UNITED STATES DEPARTMENT OF AGRICULTURE
FOOD SAFETY AND INSPECTION SERVICE
WASHINGTON, DC

FSIS DIRECTIVE

7530.1
Revision 4

9/27/18

HANDLING A PROCESS DEVIATION OR ABNORMAL CONTAINER OF THERMALLY PROCESSED, COMMERCIALLY STERILE CANNED PRODUCT

I. PURPOSE

This directive provides inspection program personnel (IPP) at thermal processing establishments or official import inspection establishments with updated procedures to follow when an abnormal container is found by IPP or by the establishment, or when there is a process deviation during the production of thermally processed, commercially sterile canned products at an official establishment. This directive supplements the information in FSIS Directive 7530.2, *Verification Activities in Canning Operations that Choose to Follow the Canning Regulations - Revision 1,* FSIS Directive 5000.1, *Verifying an Establishment's Food Safety System - Revision 5*, and FSIS Directive 9900.2, *Import Reinspection of Meat, Poultry, and Egg Products - Revision 1*. This directive has been updated to incorporate changes related to the reorganization of the Office of Field Operations (OFO) and to make changes consistent with the new consolidated canning regulations. This directive also addresses the review of process deviations and abnormal containers by the Policy Development Staff (PDS).

KEYPOINTS:

- *Updates regulatory citations with the consolidated canning regulations (9 CFR 431) published on 05/31/2018 (83 FR 25302)*
- *Clarifies procedures to be performed when process deviations are identified at an official FSIS inspected establishment*
- *Clarifies procedures to be performed when abnormal containers are identified at an official FSIS inspected establishment or an official import inspection establishment*
- *Updates FSIS forms to be completed by IPP for handling process deviation and abnormal container incidents*

II. CANCELLATION

FSIS Directive 7530.1, Revision 3, Handling a Process Deviation or Abnormal Container of Thermally Processed, Commercially Sterile Canned Product, 5/6/15

III. BACKGROUND

Canned product is defined in 9 CFR 431.1 as a meat or poultry food product with a water activity above 0.85 that receives a thermal process either before or after being packed in a hermetically sealed container. The thermal process is the heat treatment necessary to achieve shelf stability as determined by the establishment's processing authority (PA) (9 CFR 431.1). In order to be eligible to bear the FSIS mark of inspection and to be distributed in commerce, canned products must be adequately processed to achieve commercial sterility (9 CFR 431.1). Thermally processed, commercially sterile products are packed in

various types of containers, including rigid and semi-rigid containers, flexible pouches, glass jars, paperboard, and other types of containers that are designed to hold conventionally canned product or aseptically processed product. An abnormal container is defined as a container with any sign of swelling or product leakage or any evidence that the contents of the unopened container may be spoiled (9 CFR 431.1). Only normal-appearing containers can be shipped from an establishment per 9 CFR 431.10(c)(1).

IV. PROCESS DEVIATIONS

A. Whenever the actual process is less than the process schedule, any critical factor does not meet the value required by the process schedule (9 CFR 431.9(a)), or any operating parameter of the thermal processing system is not met (e.g., the venting schedule in a steam retort, come-up time in water immersion retort or steam-air retort, sterilization of packaging materials in aseptic processing systems), the event is considered a process deviation. Attachment 1 provides information on common causes of process deviations. IPP may use the attachment as a reference to identify potential types of deviations.

B. Whenever a process deviation occurs, IPP are to verify the establishment's corrective actions in a Thermally Processed-Commercially Sterile Hazard Analysis and Critical Control Point (HACCP) verification task. IPP are to schedule a directed HACCP task as necessary if there is no routine HACCP task available.

C. IPP are to verify that the establishment handles each process deviation by using one of the following methods:

1. A HACCP plan for canned product that addresses hazards associated with microbiological contamination (9 CFR 431.9(b)(1));

2. Alternate documented procedures that will ensure that only safe and stable product is shipped in commerce (9 CFR 431.9(b)(2)); or

3. The requirements of 9 CFR 431.9(c) if the establishment does not follow methods 1 or 2 above.

NOTE: The methods set out above in subparagraphs C. 1. and 2. do not require that the establishment submit process deviation information to IPP before shipping the product in commerce, but all process deviation information must be available to IPP upon request.

D. IPP are to take a regulatory control action to retain the product if the establishment does not have adequate procedures in place to prevent shipment of the product before the evaluation and disposition by one of the methods above. If the product is released into commerce, IPP are to notify the District Office (DO) through supervisory channels immediately.

