THERMAL PROCESSING TRAINING

Module 20. Process Deviations and Abnormal Containers

Thermal Processing for Meat and Poultry Products Training

USDA

Objectives

- Identify common types and causes of process deviations
- Describe regulatory requirements and processor responsibilities for identifying, managing, and documenting process deviations, corrective actions, and abnormal containers
- Understand verification procedures to follow when process deviations occur or abnormal containers are found in official establishments

Definitions – 9 CFR 431.1

- **Process Schedule (PS)**
  - Thermal process requirements and critical factors that ensure canned products are commercially sterile and shelf stable
- **Critical Factor (CF)**
  - Any characteristic, condition, or part of a product, container, or procedure affecting adequacy of PS (e.g., IT, RT, B_b)

Additional Definitions

- **Process Deviation (PD)**
  - Detected in-process or through record review
  - Thermal operating parameters not met
  - Any CF fails to meet specified PS requirements
  - Process applied is less than PS
- **Alternative Documented Procedures**
  - Other documented procedures addressing process deviations
- **Alternate Process Schedule**
  - Process schedule on file used to reprocess product in lieu of original process schedule

Operating Process Example

- **Operating Process Schedule**
  - Voluntary thermal process schedule that typically exceeds minimum PS requirements
  - *Operating process schedule a "buffer" for critical factors identified in approved process schedule*

<u>Example</u>

- Approved Process Schedule

IT = 100°F, Bb = 50 min. @ RT = 250°F

- Operating Process Schedule

IT = 100°F, Bb = 52 min. @ RT = 252°F

Handling Process Deviations – 9 CFR 431.9(b)(1)(2)(3)

- All process deviations handled through…

  (1) Canning HACCP plan addressing biological food safety hazards **OR**

  (2) Alternative documented procedures **OR**

  (3) Paragraph (c) in §431.9

Handling Process Deviations - 9 CFR 431.9(c)(1)(i)(ii)

- Processor options for handling process deviations identified <u>in-process</u>:

(i) Immediately reprocess product under original process schedule **OR**

(ii) Reprocess product using on file alternate process schedule approved by a PA

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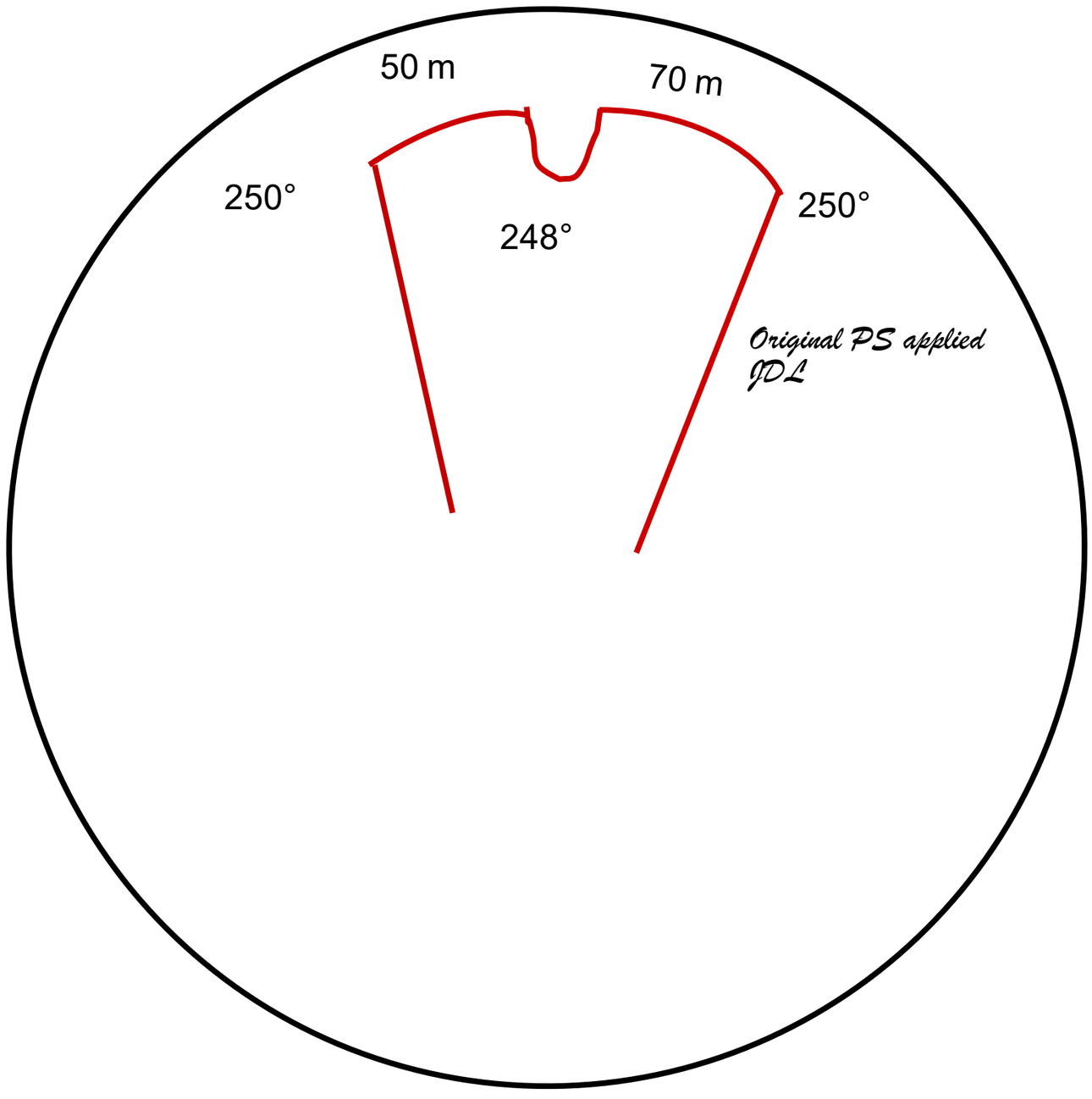
In-Process PD: Original Process Schedule Example - §431.9(c)(1)(i)



