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

DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

FDA LACF INSPECTION REPORT

This inspection report is available in PDF on the forms site: *http://www.fda.gov/opacom/morechoices/fdaforms/ora.html*. Narrative responses to each item can be entered in the item's "comments" area or where otherwise prompted. Complete documentation of deficiencies, including deviations from Part 113, should be narrated with reference to photos, exhibits, etc., in the Turbo EIR under "Objectionable Conditions and Management's Response." When necessary, refer the reader to the appropriate section of the Turbo EIR for a full explanation of details.

This form should be downloaded from the forms site prior to completion and copying. The finished report should be submitted as an attachment to the Turbo EIR.

PROCESS ESTABLISHMENT, FILING AND SCHEDULES

1. 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.? – 108.35(c) ..... Yes ☐ No ☐

   COMMENTS:

2. HAVE PROCESSES BEEN ESTABLISHED FOR ALL LACFs PROCESSED AT THIS FACILITY? – 113.83 ..... Yes ☐ No ☐

   COMMENTS:

3. LIST THE FIRM'S PROCESS AUTHORITIES: WHAT ARE THE PROCESS AUTHORITIES' CREDENTIALS *(KNOWLEDGE, TRAINING AND EXPERIENCE)* WITH RETORT SYSTEMS, CONTAINERS, PRODUCTS, ETC.? ARE PROCESS AUTHORITIES ACTIVELY INVOLVED IN EVALUATING TEMPERATURE DISTRIBUTION STUDIES, HEAT PENETRATION STUDIES AND DEVIATIONS ANALYSIS?

   COMMENTS:

4. ARE THE PROCESS AUTHORITIES THE SAME AS THOSE FILED WITH FDA? ..... Yes ☐ No ☐

   COMMENTS:

5. 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 ☐

   COMMENTS:

6. DO CRITICAL FACTORS/LIMITS LISTED IN SOURCE DOCUMENTS MATCH CRITICAL FACTORS/LIMITS FOR SELECTED PRODUCTS AND PROCESSES FILED WITH FDA? ..... Yes ☐ No ☐

*NOTE – CRITICAL FACTORS MAY EXIST THAT THE FIRM CONTROLS BUT HAVE NOT BEEN IDENTIFIED IN THE PROCESS FILING AND/OR HAS FAILED TO IDENTIFY AND DOES NOT CONTROL. CRITICAL FACTOR LIMITS RECOMMENDED BY THE PROCESS AUTHORITY **SHOULD** BE EQUAL TO OR GREATER THAN CRITICAL LIMITS FILED WITH FDA.*

COMMENTS:

7. HAVE FILED, SCHEDULED PROCESSES BEEN CHANGED IN SUCH A WAY THAT COULD AFFECT THE ATTAINMENT OF COMMERCIAL STERILITY? ..... Yes ☐ No ☐

(THERE ARE MANY FACTORS THAT MAY AFFECT HEAT PENETRATION AND THE ATTAINMENT OF COMMERCIAL STERILITY. THESE FACTORS INCLUDE CONTAINER TYPE AND POSITION; TYPE OF HEATING MEDIUM; PRODUCT FACTORS SUCH AS FILL WEIGHT, VISCOSITY, PARTICLE SIZE, AND PERCENT SOLIDS; AND EQUIPMENT FACTORS SUCH AS FILLING METHOD, HEAD SPACING AND ROTATIONAL SPEED. A CHANGE IN ANY OF THESE FACTORS COULD ADVERSELY AFFECT HEAT PENETRATION RESULTING IN AN UNDER PROCESS. (SEE PP. 8, 9 AND 22 OF LACF GUIDE, PART 2).)

COMMENTS:

8. IF PROCESS CHANGE(S) HAVE BEEN MADE THAT COULD AFFECT THE ATTAINMENT OF COMMERCIAL STERILITY, HAVE THE CHANGE(S) BEEN REVIEWED AND SUBSTANTIATED BY A QUALIFIED PROCESS AUTHORITY AND FILED WITH FDA? – 108.35(c)(2)(ii)..... Yes ☐ No ☐

COMMENTS:

9. WHEN THERE IS A CHANGE IN PRODUCT FORMULATION OR FILLING METHOD, IS THE PROCESS AUTHORITY ADVISED AND IS THERE WRITTEN DOCUMENTATION OF THIS CONTACT? – 108.35(c)(2)(ii) ..... Yes ☐ No ☐

COMMENTS:

10. HOW DOES THE FIRM DECIDE IF THE CHANGE IS SIGNIFICANT ENOUGH TO CONTACT THE PROCESS AUTHORITY?

COMMENTS:

11. THE FOLLOWING PRODUCTS WERE COVERED DURING THIS INSPECTION:

PRODUCT	STYLE OF PACK	CONTAINER TYPE/SIZE

COMMENTS:

12. LIST ALL CRITICAL FACTORS TO THE ATTAINMENT OF COMMERCIAL STERILITY PER PROCESS AUTHORITY LETTER AND FILING FORM(S) FOR PRODUCTS COVERED DURING THIS INSPECTION:

(INCLUDE VENT TIME/TEMP., INITIAL TEMPERATURE, MIN. PROCESS TIME/TEMP. AND ALL OTHER CRITICAL FACTOR TARGET VALUES — LIST OTHER CRITICAL FACTORS AND OPERATING PROCESSES IN COMMENTS.)

RETORT VENT SCHEDULE: _____ MINUTES AND TO _____ °F.