V. FSIS VERIFICATION OF PROCESS DEVIATIONS

A. When the establishment handles a process deviation under a HACCP plan that addresses hazards associated with microbiological contamination, IPP are to verify that the establishment has met the corrective action requirements in 9 CFR 417.3 (a) or (b) according to instructions in FSIS Directive 5000.1 and then verify that:

1. If the product is reprocessed, the process schedule has been authorized by the establishment's PA for that purpose; and

2. The establishment's corrective action records include all the records that relate to the handling of each deviation as specified in 9 CFR 431.9(d). The required records must include, at a minimum, the following information:

    a. The appropriate processing and production records;

b. A full description of the corrective actions taken;

c. The PA's evaluation procedures and results; and

d. The PA's disposition of the affected product.

B. When an establishment chooses to follow the canning regulations and uses an alternate documented procedure for handling a process deviation (9 CFR 431.9(b)(2)), IPP are to verify that the:

1. Establishment is implementing the alternate procedure as written (9 CFR 431.9(b)(2));
2. Alternate process schedule on file has been approved by a PA (9 CFR 431.3(a) and (b)); and
3. Establishment's process deviation file contains, at a minimum, all the records that relate to the handling of each deviation as specified in 9 CFR 431.9(d).

C. When an establishment is following the canning regulations and has no alternate documented procedures for handling process deviations, it must meet the requirements of 9 CFR 431.9(c). IPP are to verify that the deviation is handled according to one of the following three options:

1. The establishment immediately reprocessed the product using the full process schedule when the process deviation is detected in-process;
2. The establishment used an appropriate alternate process schedule (9 CFR 431.3(a)), and that the process schedule is:

    a. Developed by a PA (9 CFR 431.3(b)(1));

    b. On file with the establishment before the deviation occurred; and

    c. Available for review by IPP (9 CFR 431.3(b)(3)); or

3. The product involved has been placed on hold, and that the deviation is being evaluated by a PA (9 CFR 431.9(c)(1)(iii) and (iv)).

D. IPP are to verify that the establishment maintains process deviation records that contain, at a minimum, all the records that relate to the handling of each deviation as specified in 9 CFR 431.9(d).

NOTE: An establishment must handle any deviation in a manner that will prevent the distribution of under-processed product.

VI. WHEN IPP ARE TO SUBMIT PROCESS DEVIATIONS TO PDS FOR REVIEW

A. IPP are not to submit process deviations to PDS for review when the establishment addresses food safety hazards associated with microbiological contamination in its HACCP plan or uses an alternative documented procedure for handling process deviations except in regard to the situations noted in VI. B.

B. If the establishment does address food safety hazards associated with microbiological contamination in its HACCP plan or has an alternative documented procedure for handling process deviations, IPP are still to submit process deviations to PDS in the following situations:

1. The establishment addresses microbiological hazards in its HACCP plan but:

    a. Has not met the corrective action requirements in 9 CFR 417.3; or

b. IPP have specific concerns regarding the corrective actions that the establishment has implemented in accordance with 9 CFR 417.3.

2. The establishment uses a documented alternate procedure to handle process deviations, but IPP have specific concerns about the corrective actions taken by the establishment, the establishment's evaluation procedures and results, or the disposition of the affected product.

NOTE: When IPP have specific concerns about the corrective actions taken by the establishment, they are to discuss their concerns with their supervisor before contacting PDS.

C. If the establishment handles process deviations according to the requirements of 9 CFR 431.9(c), IPP are to submit process deviations to PDS for review in the following situations:

1. The establishment used an alternate process schedule that was not on file or that was calculated immediately when the deviation occurs, regardless of whether it has been approved or not approved by the PA (9 CFR 431.9(c)(1)(v));

2. The establishment had a deviation in a continuous retort, including, but not limited to, an emergency stop (jam or breakdown) or temperature drop that was not handled according to regulatory requirements in 9 CFR 431.9(c)(1)(vi); or

3. The establishment found the process deviation through record review (9 CFR 431.9(c)(2)).

D. When submitting process deviations to PDS, IPP are to:

1. Verify that the product involved has been placed on hold;

2. Verify that the PA has evaluated the deviation to assess the safety and stability of the product;

3. Obtain copies of all records and documentation related to the affected lot, including:

   a. The appropriate processing and production records;

   b. A complete description of the deviation along with all corrective actions;

   c. A copy of the PA's evaluation procedure and results; and

   d. A letter or other documentation from the establishment on any product disposition actions, either taken, proposed, or under consideration;

4. List their specific concerns regarding the evaluation or results on FSIS Form 10,000-6, *Canned Foods—Process Deviation Reporting Form* (Available at InsideFSIS; users need an e-authentication account to access this form).