PS=100°IT/70B_b/250°RT

Retort temperature dropped to 248°F @ 50 min. but 15 minutes later recovered to 250°F

Processor immediately reprocessed product from time of recovery using original process schedule

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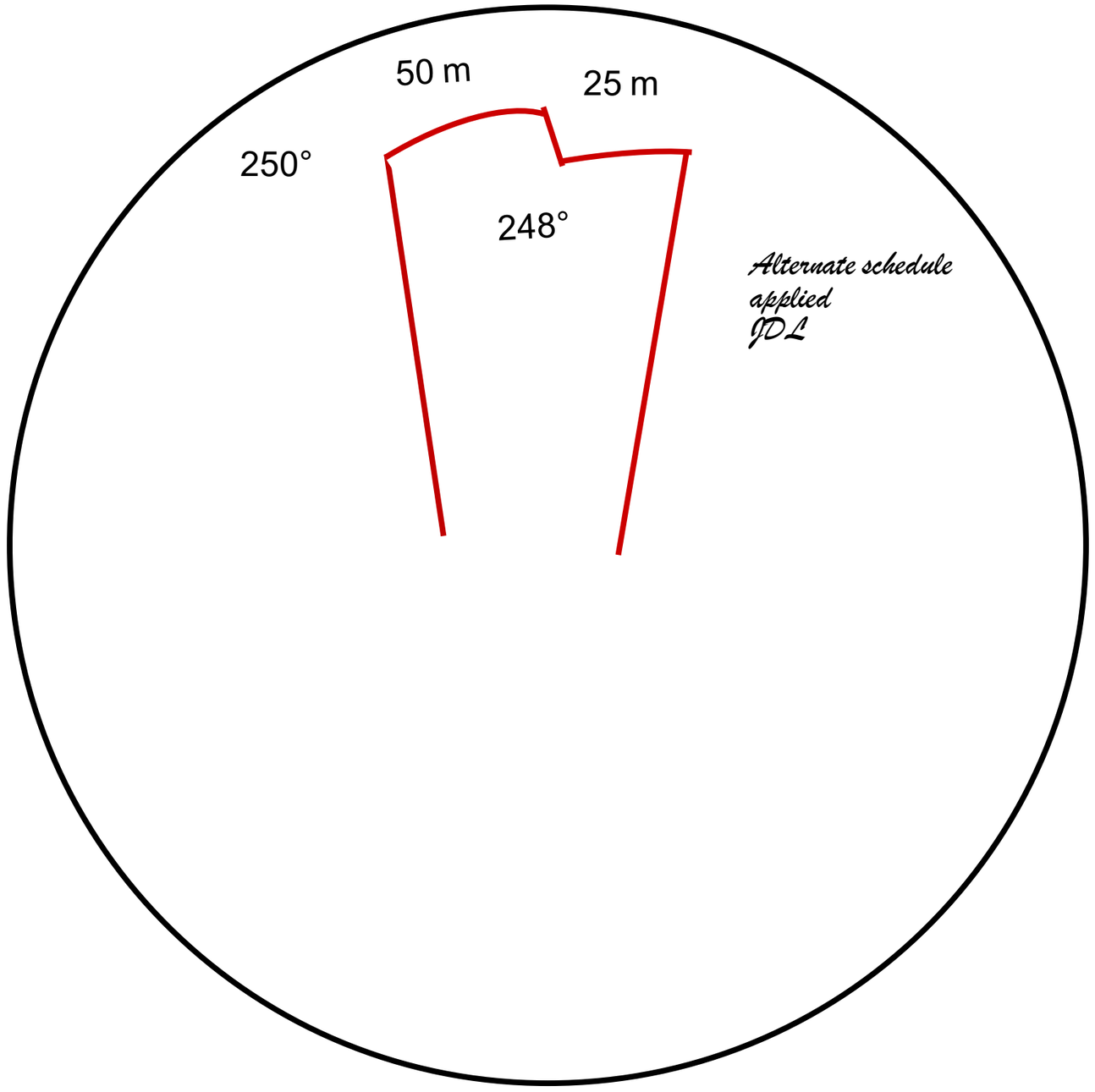
In-Process PD: Alternate Process Schedule Example - §431.9(c)(1)(ii)



PS=100°IT/70B_b/250°RT

Retort temperature dropped to 248°F @ 50 min. and remained at 248°F

Processor applied alternate process schedule on file provided by PA for that product

Alt. PS=100°IT/75B_b/248°RT

Handling Process Deviations - 9 CFR 431.9(c)(1)(iii)(A)(B)(C)

- Hold product involved until process deviation evaluated by PA for product safety and stability
- Upon completion of PA evaluation, processor must provide inspector:

(A) Complete process deviation description and all necessary supporting documentation

(B) Copy of written PA evaluation report

(C) Description of any product disposition actions taken or proposed

Product Not Shipped – 9 CFR 431.9(c)(1)(iv)

- Product handled under §431.9(c)(1)(iii) is not distributed until “the Program” has also reviewed all information submitted and approved product disposition actions

Further Evaluation – 9 CFR 431.9(c)(1)(v)

- Establishment must set aside product for further evaluation by PA and PDS if:
  - Alternate process schedule not on file with inspector is used **OR**
  - Alternate process schedule is immediately calculated and used

Continuous Rotary (Agitating) Retort PD - 9 CFR 431.9(c)(1)(vi)

- Process deviations handled per §431.9(c)(1)(iii) and (iv) **OR**
- §431.9(c)(1)(vi)(A) if an emergency reel stop
- §431.9(c)(1)(vi)(B) if a temperature drop

CRR Emergency Stops – 9 CFR 431.9(c)(1)(vi)(A)(1)(2)

Jams or Breakdowns

(1) All containers, including containers in retort intakes and transfer valves between retort shells, given emergency still process on file before retort is cooled **OR**

Retort promptly cooled, all containers removed, then either reprocessed, repacked and reprocessed, or destroyed

(2) Retort reel stop time and time retort used for emergency still process documented