PRODUCT	CONTAINER TYPE/SIZE	MIN. CRITICAL FACTORS		
		Initial Temp.	*Process Time*	*Process Temp.*

COMMENTS, INCLUDING OTHER CRITICAL FACTORS:

RAW MATERIALS – 113.81

13. DOES THE FIRM TAKE ADEQUATE MEASURES TO PREVENT THE BUILD-UP OF MICROORGANISMS IN UNPROCESSED PRODUCT BEFORE THERMAL PROCESSING? ..... Yes ☐ No ☐

*(FOR EXAMPLE, RAW VEGETABLES **SHOULD** BE ADEQUATELY CLEANED BEFORE FILLING. FILLED/SEAMED AND UNPROCESSED CANS SHOULD BE RETORTED WITHIN A REASONABLE TIME LIMIT TO PREVENT INCIPIENT SPOILAGE. HOT WATER BLANCHERS SHOULD BE MAINTAINED AT TEMPERATURES ABOVE THAT WHICH WILL SUPPORT THE GROWTH OF THERMOPHILES (ABOVE 170 DEGREES F) AND BE EMPTIED, CLEANED AND SANITIZED ON A REGULAR BASIS TO PREVENT THE GROWTH OF THERMOPHILES. RAW MATERIALS SUSCEPTIBLE TO CONTAMINATION BY THERMOPHILES (SUGAR, SALT, ETC.) **SHOULD** BE RECEIVED WITH A SUPPLIER'S GUARANTEE OR CERTIFICATE OF ANALYSIS.)*

COMMENTS:

14. WHAT IS THE SOURCE OF WATER USED FOR PROCESSING AND CLEAN-UP IN THE PLANT? IF IT IS NON-MUNICIPAL, WHAT IS ITS SOURCE – I.E., WELL OR SURFACE WATER? IF PRE-TREATED, WHAT IS THE METHOD – I.E., THROUGH SAND THEN CARBON FILTERED? IS THE WATER DISINFECTED? IF SO, DETERMINE THE METHOD OF DISINFECTION AND HOW IT IS MONITORED. IF NON-MUNICIPAL, WHAT IS THE FREQUENCY OF WATER TESTING AND THE ANALYSIS CONDUCTED? IS THE WATER REGULATED BY THE STATE OR A LOCAL HEALTH AGENCY?

COMMENTS:

15. IS THE PLANT WATER ADEQUATELY TREATED WITH CHLORINE OR OTHER APPROVED CHEMICALS TO RENDER IT POTABLE? ..... Yes ☐ No ☐

HOW AND AT WHAT FREQUENCY IS THIS TREATMENT MONITORED?

COMMENTS:

16. ARE WELL HEADS AND PIPELINES INSPECTED BY THE FIRM ON A ROUTINE BASIS TO DETERMINE IF THERE ARE ANY PROBLEMS THAT COULD CONTAMINATE WATER WITHIN THE PLANT? ..... Yes ☐ No ☐

(REVIEW WELL MAINTENANCE RECORDS NOTING THE AGE AND DEPTH OF THE WELL, AND CONDITION OF THE PIPES AND CASING. CHECK THE CONDITION OF WATER FILTERS AND DETERMINE HOW OFTEN THEY ARE CHANGED.)

COMMENTS:

17. ARE ALL FOOD AND COLOR ADDITIVES FDA APPROVED? ..... Yes ☐ No ☐ N/A ☐

COMMENTS:

18. ARE ADDITIVES USED TO TREAT BOILER WATER AND ARE THEY APPROVED FOR SUCH USE? (LIST ADDITIVES THAT ARE USED, INCLUDING CHEMICAL NAME.) ..... Yes ☐ No ☐

COMMENTS:

PRODUCT PREPARATION – 113.81

19. ARE PRODUCTS PREPARED ACCORDING TO THE METHOD (HYDRATING, DRYING, ACIDIFYING, BLANCHING, ETC.) AND/OR FORMULATION SPECIFIED IN THE RECOMMENDED SCHEDULED PROCESS? ..... Yes ☐ No ☐ N/A ☐

COMMENTS:

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? – 113.81(e) ..... Yes ☐ No ☐ N/A ☐

*(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.)*

COMMENTS:

21. 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? – 113.81(f) ..... Yes ☐ No ☐ N/A ☐

*(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 (110.40(f)).)*

COMMENTS:

22. IF PRODUCTS ARE REHYDRATED, WHAT IS THE PROCESS (% MOISTURE, ETC.) AND IS THE REHYDRATION PROCESS A CRITICAL FACTOR TO THE ATTAINMENT OF COMMERCIAL STERILITY?

COMMENTS:

23. IS THE FORMULATION OF PRODUCT, RETORT PROCESS, COOLING, PACKAGING, ETC., CONDUCTED IN A TIMELY MANNER TO PREVENT INCIPIENT SPOILAGE? ..... Yes ☐ No ☐

(CHECK FOR INSTANCES OF TIME DELAYS, CONTAINER JAMS, ETC., THAT COULD RESULT IN INCIPIENT SPOILAGE.)

COMMENTS:

24. ARE INGREDIENTS WEIGHED PROPERLY USING ACCURATE SCALES? ..... Yes ☐ No ☐

COMMENTS:

CONTAINER INTEGRITY

25. DESCRIBE THE CONTAINERS BEING USED DURING THIS INSPECTION (SIZE, MATERIAL COMPOSITION, ETC.):

COMMENTS:

26. PROVIDE THE SOURCE FOR THE FIRM'S CONTAINERS:

COMMENTS:

27. INTEGRITY TESTS PERFORMED BY THE FIRM OR THE SUPPLIER ON INCOMING CONTAINERS:

COMMENTS:

28. DESCRIBE HOW THE FIRM ASSURES THAT INCOMING CONTAINERS MEET THE SUPPLIER'S SPECIFICATION (FOR EXAMPLE, DO INCOMING CANS HAVE THE PROPER BASE WEIGHT, ENAMEL COATING, SEAMING COMPOUND, ETC.?):

COMMENTS:

29. DOES THE FIRM HAVE WRITTEN CRITERIA TO ACCEPT OR REJECT INCOMING EMPTY CONTAINER STOCK? ..... Yes ☐ No ☐

ARE RECORDS KEPT OF ACCEPTED/REJECTED CONTAINER STOCK? ..... Yes ☐ No ☐

COMMENTS:

30. DOES THE FIRM CORRELATE INCOMING CONTAINERS (NAME OF SUPPLIER, CODES, ETC.) WITH CONTAINER USAGE IN PRODUCTION? ..... Yes ☐ No ☐

COMMENTS:

31. ARE EMPTY CONTAINER HANDLING PROCEDURES ADEQUATE TO PREVENT DAMAGE? ..... Yes ☐ No ☐

COMMENTS:

