



THERMAL PROCESSING  
TRAINING

# Module 23. Process Verification and Assessment

Thermal Processing for Meat and Poultry  
Products Training



# Purpose and Objectives



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- **Purpose of Module 24**
  - Provide methods for monitoring processes and assessing canneries.
- **Performance Objective**
  - Ability to use appropriate methods to successfully verify processes at canning establishments and perform assessments of the establishment's Food Safety System.



# FSA's



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- It is important that the EIAO/CSI understand the approach to food safety assessments (FSAs) to verify the establishment is in compliance with the meat and poultry canning regulations and that the establishment responds appropriately to the results of the FSA.



# FSA/Initial Inspection Steps



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- Before the FSA:
  - Prepare
  - Review prior history (CSI to if possible)
- During the FSA:
  - Meet with management (CSI entrance meeting)
  - General walk through (CSI after entrance meeting)
  - Review temperature distribution report and scheduled process documentation (CSI also)
  - Request for records (EIAO before walk through)
  - Conduct the FSA
  - Write observations
  - Review observations and obtain management's response



# FSA Procedures



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- Preparation for the FSA
  - Review of previous FSA reports
  - Review the FSA tool questions and PHRE findings to identify specific areas of focus
  - Contact previous EIAOs if necessary
  - Review the establishment's HACCP system



## Recommended References



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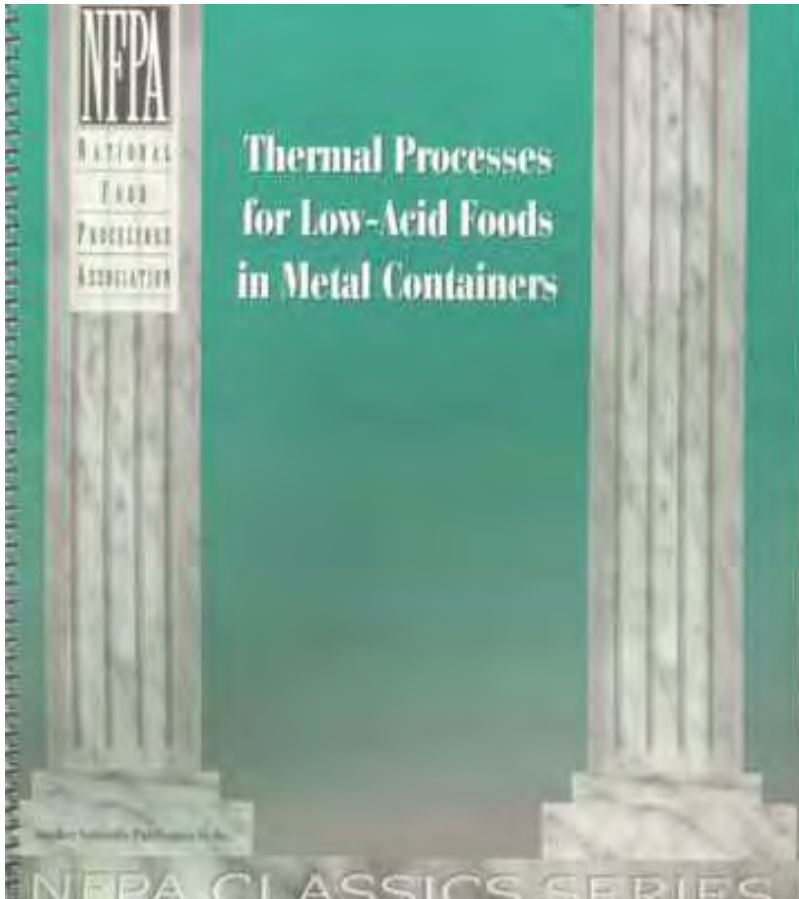
- 9 CFR Part 431– Meat and Poultry Canning Regulations
- FSIS Canning Reference Manual
- Review specific information on products
- Procedures specified in FSIS Directive 5100.1  
- EIAO Food Safety Assessment Methodology



