

Firm Name:  
City, State  
Inspection Date(s):

FEI Number:  
FCE Number:  
Investigators:

DEPARTMENT OF HEALTH AND HUMAN SERVICES  
FOOD AND DRUG ADMINISTRATION

**PROCESSING IN STEAM IN HYDROSTATIC RETORTS  
(Retort Survey)**

**INSTRUCTIONS**

Complete the question blocks below. Narrative responses to each item can be entered in the item's "comments" area or where otherwise prompted.

**Before entering the interior of the retort, you must confirm with the firm that you are following the firm's Standard Operating Procedures designed to meet OSHA confined space requirements. If the firm insists that only plant personnel enter the retort, witness the measurement procedure and data collection. To obtain OSHA confined space information and safety procedures, see the confined space presentation on the FDA training web site. If the firm is not aware of the OSHA confined space requirements or does not have a confined space program, DO NOT ENTER THE RETORT.**

If problems are found with the firm's retort equipment or processing system, refer the reader to the EIR for a narrative description of specific problems with supporting evidence, under "Objectionable Conditions and Management's Response." Submit the completed form as an EIR attachment.

**PROCESS ESTABLISHMENT AND SCHEDULED PROCESSES - 21 CFR 108.35**

1. Report the Product(s) and SID number(s) covered on this inspection.

Product(s)	SID(s)

2. Has the firm registered the facility with the FDA and filed a process for all LACF products manufactured? - 21 CFR 108.35 (c)  Yes  No

3. 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  No

*Based on the processing authorities' evaluation critical factors are specific to an individual product or on occasion listed for a grouping of products (eg: turnip greens in brine, kale in brine, mixed greens in brine etc.).*

4. Do critical factors or limits listed in source documents match critical factors or limits for selected products and processes filed with FDA?  Yes  No

**RETORT DESCRIPTION**

5. Retort Manufacturer and Retort Number(s):

6. Container Size(s)

7. Cooker capacity

8. Number of carrier chains  1  2  3  4  5

9. Number of carriers in steam dome

10. Number of containers/carrier

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11. Does a computer control any of the retort functions?  Yes  No
12. Does the firm have documentation on hand which indicates that the computer system has been validated?  N/A  Yes  No

**HEAT AND TEMPERATURE DISTRIBUTION - 21 CFR 113.83**

13. Have there been any changes to the retorts or thermal processing system since the last temperature distribution study that could affect temperature distribution?  Yes  No

*While reviewing the process authority's supporting documentation, compare the study parameters to actual operating conditions.*

*Pay attention to any changes during operating conditions that do not match the PA documentation. These could include (static cook vs. rotary cook; circulating water system turned off; changes to plumbing for the retort installation; different loading configurations, change in container size and other factors that can affect the attainment of temperature distribution or heat penetration in the retort.*

*If a change has been made in the thermal processing system that could affect temperature distribution, the firm must have on file documentation of the change, including the review and approval by a qualified process authority.*

**PRODUCT PREPARATION - 21 CFR 113.81**

15. Are products prepared according to the method (rehydrating, drying, acidifying, blanching etc.) and / or formulation specified in the recommended scheduled process?  Yes  No

*Be aware of changes in starches and other minor ingredients. If the wrong starch is used it can change the heat penetration inside the container.*

16. When maintenance of pH (above 4.6) of a normally low acid food is a basis for a scheduled process does the firm ensure that the equilibrium pH of the finished product meets the value specified in the scheduled process?  N/A  Yes  No

*In this case the firm must monitor pH as a critical factor at intervals of sufficient frequency and prepare maintain records the pH meter should be calibrated to ensure its accuracy. (113.81(e))*

17. For water activity controlled processes is the water activity (Aw) carefully controlled to ensure that the Aw of the finished product meets that of the scheduled process?  N/A  Yes  No

*When normally low acid foods require sufficient solute to permit safe processing at low temperatures such as in boiling water there shall be careful supervision to ensure that the equilibrium water activity of the finished product meets that of the scheduled process 113.81(f). In this case the firm must monitor water activity at intervals of sufficient frequency and prepare maintain records the water activity meter should be calibrated to ensure its accuracy (117.40(f)).*

18. Is the formulation of the product and retorting process etc. conducted in a timely manner to prevent incipient spoilage?  N/A  Yes  No

**CRITICAL FACTORS - 21 CFR 113.40(f)(9)**

19. Are all critical factors defined in the scheduled process measured and recorded at intervals of sufficient frequency to ensure the process is under control?  Yes  No