E. IPP are to submit information to PDS regarding process deviations and notify the DO of such submissions as follows:

1. Complete FSIS Form 10,000-6; and

2. Attach the required documentation as detailed above and distribute the form as follows:

   a. Send the completed form and required documentation to PDS through askFSIS. IPP may contact PDS at 1-800-233-3935 if they need assistance sending the information;

b. Send one copy of the completed FSIS Form 10,000-6 to the DO through supervisory channels; and

c. Retain a copy of the completed form and required documentation in the government office case file at the establishment.

F. IPP are to follow instructions in Section XI below for the disposition of affected lots.

VII. ABNORMAL CONTAINERS IDENTIFIED AT AN OFFICIAL FSIS INSPECTED ESTABLISHMENT

A. An abnormal container is a container with any sign of swelling or product leakage or with any evidence that the contents of the unopened container may be spoiled (9 CFR 431.1).

NOTE: Isolated incidents of containers with obvious or assignable cause (e.g., forklift damage) that do not present a risk of causing spoilage in other containers (e.g., the integrity of the sealed container is not compromised) do not need to be held or to be evaluated by PDS, provided that the establishment ensures that only normal appearing containers are shipped (9 CFR 431.10(c)(1)).

B. When the establishment chooses to follow the canning regulations, IPP are to verify that the establishment notifies IPP when abnormal containers are detected:

1. During the incubation when the establishment handles finished product inspection as specified in 9 CFR 431.10(b); or

2. By any means other than incubation (9 CFR 431.10(c)(2)).

C. When abnormal containers are found by IPP, they are to retain the product lot associated with the abnormal containers, notify the establishment about the finding and document the incident in a Memorandum of Interview (MOI).

D. Whenever abnormal containers are found by IPP or the establishment, IPP are to verify that the establishment handled the incident appropriately in accordance with 9 CFR 431.10(a) and document their findings in a Thermally Processed - Commercially Sterile HACCP task. IPP are to schedule a directed HACCP task as necessary if there is no routine HACCP task available.

E. When the establishment has a HACCP plan or a documented procedure for handling abnormal containers, IPP are to:

1. Verify that the establishment has adequate procedures in place to control and prevent shipment of the affected lot. IPP are to retain the affected lot if the establishment does not have or follow documented procedures to control the affected lot;

2. Verify that the establishment has initiated action to determine and eliminate the cause of the abnormal containers;

3. Verify the safety and stability of the affected lot by reviewing any supporting documentation provided by the establishment, such as the incubation records, laboratory microbial testing results, the PA's evaluation, and other supporting documentation;

NOTE: If IPP need assistance in evaluating the supporting data, they are to submit the supporting documents to Policy Development Staff (PDS) for review through askFSIS as stated in Section XII.

4. Verify that;

a. The establishment has met all the corrective action requirements in 9 CFR 417.3 (a) or (b) according to instructions in FSIS Directive 5000.1 if the establishment addresses microbiological hazards in its HACCP plan; or

b. The establishment has fully implemented the documented procedure if the establishment has an alternative documented procedure (9 CFR 431.10(a)(3));

5. Document the findings in an MOI; and

6. Verify that the establishment disposed of the affected containers in the suspect lot. When the establishment has a documented program for disposal of abnormal containers in its HACCP plan or other documented procedure, IPP are to verify that the establishment has fully implemented the program as written. Once disposition is complete, IPP are to release control of normal-appearing product containers if IPP have applied U.S. Rejected – U.S. Retained Tags.

F. When the establishment does NOT have, or is not following, a HACCP plan or a documented procedure for handling abnormal containers, IPP are to:

1. Retain product lot associated with abnormal containers pending laboratory analysis using U.S. Rejected – U.S. Retained Tags. The minimum amount of product IPP are to retain will be 2 hours of continuous production. There is no maximum. Depending on the cause of the abnormal containers, the amount of product retained may include product from one or more retorts or production days.