# GMA Bulletins



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- NFPA Bulletin 26L for metal containers
- Other NFPA bulletins:
  - 30L for glass containers
  - 44L for rotary sterilizers



# Establishment Equipment Needed for Demonstrating Compliance



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- Stopwatch
- Handheld thermometer
- Drill bits
- Tape measure
- Dial caliper
- Can teardown equipment
- pH paper
- Dividers
- Head space gauge and other CF measuring instrumentation
- Method to test cooling water chlorine (sanitizer) level





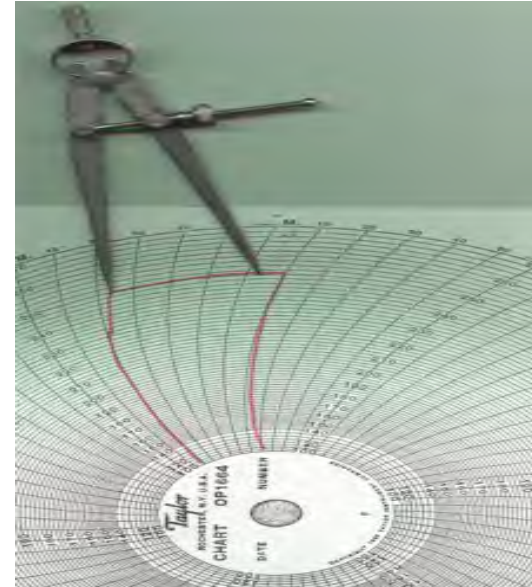
# Dividers



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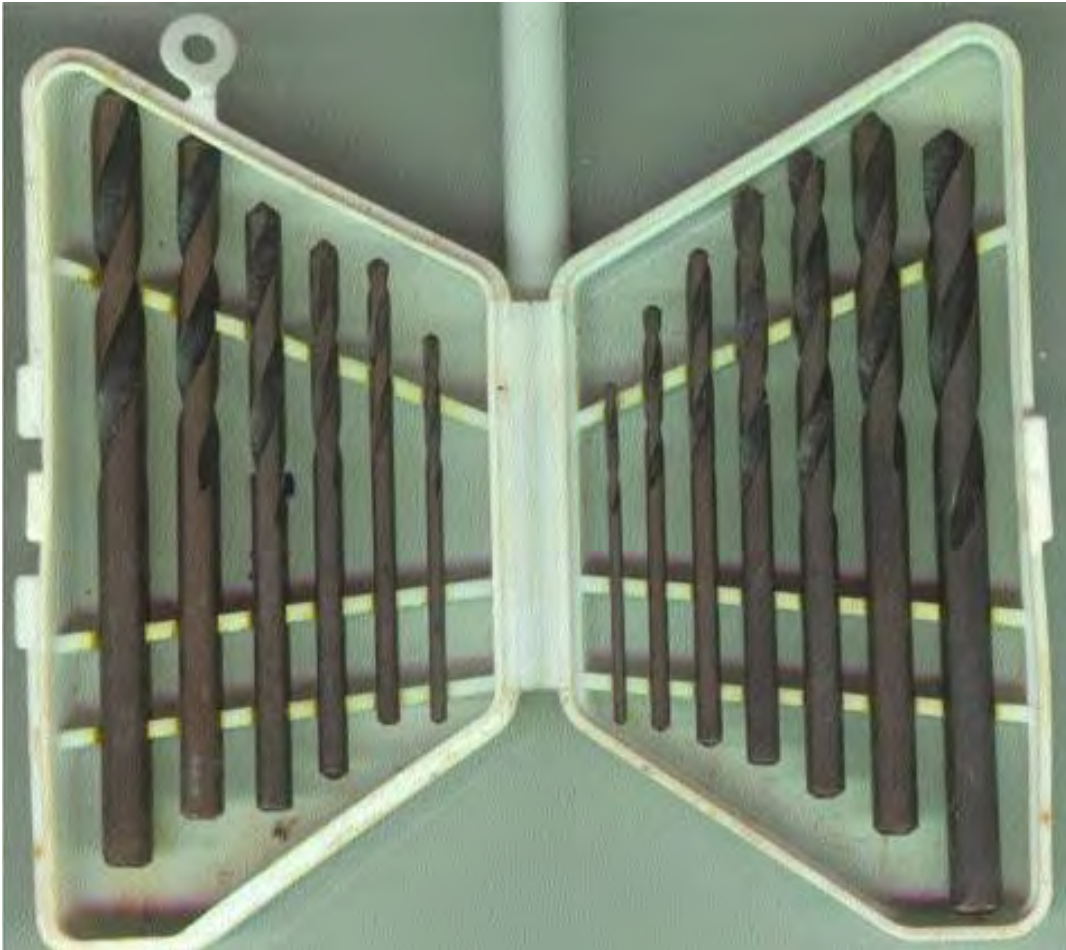
- Dividers are used to measure times on temperature curves.



