VERMONT AGENCY OF AGRICULTURE, FOOD & MARKETS
FOOD SAFETY CONSUMER PROTECTION DIVISION
Meat Inspection Service
MONTPELIER, VT
Chuck Ross, Secretary

	MIS DIRECTIVE **Adopted from FSIS Directive 7530.1 Rev. 3**	**7530.1 Rev. 3**	6/1/15

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 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 (shelf-stable) canned products at an official establishment. It also addresses the review of process deviations and abnormal containers by the Policy Development Staff (PDS).

II. CANCELLATION

FSIS Directive 7530.1, Revision 2, Handling Process Deviations and Abnormal Container Incidents for Shelf-Stable Canned Products, 3/25/10

III. SIGNIFICANT CHANGES

The Agency is reissuing this directive to clarify the role of IPP in the handling of process deviation and abnormal container information and to instruct IPP that they are to verify that establishments comply with the applicable regulations. There are no changes to current policy. The updates are as follows:

1. The section DEVIATIONS IN PROCESSING has been rewritten to clarify what options the regulations already provide for compliance;

2. A new section VERIFICATION OF PROCESS DEVIATIONS has been added to detail the inspection tasks;

3. The section WHEN DO IPP SUBMIT PROCESS DEVIATIONS TO PDS FOR REVIEW contains step-by-step instructions to eliminate any confusion about the procedures;

4. A new section PDS REVIEW separates the review process from inspector instructions;

5. The Abnormal Container Section has been reorganized into four separate, clearly defined, sections as follows:

    a. ABNORMAL CONTAINERS IDENTIFIED AT AN OFFICIAL INSPECTED ESTABLISHMENT;

    b. IPP INSTRUCTIONS FOR SUBMITTING SAMPLES FOR LABORATORY ANALYSIS; and

6. A new section has been added to detail the DISPOSITION OF AFFECTED LOTS; and

7. A DATA ANALYSIS section has been added.

IV. BACKGROUND

Only products that have received a full thermal process as determined by the established process schedule are eligible to bear the VT mark of inspection and to be distributed in commerce. Canned product is defined in 9 CFR 318.300(d) and 381.300(d) 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. Thermally processed 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 thermally processed, commercially sterile (canned) product or aseptically processed product. This directive supplements but does not replace FSIS Directive 7530.2, *Verification Activities in Canning Operations that Choose to Follow the Canning Regulations*, which delineates the verification responsibilities of IPP during production of thermally processed, commercially sterile canned product.

V. DEVIATIONS IN PROCESSING

A. Whenever the actual process or a critical factor is less than what is required by the process schedule (9 CFR 318.308(a) and 381.308(a)), or any operating parameter of the thermal processing system is not met (e.g., the vent schedule in a steam retort or come-up time in water immersion retort, or steam-air retort), such an event is considered a process deviation. Attachment 1 provides information on Causes of Process Deviations. The canning regulations specify the requirements that an establishment must follow when handling a process deviation identified either in-process or through a records review (9 CFR 318.308(d)(1)(2) or 381.308(d)(1)(2)). Additionally, 9 CFR 417.2(a)(3) allows establishments that thermally process products to decide how to address identified food safety hazards associated with microbiological contamination, whether in their Hazard Analysis & Critical Control Points (HACCP) plan or by following the canning regulations (9 CFR 318.308 and 381.308).

B. Therefore, when a process deviation occurs, IPP are to verify that the establishment handles it by using one of the following methods:

1. Following their HACCP plan for canned product that addresses hazards associated with microbial contamination (9 CFR 318.308(b)(1)(i) and 381.308(b)(1)(i));

2. Following an alternate documented procedure that will ensure that only safe and stable product is shipped in commerce (9 CFR 318.308(b)(1)(ii) and 381.308(b)(1)(ii)); or

3. If the establishment does not follow methods 1 or 2 above, then IPP are to verify that the establishment has met the requirements of 9 CFR 318.308(d) or 381.308(d). These sections of the regulations require that the establishment submit process deviation information to IPP for PDS evaluation before the product can be shipped. Conversely, although the methods set out in subparagraphs B. 1. and 2., above, do not require that the establishment submit process deviation information to IPP before shipping the product in commerce, all process deviation information must be available to IPP upon request.

C. IPP are to initiate an official control action to retain the product if the establishment does not have adequate procedures in place to prevent shipment of product before the evaluation and disposition by one of the methods above. If the product is shipped, IPP are to notify their immediate supervisor.

VI. VERIFICATION OF PROCESS DEVIATIONS

A. When the establishment handles a process deviation under a HACCP plan that addresses hazards associated with microbial contamination, IPP are to:

1. Verify that the establishment has met the corrective action requirements in 9 CFR 417.3;

NOTE: A deviation from a critical limit that occurs in an establishment that addresses food safety hazards associated with microbial contamination in a HACCP plan is an unforeseen food safety hazard if the deviation is not covered in that plan by a specific corrective action.