2. Contact the FSIS Western Laboratory by phone at (510) 814-3000, per the instructions in Section VIII below;

NOTE: When the cause of the abnormal containers is already known, the FSIS Western Laboratory may not need to request samples. IPP are to still contact PDS and the PDS canning team will review the findings and determine whether any further action is needed.

3. Send a copy of completed forms and required documentation as set out in in Section VIII to PDS through askFSIS;

4. Inform establishment management that it needs to segregate the remaining abnormal containers that have been sampled from the retained product and refrigerate them pending evaluation, per the FSIS Western Laboratory's instructions;

NOTE: Refrigeration is necessary to prevent rupture and to preserve the contents of the abnormal containers. Abnormal or normal appearing containers should not be frozen.

5. Verify that the establishment has initiated action to determine and eliminate the cause of the abnormal containers; and

6. Document the findings in an MOI.

VIII. IPP INSTRUCTIONS FOR SUBMITTING DOMESTIC SAMPLES FOR LABORATORY ANALYSIS

A. When IPP at a domestic official establishment observe abnormal containers that need to be submitted for laboratory analysis, they are to contact the FSIS Western Laboratory by phone at 510-982-4900 (micro section). IPP are to provide the FSIS Western Laboratory with their supervisor's contact information. The Western Laboratory is to make the determination on the number of samples to be submitted based on the cause and level of abnormal containers observed in the affected lot as well as any product disposition actions either taken or proposed by the establishment. FSIS Western Laboratory is to copy the Frontline Supervisor (FLS) or Inspector-in-Charge (IIC) in the e-mails.

B. When submitting samples to the FSIS Western Laboratory, IPP are to:

1. Provide the laboratory with all information requested during the initial phone call, and any additional information requested in the e-mail received from the laboratory;

2. Submit both normal and abnormal samples following the instructions from the laboratory; and

3. Place abnormal containers under refrigeration before mailing to prevent rupture and preserve their contents.

NOTE: IPP are not to freeze either the abnormal containers or normal-appearing containers.

C. IPP may share any remaining abnormal containers with the domestic producing establishment after they have submitted the requested abnormal containers to the laboratory. IPP are to inform the FSIS Western Laboratory when they have shared abnormal containers with the domestic establishment.

D. IPP are to complete the following required forms, and then place the forms with the submitted samples:

1. FSIS Form 10,000-2, *Domestic Laboratory Report*; and

2. FSIS Form 10,000-3, *Canned Foods—Domestic Abnormal Containers Reporting Form* (Available at InsideFSIS);

NOTE: FSIS Form 7500-1 is no longer needed for domestic sample submissions.

E. IPP are to send one copy of each completed form, and any additional information requested to their FLS and the PDS canning team through askFSIS.

F. IPP are to retain one copy of each completed form in the government office case file.

IX. ABNORMAL CONTAINERS IDENTIFIED AT AN OFFICIAL IMPORT INSPECTION ESTABLISHMENT

A. IPP are to follow the instructions in FSIS Directive 9900.2, Section XV, to add a Condition of Container type of inspection (TOI) when necessary. When there are any abnormal conditions such as wet cartons or trays, ruptured containers, corroded or leaking containers, damaged cartons/trays or containers, IPP are to add an unscheduled Condition of Container TOI if not already assigned by PHIS. IPP are to place abnormal containers under refrigeration and contact the FSIS Western Laboratory for instructions when they finish the Condition of Container TOI.

NOTE: When there is obvious forklift or definite transportation damage and the damage is not a prevailing condition throughout the lot, IPP may permit removal of the damaged containers without refusing the lot.

B. Upon completion of the Condition of Container examination for a lot in which abnormal containers are observed, IPP are to follow the instructions in FSIS Directive 9900.2, Section XV Part E, for recording the results.

C. When abnormal container defects are recorded for a Condition of Container TOI, IPP are to follow the instructions in FSIS Directive 9900.2, Section XV Part E, to ensure that an Abnormal Container TOI is added to the lot. IPP are to follow the instructions regarding submitting import samples to the Western Laboratory in Section X below.

D. When an Incubation TOI is assigned to the lot or the Western Laboratory instructs IPP to incubate the samples, IPP are to perform an Incubation TOI following the instructions in FSIS Directive 9900.2, Section XVI.

E. IPP are to provide the details of the inspection to the importer of record (IOR), either directly or through import inspection establishment management.