# Drill Bits



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- Drill bits are used to measure holes in steam spreaders and water spreaders.



# Tape Measure



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- Tape measures are used to measure retort diameters and pipe length.



# Dial Calliper



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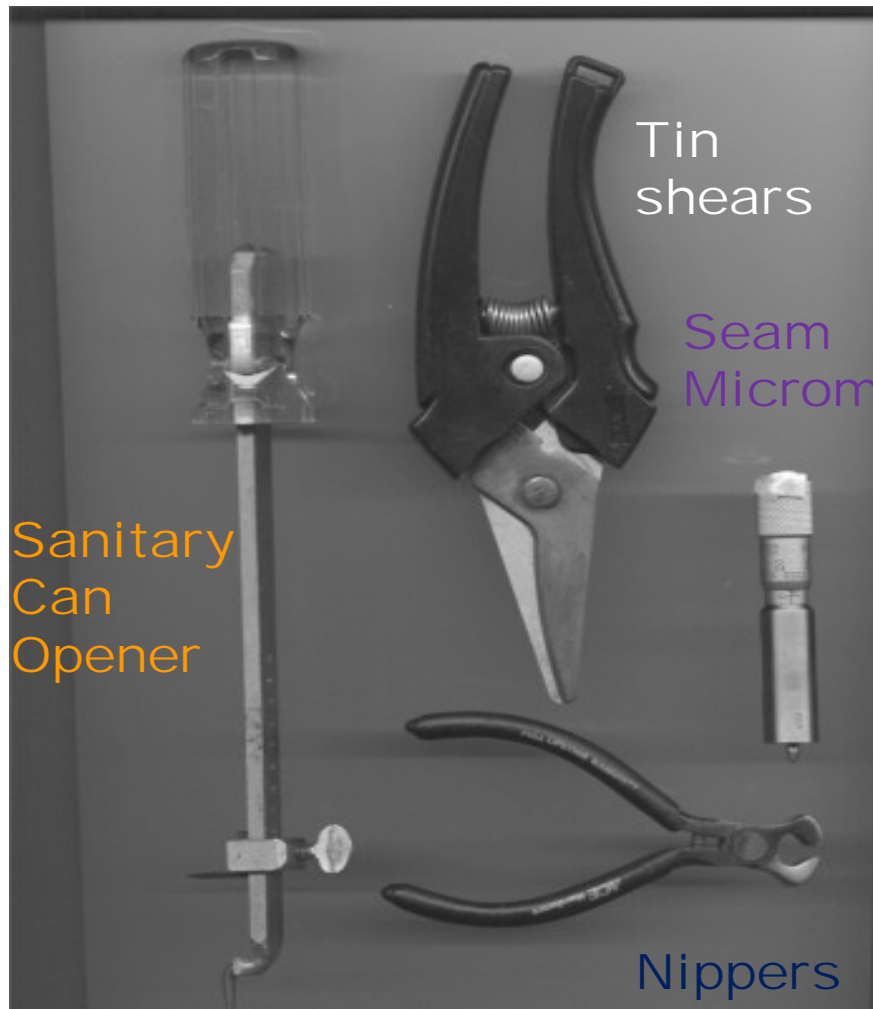
- Dial callipers are used to measure inside and outside pipe diameters.



# Seam Teardown Equipment



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- Need some way to tear down cans to observe seams.
- Possibilities include can opener, nippers, and seam micrometer.

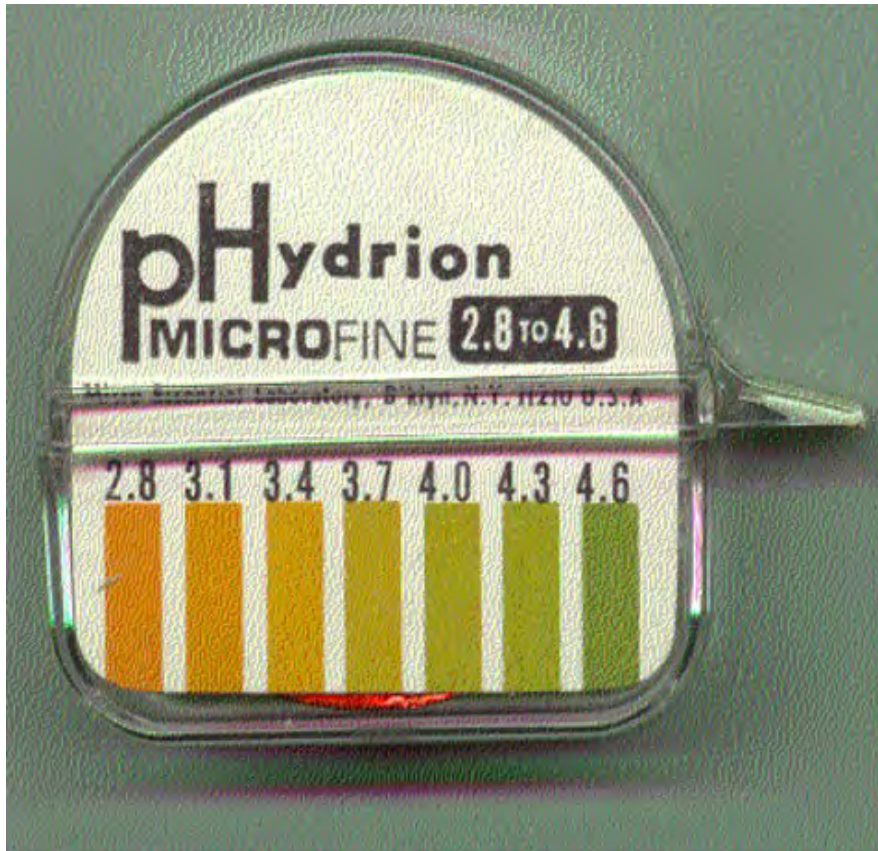




# pH Paper



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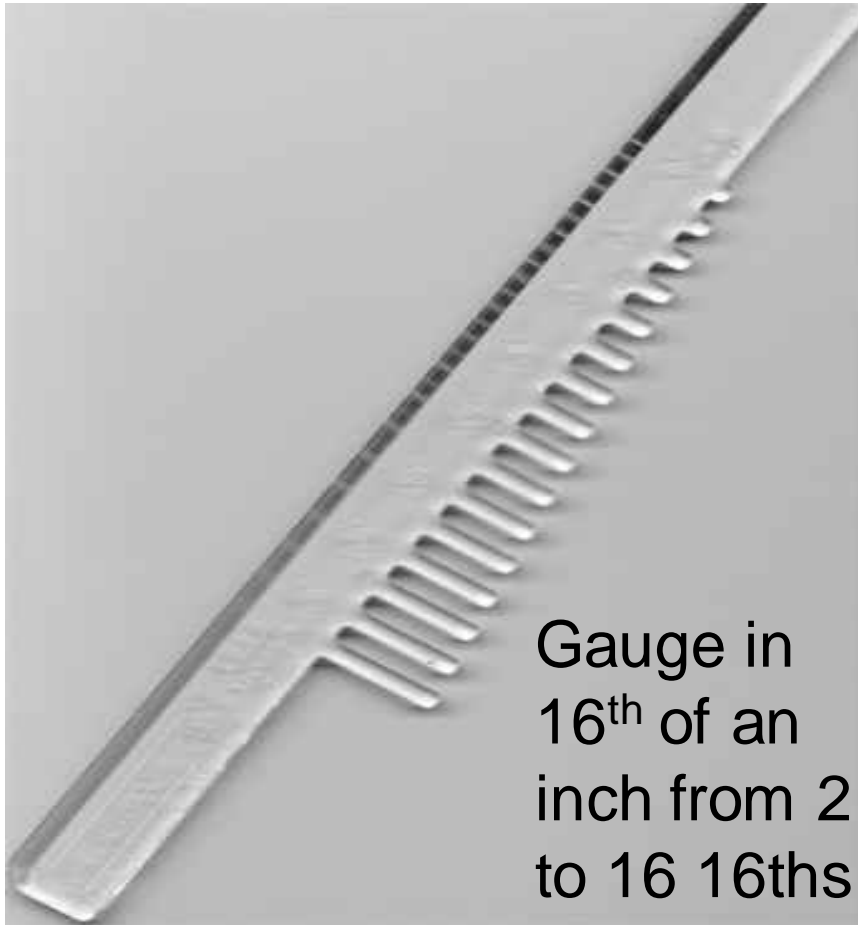
- A narrow range pH paper works best.
  - Should be able to determine if the food is acidified with the pH paper.
- pH meters can be used if available.



# Headspace Gauge



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Gauge in  
16<sup>th</sup> of an  
inch from 2  
to 16 16ths

- Gauge sets on top of the container.
- When a prong touches the product, it turns opaque.



# Method to Determine Cooling Water Chlorine Level



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- Change in color compared to chart.
- Pool test kit can be used.
- Low level test strips are available.





# FSA Procedures



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- Assess and evaluate the establishment's comprehensive food safety system
- Follow instructions in FSIS Directive 5100.1 and use the FSA tool
- Choose a product and production line that represents one of the most difficult to control
- Do not try to cover all products and production lines during one FSA



## FSA Procedures (2)



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- Four basic areas of concern:
  - Establishment of the process
  - Delivery of the process
  - Documentation of the process
  - Container integrity



## FSA Procedures (3)



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- Establishment scheduled processes, including documentation from a process authority
  - Temperature distribution test
    - Minimum requirement is a letter from a processing authority



## FSA Procedures (4)



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- Delivery of the scheduled process:
  - Does the establishment's equipment and operating procedures deliver the scheduled process?
  - Includes product preparation, filling, closing, thermal processing, and post process handling



## FSA Procedures (5)



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- Documentation of process delivery:
  - Do the establishment records reflect the operations in the establishment?
  - Are the records accurate and complete?
- Are process deviations recognized and handled correctly?



## FSA Procedures (6)



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- How are records selected for the review?
  - Randomly select 13 production day records from the preceding 60 days.
  - Use random number generator.






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# Random Number Example

## Example Production Dates

Oct 10 = 1	Nov 3 = 8
Oct 12 = 2	Nov 7 = 9
Oct 14 = 3	Nov 14 = 10
Oct 22 = 4	Nov 18 = 11
Oct 25 = 5	Nov 22 = 12
Oct 27 = 6	Nov 27 = 13
Nov 1 = 7	

 **Random Number Generator**

Lower Bound

Upper Bound

How many

1

14

7

Generate Random Number(s)

Random Number(s):

2, 4, 5, 6, 8, 12, 13



# FSA Procedures: Container Integrity



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- Are the containers protected from post processing contamination?
- Are container closures examined and the results recorded?





# FSA Procedures: Warehouse



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- Examine product for signs of leaking and swollen containers.
- Examine the distressed goods area for signs of problems.
- Determine why lots are on hold.



# FSA Procedures: Containers



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- Examination of containers:
  - Follow appropriate FSIS Directive 7520.2.
  - Handle swollen containers with care and follow FSIS Directive 7530.1.
- Hard swells may need to be refrigerated (not frozen).



# Sample Schedule Chart



## THERMAL PROCESSING TRAINING

FSIS FORM 7520-1 (REVERSE)

### C. SAMPLING PLANS

Table 1

LOT SIZE (CONFIRMING)	SAMPLE SIZE (CONFIRMING)	CRITICAL SAMPLES (1)		EDTA (EMPHASIS ANTIMONY)			
				ORIGIN		DESTINATION	
NORMAL PLAN	2-STEP SAMPLING	AC	RE	AC	RE	AC	RE
6,000 or Less	1st Step 120	0	1	2	5	2	6
	2nd Step 60						
	Total 180	0	1	4	6	5	6
6,001-12,000	1st Step 168	0	2	1	5	2	7
	2nd Step 180						
	Total 348	1	2	7	8	9	10
12,001-36,000	1st Step 228	0	3	2	7	3	9
	2nd Step 288						
	Total 516	2	3	9	10	12	13
36,001 or Larger	1st Step 456	0	4	5	10	8	13
	2nd Step 408						
	Total 864	3	4	14	15	19	20
TIGHTENED	SINGLE SAMPLING						
6,000 or Less	300	0	1	5	6	6	7
6,001-12,000	475	1	2	8	9	11	12
12,001-36,000	630	2	3	10	11	14	15



# Common Problems Noted



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- Failure to recognize and handle process deviations.
- Failure to identify and control critical factors.
- Out of specification container seams.
- Use of computer systems with no validation.
- MIG thermometer broken or not checked for accuracy.



## Common Problems Noted (2)



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- No information to support process schedule development.
- No information to support retort operation to achieve adequate temperature distribution.
- Processing records do not include all critical factors.
- Use of retort system other than what was identified on process schedule.



# Determining Noncompliance



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- Review the regulations for the retort system being inspected (§431.6).
- Review the regulations before attempting to write a list of observations.
  - Observation items should reflect the regulations.



# FSA Procedures



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- Plan FSA flow.
  - Following the product flow usually works best.
- Ask establishment personnel to conduct the required measurements on the retort system for pipe sizes, bleeder holes, etc.



# Key to FSA/Inspection



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- Adequate time must be spent on the cannery floor to observe the operation.



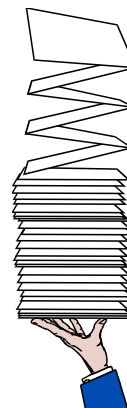


# Reporting the Observations



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- Discussion of observations with the establishment.
  - Provide information about observations.
  - Obtain establishment management's response to FSA observations.



## Example Observation Item



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- “There is no written documentation on hand to support your vent procedure of venting to at least 212°F that ensures that all the air is removed from the retort prior to the beginning of the timing of the process for sterilization.”