CRR Temperature Drops – 9 CFR 431.9(c)(1)(vi)(B)(1)

Temperature Drop <10°F:

(i) All containers given emergency still process on file before reel restarted **OR**

(ii) Container entry to retort prevented and emergency agitating process on file given before container entry to retort restarted **OR**

(iii) Containers prevented entry to retort, retort emptied, and discharged containers reprocessed, repacked and reprocessed, or destroyed

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CRR Temperature Drops – 9 CFR 431.9(c)(vi)(1)(B)(2)

Temperature Drop ≥10°F:

- Container entry to retort prevented
- All containers given emergency still process on file before reel restarted **AND**
- Reel stop time and time retort used as still retort noted **OR**
- Reel restarted, retort emptied, and discharged containers reprocessed, repacked and reprocessed, or destroyed

Process Deviations - 9 CFR 431.9(c)(2)

- Process deviations identified during <u>record review</u> of processing and productions records required by §431.8(a) and (b) must be reviewed and evaluated by PA and PDS before involved product shipped from establishment

Process Deviation File - 9 CFR 431.9(d)

- Maintained in separate file or log
  - Processing and production records
  - Description of corrective actions taken
  - Evaluation procedures and results
  - Disposition of affected product
- Retained in accordance with §431.8(e)

Pop Quiz

A plant using an operating process has a temperature drop in the retort, but the temperature is not below the minimum retort temperature established in the process schedule.

Is this a process deviation?

Yes

No

Pop Quiz

The biggest concern with reprocessing product that has already received a thermal process is that the product may become mushy and not saleable.

False

True

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Process Deviations - Detection, Correction, and Handling

- PD types and causes
- Plant responsibilities
  - In-process PD detection and handling
  - Record review PD detection
  - Product reprocessing
  - Reporting process deviation to PA
  - Evaluation results and product dispositions
- CSI responsibilities

Types of Process Deviations – Directive 7530.1

- Mechanical
  - Still retorts
  - Batch agitating retorts
  - Continuous rotary agitating Retorts
  - Aseptic Processing Systems, including Surge Tanks
  - Hydrostatic Retorts
- Product Related
- Human Element

Process Deviations Impacting Heating Parameters

- Low initial temperature
- No or improper vent procedure used
- Insufficient venting time
- Low venting/CUT temperature
- Inconsistent retort temperature
  - Down spikes (no measurable duration)
  - Drops (measurable duration)
  - Excessive fluctuations
- Shortened process time

Steam Retort Process Deviations - Mechanical

- Blown retort door gasket
- Contaminated or ruptured air lines
- Leaky or stuck air or water valves
- Ruptured steam valve diaphragm
- Thermometer failures
- Steam or water spreader problems
- Venting issues (e.g., divider/crate open area, piping valves, diameter, and obstructions)

Steam Retort Process Deviations – Mechanical *(cont.)*

- Nonfunctioning or fast running automatic retort timers
- Digital programmer circuit failures
- Boiler or electrical failures
- Pump/turbine fan failures
- Air compressor failures, especially in overpressure or air agitation processes

Continuous Rotary Agitating Retort Process Deviations - Mechanical

- Incorrect RPM (high, low, or none)
- Slipping or broken drive belts or mechanisms in agitating retorts
- Reel jams/stops
- Condensate build-up
- Cooling shell pressure too high
- Unprocessed containers in inlet and transfer valves not separated from processed containers following emergency still process

Hydrostatic Retort Process Deviations - Mechanical

- High water level in steam dome
- Conveyor speed too fast
- Temperature drops in water leg(s) not considered in process schedule
- Prolonged container stops in-feed leg(s)

Water Cascade/Spray Retort Process Deviations - Mechanical

- Clogged nozzles, plates, filters, strainers, or pump suction ports
- Low water recirculation flow rates
- Low water level
- Wrong basket or container load configuration
- Improper overpressure (low or high)
- Improper retort control/operation

Process Deviations – Aseptic Systems

- System pressure drops
- Temperature drop in hold tube
- Hold tube installed with wrong pitch or length too short
- Water flow rate too fast
- Low temperature
- Low sanitizer concentration in bath
- Clogged spray nozzles

Process Deviations - Product Related

- Different heating method
- Formulation errors
  - Unauthorized ingredients
  - Inaccurate or incorrect percentages
  - Concentration changes
- High fill weights/viscosity/pH/water activity, wrong container position (if critical factors)
- Inadequate head space (if agitating)
- Holding product too long

Process Deviations – Product Related *(cont.)*

- Preparation errors
  - Improper ingredient hydration or blanching procedures
  - Frozen ingredients used instead of canned ingredients and vice versa
  - Improper mixing of ingredients
  - Incorrect slice thickness or dice size
  - Holding product too long

Process Deviations – Human Element

- Improper CF measurements (e.g., IT, RT, Bb, pH, fill weight, etc.)
- Wrong process schedule/product formula used
- Improper retort control/early shut down
- Retort by-pass
- Improper controller/recorder pen settings, pen not inked, improperly affixed/wrong recorder chart
- Incorrect, pre-recorded, or falsified record entries

Record Deviations

- Improper controller/recorder pen settings, pen not inked
- Improperly affixed/slipping recorder chart
- Wrong recorder chart
- Temperature recorder chart temperature higher than accurate indicating temperature device
- Missing vent time and temperature entries*
- Tracing skips/blots*