20. If maximum fill weight or drained weight are critical, are they measured and recorded as specified in the scheduled process?  N/A  Yes  No

21. If minimum closing machine vacuum for a vacuum-packed product, maximum fill-in or drained weight, minimum net weight and / or percent solids is required, is it as specified in the scheduled process?  N/A  Yes  No

22. Is minimum headspace of containers as specified in the scheduled process?  N/A  Yes  No

23. Are the product characteristics (formulation, particle size, viscosity, brix, etc.) as specified in the scheduled process?  N/A  Yes  No

**THERMAL PROCESSING ROOM OPERATIONS - 21 CFR 113.87**

24. Is the system operated in the same state that was used during the last temperature distribution study?  Yes  No

*The retort design loading configuration, changes in divider plates, smallest container size and many other factors can affect the attainment of temperature distribution in the retort - see pp. 21-22 of LACF guide part 2. A change in any of these factors could necessitate a new temperature distribution study and possibly a new vent schedule. If a change has been made in the thermal processing system that could affect temperature distribution the firm should have on file documentation of the change including the review and approval by a qualified process authority.*

25. Are scheduled processes and venting procedures (if applicable) posted in the retort room or readily available to the retort operator?  Yes  No

21 CFR 113.87(a)

26. Has the firm established an adequate system for product traffic control in the retort room to prevent un-retorted product from bypassing the retort process?  Yes  No

*Containers shall be plainly marked with heat-sensitive indicator tape dye or paint or by other effective means visually indicating to thermal processing personnel those units that have been retorted. A visual check shall be performed to determine whether or not the appropriate change has occurred in the heat-sensitive indicator as a result of retorting to ensure that each unit of product has been retorted. A written record of these checks should be made. (113.87(b))*

27. Is the initial temperature ("IT") of the contents of the coldest containers to be processed determined and recorded with sufficient frequency?  Yes  No

*Measure the "IT" of at least 1 retort load with a calibrated thermometer and report the results in "comments." (113.87(c))*

28. Are records maintained demonstrating that IT thermometers are properly calibrated?  Yes  No

29. Are thermal process timing devices (clocks, charts, stopwatches etc.) accurate?  Yes  No

**CONTAINERS - 21 CFR 113.60**

30. For products covered during this inspection describe the method of filling containers (hand, vibration, pocket, etc.). If other, describe below.  Hand  Piston  
 Vibration  Other  
 Pocket

31. Is this method the same as that used during process establishment tests?  Yes  No

32. Are can flanges free of damage after filling?  Yes  No

33. Do product codes comply with part 113.60(c)?  Yes  No

*The code shall be permanently visible to the naked eye and shall identify the packer, product, year, day and period of packing. Describe the coding system including a code breakdown for products produced during this inspection.*

34. Are regular observations performed during production for container defects?  Yes  No

35. Are records of visual and destructive tests of containers performed and documented by qualified individuals?  Yes  No

36. Are corrective actions for defects taken and recorded?  Yes  No

37. For metal cans, are destructive tests performed on cans from each seaming head by qualified individuals and are all required measurements documented?  N/A  Yes  No

*Collect supporting evidence for sealing closing parameters or specification values necessary for sealing/closing*

38. For glass containers, are cold water vacuum tests for capper efficiency performed and recorded?  N/A  Yes  No

*Collect supporting evidence for sealing closing parameters or specification values necessary for sealing/closing*

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39. For other containers, are appropriate tests and detailed inspections performed to ensure a consistently reliable hermetic seal?  N/A  Yes  No  
*Collect supporting evidence for sealing closing parameters or specification values necessary for sealing/closing*

40. What type of container testing is performed?  
*Identify all that apply. For additional details on package integrity, refer to the FDA BAM (Bacteriological Analytical Manual)*

<input type="checkbox"/> Abuse	<input type="checkbox"/> Air leak	<input type="checkbox"/> Burst	<input type="checkbox"/> Conductivity	<input type="checkbox"/> Dye	<input type="checkbox"/> Electrolytic
<input type="checkbox"/> Etching	<input type="checkbox"/> Gas leak	<input type="checkbox"/> Incubation	<input type="checkbox"/> Light	<input type="checkbox"/> Machine Vision	<input type="checkbox"/> Pull Up
<input type="checkbox"/> Peel (Tensile)	<input type="checkbox"/> Proximity	<input type="checkbox"/> Seam scope	<input type="checkbox"/> Security	<input type="checkbox"/> Sound	<input type="checkbox"/> Squeeze
<input type="checkbox"/> Teardown	<input type="checkbox"/> Torque	<input type="checkbox"/> Vacuum	<input type="checkbox"/> Visual	<input type="checkbox"/> Other	

**RETORT SYSTEM - 21 CFR 113.40(f)**

*Temperature Indicating Device*

41. Is the retort equipped with at least one temperature-indicating device (TID) that accurately indicates the temperature during processing?  Yes  No

42. When the scheduled process specifies maintenance of particular temperatures in the hydrostatic water legs, is a TID located in each hydrostatic water leg in a position near the bottom automatic recorder?  Yes  No

43. Is the TID sensor installed in the steam dome near the steam water interface or within a well attached to the steam dome?  Yes  No

44. Is the TID installed where it can be accurately and easily read?  Yes  No

45. Is the TID used as the referenced instrument during processing?  Yes  No

46. Are calibration records for the TID established and maintained?  Yes  No

47. Is the TID accurate to 1 °F (0.5 °C)?  Yes  No

*Temperature Recording Device*

48. Is the retort equipped with a temperature recording device?  Yes  No

49. Is the temperature chart adjusted to agree as nearly as possible with but not higher than the known accurate TID during the processing period?  Yes  No

50. Is a temperature recording device in the Steam Chamber between the steam-water interface and the lowest container position?  Yes  No

51. Is a temperature recording sensor installed near the top and the bottom of each Hydrostatic Water Leg if the scheduled process specifies maintenance of particular temperatures in the legs?  
*The temperature recorder sensor shall be installed either in the steam dome or in a well attached to the dome - 113.40(f)(2)*  Yes  No

52. Does the temperature recording device record temperatures to a permanent record?  Yes  No

53. Is the appropriate chart paper used with the temperature recording device?  
*Chart paper must have both the appropriate **range** (2 °F or 1 °C) within a range of 10 °F (5 °C) of the process temperature and **working scale** (< 55 °F per inch or 12 °C per centimeter) within a range of 20 °F (10 °C) of the process temperature.*  Yes  No

54. If the chart is a multipoint plotter, does it record at intervals that assures that the parameters of the process time and process temperature were met?  N/A  Yes  No  
*Shall requirement*

55. Does the digital temperature recorder record data at sufficient intervals to assure that the parameters of the process time and process temperature were met?  N/A  Yes  No

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**Processing Steam**

56. Is the retort equipped with an automatic steam control valve?  Yes  No  
*Each retort shall be equipped with an automatic steam controller to maintain the retort temperature.*

57. Is the retort vented to remove air prior to processing?  Yes  No

**Bleeders**

58. Are bleeders installed on the retort to ensure adequate removal of air and circulation of steam in the system?  Yes  No  
*On hydrostatic retorts, at least 1/4" (6 mm) bleeder openings shall be located at the top of the steam chamber(s) opposite the steam inlet.*

59. Are the bleeders observed during operation?  Yes  No

60. Are the bleeders wide open and continually emitting steam during the entire process, including the come-up time?  Yes  No

**Processing Water**

61. Is the retort equipped with a method for determining water level in the retort during temperature drops?  Yes  No  
*If containers in the steam dome contact water during temperature drops, those containers must be segregated from other containers and handled as part of a process deviation.*

**Retort Speed**

62. Is the speed of the container conveyor chain speed adjusted, as necessary, to ensure that the speed is as specified in the scheduled process?  Yes  No  
*Shall requirement*

63. Is the speed of the container conveyor chain determined and recorded at the start of processing and at least once every 4 hours during processing?  Yes  No  
*The speed shall be determined and recorded at the start of processing and at intervals of sufficient frequency to assure that the retort speed is maintained as specified. the speed should be determined and recorded every 4 hours. Carrier conveyor speed may be measured as the number of flights per minute using a stopwatch, or electronically with a sensing probe. electronic measurement of the conveyor speed should be verified by using a stopwatch on a routine basis.*

64. Determine the carrier conveyor speed (times 50 carriers) using a calibrated stopwatch. Is the retort speed as specified in the scheduled process?  Yes  No  
*The number of **desired** carriers per minute to meet process time requirements is determined by the following formula: carriers per minute = number of carriers in steam chamber/process time in minutes*  
*The **actual** number of carriers per minute is determined by using the following formula: carriers per minute = (number of carriers in steam dome) /seconds for 50 carriers*

65. Is the retort speed sufficient to allow for a process time at least equal to the minimum process time filed with FDA?  Yes  No

66. Is there a means for preventing unauthorized speed changes?  Yes  No  
*A lock, notice or password protection posted at or near the speed adjustment controls which provides a warning that only authorized personnel are permitted to make adjustments is a satisfactory means of preventing unauthorized changes.*

67. Is container cooling water chlorinated or otherwise sanitized for recirculated water supplies?  Yes  No  
*There should be a measurable residual of the sanitizer employed at the water discharge point of the container cooler.*

**POST PROCESS HANDLING - 21 CFR 113.60(d)**

68. Are container handling procedures and conveyance equipment adequate to protect container bodies and seals from damage that could result in leakage and post-process contamination?  Yes  No

*Conveyor tracks should be maintained in a clean sanitary dry way. These conveyors are often neglected and contain build-up of food and dirt residues. The seams are most vulnerable to post-process leakage at this time because of the negative pressure developing inside the container as the contents cool. Conveyor tracks should not contain sharp edges or projections that could dent and damage can bodies and seams. Conveyors should be designed so that excessive heavy contact between cans does not occur and the double seams do not roll on or contact the conveyor during conveyance.*

69. Are lots containing spoiled or swollen cans properly investigated?  Yes  No

*Note that an acceptable level for can food spoilage in the LACF industry is 0.1% or 1 abnormal container per 10000 containers - at levels above this the firm should perform a spoilage diagnosis including microbiological analysis to determine the cause of the spoilage. In addition the firm should determine the cause of the problem and document this and any corrective action taken to prevent the problem from reoccurring.*

**PROCESS DEVIATIONS - 21 CFR 113.89**

70. Does the firm maintain a separate file or log for documenting process deviations?  Yes  No

71. Did the firm properly handle all scheduled process deviations?  Yes  No

**RECORDS - 21 CFR 113.100**

72. Are all lots that are shipped in interstate commerce free from instances of public health significance and otherwise not injurious to health?  Yes  No

73. Do operators document processing and production information on forms that include the product, code number, date, retort or processing system, container size, approximate number of containers, initial temperature, actual processing time, TID readings, temperature recorder device readings and other appropriate processing data?  Yes  No

74. Is processing and production information recorded at the time it is observed by the retort operator?  Yes  No

75. Are recording thermometer charts (analog, graphical or digital) identified by date, retort number, and other data as necessary so that they can be correlated with the written record of lots processed?  Yes  No

76. Are processing and production records signed or initialed by the retort operator and reviewed for completeness and signed or initialed and dated by plant management within 1 working day after the actual process to assure that the product received the scheduled process?  Yes  No

77. Are all operators of thermal processing systems and container closure inspections under the operating supervision of a person who has attended a Better Process Control School (BPCS) or other school approved by FDA?  Yes  No

78. Does the firm have recall procedures on file that comply with 108.35(f)?  Yes  No

79. Does the firm maintain initial distribution records per 113.100(f)?  Yes  No

**Still Retort Records – 113.100(a)(1)**

80. Are records maintained documenting the temperature in the steam chamber between the steam-water interface and the lowest container position and the speed of the container conveyor chain?  Yes  No

81. Are records maintained for the temperatures near the top and the bottom of each hydrostatic water leg?  Yes  No

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82. Are records maintained for all critical factors specified in the formulation of the product and the scheduled process?  Yes  No

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*TID and Reference Device Records - 113.100(c) and 113.100(d)*

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83. Do the TID calibration records include: A reference to the tag or seal, the name of the manufacturer, the ID of the reference device, NIST traceability, ID of the person who performed the test, the date and results of the testing including adjustments, and the date the next test is to be performed?  Yes  No

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84. Do the reference device calibration records include: A reference to the tag or seal, the name of the manufacturer, the ID of the reference device, NIST traceability, ID of the person who performed the test, the date and results of the testing including adjustments, and the date the next test is to be performed?  Yes  No

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*Container Integrity Records - 113.100(e)*

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85. Do container closure records include the product code, date, time, measurements and corrective actions taken?  Yes  No

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86. Are container integrity records signed and dated by the inspector and reviewer?  Yes  No

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87. Are container integrity records reviewed with sufficient frequency to ensure containers are hermetically sealed?  Yes  No

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**COMMENTS**

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