# Example Inspection Report

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FDA LACF INSPECTION REPORT	
1	<b>SUMMARY OF FINDINGS</b>
2	<b>HISTORY OF BUSINESS</b>
3	<b>PERSONS INTERVIEWED</b>
4	<b>INDIVIDUAL RESPONSIBILITY</b>
5	<b>PROCESS ESTABLISHMENT, FILING AND SCHEDULES</b>
6	HAS THE FIRM REGISTERED WITH FDA AND FILED A PROCESS FOR ALL LACFS PROCESSED AT THIS FACILITY, AND FOR FOREIGN FIRMS, ALL PRODUCTS PROCESSED AND SHIPPED TO THE U.S.? YES <input type="checkbox"/> NO <input type="checkbox"/>
	REMARKS:
7	HAVE PROCESSES BEEN ESTABLISHED FOR ALL LACFS PROCESSED AT THIS FACILITY? 113.83 YES <input type="checkbox"/> NO <input type="checkbox"/>
	REMARKS:
8	LIST THE FIRM'S PROCESS AUTHORITIES.
9	ARE THE PROCESS AUTHORITIES THE SAME AS THAT FILED WITH FDA? YES <input type="checkbox"/> NO <input type="checkbox"/>
	REMARKS:
10	DOES THE FIRM HAVE A PROCESS LETTER OR OTHER PROCESS SOURCE DOCUMENTATION LISTING CRITICAL FACTORS NECESSARY TO CONTROL IN THE ATTAINMENT OF COMMERCIAL STERILITY? YES <input type="checkbox"/> NO <input type="checkbox"/>
	REMARKS:
11	DO CRITICAL FACTORS/LIMITS LISTED IN SOURCE DOCUMENTS MATCH CRITICAL FACTORS/LIMITS FOR SELECTED PRODUCTS AND PROCESSES FILED WITH FDA? YES <input type="checkbox"/> NO <input type="checkbox"/>  NOTE - CRITICAL FACTORS MAY EXIST WHICH THE FIRM CONTROLS BUT HAVE NOT BEEN IDENTIFIED IN THE PROCESS FILING AND/OR HAS FAILED TO IDENTIFY AND DOES NOT CONTROL) REMARKS:



# Example Retort Survey Form



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## PROCESSING IN STEAM IN STILL RETORTS

INSTRUCTIONS			
<p>COMPLETE THE QUESTION BLOCKS BELOW. EACH BLOCK IS EXPANDABLE TO ACCOMMODATE NARRATION AS NEEDED. DRAW A DIAGRAM OF THE RETORT OR OBTAIN ONE FROM THE FIRM. ATTACH THE DIAGRAM TO THIS SURVEY REPORT. REPORT ALL PIPE SIZES AS INSIDE DIAMETER (ID). CROSS-SECTIONAL AREA = <math>3.14R^2</math> (<math>R = \frac{1}{2}</math> DIAMETER). MAKE A HARD COPY OF THE COMPLETED FORM AND ATTACH TO THE LACF INSPECTION REPORT.</p>			
RETORT DESCRIPTION			
RETORT NO.	TYPE OF RETORT: VERTICAL <input type="checkbox"/> HORIZONTAL <input type="checkbox"/> VERTICAL (CRATELESS) <input type="checkbox"/>	LENGTH OR HEIGHT	DIAMETER
FOR VERTICAL RETORTS, BOTTOM CRATE SUPPORTS ARE PRESENT. YES <input type="checkbox"/> NO <input type="checkbox"/>			
ARE BAFFLE PLATES PRESENT IN THE BOTTOM OF RETORT? YES <input type="checkbox"/> NO <input type="checkbox"/>			
ARE THERE ANY PROTRUSIONS INSIDE THE RETORT OR THE RETORT DOOR CASING WHICH COULD DAMAGE CONTAINERS DURING LOADING/UNLOADING OF CRATES? YES <input type="checkbox"/> NO <input type="checkbox"/>			
COMPUTER CONTROLS			
DOES A COMPUTER CONTROL ANY OF THE RETORT FUNCTIONS? YES <input type="checkbox"/> NO <input type="checkbox"/>			
DOES THE FIRM HAVE DOCUMENTATION ON HAND THAT INDICATES THAT THE COMPUTER SYSTEM HAS BEEN VALIDATED? YES <input type="checkbox"/> NO <input type="checkbox"/>			
EXPLAIN:			
IS RECORD KEEPING PART OF THE COMPUTER FUNCTION? YES <input type="checkbox"/> NO <input type="checkbox"/>			
IF YES, DOES THE RECORD KEEPING COMPLY WITH 21CFR PART 11 YES <input type="checkbox"/> NO <input type="checkbox"/>			