2. Verify that the process schedule used to reprocess the product has been authorized by the establishment's processing authority (PA); and

3. Verify that the establishment's process deviation file contains all of the records that relate to the handling of each deviation (9 CFR 318.308(e) and 381.308(e)). The establishment's process deviation file is to contain, 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 uses an alternate documented procedure for handling a process deviation, IPP are to verify that:

1. The establishment is implementing the alternate procedure as written (9 CFR 318.308(b)(1)(ii) or 381.308(b)(1)(ii));

2. The establishment applies an alternate process schedule on file that has been approved by a processing authority (318.302(a) and (b) or 381.302(a) and (b));

3. The establishment has indicated on the thermal processing operator's record and the temperature recording chart that an alternate process schedule was used;

4. The establishment's process deviation file contains all of the records that relate to the handling of each deviation (9 CFR 318.308(e) or 381.308(e)).

C. When an establishment does not address biological hazards under a HACCP plan or has no alternate documented procedures for handling of process deviations, they must meet the requirements of 9 CFR 318.308(d) or 381.308(d)). IPP are to verify that:

1. The establishment immediately reprocessed the product using the full process schedule when the process deviation is detected in-process; or

2. The establishment used an appropriate alternate process schedule (9 CFR 318.302(a) and (b) or 381.302(a) and (b)), and that the process schedule is;

    a. Approved by a PA;

    b. On file with the establishment; and

c. Available for review by IPP.

3. The product involved has been placed on hold, and that the deviation is being evaluated by a processing authority (9 CFR 318.308(d)(1)(iii) and (iv) or 381.308(d)(1)(iii) and (iv)); and

4. The establishment's process deviation file contains all of the records that relate to the handling of the deviation (9 CFR 318.308(e) and 381.308(e)).

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

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

A. Some process deviations are not submitted to PDS for review. Process deviations are submitted to PDS for review in accordance with 9 CFR 318.308(d) and 9 CFR 381.308(d) when the establishment does not address food safety hazards associated with microbial contamination in its HACCP plan, does not use an alternative documented procedure for handling process deviations, and:

1. Uses an alternate process schedule that is not on file, or it immediately calculates and uses an alternate process schedule, regardless whether it has been approved or not approved by the PA (9 CFR 318.308(d)(1)(v)) or 381.308(d)(1)(v)));

2. Has a deviation in a continuous retort, including, but not limited to, an emergency stop (jam or breakdown) or temperature drop, and does not handle it according to regulatory requirements in 9 CFR 318.308(d)(1)(vi) or 381.308(d)(1)(vi); or

3. The process deviation is found through records review (9 CFR 318.308(d)(2) or 381.308(d)(2)).

B. If the establishment does address food safety hazards associated with microbial 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 has:

    a. Not met the corrective action requirements in 9 CFR 417.3(b); 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, or the establishment's evaluation procedures and results, or the disposition of the affected product.

NOTE: In addition to submitting process deviations for PDS review as detailed in this directive, IPP may request assistance from PDS through supervisory channels using askFSIS.

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

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

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

3. Obtain copies of all information that the processing authority has given the establishment, including:

a. A complete description of the deviation along with all supporting documentation;

b. A copy of the processing authority's evaluation report; and

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

4. List their specific concerns regarding the evaluation or results on FSIS Form 10,000-6, Canned Foods--Process Deviation.

D. IPP are to submit process deviations in the following manner:

1. Complete FSIS Form 10,000-6, Canned Foods--Process Deviation; and

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

a. Send the completed form and required data to PDS either by mail, fax, or through askFSIS http://askfsis.custhelp.com. IPP may contact PDS at 800-233-3935 if they need assistance sending the information;

b. Send one copy of the completed FSIS Form 10,000-6 to the meat inspection office, and

c. Retain a copy in the government office file at the establishment.

VIII. PDS REVIEW

Before the product can be shipped, PDS will review the information or concerns submitted by IPP, the establishment or the PA's evaluation of the deviation, and the proposed corrective actions. PDS will make a recommendation based upon all data and information evaluated. Reviews have averaged 10 working days but may take more or less time than that depending upon the complexity of the deviation and whether any follow-up information is required. The Meat Inspection Office will determine what action to take and inform IPP and the establishment of its decision.

IX. ABNORMAL CONTAINERS IDENTIFIED AT AN OFFICIAL 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 318.300(a) or 381.300(a)).

NOTE: Abnormal containers can be detected on the inspected premise, in an uninspected ID warehouse, or in commerce.

B. The finished product regulations (9 CFR 318.309(d)(2)(ii) and 381.309(d)(2)(ii)) require that an establishment notify IPP when abnormal containers are detected by any means other than incubation. When notified, IPP are to verify that the establishment addresses finished product inspection by following:

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

2. Alternative documented procedures that will ensure that only safe and stable product is shipped in commerce; or

3. 9 CFR 318.309(d) or 381.309(d) for incubation of shelf-stable, canned product.