**NR and PA evaluation may not be required*

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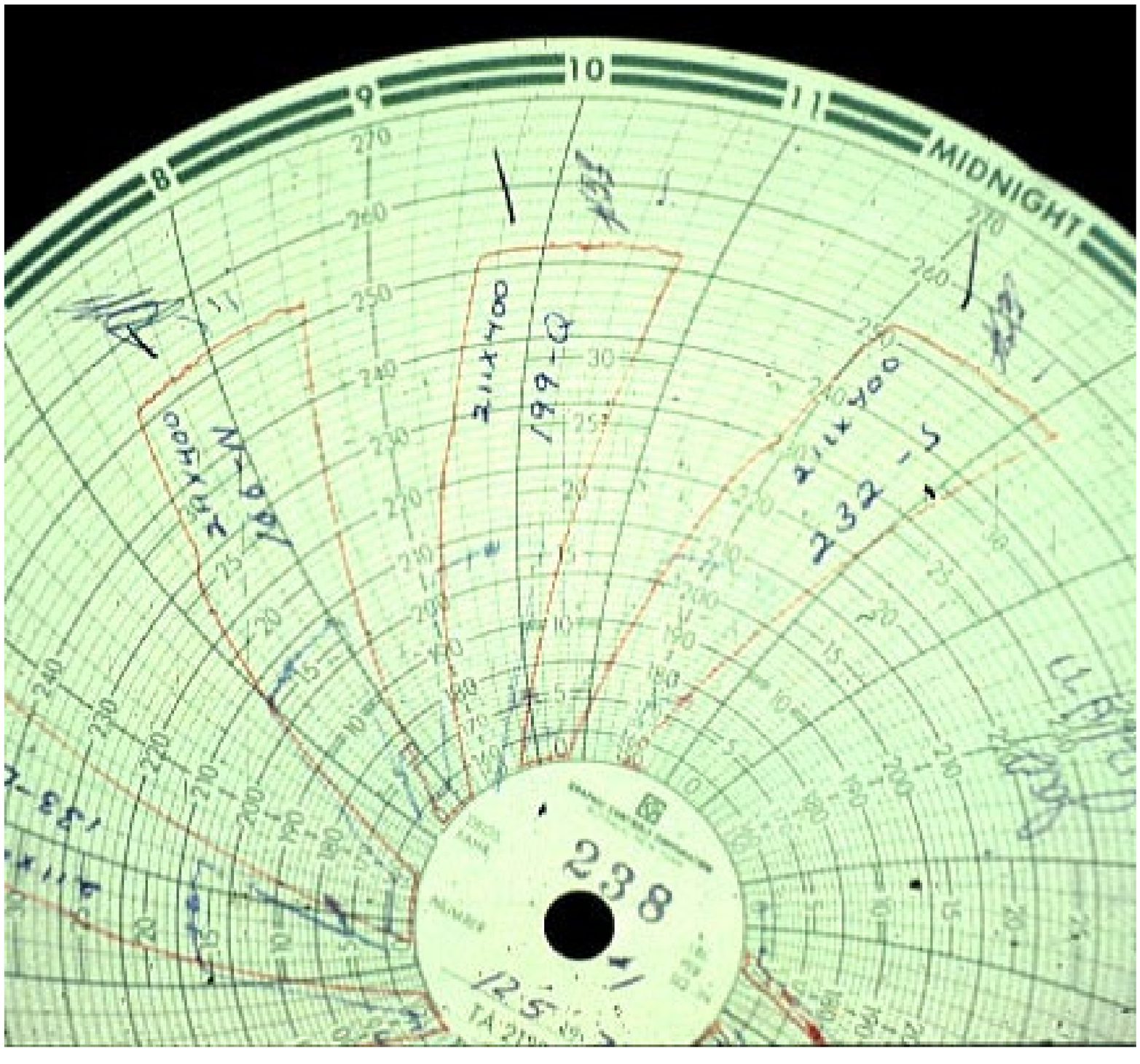
Record Deviations – Tracing Waviness



Record Deviations - Ink Skip

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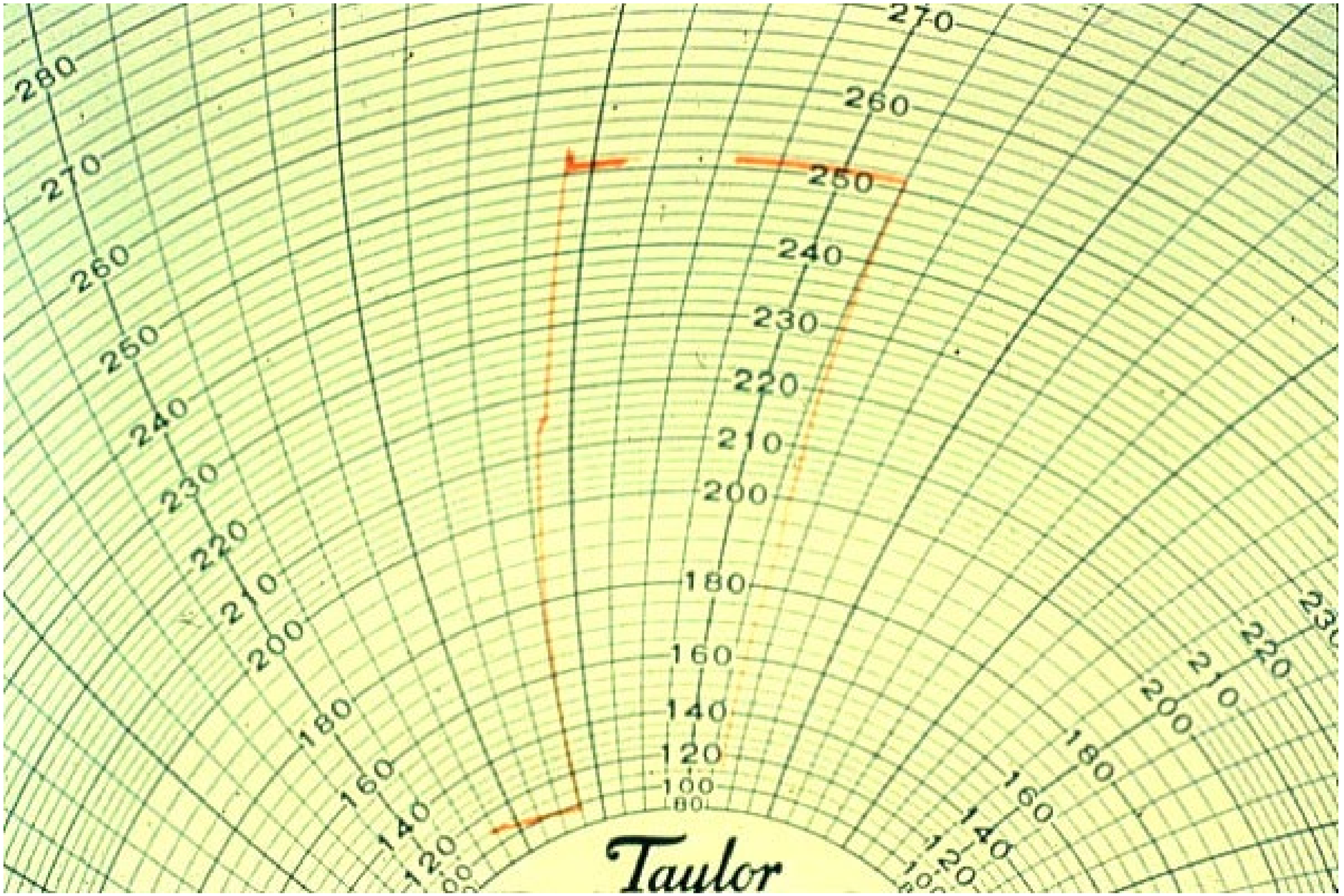