F. After the FSIS Western Laboratory completes its analysis of abnormal containers, it is to send the lab report to PDS. PDS is to send a disposition recommendation to the IPP and the FLS. The disposition of the affected lot will be made according to Section XI below. IPP are to notify the IOR of the findings and the IOR's options for the lot. The options vary but normally are:

1. Refuse entry on the lot without further sorting;

2. Refuse entry on the lot with the IOR having the option to rectify the refused entry by sorting the abnormal and defective containers from the lot; or

3. Release the lot without further action.

G. When the IOR opts to have the lot sorted to remove abnormal and defective containers, IPP are to perform a tightened reinspection on the remaining product. The parameters for a tightened reinspection can be found in FSIS Directive 9900.2 Table C.

X. INSTRUCTIONS FOR SUBMITTING IMPORT SAMPLES FOR LABORATORY ANALYSIS

A. When IPP at an official import establishment observe defective or abnormal containers that need to be submitted for laboratory analysis, they are to contact the FSIS Western Laboratory by phone at 510-982-4900 (micro section). The Western Laboratory is to make the determination on the number of samples to be submitted based on the cause and level of abnormal containers observed in the affected lot as well as any product disposition actions either taken or proposed by the establishment.

B. The FSIS Western Laboratory is to provide IPP with specific instructions based on the information provided during the initial call and send an e-mail to the inspector requesting specific information about the affected lot. The FSIS Western Laboratory is to copy the FLS or IIC in the e-mails.

C. When submitting samples to the FSIS Western Laboratory, IPP are to:

1. Provide the laboratory with all information requested during the initial phone call, and any additional information requested in the e-mail received from the laboratory;

2. Submit samples following the instructions received from the laboratory; and

3. Place abnormal containers under refrigeration before mailing to prevent rupture and to preserve their contents. IPP are not to freeze either the abnormal containers or normal appearing containers.

D. IPP are to complete the laboratory sample form 8000-21 and the questionnaire in the Abnormal Container TOI.

NOTE: FSIS Form 7500-1 is no longer needed for import sample submissions.

E. IPP are to submit the product samples, completed forms, and any additional information requested to the FSIS Western Laboratory.

F. IPP are to send one copy of each completed form, and any additional information requested to Importinspection@fsis.usda.gov, the DO, and the PDS canning team through askFSIS.

G. IPP are to retain one copy of each completed form in the government office case file.

H. When the cause of the abnormal containers is already known, the FSIS Western Laboratory may not need to request samples. IPP are to still contact PDS. The PDS canning team will review the findings and determine whether any further action is needed.

XI. DISPOSITION OF AFFECTED LOTS

A. For process deviation submissions, PDS is to review the information or concerns submitted by IPP, the establishment's or the PA's evaluation of the deviation, and the proposed corrective actions. PDS is to make a recommendation to the DO through the FLS based upon all data and information evaluated. The DO is to determine what action to take and inform IPP of its decision.

B. For abnormal container submissions, the FSIS Western Laboratory is to forward the findings to PDS once it completes its analysis of abnormal containers. PDS is to review the laboratory analysis and container evaluation findings and issue a disposition recommendation to the DO through the FLS. PDS is to send a copy of the disposition recommendation to Importinspection@fsis.usda.gov for import product.

1. Domestic abnormal container incidents: the DO is to review the disposition recommendation from PDS and any additional findings by IPP and the FLS. The DO is to make the final ruling on the disposition of the affected lot and notify IPP through the chain of command.

2. Import abnormal container incidents: the DO is to review the disposition from PDS and make the final ruling on the disposition of the affected lot. IPP are to follow instructions from their chain of command and assure disposition per the instructions in FSIS Directive 9900.2 and FSIS Directive 9900.8.

XII. QUESTIONS

Refer questions regarding this directive to the Office of Policy and Program Development through askFSIS or by telephone at 1-800-233-3935. When submitting a question, use the Submit a Question tab, and enter the following information in the fields provided:

Subject Field:	Enter **Directive 7530.1**
Question Field:	Enter your question with as much detail as possible.
Product Field:	Select **General Inspection Policy** from the drop-down menu.
Category Field:	Select **Processing**, then select **Thermal Processing** from the drop-down menu.
Policy Arena:	Select **Domestic (U.S.) Only** from the drop-down menu.

When all fields are complete, press **Continue** and at the next screen press **Finish Submitting Question.**

NOTE: Refer to FSIS Directive 5620.1, *Using askFSIS,* for additional information on submitting questions.