32. ARE CONTAINERS AND LIDS CLEAN BEFORE FILLING? ..... Yes ☐ No ☐

COMMENTS:

FILLING

33. FOR PRODUCTS COVERED DURING THIS INSPECTION, DESCRIBE THE METHOD OF FILLING CONTAINERS (HAND, VIBRATION, POCKET, ETC.). IS THIS METHOD THE SAME AS THAT USED DURING PROCESS ESTABLISHMENT TESTS? ..... Yes ☐ No ☐

COMMENTS:

34. ARE ALL CRITICAL FACTORS (FILL WT, HEAD SPACE, ETC.) BEING ADEQUATELY CONTROLLED? ..... Yes ☐ No ☐

*(CRITICAL FACTORS SPECIFIED IN THE SCHEDULED PROCESS **SHALL** BE MEASURED AND RECORDED ON THE PROCESSING RECORD AT INTERVALS OF SUFFICIENT FREQUENCY TO ENSURE THAT THE FACTORS ARE WITHIN THE LIMITS SPECIFIED IN THE SCHEDULED PROCESS – 113.40(a)(14). THERE ARE NUMEROUS CRITICAL FACTORS TO CONTROL, DEPENDING ON THE PRODUCT, CONTAINER AND PROCESSING SYSTEM, ETC. – 113.81(c) (SEE LACF GUIDE, PART 2).)*

COMMENTS:

35. DOES PRODUCT OVERLAY THE EDGES OF FILLED CONTAINERS? ..... Yes ☐ No ☐

COMMENTS:

36. ARE CAN FLANGES FREE OF DAMAGE AFTER FILLING? ..... Yes ☐ No ☐

COMMENTS:

CLOSING

37. LIST THE MANUFACTURER, MODEL NO. AND TYPE OF CLOSING MACHINES IN USE BY THE FIRM:

COMMENTS:

38. IS CONTAINER CLOSURE EQUIPMENT MAINTAINED IN A SANITARY WAY AND IN A GOOD STATE OF REPAIR? ..... Yes ☐ No ☐

(FOR EXAMPLE, CHECK TO SEE IF THE FIRM HAS A MAINTENANCE LOG FOR THE DOUBLE SEAMERS THAT DOCUMENTS ROUTINE MAINTENANCE SUCH AS ADJUSTING OR CHANGING CHUCKS & ROLLS, ETC.; VISUAL OBSERVATION OF THE SEAMER LOG AND REVIEW OF SANITATION MONITORING RECORDS CAN INDICATE HOW THE FIRM CLEANS AND MAINTAINS ITS DOUBLE SEAMING EQUIPMENT.)

COMMENTS:

39. DURING PRODUCTION RUNS, DOES THE FIRM PERFORM VISUAL AND DESTRUCTIVE TESTS ON CONTAINER SEAMS/SEALS IN ACCORDANCE WITH PART 113.60(a)? ..... Yes ☐ No ☐

(DESCRIBE ALL VISUAL AND DESTRUCTIVE TESTS PERFORMED, INCLUDING TESTING FREQUENCY AND ALL MEASURED PARAMETERS (SEE LACF GUIDE, PART 3, FOR A DESCRIPTION OF METAL, GLASS AND FLEXIBLE PACKAGE CLOSURES, SEALING PARAMETERS, CONTAINER DEFECTS AND INTEGRITY TESTS).)

COMMENTS:

40. OBSERVE THE FIRM'S SEAM INSPECTORS TEAR DOWN AND EVALUATE DOUBLE SEAMS.

ARE CONTAINER INTEGRITY EVALUATIONS CONDUCTED CORRECTLY BY TRAINED INDIVIDUALS WITH ADEQUATE INSTRUCTIONS, SUFFICIENT LIGHTING, ETC.? ARE THEY CORRECTLY EVALUATING KEY FACTORS IN CAN SEAM EVALUATIONS INCLUDING OVERLAP AND TIGHTNESS? ..... Yes ☐ No ☐

COMMENTS:

41. ARE SEAM INSPECTORS DETECTING LOOSE SEAMS WHEN THEY EXIST? ..... Yes ☐ No ☐

*(EVALUATE COVER HOOK WRINKLE AND COMPARE YOUR OBSERVATIONS WITH THE FIRM'S OBSERVATIONS (NOTE – INVESTIGATORS EVALUATING COVER HOOKS FOR WRINKLING **SHOULD** BE KNOWLEDGEABLE AND PROFICIENT IN DOUBLE SEAM EVALUATION INCLUDING EVALUATION OF THE COVER HOOK FOR WRINKLES).)*

COMMENTS:

42. DO RECORDS EXIST DOCUMENTING ADJUSTMENTS MADE TO DOUBLE SEAMING EQUIPMENT TO CORRECT FOR LOOSE SEAMS? ..... Yes ☐ No ☐

*(ADJUSTMENTS MADE TO DOUBLE SEAMS **SHOULD** BE DOCUMENTED ON CAN SEAM VISUAL AND/OR TEARDOWN RECORDS. IF NO RECORDS EXIST DOCUMENTING THIS KIND OF ADJUSTMENT, THE FIRM MAY NOT BE DETECTING LOOSE SEAMS WHEN THEY OCCUR AND MAY NOT BE MAKING NECESSARY ADJUSTMENTS TO CORRECT FOR LOOSE SEAMS. IF WARRANTED BY RECORD REVIEW OR OBSERVATION OF SPOILAGE POSSIBLY CAUSED BY SEAM DEFECTS, REVIEW MAINTENANCE RECORDS FOR INDIVIDUAL SEAMERS OVER A PERIOD OF 6 MONTHS OR MORE TO DETERMINE WHAT ADJUSTMENTS WERE MADE.)*

COMMENTS:

43. IF LOOSE SEAMS ARE SUSPECT, COMPARE CAN SEAM TEARDOWN RECORDS PREPARED BY THE FIRM WITH SIMILAR RECORDS PREPARED BY THE CAN SUPPLIER DURING SERVICE CALLS ON SPECIFIC DATES AND AT SPECIFIC TIMES.

