1986, as amended at 65 FR 34390, May 30, 2000]

§ 381.308 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.

(2) 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 § 381.302 (a) and (b) and is filed with the inspector in accordance with § 381.302(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:

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(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 shall not be shipped from the establishment until the Program has reviewed all of the information submitted and approved the product disposition actions.

(v) If an alternate process schedule is used that is not on file with the inspector or if an alternate process schedule is immediately calculated and used, the product shall be set aside for further evaluation in accordance with paragraphs (d)(1) (iii) and (iv) of this section.

(vi) When a deviation occurs in a continuous rotary retort, the product shall be handled in accordance with paragraphs (d)(1) (iii) and (iv) of this section or in accordance with the following procedures:

(a) Emergency stops.

(1) When retort jams or breakdowns occur during the processing operations, all containers shall be given an emergency still process (developed per §381.302(b)) before the retort is cooled or the retort shall be cooled promptly and all containers removed and either reprocessed, repacked and reprocessed, or destroyed. Regardless of the procedure used, containers in the retort intake valve and in transfer valves between retort shells at the time of a jam or breakdown shall be removed and either reprocessed, repacked and reprocessed, or destroyed. Product to be destroyed shall be handled as “U.S. Inspected and Condemned”, as defined in §301.2(ee) of this chapter, and disposed of in accordance with part 314 of this chapter.

(2) The time the retort reel stopped and the time the retort is used for an emergency still retort process shall be noted on the temperature/time recording device and entered on the other production records required in §381.306.

(b) Temperature drops. When the retort temperature drops below the temperature specified in the process sched-

ule, the reel shall be stopped and the following actions shall be taken:

(1) For temperature drops of less than 10 °F (or 5.5 °C) either (i) all containers in the retort shall be given an emergency still process (developed per §381.302(b)) before the reel is restarted; (ii) container entry to the retort shall be prevented and an emergency agitating process (developed per §381.302(b)) shall be used before container entry to the retort is restarted; or (iii) container entry to the retort shall be prevented and the reel restarted to empty the retort. The discharged containers shall be reprocessed, repacked and reprocessed, or destroyed. Product to be destroyed shall be handled as “U.S. Inspected and Condemned”, as defined in §301.2(ee) of this chapter, and disposed of in accordance with part 314 of this chapter.

(2) For temperature drops of 10 °F (or 5.5 °C) or more, all containers in the retort shall be given an emergency still process (developed per §381.302(b)). The time the reel was stopped and the time the retort was used for a still retort process shall be marked on the temperature/time recording device by the establishment and entered on the other production records required in §381.306. Alternatively, container entry to the retort shall be prevented and the reel restarted to empty the retort. The discharged containers shall be either reprocessed, repacked and reprocessed, or destroyed. Product to be destroyed shall be handled as “U.S. Inspected and Condemned” as defined in §301.2(ee) of this chapter, and disposed of in accordance with part 314 of this chapter.

(2) *Deviations identified through record review.* Whenever a deviation is noted during review of the processing and production records required by §381.307 (a) and (b), the establishment shall hold the product involved and the deviation shall be handled in accordance with paragraphs (d)(1) (iii) and (iv) of this section.

(e) *Process deviation file.* The establishment shall maintain full records regarding the handling of each deviation. Such records shall include, at a minimum, the appropriate processing and production records, a full description of the corrective actions taken, the evaluation procedures and results, and the

disposition of the affected product. Such records shall be maintained in a separate file or in a log that contains the appropriate information. The file or log shall be retained in accordance with §381.307(e) and shall be made available to Program employees upon request.

(Approved by the Office of Management and Budget under control number 0583-0015)

[51 FR 45634, Dec. 19, 1986, as amended at 62 FR 45027, Aug. 25, 1997; 65 FR 34390, May 30, 2000; 65 FR 53533, Sept. 5, 2000]

§ 381.309 Finished product inspection.

(a) Finished product inspections must be handled according to:

(1) A HACCP plan for canned product that addresses hazards associated with microbiological contamination; or

(2) An FSIS-approved total quality control system; or

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

(4) Paragraph (d) of this section.

(b)-(c) [Reserved]

(d) Procedures for finished product inspections 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) *Incubation of shelf stable canned product*—(i) *Incubator*. The establishment shall provide incubation facilities which include an accurate temperature/time recording device, an indicating temperature device, a means for the circulation of the air inside the incubator to prevent temperature variations, and a means to prevent unauthorized entry into the facility. The Program is responsible for the security of the incubator.

(ii) *Incubation temperature*. The incubation temperature shall be maintained at 95±5 °F (35±2.8 °C). If the incubation temperature falls below 90 °F (or 32 °C) or exceeds 100 °F (or 38 °C) but does not reach 103 °F (or 39.5 °C), the incubation temperature shall be adjusted within the required range and the incubation time extended for the

time the sample containers were held at the deviant temperature. If the incubation temperature is at or above 103 °F (or 39.5 °C) for more than 2 hours, the incubation test(s) shall be terminated, the temperature lowered to within the required range, and new sample containers incubated for the required time.

(iii) *Product requiring incubation*. Shelf stable product requiring incubation includes:

(a) Low acid products as defined in §381.300(m); and

(b) Acidified low acid products as defined in §381.300(b).

(iv) *Incubation samples*. (a) From each load of product processed in a batch-type thermal processing system (still or agitation), the establishment shall select at least one container for incubation.

(b) For continuous rotary retorts, hydrostatic retorts, or other continuous-type thermal processing systems, the establishment shall select at least one container per 1,000 for incubation.

(c) Only normal-appearing containers shall be selected for incubation.

(v) *Incubation time*. Canned product requiring incubation shall be incubated for not less than 10 days (240 hours) under the conditions specified in paragraph (d)(1)(ii) of this section.

(vi) *Incubation checks and record maintenance*. Designated establishment employees shall visually check all containers under incubation each working day and the inspector shall be notified when abnormal containers are detected. All abnormal containers should be allowed to cool before a final decision on their condition is made. For each incubation test the establishment shall record at least the product name, container size, container code, number of containers incubated, in and out dates, and incubation results. The establishment shall retain such records, along with copies of the temperature/time recording charts, in accordance with §381.307(e).

(vii) *Abnormal containers*. The finding of abnormal containers (as defined in §381.300(a)) among incubation samples is cause to officially retain at least the code lot involved.

(viii) *Shipping*. No product shall be shipped from the establishment before