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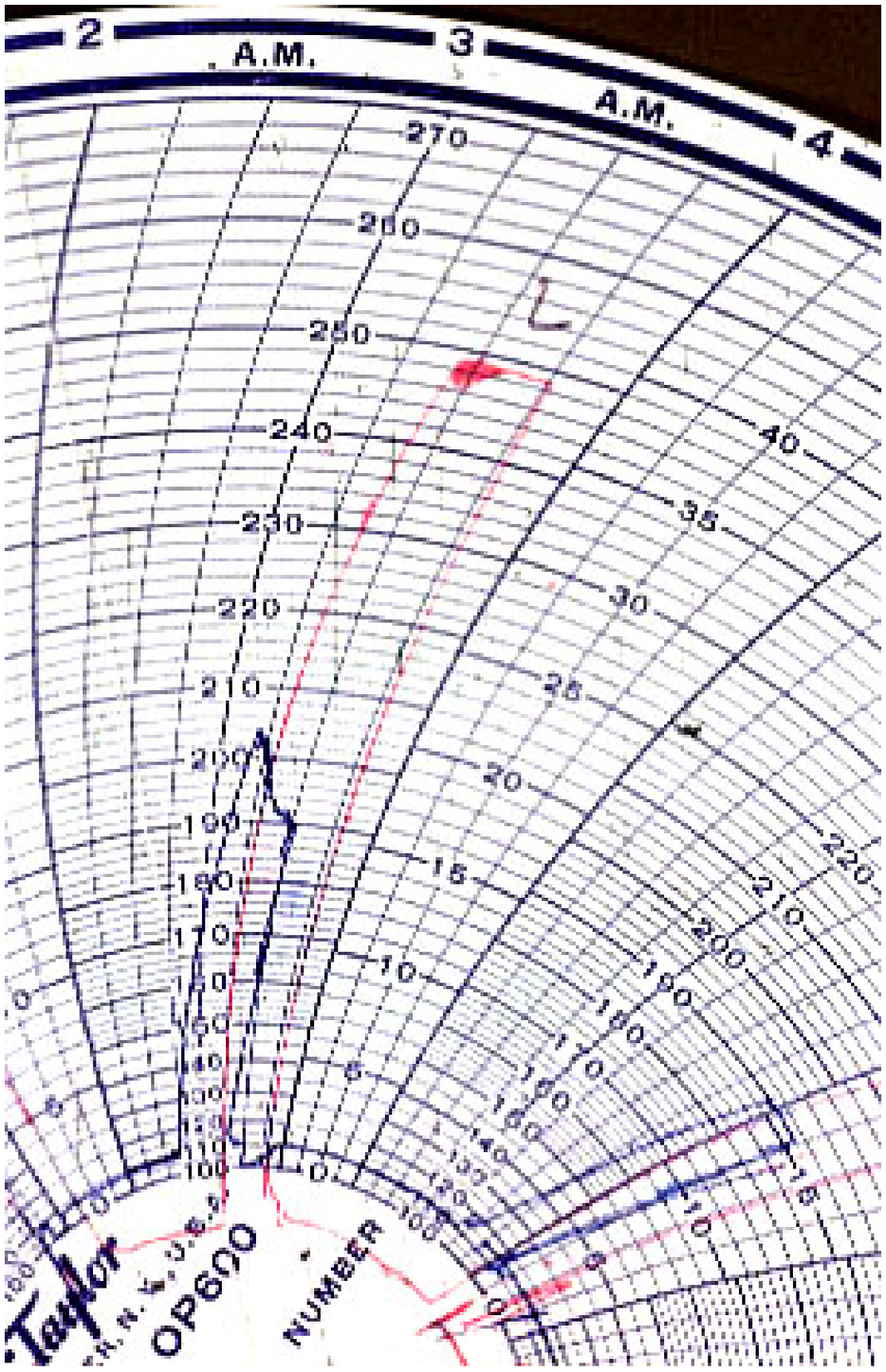
Record Deviations - Ink blot



Pop Quiz

The plant measures a low IT prior to applying the intended (posted) process schedule to any product, switches to the alternate process schedule on file, and successfully applies it.

Is this a process deviation?

Yes

No

Pop Quiz

The recording chart stopped 20 minutes into a 43-minute process. The retort operator observed and recorded MIG thermometer readings every 1 minute from the time the chart stopped until the process was done.

Is this a process deviation?

Yes

No

Pop Quiz

While removing the cans from retort baskets, the labeling department notices that an extra divider plate (double) was used between one layer of cans. The heat distribution data does not address the use of 2 dividers between layers.

Is this a process deviation?

Yes

No

Process Deviations - Plant Responsibilities

- Detect and handle all process deviations:
  - As described in a canned product HACCP plan **OR**
  - As described in alternative documented procedures **OR**
  - In accordance with §431.9(c)
- Reprocess or rework product under original or alternate schedule authorized by PA

Process Deviations - Plant Responsibilities *(cont.)*

- Maintain a separate PD file or log with:
  - Description of each deviation
  - Description of corrective actions
  - Associated processing/production records
  - Evaluation procedures and results
  - Disposition of affected product

The most egregious deviation is an establishment not properly handling a PD and distributing that product in commerce!

