Module 20. Processing Deviations

9 CFR 431.1 - Process Schedule

A process schedule (PS) is the thermal process and any specified critical factor for given canned product required to achieve shelf stability. The PS is established by a Processing Authority (PA) and addresses critical factors (CF), or characteristics, conditions, or aspects of thermal processing procedures, containers, and products that could affect the PS. The process schedule includes a minimum initial temperature (I.T.), minimum process time (B_b), minimum process retort temperature (RT), and, when established as critical factors, minimum container headspace and maximum product consistency.

§431.9(a) - Processing Deviations

A processing deviation (PD) occurs when the actual applied process is less than the minimum requirements of the process schedule or when any critical factor does not comply with the requirements for that factor. A PD may be detected on the production floor (in-process) or through records review (after process) and is not the same as a HACCP deviation, which is a failure to meet an established critical limit at a CCP.

To prevent the distribution of under-processed product, the establishment may utilize an operating process that equals or exceeds the minimum requirements set in PS. The operating process must be conspicuously posted near thermal processing equipment or available to thermal processing system operator and the inspector.

§431.9(b) - Handling Processing Deviations

Processors must handle processing deviations according to:

1. A HACCP plan that addresses food safety hazards associated with microbial contamination for canned product, or
2. An alternative documented procedure that ensures only safe and stable product is shipped in commerce, or
3. Meet §431.9(c) requirements.

§431.9(c)(1) - Options for Handling In-process Processing Deviations

The processor has 3 options for handling PDs when there is no HACCP plan that addresses food safety hazards associated with microbial contamination, no approved total quality control system, or no alternative documented procedures:
(i) Immediately reprocess product using a full process schedule, or
(ii) Use an appropriate alternative process schedule approved by a PA, or
(iii) Hold product until the PD is evaluated by a PA to assess product safety and stability. Upon completion of the evaluation, the processor must provide the inspector the complete deviation description and all necessary supporting documentation, a copy of the evaluation report, and a description of any taken or proposed product disposition actions.

§431.9(c)(1)(iv) - Product handled under §431.9(c)(1)(iii) must not be shipped from the establishment until FSIS Policy Development staff (PDS) has reviewed all information submitted and approved product disposition actions.

§431.9(c)(1)(v) – If an alternate process schedule used is not on file with the inspector or if an alternate process schedule is immediately calculated and used, the establishment must set product aside for further evaluation by both the PA and PDS in accordance with §431.9(c)(1)(iii) and (iv).

§431.9(c)(1)(vi) – Processing deviations in continuous rotary (agitating) retort caused by emergency reel stops and temperature drops must be either be evaluated by a PA and PDS, all containers must be given an emergency process developed by a PA before the retort is restarted or cooled, or all containers removed or prevented entry into retort and either reprocessed, repacked and reprocessed, or destroyed.

§431.9(c)(2) - Handling Processing Deviations Identified in Record Reviews

Whenever plant management or the inspector identify a PD during reviews of processing and production records, the establishment must hold the product involved. Before the product can be shipped from the establishment, the deviation must be reviewed and evaluated by both the PA and PDS in accordance with §431.9(c)(1)(iii) and (iv).

§431.9(d) - Documented Handling of Process Deviations

Processors must maintain complete records regarding the handling of each PD, including appropriate processing and production records, a full description of any corrective actions taken, the procedures and results of PD evaluations, and the disposition of affected product.
Full records containing the appropriate information must be maintained in a separate file or in a log and made available to FSIS employees upon request.

Processing Deviation Options

Processing deviations can occur from mechanical failures to product formulation errors or changes. If the PD cannot be corrected in progress, the plant has 3 options:

1. **Rework:** The plant can open the containers and rework the product back into another batch of product to be commercially sterilized or rework it the product into another process like frozen foods if proper precautions (e.g., cooling) were taken. Rework can change product properties and effect heat penetration.
2. **PA Evaluation:** The establishment may hold product and submit the PD information (e.g., processing records) to the designated PA for evaluation and review.
3. **Destroy the product:** The District Office has the responsibility to determine how FSIS will observe or accept necessary documentation demonstrating product destruction.

Process Deviation Verification

The inspector will verify that the plant implements its HACCP plan or alterative procedures for handling PDs as written, including reviews of the plant's corrective actions, the cause of the PD, and product disposition.