(IF THE CAN SUPPLIER FOUND LOOSE SEAMS REQUIRING ADJUSTMENTS TO THE DOUBLE SEAMER AND THE FIRM'S TEARDOWN EXAMINATIONS OF DOUBLE SEAMS ON THE SAME DATE AND APPROXIMATE TIME FOUND TIGHT SEAMS, THIS MAY INDICATE THAT THE FIRM'S SEAM INSPECTORS ARE NOT DETECTING LOOSE SEAMS WHEN THEY OCCUR.)

COMMENTS:

44. REVIEW MAINTENANCE RECORDS FOR DOUBLE SEAMERS TO DETERMINE WHAT MAINTENANCE IS ROUTINELY PERFORMED AND THE FREQUENCY (FOR EXAMPLE, THE FREQUENCY OF REPLACING SEAMING CHUCKS, ROLLS AND OTHER PARTS AS WELL AS PERFORMING A COMPLETE OVERHAUL OF THE SEAMER).

(IF MAINTENANCE IS INFREQUENT DURING A VERY BUSY PRODUCTION PERIOD, THE QUALITY AND INTEGRITY OF CAN DOUBLE SEAMS COULD BE ADVERSELY AFFECTED. IF EVIDENCE OF INFREQUENT OR POOR MAINTENANCE IS OBSERVED, VISUALLY EXAMINE THE FDA FINISHED PRODUCT IN STORAGE TO CHECK FOR SEAM DEFECTS.)

COMMENTS:

45. ARE FILLED/SEALED CONTAINERS ADEQUATELY HANDLED? ..... Yes ☐ No ☐

*(FOR EXAMPLE, RETORT CRATES **SHOULD** NOT HAVE SHARP OR POINTED SURFACES THAT COULD PUNCTURE CONTAINERS; CONTAINERS SHOULD BE LOADED INTO CRATES AND RETORTS AND UNLOADED WITHOUT CAUSING CONTAINER DAMAGE; EXCESSIVE BUCKLING OF NO. 10 CANS DURING PROCESSING IN CONTINUOUS AGITATING RETORTS CAN ADVERSELY AFFECT THE QUALITY AND INTEGRITY OF THE DOUBLE SEAM, RAISING THE POTENTIAL FOR POST-PROCESS LEAKAGE AND CONTAMINATION DURING COOLING. – SEE FORM 3511(c).)*

COMMENTS:

46. 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.)*

COMMENTS:

THERMAL PROCESSING EQUIPMENT AND PROCEDURES – 113.40

47. WHAT TYPE OF THERMAL PROCESSING EQUIPMENT DOES THE FIRM USE? (LIST THE NUMBER AND TYPE OF RETORTS; SPECIFY WHICH RETORTS WERE BEING USED DURING THIS INSPECTION.)

COMMENTS:

48. DOES THE THERMAL PROCESSING EQUIPMENT COMPLY WITH PART 113.40? ..... Yes ☐ No ☐

(FOR A DETAILED DESCRIPTION OF DIFFERENT THERMAL PROCESSING EQUIPMENT AND SYSTEMS AND THE REGULATION REQUIREMENTS, SEE PP. 23-40 OF LACF GUIDE, PART 2, AND 21 CFR PART 113.40; REFER TO FORMS 3511a-i COVERING THE DIFFERENT THERMAL PROCESSING SYSTEMS.)

COMMENTS:

49. WHERE VENTING ARRANGEMENTS VARY FROM THE EXAMPLES IN 113.40(a)(12), HAVE TEMPERATURE DISTRIBUTION STUDIES BEEN CONDUCTED ON THE RETORTS TO ESTABLISH EQUAL TEMPERATURE DISTRIBUTION AND, WHERE APPLICABLE, A VENT CYCLE? ..... Yes ☐ No ☐

(FOR AN EXPLANATION OF TEMPERATURE DISTRIBUTION – SEE P. 21 OF LACF GUIDE, PART 2. SPECIFIC DETAILS REGARDING TEMPERATURE DISTRIBUTION ARE ADDRESSED ON RETORT SURVEY FORMS FOR THE DIFFERENT PROCESSING SYSTEMS – FORMS 3511(a – i).)

COMMENTS:

50. 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 – 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.)*

COMMENTS:

51. DOES THE FIRM OPERATE THE RETORTS USING PROCEDURES DEVELOPED DURING THE TEMPERATURE DISTRIBUTION STUDY OR AS OUTLINED IN OTHER SUPPORTING DOCUMENTATION? ..... Yes ☐ No ☐

COMMENTS:

52. DO CRATES, TRAYS, GONDOLAS, ETC., FOR HOLDING CONTAINERS FOR PROCESSING IN STEAM IN STILL RETORTS MEET THE REQUIREMENTS OF 113.40(a)(9)? ..... Yes ☐ No ☐

COMMENTS:

THERMAL PROCESSING ROOM OPERATIONS – 113.87

53. ARE SCHEDULED PROCESSES AND VENTING PROCEDURES (IF APPLICABLE) POSTED IN THE RETORT ROOM OR READILY AVAILABLE TO THE RETORT OPERATOR? – 113.87(a) ..... Yes ☐ No ☐

COMMENTS:

54. DO POSTED (OPERATING) SCHEDULED PROCESSES MEET OR EXCEED THE RECOMMENDATIONS OF THE PROCESS AUTHORITY AND PROCESS SCHEDULES FILED WITH FDA? ..... Yes ☐ No ☐

COMMENTS:

55. HAS THE FIRM ESTABLISHED AN ADEQUATE SYSTEM FOR PRODUCT TRAFFIC CONTROL IN THE RETORT ROOM TO PREVENT UNRETORTED 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)).)*

COMMENTS:

56. IS THE INITIAL TEMPERATURE ("IT") OF THE CONTENTS OF CONTAINERS TO BE PROCESSED DETERMINED AND RECORDED WITH SUFFICIENT FREQUENCY? – 113.87(c) ..... Yes ☐ No ☐

(MEASURE THE "IT" OF AT LEAST 1 RETORT LOAD WITH A CALIBRATED THERMOMETER AND REPORT THE RESULTS IN "COMMENTS.")