Process Deviations - Processor Detection and Correction

- Once detected, a process deviation must be handled by:
  - Immediately reprocessing affected product per §431.9(c)(1)(i) or (ii) if found in-process **OR**
  - Holding affected product for evaluation by PA to assess safety and commercial sterility in accordance with §431.9(c)(1)(iii) or (2) **OR**
  - Condemning and destroying product - 9 CFR Part 314 or §381.95

Process Deviations - Corrected In-Process

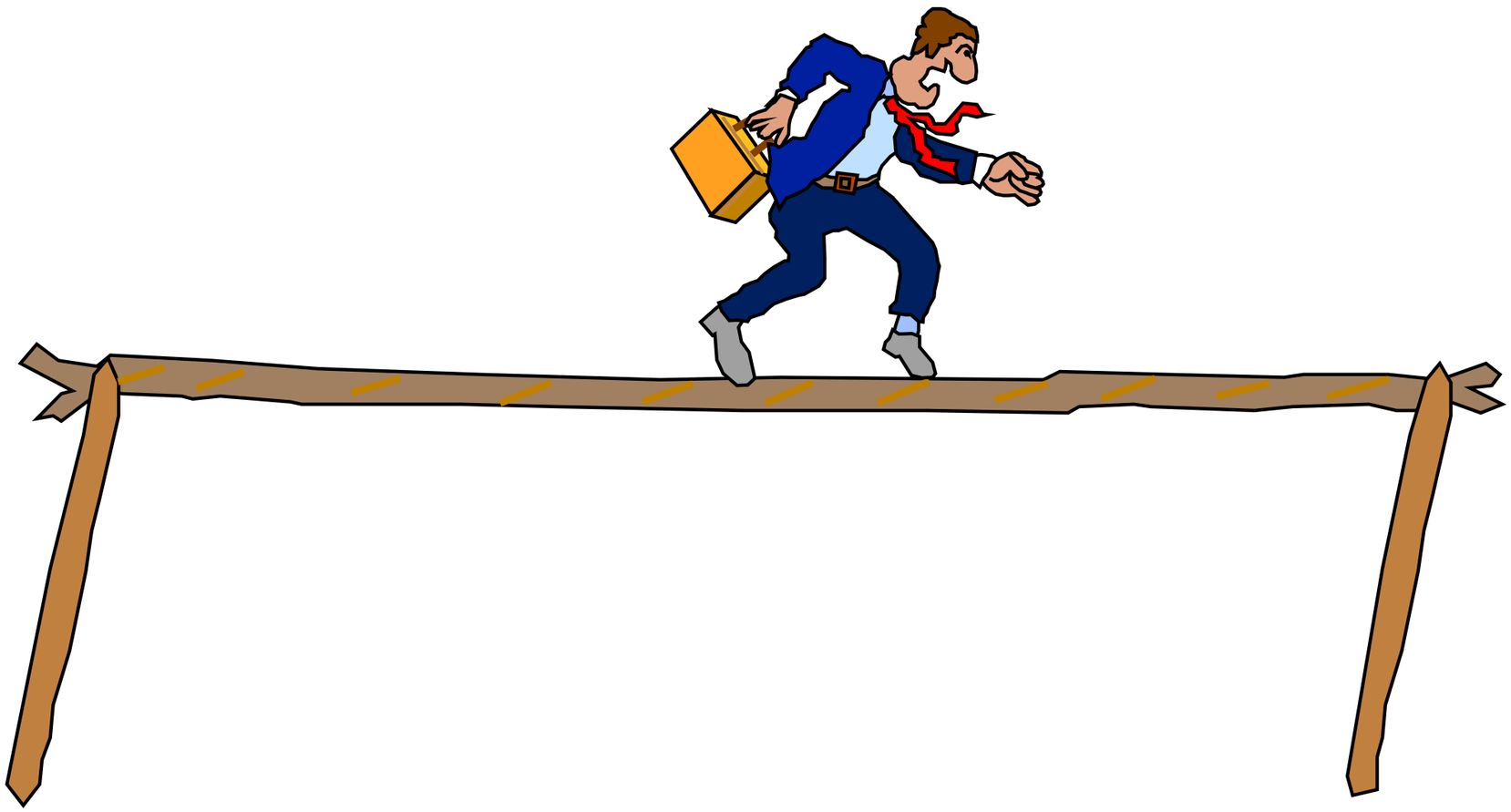
- Unless a documented reprocessing schedule or alternate process schedule is met, PA evaluation of the process deviations is required
- Corrective actions documented
  - Retort malfunctions (e.g., air or cold-water intrusion) jeopardize corrective actions
  - PA may simulate temperature distribution
  - Worst-case scenario
  - No reliability of “assumptions”

Process Deviations - Corrected In-Process *(cont.)*

- Calculation of new or alternate process schedule not on file during PD require PA evaluation
- Corrective actions documented
  - Implemented emergency procedures may change process parameters following calculations

Process Deviations - Corrected In-Process *(cont.)*

- Arbitrary corrections can be applied but product must still be evaluated by PA



Process Deviations - Correcting From Record Reviews

- Final chance to detect PD
- Examine records more frequently when excessive record process deviations identified
- Complications with isolating commingled product

Process Deviations - Isolating Affected Product

- Product isolation documentation
- Continuous system consequences for improper isolation
- Product bracketing – last good check
  - Critical factor deviations
  - Retort malfunction

Process Deviations - Reprocessing Concerns

- Valid reprocess schedule
  - Original or alternate process schedule
- Heat penetration rate differences
  - Binders, extenders, thickeners
- Storage effects
  - Viscosity changes
  - Product swelling

Process Deviations - Reprocessing Concerns *(cont.)*

- Potential *S. aureus* enterotoxin
  - Gross under-processing
  - Heat resistant enterotoxin
- Rework
  - Level limit
  - Procedure
    - Ex. - 110 Bb original/180 Bb reprocess
- Appropriate documentation