C. When abnormal containers are detected by the establishment during incubation or by means other than incubation, IPP are to:

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

2. Verify that the establishment has initiated action to determine the cause of the abnormal containers under its HACCP plan as set out in Chapter III – HACCP and Chapter V-- Documentation & Enforcement, FSIS Directive 5000.1, *Verifying an Establishment's Food Safety System,* and that it is implementing those procedures as described. The establishment is required to share with IPP the incubation records, laboratory microbial testing results, and other documentation that demonstrates food safety; and

3. Verify that the establishment disposed of the affected containers in the suspect lot. When an 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 VT Rejected – VT Retained Tags.

NOTE: When IPP observe abnormal containers among incubation samples, and the establishment has documented procedures for finished product inspection (either under its HACCP plan or other documented procedures), IPP are not to submit samples to the Laboratory for analysis per the instructions in Section XI. SUBMITTING SAMPLES FOR LABORATORY ANALYSIS, below.

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

1. Retain product associated with abnormal containers that are swollen, leaking or exhibit signs of spoilage, pending laboratory analysis using VT Rejected – VT Retained Tags;

NOTE: 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 Meat Inspection Office per the instructions in Section XI. SUBMITTING SAMPLES FOR LABORATORY ANALYSIS, below; and

3. Inform establishment management that it needs to segregate and refrigerate all abnormal containers that have been sampled, per the Laboratory's instructions, from the retained product pending evaluation. Refrigeration is necessary to prevent rupture and to preserve their contents. Abnormal or normal appearing containers should not be frozen.

NOTE: Isolated cases of containers with obvious or assignable cause (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 evaluated by PDS or to be held, provided that the establishment ensures that only normal appearing containers are shipped.

X. IPP INSTRUCTIONS FOR SUBMITTING SAMPLES FOR LABORATORY ANALYSIS

A. When IPP observe abnormal containers that need to be submitted for laboratory analysis, they are to contact the Chief of Inspection or immediate supervisor. They will make contact with the VT Dept. of Health Laboratory. The determination on the number of samples to be submitted takes into account 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.

NOTE: If the establishment decides to condemn the affected product, no further action is required by IPP other than to ensure that the establishment properly documents and disposes of the affected lot.

B. If the establishment decides to reprocess the lot or retain the lot pending a disposition by the processing authority and VT, IPP are to follow the instructions below for submitting samples.

C. The VDH will provide the meat inspection section with specific instructions based on the information provided during the initial call. IPP are to submit both abnormal and normal appearing containers.

D. IPP may share any remaining abnormal containers with the domestic producing establishment after they have submitted the requested abnormal containers to the laboratory.

E. When submitting samples to the VDH, 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.

F. IPP at an official establishment are to schedule the laboratory sample submittal via PHIS, print the following required forms, and then place the forms in the shipper with the submitted samples:

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

2. FSIS Form 10,000-3, Canned Foods--Abnormal Containers (not yet in PHIS. There is an electronic/fillable version in the Forms database in the FSIS Intranet - Forms.); and

3. FSIS Form 7500-1, Canned Food Sample Reporting (not yet in PHIS. There is an electronic/fillable version in the Forms database in the FSIS Intranet - Forms.).

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

H. IPP at official establishments are to send (e-mail, FAX, or via askFSIS to PDS) one copy of each completed form, and any additional information requested to their DO and the PDS canning team.

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

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

XIII. DISPOSITION OF AFFECTED LOTS

A. Once the FSIS Western Laboratory completes its analysis of abnormal containers submitted, it will forward the findings to PDS. PDS is to review the laboratory analysis and container evaluation findings and issue a disposition recommendation to the DO.

B. The DO is to review the disposition recommendation that PDS has issued to them and any additional information provided by IPP or import inspection personnel and FLS. The DO is to make the final ruling on the disposition of the affected product and notify the inspector-in-charge (IIC) or import inspection personnel through the RIS.

C. IPP are to follow instructions from their chain of command. Import inspection personnel are to review the disposition decision from the DO and assure disposition per the instructions in FSIS PHIS Directive 9900.2 and FSIS PHIS Directive 9900.8.

XIV. DATA ANALYSIS

Data analysis will be addressed on an ad hoc basis if the need arises. The need for data analysis will be addressed by the Data Analysis and Integration Staff using the newer effort to define annual analysis priorities.

XV. QUESTIONS

Refer questions regarding this directive to the PDS 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

Attachment 1

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, formulations issues, or human error. As a resource to inspection personnel, the following is a list of other 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 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:
  - o Dividers – unauthorized use or misuse
  - o Crates – unauthorized use
  - o Piping changes

  - o Obstruction of valves, manifolds, headers, and pipes
  - o Re-venting if temperature drops below 212ºF 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 processing authority)
- 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
- Unauthorized reel speeds from heat distribution aspects

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