COMMENTS:

(THE "IT" IS A CRITICAL FACTOR IN THE ATTAINMENT OF COMMERCIAL STERILITY— EQUALLY IMPORTANT AS PROCESS TIME, RETORT TEMPERATURE AND ANY OTHER CRITICAL FACTORS.)

DOES THE "IT" MEASURED BY THE INVESTIGATOR AGREE WITH THE FIRM'S MEASURED "IT" AND DOES THIS "IT" AT LEAST MEET OR EXCEED THE MINIMUM "IT" FILED WITH FDA? ..... Yes ☐ No ☐

IF NO, EXPLAIN:

57. ARE PROCEDURES FOR MEASURING "IT" PROPERLY MADE? ..... Yes ☐ No ☐

*("IT" IS DETERMINED BY SELECTING A CONTAINER REPRESENTING THE COLDEST CONTAINER IN THE RETORT LOAD; JUST PRIOR TO THE START OF THE PROCESS, THE CONTENTS OF THE CONTAINER ARE THOROUGHLY MIXED AND THE TEMPERATURE IS DETERMINED USING A CALIBRATED THERMOMETER. FOR THOSE RETORT SYSTEMS THAT USE WATER PRIOR TO OR DURING PROCESSING, PROVISIONS **SHALL** BE MADE TO ENSURE THAT THE "IT" IS REPRESENTATIVE OF EITHER THE COLDEST CONTAINER (TEMP. OF PRODUCT IN CONTAINER) OR THE WATER IN THE RETORT, WHICHEVER IS COLDER.) – 113.87(c)*

IF QUESTIONABLE, DESCRIBE THE FIRM'S PROCEDURE AND FREQUENCY FOR CHECKING PRODUCT "IT":

COMMENTS:

---

58. ARE THERMAL PROCESS TIMING DEVICES 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)

COMMENTS:

---

59. WHEN AN INKJET CODER IS USED FOR DOCUMENTATION OF PRODUCTION TIME, IS THE OFFICIAL CLOCK USED FOR RECORDING OF RETORT PROCESSING TIME (MANUAL DOCUMENTATION AND CONTINUOUS RECORDING CHART) SYNCHRONIZED WITH THE INKJET CODING DEVICE? ..... Yes ☐ No ☐

*(ALTHOUGH THIS IS NOT A REGULATORY REQUIREMENT, IT IS ESSENTIAL FOR ADEQUATE TRACEABILITY OF PRODUCT THAT MAY HAVE BEEN SUBJECT TO PROCESS DEVIATIONS; INKJET CODE/RETORT TIMING DEVICE SYNCHRONIZATION IS ESPECIALLY IMPORTANT WHEN CRATELESS RETORTS ARE BEING USED AND WHERE THE TIME THAT THE FIRST CAN ENTERS THE RETORT IS DOCUMENTED BY THE RETORT OPERATOR – THE MILITARY TIME SPECIFIED BY THE PRODUCT CODE **SHOULD** AGREE WITH THE RETORT TIMING DEVICE.)*

---

60. DOES THE RETORT OPERATOR ADEQUATELY CONTROL AND MONITOR THE RETORT DURING PROCESSING? ..... Yes ☐ No ☐

*(THE OPERATOR **SHOULD** VISUALLY MONITOR THE TEMPERATURE INDICATING DEVICE (TID) AT THE END OF THE COME-UP TIME (START OF THERMAL PROCESS) AND DURING THE PROCESS. THE RECORDING THERMOMETER CHART **SHALL BE** ADJUSTED TO AGREE AS NEARLY AS POSSIBLE WITH BUT NOT BE HIGHER THAN THE TID DURING THE PROCESSING PERIOD (113.40(a)(2)).)*

COMMENTS:

---

61. IS THE STEAM SUPPLY (PRESSURE) TO THE RETORTS SUFFICIENT TO ASSURE AN ADEQUATE COME-UP AND THERMAL PROCESS? ..... Yes ☐ No ☐

*(THERE **SHOULD** BE SUFFICIENT PRESSURE IN THE STEAM HEADER PIPE SUPPLYING STEAM TO THE RETORTS, ESPECIALLY WHEN MORE THAN ONE RETORT IS VENTED SIMULTANEOUSLY. THE PRESSURE IS USUALLY INDICATED BY A PRESSURE GAGE IN THE STEAM HEADER PIPE LOCATED IN THE RETORT AREA. THE MINIMUM PRESSURE INDICATED BY THIS GAGE **SHOULD** BE EQUAL TO OR GREATER THAN THAT SPECIFIED BY THE PROCESS AUTHORITY OR OTHER QUALIFIED PERSONS CONDUCTING TEMPERATURE DISTRIBUTION STUDIES OF THE RETORTS. IT IS IMPORTANT THAT THERE BE ENOUGH PRESSURE FOR VENTING MULTIPLE RETORTS SIMULTANEOUSLY. THE FIRM **SHOULD** HAVE DOCUMENTATION SPECIFYING HOW MANY RETORTS CAN BE VENTED SIMULTANEOUSLY GIVEN THE AVAILABLE STEAM SUPPLY.)*

COMMENTS:

62. WHEN ADDITIONS/REVISIONS TO THE RETORT OR BOILER CONFIGURATION OCCUR, IS THE PROCESS AUTHORITY ADVISED AND IS THERE WRITTEN DOCUMENTATION OF THIS CONTACT?..... Yes ☐ No ☐

COMMENTS:

63. OBSERVE A FULL RETORT CYCLE USING A CALIBRATED STOPWATCH.

COMPARE YOUR OBSERVATIONS WITH THE FILED AND POSTED PROCESSES. DO YOUR OBSERVATIONS OF THE VENT TIME/COME-UP TIME AND THE PROCESS TIME AND TEMPERATURE AGREE WITH OR EXCEED THE VENT AND SCHEDULED PROCESSES ESTABLISHED BY THE PROCESS AUTHORITY AND FILED WITH FDA? ..... Yes ☐ No ☐

COMMENTS:

POST-PROCESS HANDLING

64. WATCH FOR EVIDENCE OF CONTAINER ABUSE DURING PROCESSING THAT COULD DAMAGE THE CONTAINER AND SEAMS, RESULTING IN AN INCREASED POTENTIAL FOR POST-PROCESS LEAKAGE DURING COOLING. THIS HAS BEEN A PROBLEM FOR NO. 10 SIZE CANS PROCESSED IN CRATELESS RETORTS AND IN CONTINUOUS AGITATING RETORTS WHERE THE CONTAINERS ARE COOLED IN THE RETORT FOLLOWING CAN JAMS AND STILL COOKS – SEE FORM 3511c FOR MORE DETAILS.