Process Deviations - Critical Role of Processing Authority

- Adequate evaluation methods
  - Consequences of failure
- Evaluates each incident individually
- Advises processors
  - Identifies deviations requiring evaluation
  - Deviation prevention

Process Deviations - Records Submitted to PA

- Product identification
- Type of container and code
- Production date
- Processing vessel identification
- Process cycle or time span
- Quantity held
- Nature/cause of deviation
- Corrective actions taken
- Copies of pertinent records
- Disposition of product

Process Deviations - Documenting Inadequate Information Submittals

- Records not submitted per §431.9(d)
  - No critical factor records
- Insufficient detail provided
  - Cause of temperature drop not identified
  - Product disposition unknown
- Irrelevant QC biological sample results

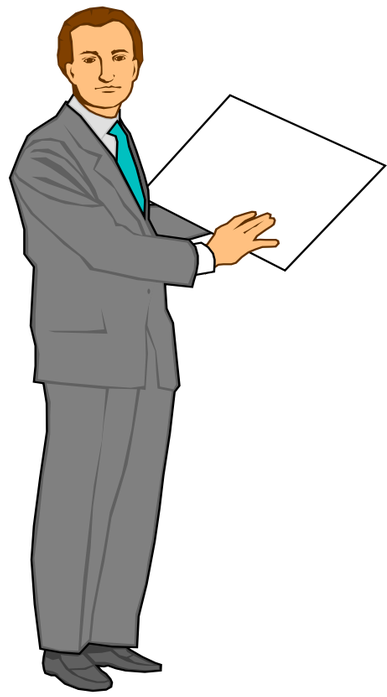
Process Deviations - Handling Missing Entries on Records

- Computerized recordkeeping failures
  - Manual retort operator logs
    - No PD if MIG or digital thermometer readings
- Missing temperature tracings, log entries
  - Pressure tracings for steam
  - Concerns with worst case evaluation
    - Simulations based on no venting

Process Deviations - PA Evaluation Concerns

- Evaluation without original test data
- Limits of original data stretched to cover conditions
- Reluctance to conduct additional studies
  - Reliance on experience and suppositions without data
- Incubate, sort, and ship disposition without evaluation

Process Deviations - PA Evaluation Reports



- Evaluation must be written
- Essential contents of report:
  - Processing conditions causing deviation
  - Processing parameters used
  - Method employed (Ball, Stumbo, other)
  - Resulting sterilizing value (F0)
  - Summary of records utilized
  - Statement if process meets CS or minimum health values

PA Evaluation Reports – Product Disposition

Commercial Sterile

- Product free of viable organisms of public health and non-health significance which are capable of reproducing under normal non-refrigerated storage and distribution environmental conditions

PA Evaluation Reports – Product Disposition *(cont.)*

Above Minimum Health

- Product received a thermal process that rendered it free of microorganisms of potential public health significance

Below Minimum Health

- Product may contain microorganisms of potential public health significance

PA Evaluation Reports – Product Disposition *(cont.)*

- Recommended PA disposition procedures for product not commercially sterile
  - Above minimum health
    - Reprocess to commercial sterility
    - 100% incubation and sort (evaluate for swollen containers)
  - Below minimum health
    - Reprocess to CS as above or destroy product

Pop Quiz

The disposition of thermally processed product that may contain spoilage microorganisms capable of reproducing under normal non-refrigerated conditions but has been rendered free of microorganisms of potential public health significance would be:

Commercially Sterile

Above Minimum Health

Below Minimum Health

Process Deviations - Product Release Criteria

- Affected product distribution contingent on acceptable PA evaluation
- Written response required for each incident
  - Verbal release not in compliance
- Detailed PA deviation reports and plant actions taken maintained in file/log

FSIS Directive 7530.1 (Rev. 4)

"Handling a Process Deviation or Abnormal Container of Thermally Processed, Commercially Sterile Canned Product"

- Identifies abnormal containers and causes of process deviations
- Identifies procedures IPP to follow when PD or abnormal containers found
- Addresses PDS evaluation of process deviations and FSIS laboratory analysis of abnormal containers

Process Deviations - CSI Responsibilities

- Verify the plant handles process deviations through either:
  - A HACCP plan as written, documenting corrective actions and reassessing the HACCP plan if necessary, **OR**
  - An alternate process schedule authorized by a PA and on file if required for product reprocessing **OR**
  - Alternative documented procedures

Process Deviations - CSI Responsibilities *(cont.)*

- If a plant follows canning regulations and has no alternative documented procedures for handling a PD, verify that:
  - If the PD was detected in-process, product was immediately reprocessed under a original process schedule **OR**
  - A PA developed alternate process schedule on file before the PD occurred was used **OR**
  - Product involved was placed on hold until PD was evaluated by a PA

Process Deviations - CSI Responsibilities *(cont.)*

- Verify that:
  - Each process deviation was evaluated by the plant, a PA, or PDS as necessary
  - All process deviation evaluations and required records are maintained in a separate file or log
  - All process deviation evaluations and corrective actions documented

Process Deviations - CSI Responsibilities *(cont.)*

- Verify the plant maintains full records for handling each process deviation in a separate file or log, including:
  - Appropriate processing and production records
  - Full descriptions of corrective actions
  - Evaluation procedures and results
  - Disposition of affected product

Process Deviations Submitted to PDS

- Corrective action requirements of §417.3 not met
- Alternative documented procedures not used
- Alternate process schedule not on file used, or alternative process schedule on file immediately calculated and used
- Process deviation in a continuous rotary retort not handled per §431.9(c)(1)(vi)
- Process deviation found through records review
- IPP concerns - FSIS Form 10,000-6

Process Deviations Not Evaluated by PDS

- PDS will not usually review a process deviation when:
  - The plant addressed microbial food safety hazards in a HACCP plan and implemented corrective actions
  - The plant used an alternative documented procedure for handling process deviations
  - No process deviation handling concerns

