

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

FEI Number:
FCE Number:
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

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9. What is the primary medium for heating containers?
If other, describe below.

- | | |
|-----------------------------------|------------------------------------|
| <input type="checkbox"/> Steam | <input type="checkbox"/> Steam-Air |
| <input type="checkbox"/> Water | <input type="checkbox"/> Ohmic |
| <input type="checkbox"/> Electric | <input type="checkbox"/> Other |

10. Select the method used to heat the processing medium:
If other, describe below.

- | | |
|--|-----------------------------------|
| <input type="checkbox"/> Heat Exchanger | <input type="checkbox"/> Electric |
| <input type="checkbox"/> Steam Injection | <input type="checkbox"/> Other |
| <input type="checkbox"/> Steam Infusion | |

11. How is the heating medium distributed within the retort?
If other, describe below.

- | | |
|--|-----------------------------------|
| <input type="checkbox"/> Steam Spreader | <input type="checkbox"/> Spray |
| <input type="checkbox"/> Steam-Air | <input type="checkbox"/> Manifold |
| <input type="checkbox"/> Water Circulation | <input type="checkbox"/> Other |

12. How does the firm ensure proper operation of the heating medium distribution system?
If other, describe below.

- | | |
|---------------------------------------|-----------------------------------|
| <input type="checkbox"/> Visual Check | <input type="checkbox"/> Computer |
| <input type="checkbox"/> Flow rate | <input type="checkbox"/> Fan |
| <input type="checkbox"/> Pump speed | <input type="checkbox"/> 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))

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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)

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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?
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. Yes No

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)
- | | | | | | |
|---|------------------------------------|-------------------------------------|---------------------------------------|---|---------------------------------------|
| <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 | |

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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%.

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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?
If not, the lot could be under processed and should be handled as a process deviation. N/A Yes No
77. Is there a means for preventing unauthorized speed changes?
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. N/A Yes No

Container Cooling

78. Is container cooling water chlorinated or otherwise sanitized for recirculated water supplies?
There should be a measurable residual of the sanitizer employed at the water discharge point of the container cooler. Yes No
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?
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. Yes No
81. Are lots containing spoiled or swollen cans properly investigated?
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. Yes No

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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

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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