COMMENTS:

65. ARE POST-PROCESS CAN CONVEYOR TRACKS MAINTAINED IN A SANITARY WAY?..... Yes ☐ No ☐

COMMENTS:

66. 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 CAN 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.)*

COMMENTS:

67. IS RETORT COOLING WATER RECIRCULATED OR HELD IN A COOLING CANAL? ..... Yes ☐ No ☐

COMMENTS:

68. IS RETORT COOLING WATER TREATED WITH CHLORINE OR OTHER SANITIZER(S)? ..... Yes ☐ No ☐

LIST THE SANITIZER(S) AND CONCENTRATION USED IN THE RETORT COOLING WATER. WHAT IS THE FIRM'S PROCEDURE (INCLUDING WHERE IT DRAWS THE WATER SAMPLE) AND FREQUENCY OF TESTING? HOW DOES THE FIRM DETERMINE THE AMOUNT OF CHLORINE NECESSARY TO PROVIDE FOR A MEASURABLE LEVEL OF CHLORINE?

*(CONTAINER COOLING WATER **SHALL** BE CHLORINATED OR OTHERWISE SANITIZED AS NECESSARY FOR COOLING CANALS AND FOR RECIRCULATED WATER SUPPLIES; THERE **SHOULD** BE A MEASURABLE RESIDUAL OF THE SANITIZER AT THE WATER DISCHARGE POINT OF THE CONTAINER COOLER – 113.60(b).)*

COMMENTS:

WAREHOUSING

69. IS THERE EVIDENCE OF ABNORMAL, SPOILED OR LEAKING CANS OF PRODUCT IN THE WAREHOUSE? ..... Yes ☐ No ☐

*(DETERMINE HOW THE FIRM HANDLES, INVESTIGATES AND DOCUMENTS LOTS CONTAINING ABNORMAL CONTAINERS. DOES THE FIRM EVALUATE SUCH CONTAINERS BY AGGRESSIVELY INCUBATING SAMPLES (E.G., AT 95 DEGREES F) AND TESTING FOR COMMERCIAL STERILITY? WHAT IS THE PROCEDURE (IS IT A PERCENTAGE OF PRODUCTION; IS INCUBATION PERFORMED IN A CONTROLLED ENVIRONMENT OR AT TRADITIONAL WAREHOUSE TEMPERATURES?). BE AWARE THAT FIRMS MAY BE SORTING LOTS WITH ABNORMAL CONTAINERS AND SHIPPING THE NORMAL-APPEARING CANS WITHOUT PROPER EVALUATION BASING THEIR DECISION TO SHIP THE NORMAL CANS ON THEIR EVALUATION OF PROCESSING RECORDS THAT SHOW THE PRODUCTS RECEIVED PROPER COOKING TO ACHIEVE COMMERCIAL STERILITY. IF AVAILABLE, REVIEW SORT AND DESTRUCTION RECORDS TO DETERMINE THE PERCENTAGE OF DEFECTIVE PRODUCT CULLED BY THE FIRM. WHEN ABNORMAL CANS ARE DETECTED IN PROCESSED LOTS THAT EXCEED ACCEPTABLE LEVELS FOR SPOILAGE, WHAT ARE THE FIRM'S ACTIONS TO DETERMINE THE CAUSE OF THE SPOILAGE AND THE PREVENTION OF REOCCURRENCE? NOTE THAT AN ACCEPTABLE LEVEL FOR CAN FOOD SPOILAGE IN THE LACF INDUSTRY IS .1% 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.)*

COMMENTS:

70. IS A DUD DETECTOR USED FOR IDENTIFICATION OF SPOILAGE AND SEGREGATION? DOES THE DETECTOR DETECT LOW VACUUM ON 1 OR BOTH ENDS OF THE CAN? IS THE DUD DETECTOR USED ROUTINELY DURING OR BEFORE LABELING OR IS IT USED ONLY FOLLOWING AN INCUBATION PROCESS?

(NOTE – CANS OF FINISHED LACF PRODUCTS CONTAINING VIABLE BOTULISM SPORES COULD PASS DUD DETECTION IF THE SPORES HAVE NOT YET GERMINATED, GROWN AND PRODUCED GAS IN THE CONTAINERS.)

COMMENTS:

71. DOES THE FIRM RECONDITION ABNORMAL/DEFECTIVE CANS (DENTS, SWELLS, ETC.) WITH A CAN REFORMING DEVICE? ..... Yes ☐ No ☐

IF SO, WHAT IS THE PERCENTAGE OF PRODUCTION THAT IS REFORMED?
WHAT IS THE CONDITION OF CANS PRIOR TO REFORMING (EXTENT OF SWELLS, DENTS, ETC.)?

(NOTE - DEBUCKLING CANS CAN CONCEAL THE PRESENCE OF CONTAMINATING BACTERIA IN THE CAN OF PUBLIC HEALTH SIGNIFICANCE AND IS NOT A GOOD PRACTICE.)

COMMENTS:

72. DOES THE FIRM KEEP A RECORD OF CAN SEAM DEFECTS PER 1,000 CANS? ..... Yes ☐ No ☐

COMMENTS:

73. WHAT IS THE PERCENTAGE OF ABNORMAL (SWELLS, BUCKLES) OR DEFECTIVE CANS PRODUCED BY THE FIRM?

(ALTHOUGH NOT A REGULATION REQUIREMENT, IT IS COMMON INDUSTRY PRACTICE TO AVOID SHIPPING FINISHED PRODUCT IN EXCESS OF A SPECIFIC DEFECT LEVEL. THIS LEVEL MAY BE DETERMINED BY SCIENTIFIC DATA OR BY PROCESS AUTHORITY'S RECOMMENDATION.)