Assistant Administrator
Office of Policy and Program Development

CAUSES OF PROCESS DEVIATIONS

There are several types of process deviations that may be encountered in a thermal processing canning environment such as problems with processing equipment, formulation issues, or human error. As a resource to inspection personnel, the following is a list of types of deviations that may occur. This list is not meant to be all-inclusive.

Mechanical Process Deviations

- Blown retort door or gasket
- Contaminated air lines to air operated instrumentation (e.g., recorder controller)
- Leaky air or water valves – particularly in top steam and bottom vented retorts. Usually requires process abort, re-vent, and retiming the process.
- Nonfunctioning or fast running automatic retort timers
- Digital programmer circuit failures
- Mercury thermometer failures for both initial and retort temperature
- Stuck valves
- Ruptured steam valve diaphragms
- Ink skips or runs out on the recorder chart. If not supplemented by MIG thermometer readings, a designated process authority may be able to evaluate the process up to the time the ink skipped or ran out
- Venting deviations:
    - Dividers – unauthorized use or misuse
    - Crates – unauthorized use
    - Piping changes
    - Obstruction of valves, manifolds, headers, and pipes
    - Re-venting if temperature drops below 212 °F on steam retorts
- Boiler failures
- Electrical failures
- Air compressor failures, especially water with overpressure or with air agitation
- Pump failures causing inadequate circulation of water or steam-air mixtures (pumps or turbine fans)
- Slipping/broken drive belts or mechanisms on agitating retorts

Product Related Process Deviations

- Low initial temperatures
- Wrong container orientation, if critical
- Unauthorized ingredient change (e.g., sugars, starches, and nitrite)
- Heating ingredients differently (e.g., steam blanch instead of oven braising)
- Re-hydration of ingredients
- Changes to the state of ingredients (e.g., raw vs. cooked vs. frozen vs. canned)
- Change in slice thickness, diced size, or form size
- Different blanch procedures
- High pH, if a maximum pH is critical to process schedule
- High water activity, if a maximum water activity is critical to process schedule
- High fill weights, drain weights, net weights, or inadequate methods
- High viscosity
- Low machine vacuum, if critical to the process schedule
- Products held too long – thickening
- Formulation percentage changes
- Headspace control, if critical to the process schedule
- Improper mixing of ingredients (not in order designated by PA)
- Improper dispersion (mixing) of starches

Human Element Process Deviations

- Retort by-pass
- Wrong process selection (temperature, time, product, container size, retort method)
- Vent valve not fully opened
- Cold water and air line valves not properly closed (steam retorts)
- Improper record entries, missed or omitted record entries, wrong recorder chart
- Errant measurements of pH, weights, headspace, and other critical factors
- Bleeders closed
- Pre-recorded or falsified entries

- Mistakes in retort log entries
- Failure to properly affix the recorder chart
- Failure to monitor MIG thermometer when recorder fails
- Improper settings of the controller and recorder pens
- Misuse of steam by-pass causing early activation of process schedule automatic timer before the vent cycle is completed
- Under or over component calculations at the formulation step
- Not inking the recorder
- Boredom or inattention
- Initial Temperature (IT) not correctly measured

Process Deviations Unique to Water Retorts

- Low water level
- Failure of circulation systems
- Addition of cold water
- Overpressure, if critical for retort pouches and semi-rigid containers

Process Deviations for Batch Agitating Retorts

- Low or high reel speeds
- Broken drive belts
- Unauthorized rotation mode

Deviations for Continuous Rotary Retorts

- Reel speed
- Segregation of transfer valve and intake valve cans when still emergency process has been applied followed by cooling
- Prolonged stops of reel
- IT problems with product in in-feed conveyor or between closing machine and intake valve

Process Deviations for Hydrostatic Retorts

- Excessive conveyor speed
- High water levels

- IT problems from prolonged stops with in-feed leg
- Temperature drops in in-feed leg if in-feed leg heat treatment is part of process schedule

Process Deviations for Aseptic Packaging Systems

- Sterilant (e.g., temperature, concentration, amount, line speed/contact time etc.)
- Sterile air (e.g., filters, temperature, overpressure, etc.)
- High flow rate

Process Deviations for Aseptic Processing Systems

- End of hold tube temperature
- Unauthorized pitch, length, or diameter of the hold tube
- High flow rate
- Differential pressure
- Inadequate system cleaning or pre-sterilization (e.g., temperature, time, etc.)

Process Deviations for Surge Tanks in Aseptic Systems

- Cleaning
- Sterilization
- Overpressure