Firm Name:	**FEI Number:**
City, State	**FCE Number:**
Inspection Date(s):	**Investigators:**

DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

PROCESSING IN OTHER UNIQUE RETORT SYSTEMS
(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	SID

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. Is the retort operated as a static system, in an agitating mode, or both? ☐ Agitating ☐ Both ☐ Static

8. Processing mode ☐ Still ☐ Rocking ☐ End over End ☐ Lateral ☐ Axial ☐ Other

9. What is the primary medium for heating containers?
If other, describe below.
☐ Steam ☐ Steam-Air ☐ Water ☐ Ohmic ☐ Electric ☐ Other

10. Select the method used to heat the processing medium:
If other, describe below.
☐ Heat Exchanger ☐ Electric ☐ Steam Injection ☐ Other ☐ Steam Infusion

11. How is the heating medium distributed within the retort?
If other, describe below.
☐ Steam Spreader ☐ Spray ☐ Steam-Air ☐ Manifold ☐ Water Circulation ☐ Other

12. How does the firm ensure proper operation of the heating medium distribution system?
If other, describe below.
☐ Visual Check ☐ Computer ☐ Flow rate ☐ Fan ☐ Pump speed ☐ Other

13. Does a computer control any of the retort functions? ☐ Yes ☐ No

14. 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

15. 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

The retort design, loading configuration, smallest container size and many other factors can affect the attainment of temperature distribution in the retort. 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.

16. Have heat transfer rate studies been performed on the firm's retorts? ☐ Yes ☐ No

With steam-air retorts that incorporate additional air over-pressure to maintain container shape and seal integrity, the formation of air pockets due to condensing steam on the outside surface of containers and the lack of convection currents during come-up and processing are problems that affect heat distribution and ultimately the heating rate of the product to be processed.

Heat distribution studies of steam-air retorts should include placement of thermocouples in the retort as well as inside of test cans containing a material of known heating characteristics to measure temperature in various different areas of the retort as well as the rate of heat transfer into select cans.

17. Are partial loads processed in the firm's retorts? ☐ Yes ☐ No

18. Have temperature distribution studies been performed with partial loads? ☐ N/A ☐ Yes ☐ No

PRODUCT PREPARATION - 21 CFR 113.81

19. 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.

20. 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))

21. For water activity controlled processes is the water activity (A_W) carefully controlled to ensure that the A_W 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)).

22. 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(j)

23. 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

24. 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

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

26. 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

27. 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.

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

29. 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

Each retort basket or one or more cans within a basket 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 for all retort baskets to ensure that each unit of product has been retorted. A written record of these checks should be made. (113.87(b))

30. 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))

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

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

Pocket or wristwatches are not considered satisfactory. Digital clocks that do not display seconds may be used if the operating process and the venting schedule have a 1-minute or greater safety factor over the scheduled process. - 113.87(d)

Retort Crates and Racks

33. Are the retort basket and divider plates used for holding containers made of adequate materials and uniformly perforated to allow even circulation of the heating medium? *For example are perforations at least 1-in. holes on 2-in. centers or the equivalent?* ☐ Yes ☐ No

34. Are trays or divider plates in good condition with no sharp or rough points that could puncture containers? ☐ Yes ☐ No

35. Are containers positioned in the retort as specified in the scheduled process? ☐ Yes ☐ No

36. If nesting is possible, does the firm control nesting of containers? ☐ Yes ☐ No

37. For pouches, are trays adequately designed to contain and restrain individual pouches during processing? ☐ N/A ☐ Yes ☐ No

38. If pouches are not restrained in trays, does the firm have temperature studies to support the current tray loading configuration? ☐ Yes ☐ No

These could include additional heat penetration studies to account for shingling or temperature distribution studies due to changes in stacking configuration or different basket and tray designs.

CONTAINERS - 21 CFR 113.60

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

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

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

42. 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.

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

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

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

46. 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

47. 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

48. 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

49. 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)

☐ Abuse ☐ Air leak ☐ Burst ☐ Conductivity ☐ Dye ☐ Electrolytic
☐ Etching ☐ Gas leak ☐ Incubation ☐ Light ☐ Machine Vision ☐ Pull Up
☐ Peel (Tensile) ☐ Proximity ☐ Seam scope ☐ Security ☐ Sound ☐ Squeeze
☐ Teardown ☐ Torque ☐ Vacuum ☐ Visual ☐ Other

RETORT SYSTEM - 21 CFR 113.40(j)

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

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

Describe where the TID and recorder are located in the system.

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

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

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

Temperature Recording Device

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

56. 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

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

58. Is the appropriate chart paper used with the temperature recording device? ☐ Yes ☐ No

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

59. 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

60. 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

Processing Steam

61. Is the retort equipped with an automatic steam control valve? ☐ Yes ☐ No

Citations are under 21 CFR 113.40(i) - refer to the applicable section of 113.40(a)(2) for language to include in the "Specifically" section of the 483 observation.

62. If come up steps are critical, did the firm identify process come-up steps as critical on the process filing forms? ☐ N/A ☐ Yes ☐ No

Processing steps are required on the process filing form when they have been identified as critical to the thermal process.

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

64. Are bleeders installed on the retort to ensure adequate removal of air and circulation of steam in the system? ☐ N/A ☐ Yes ☐ No

65. Are the bleeders arranged so that the operator can observe that they are operating properly? ☐ N/A ☐ Yes ☐ No

66. Are the bleeders wide open and continually emitting steam during the entire process, including the come-up time? ☐ N/A ☐ Yes ☐ No

67. If the firm utilizes steam/air during sterilization, what is the percentage of steam-air mixture used during processing? ☐ N/A

Note - the percentage of steam-air retort can be determined by dividing the absolute retort pressure (psia) before adding air (steam table pressure plus atmospheric pressure - 14.7 psi) by the absolute retort pressure after adding air; example - 10 psig at 240 degrees f (from steam table) plus 14.7 psi/15 psig + 14.7 psi = 24.7 psia/29.7 psia = 83%.

68. What method is used to mix the steam and air to ensure uniform temperatures inside the retort? If other, describe below. ☐ N/A ☐ Fan ☐ Bleeder ☐ Other

69. How does the firm ensure that the fan or other method to mix the stream and air is operating? If other, describe below. ☐ N/A ☐ Computer ☐ Visual Check ☐ Indicator Light ☐ Other

Processing Water

70. Are screens used over all suction outlets and drain openings to prevent clogging of drains? ☐ N/A ☐ Yes ☐ No

71. Is the water flow rate checked with sufficient frequency during the entire processing time? ☐ N/A ☐ Yes ☐ No

72. Are the hole openings used for water distribution free and clear from product or mineral build-up? ☐ N/A ☐ Yes ☐ No

73. Are water flow problems handled as process deviations? ☐ N/A ☐ Yes ☐ No

Retort Speed

74. Is the speed of the retort adjusted, as necessary, to ensure that the speed is as specified in the scheduled process? ☐ N/A ☐ Yes ☐ No

75. Is the speed of the retort recorded during processing? ☐ N/A ☐ Yes ☐ No

76. Is the retort speed sufficient to allow for a process time at least equal to the minimum process time filed with FDA? ☐ N/A ☐ Yes ☐ No

If not, the lot could be under processed and should be handled as a process deviation.

77. Is there a means for preventing unauthorized speed changes? ☐ N/A ☐ 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.

Container Cooling

78. 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.

79. Were water cooling valves noted to be leaking? ☐ N/A ☐ Yes ☐ No

POST PROCESS HANDLING - 21 CFR 113.60(d)

80. 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.

81. 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 0.01% or 1 abnormal container per 10,000 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

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

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

RECORDS - 21 CFR 113.100

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

85. 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

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

87. 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

88. 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

89. 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

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

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

Still Retort Records - 113.100(a)(1)

92. Are records maintained documenting: the time that steam was turned on, the time that the retort reached processing temperature, the time that steam was shut off, the venting time and the venting temperature? ☐ N/A ☐ Yes ☐ No

Agitating Retort Records - 113.100(a)(2)

93. Are records maintained for retort speed and the functioning of the condensate bleeder (if applicable)? ☐ N/A ☐ Yes ☐ No

94. If applicable to the scheduled process, are records maintained for container headspace, product consistency, maximum drained weight, minimum net weight or percent solids? ☐ N/A ☐ Yes ☐ No

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

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

96. 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

97. 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

Container Integrity Records - 113.100(e)

98. Do container closure records include the product code, date, time, measurements and corrective actions taken?	☐ Yes	☐ No
99. Are container integrity records signed and dated by the inspector and reviewer?	☐ Yes	☐ No
100. Are container integrity records reviewed with sufficient frequency to ensure containers are hermetically sealed?	☐ Yes	☐ No

COMMENTS