COMMENTS:

74. IS FINISHED PRODUCT EXPOSED TO ELEVATED TEMPERATURES DURING STORAGE OR SHIPMENT THAT COULD CAUSE THERMOPHILIC GROWTH AND SPOILAGE? ..... Yes ☐ No ☐

COMMENTS:

75. ARE DEFECTIVE CONTAINERS STORED IN THE WAREHOUSE IN AN ADEQUATE MANNER TO PROTECT OTHER NORMAL CONTAINERS FROM DAMAGE AND CONTAMINATION? ..... Yes ☐ No ☐

(FOR EXAMPLE, LOOK FOR SWOLLEN OR BUCKLED CONTAINERS STORED ABOVE OR ALONGSIDE NORMAL CONTAINERS. IF THE SWOLLEN/BUCKLED CONTAINERS EXPLODE, THEIR CONTENTS COULD SPRAY ONTO THE NORMAL CONTAINERS, RESULTING IN RUSTING, CORROSION AND EVENTUAL PIN HOLING OF THOSE CONTAINERS.)

COMMENTS:

76. WHAT IS THE FIRM'S PROCEDURE IF ABNORMAL CONTAINERS OR SEAM DEFECTS ARE FOUND AFTER THERMAL PROCESSING TO ASSURE THAT THE LOT IS SAFE FOR DISTRIBUTION?

COMMENTS:

77. EXAMINE ANY SUSPECT PRODUCT CODES IDENTIFIED THROUGH WAREHOUSE INSPECTION OR RECORD REVIEW. IF ANY LOTS ARE SUSPECT DUE TO SWELLS, BUCKLES OR BLOWN OR LEAKING CONTAINERS, PERFORM A FIELD EXAMINATION OF SUSPECT CODES. RANDOMLY SELECT SEVERAL CODES FOR VISUAL FIELD EXAMINATION. REPORT ITS RESULTS UNDER AN EIR SUBHEADING. IF ABNORMAL CONTAINERS ARE IDENTIFIED THROUGH WAREHOUSE EXAMINATION, REVIEW THE CORRESPONDING PROCESSING AND/OR CONTAINER INSPECTION RECORDS. SAMPLE ABNORMAL LOTS FOLLOWING IOM SAMPLE SCHEDULE CHART 2.

COMMENTS:

RECORDS – 113.100

78. IS PROCESSING AND PRODUCTION INFORMATION RECORDED AT THE TIME IT IS OBSERVED BY THE RETORT OPERATOR? – 113.100(b) ..... Yes ☐ No ☐

COMMENTS:

79. DO PROCESSING AND PRODUCTION RECORDS INCLUDE THE PRODUCT, PRODUCT CODE, DATE, RETORT NO., APPROX. NUMBER OF CONTAINERS PER CODING INTERVAL, "IT", ACTUAL PROCESSING TIME, TID AND RECORDING THERMOMETER READINGS AND OTHER APPROPRIATE PROCESSING DATA PER PART 113.100(a)? ..... Yes ☐ No ☐

COMMENTS:

80. 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? – 113.100(b) ..... Yes ☐ No ☐

COMMENTS:

81. ARE PROCESSING AND PRODUCTION RECORDS SIGNED OR INITIALED BY THE RETORT OPERATOR AND REVIEWED FOR COMPLETENESS & 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? – 113.100(b) ..... Yes ☐ No ☐

COMMENTS:

82. ARE THE RESULTS OF VISUAL AND DESTRUCTIVE CONTAINER INTEGRITY TESTS DOCUMENTED PER PART 113.60(a)? ..... Yes ☐ No ☐

*(WRITTEN RECORDS **SHALL** SPECIFY THE PRODUCT CODE, THE DATE AND TIME OF CONTAINER CLOSURE INSPECTIONS, THE MEASUREMENTS OBTAINED AND ALL CORRECTIVE ACTIONS TAKEN; THE RECORDS **SHALL** BE SIGNED OR INITIALED BY THE CONTAINER CLOSURE INSPECTOR AND REVIEWED BY MANAGEMENT WITH SUFFICIENT FREQUENCY TO ASSURE THE CONTAINERS ARE HERMETICALLY SEALED – 113.100(c)).)*

COMMENTS:

83. REVIEW A SELECT NUMBER OF PROCESSING RECORDS (RETORT LOGS, RECORDING THERMOMETER CHARTS, RECORDS OF OTHER CRITICAL FACTOR MONITORING), AND CONTAINER INTEGRITY TEST RECORDS (BOTH VISUAL AND TEARDOWN INSPECTION RECORDS) REPRESENTATIVE OF UP TO 7 PRODUCTION DAYS DURING A 3-MONTH PERIOD, IF AVAILABLE, IMMEDIATELY PRIOR TO THIS INSPECTION. FOLLOW THE PROCEDURES FOR SELECTING RECORDS OUTLINED ON P. 83 (ATTACHMENT 12) OF LACF GUIDE, PART 2.

DID THE REVIEW OF THESE RECORDS DISCLOSE ANY DEVIATIONS FROM PART 113 OR ANY DEFICIENCIES OR INFORMATION INDICATING THAT ANY LOT OF LACF PRODUCED AT THIS ESTABLISHMENT MAY HAVE THERMAL PROCESS DEVIATIONS OR CONTAINER INTEGRITY DEFICIENCIES? ..... Yes ☐ No ☐

(IF YES, EXPLAIN IN "COMMENTS" BELOW. REPORT THE TYPE AND DATES OF RECORDS REVIEWED.)