Process Deviations Not Evaluated by PDS *(cont.)*

- Process deviation found in-process not usually evaluated by PDS when plant:
  - ✓ Immediately reprocessed product using original process schedule
  - ✓ Used approved alternate process schedule on file
  - ✓ Handled emergency stops/temperature drops in continuous rotary retort per §431.9(c)(1)(vi)

Abnormal Containers – 9 CFR 431.10(a)

- Processor handles finished product inspections according to:
  - HACCP plan addressing biological hazards **OR**
  - FSIS-approved TQ control system **OR**
  - Alternative documented procedures **OR**
  - §431.10(b)

Abnormal Containers – 9 CFR 431.10(b)(1)

(i) Incubation facilities - temperature/time recording and indicating temperature devices, air circulation, restricted entry

- "Program" responsible for incubator security

(ii) Incubation temperature 95±5°F (35±2.8°C)

- If temperature <90°F (32°C) or >100°F (38°C) but <103°F (39.3°C), adjust to range, extend incubation time containers out of temperature
- If temperature ≥ 103.5°F >2 hours, test terminated and new containers incubated

Abnormal Containers – 9 CFR 431.10(b)(1) *(con't.)*

(iii) Shelf stable product requiring incubation:

(A) Low acid products - §431.1

(B) Acidified low acid products - §431.1

(iv) Incubation samples:

(A) Still or agitation batch type retort – one container each load

(B) Continuous rotary, hydrostatic, other continuous-type retort – one container per 1,000

(C) Normal appearing containers only

Abnormal Containers – 9 CFR 431.10(b)(1) *(con't.)*

(v) Incubation time >10 days/240 hours

(vi) Incubation checks and record maintenance

- Designated employees visually check all incubating containers each working day
- CSI notified when abnormal containers found
- All abnormal containers cooled before final decision on condition made

Abnormal Containers – 9 CFR 431.10(b)(1) *(con't.)*

(vi) *(con't.)*

- Document at least product name, container size/code, number of containers incubated, in/out dates, incubation results
- Retain records, including temperature/time recording charts and initial distribution

(vii) Retain at least code lot involved if abnormal containers found in incubation samples

(viii) No product shipped from establishment before required incubation period completed

Abnormal Containers – 9 CFR 431.10(c)

(1) Establishment only ships normal-appearing containers determined by sampling plan or other acceptable means

(2) Inspector informed if abnormal containers detected by other than incubation and affected lot not shipped until Program determines product safety and suitability

- Cause and level of abnormals
- Product disposition actions taken or proposed

Abnormal Containers - CSI Responsibilities

- IPP verify notification received when processors following canning regulations detects abnormal containers:
  - During finished product incubation - §431.10(b) **OR**
  - By any means other than incubation - §431.10(c)(2)

Abnormal Containers - CSI Responsibilities *(con't.)*

- When IPP detect abnormal containers:
  - Retain product lot associated with the abnormal containers
  - Notify establishment about finding and document incident in MOI

Abnormal Containers - CSI Responsibilities *(con't.)*

- If establishment handles abnormal containers under HACCP plan or documented procedures, IPP verify plant:
  - Controls and prevents shipment of affected lot
    - Retain lot if necessary
  - Initiates actions to determine and eliminate cause of abnormal containers, including §417.3 corrective actions
- Verify lot safety and stability (review microbial results, PA evaluations, incubation records, etc.)

Abnormal Containers - CSI Responsibilities *(con't.)*

- When plant does not handle abnormal containers under a HACCP plan or documented procedures:
  - Retain product lot associated with abnormal containers
    - Minimum amount of 2 hours continuous production retained
  - Contact FSIS Western Laboratory by phone per Directive instructions

Abnormal Containers - CSI Responsibilities *(con't.)*

- When IPP observe abnormal containers at domestic plant:
  - Contact FSIS Western Laboratory per Directive and provide supervisor's contact
  - Provide lab with all information requested
  - Submit both normal and abnormal samples
  - Refrigerate abnormal containers before mailing *(DO NOT FREEZE CONTAINERS)*
  - Complete FSIS Forms 10,000-2, 10,000-3

Abnormal Containers - CSI Responsibilities *(con't.)*

- When IPP observe abnormal containers at an official import establishment:
  - Follow Directive 9900.2, Section XV instructions to add a Condition of Container type of inspection (TOI) when necessary
  - Provide inspection details to importer of record (IOR)
  - Handle abnormal containers same as those found at domestic official establishments
  - Follow product disposition instructions

Abnormal Containers - CSI Responsibilities *(con't.)*

- When IPP observe abnormal containers at official import establishments:
  - Follow Directive 9900.2, Section XV to add Condition of Container type of inspection (TOI) when necessary
  - Follow same procedures for submitting domestic samples
  - Complete lab sample Form 8000-21 and Abnormal Container TOI questionnaire
  - Send copy to Import Inspection, DO, PDS

Abnormal Containers - CSI Responsibilities *(con't.)*

- Final disposition of abnormal containers
  - DO reviews PDS recommendation and any additional findings by IPP and the FLS to make final ruling on affected lot disposition
  - IPP notified of any additional actions to take through chain of command
  - IPP verify disposition of imported abnormal containers per FSIS Directives 9900.2 and 9900.8

Pop Quiz

A plant has no HACCP plan addressing microbial contamination and no alternative documented procedures for handling process deviations. A process deviation detected in-process and a process not on file is immediately calculated. Product is held and a PA evaluates the deviation. Upon receiving the PA's commercial sterility disposition, the product is shipped.

In Compliance

Out of Compliance

Pop Quiz

A plant has no HACCP plan addressing microbial contamination and no alternative documented procedures for handling process deviations. The computer program detected a process deviation in-process and calculated/applied an alternate process not on file. Should the process deviation be submitted to PDS?

Yes

No

Objectives Summary

- Identify common types and causes of process deviations
- Describe regulatory requirements and processor responsibilities for identifying, managing, and documenting process deviations, abnormal containers, and corrective actions
- Perform verification activities for determining plant compliance in handling process deviations and abnormal containers

Questions?