# Retort Diagram



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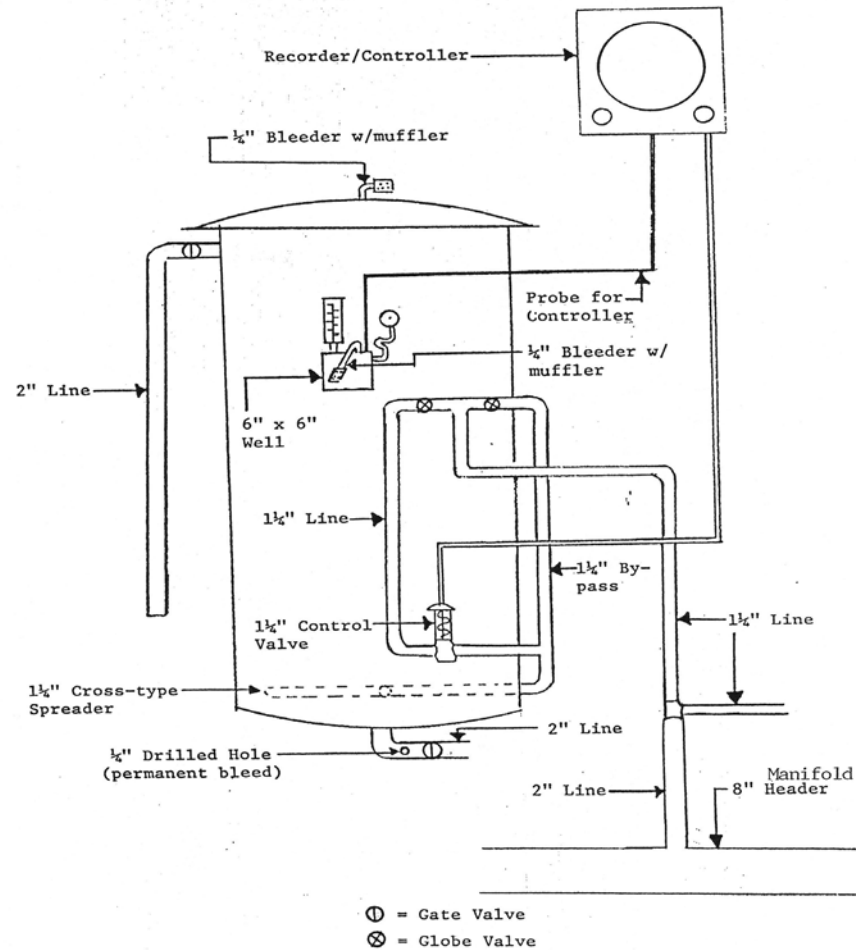
- A description of the retort system should be available for review.
- If it does not:
  - Obtain simple diagram from the establishment.
  - Draw a diagram.





# Example Retort Diagram

## THERMAL PROCESSING TRAINING



## Key Points



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- Follow instructions in FSIS Directive 5100.1.
- Acquire references and prepare for the FSA.
- Use this presentation for additional pointers for conducting an FSA in a canning establishment.
- Ensure that the establishment has the tools needed and ensure they know how to use them (e.g., seam teardown tools, etc.).



## Key Points (2)



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- Procedures for FSAs require planning and organization.
- Observations should be reported to establishment management.





# Questions



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*Questions?*