COMMENTS:

84. ARE COPIES OF ALL RECORDS PROVIDED FOR IN PART 113 EXCEPT THOSE PERTAINING TO THE ESTABLISHMENT OF SCHEDULED PROCESSES RETAINED AT THE PROCESSING PLANT FOR AT LEAST 1 YEAR FROM THE DATE OF MANUFACTURE AND AT THE PROCESSING PLANT OR OTHER REASONABLY ACCESSIBLE LOCATION FOR AN ADDITIONAL 2 YEARS? – 113.100(e)..... Yes ☐ No ☐

COMMENTS:

85. REVIEW RECORDS COVERING MAINTENANCE OF PROCESSING, SEAMING AND MONITORING EQUIPMENT FOR THE LAST MAINTENANCE CYCLE TO DEMONSTRATE THAT THE EQUIPMENT IS ADEQUATE TO ENSURE THAT THE SCHEDULED PROCESS IS DELIVERED. FOCUS ATTENTION ON THE FOLLOWING ITEMS:

- MAINTENANCE OF ANY EQUIPMENT USED TO MEASURE CRITICAL FACTORS: SCALES, THERMOMETERS, GAGES AND CONSISTENCY METERS OR DEVICES
- REPLACEMENT OF ANY EQUIPMENT FOUND TO BE OUT OF SPECIFICATIONS
- MODIFICATIONS TO ANY EQUIPMENT CRITICAL TO CONTROL OF THE TIME/TEMPERATURE PARAMETERS OF SCHEDULED PROCESSES

BRING ANY EQUIPMENT MALFUNCTIONS TO THE ATTENTION OF THE FIRM'S MANAGEMENT, AND DETERMINE CORRECTIONS THE FIRM PLANS TO MAKE TO ADDRESS THE MALFUNCTIONS.

COMMENTS:

PROCESS DEVIATIONS – 113.89

86. DOES THE FIRM HAVE A WRITTEN PROCEDURE FOR HANDLING PROCESS DEVIATIONS? ..... Yes ☐ No ☐

COMMENTS:

87. DOES THE FIRM MAINTAIN A SEPARATE FILE OR LOG FOR DOCUMENTING PROCESS DEVIATIONS? ..... Yes ☐ No ☐

COMMENTS:

88. WERE ANY PROCESS DEVIATIONS NOTED DURING THE INSPECTION? ..... Yes ☐ No ☐

IF SO, WERE THE DEVIATIONS PROPERLY HANDLED? (I.E., WERE ADEQUATE CORRECTIVE STEPS TAKEN TO ADDRESS THE DEVIATIONS, SUCH AS REPROCESSING, DESTRUCTION OR EVALUATION BY A PROCESS AUTHORITY.) ..... Yes ☐ No ☐

(THIS INCLUDES ANY DEVIATIONS IN THE PROCESSING OF PRODUCTS OBSERVED DURING THIS INSPECTION (I.E., FAILURE TO ACHIEVE CRITICAL FACTOR LIMITS AS LISTED ON PROCESS FILING FORMS AS NECESSARY FOR THE ATTAINMENT OF COMMERCIAL STERILITY). THIS ALSO INCLUDES PROCESS DEVIATIONS OBSERVED ON PROCESSING RECORDS DURING RECORD REVIEW – COVERED IN BL. 75.)

COMMENTS:

89. WERE LOTS CONTAINING PROCESS DEVIATIONS HANDLED PROPERLY? ..... Yes ☐ No ☐

IF NOT PROPERLY HANDLED, WERE THESE LOTS SHIPPED INTERSTATE? ..... Yes ☐ No ☐

COMMENTS:

CONSUMER COMPLAINTS

90. REVIEW CONSUMER COMPLAINT FILES FOR THE LAST 6 MONTHS. FOCUS THE REVIEW ON REPORTS OF SPOILAGE, SWOLLEN CANS, ETC. DETERMINE THE FREQUENCY OF SUCH REPORTS AND WHAT, IF ANY, ACTION THE FIRM TOOK IN RESPONSE TO THE REPORTS.

COMMENTS:

91. DOES MANAGEMENT FULLY UNDERSTAND THE DEFINITION AND MEANING OF THE TERM "PROCESS DEVIATION" AND PROCEDURES FOR HANDLING THEM AS DEFINED AND STATED IN 113.89? ..... Yes ☐ No ☐

COMMENTS:

INCUBATION – 113.40(g)(3)

92. ARE RESULTS OF INCUBATION TESTS RECORDED? ..... Yes ☐ No ☐

DESCRIBE ANY INCUBATION TESTS PERFORMED ON FINISHED PRODUCTION LOTS (INCLUDE SAMPLING, INCUBATION AND TEST PROCEDURES):

IF POSITIVE RESULTS ARE FOUND, WHAT FOLLOW-UP ACTION DOES THE FIRM TAKE TO ASSURE THAT THE AFFECTED LOT IS SAFE FOR DISTRIBUTION?

(NOTE – INCUBATION TESTING IS RECOMMENDED BUT NOT REQUIRED FOR ASEPTICALLY PROCESSED PRODUCTS – 113.40(g)(3). INCUBATION TESTING IS NEITHER RECOMMENDED NOR REQUIRED FOR OTHER LACF PRODUCTS REGULATED BY FDA.)

PERSONNEL – 108.35/113.10

93. ARE ALL OPERATORS OF THERMAL PROCESSING SYSTEMS AND CONTAINER CLOSURE INSPECTIONS UNDER THE OPERATING SUPERVISION OF A PERSON WHO HAS ATTENDED A SCHOOL APPROVED BY FDA? ..... Yes ☐ No ☐

COMMENTS:

PLANT AND EQUIPMENT SANITATION – 110.35/40

94. IS PLANT AND EQUIPMENT SANITATION ADEQUATE TO PREVENT THE ADULTERATION OF FOOD WITH PHYSICAL, CHEMICAL OR MICROBIOLOGICAL CONTAMINANTS? ..... Yes ☐ No ☐

(SUMMARIZE THE FIRM'S PROCEDURES FOR CLEANING AND SANITIZING FOOD CONTACT EQUIPMENT BOTH PRE- AND POST-PROCESS – INCLUDE FILLERS AND DOUBLE STEAMERS.)

COMMENTS:

RECALL PROCEDURES

95. DOES THE FIRM HAVE RECALL PROCEDURES ON FILE THAT COMPLY WITH 108.35(f)? ..... Yes ☐ No ☐
COMMENTS:

96. DOES THE FIRM MAINTAIN INITIAL DISTRIBUTION RECORDS PER 113.100(d)? ..... Yes ☐ No ☐
COMMENTS: