

Firm Name, City & State:

FEI Number:

Inspection Date(s):

FCE Number:

Investigators:

DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

PROCESSING IN STEAM IN CONTINUOUS AGITATING 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. Draw a diagram of the retort, or obtain one from the firm and attach it to the EIR as an exhibit. Measure and verify retort plumbing - record on this form. Report all pipe sizes as inside diameter (ID). Refer to 21 CFR Part 113.40(c) and pp. 28-30 of LACF Guide, Part 2.

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 ORAU 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 Turbo 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.

RETORT DESCRIPTION

Table with 4 columns: RETORT NO. & DIMENSIONS, \*CAN SIZE, COOKER CAPACITY, STEPS/REEL. Sub-headers: NO. OF PRECOOKERS, NO. OF PRESS COOLERS, NO. OF ATMOS. COOLERS

\* List the can size covered during the inspection.

COMPUTER CONTROLS

DOES A COMPUTER CONTROL ANY OF THE RETORT FUNCTIONS? Yes No

EXPLAIN:

DOES THE FIRM HAVE DOCUMENTATION ON HAND WHICH INDICATES THAT THE COMPUTER SYSTEM HAS BEEN VALIDATED? Yes No

EXPLAIN:

IS RECORD KEEPING PART OF THE COMPUTER FUNCTION? Yes No

IF YES, DOES THE RECORD KEEPING COMPLY WITH 21 CFR PART 11? Yes No

COMMENTS:

INDICATING MERCURY-IN-GLASS THERMOMETERS (113.40(c)(1))

IS THE RETORT EQUIPPED WITH AT LEAST ONE MERCURY-IN-GLASS (MIG) THERMOMETER?

COMMENTS:

Firm Name:

FEI Number:

IS THE RETORT EQUIPPED WITH ANOTHER TYPE OF TEMPERATURE INDICATING DEVICE? ..... Yes  No

IF YES, DESCRIBE THE INDICATOR:

ARE SCALE DIVISIONS EASILY READABLE TO 1°F (.5°C)? ..... Yes  No

NO. OF DEGREES F OR C/IN. OF GRADUATED SCALE: \_\_\_\_\_  
(TEMP. RANGE MUST NOT EXCEED 17°F (8°C) PER INCH (4°C/CM) OF GRADUATED SCALE. SEE LACF GUIDE, P. 14.)

DATE LAST TESTED FOR ACCURACY:

*(THERMOMETERS **SHALL** BE TESTED FOR ACCURACY AGAINST A KNOWN ACCURATE STANDARD THERMOMETER UPON INSTALLATION AND AT LEAST ONCE A YEAR THEREAFTER; RECORDS OF ACCURACY CHECKS THAT SPECIFY DATE, STANDARD USED, METHOD USED AND PERSON PERFORMING THE TEST **SHOULD** BE MAINTAINED. EACH THERMOMETER **SHOULD** HAVE A TAG, SEAL OR OTHER MEANS OF IDENTITY THAT INCLUDES THE DATE IT WAS LAST TESTED FOR ACCURACY.)*

STANDARD USED FOR THE TEST:

NAME AND TITLE OF PERSON WHO PERFORMED TEST:

IS THE LAST TEST DATE IDENTIFIED ON THE THERMOMETER? ..... Yes  No

WERE CALIBRATING TEST RECORDS PREPARED/MAINTAINED? ..... Yes  No

*(**SHOULD** REQUIREMENT)*

COMMENTS:

DESCRIBE THE FIRM'S ACTIONS REGARDING MIG THERMOMETERS THAT WERE OUT OF CALIBRATION:

IS THE MERCURY UNDIVIDED? ..... Yes  No

*(A THERMOMETER THAT HAS A DIVIDED MERCURY COLUMN OR THAT CANNOT BE ADJUSTED TO THE STANDARD **SHALL** BE REPAIRED OR REPLACED.)*

COMMENTS:

WHEN MIG THERMOMETERS ARE FOUND TO BE PROVIDING READINGS ABOVE THE ACTUAL TEMPERATURES, DOES THE FIRM EVALUATE PRODUCTS PRODUCED USING THOSE THERMOMETERS? ..... Yes  No

DESCRIBE THE FIRM'S PROCEDURES:

IS THE THERMOMETER LOCATED WHERE IT IS EASY TO READ ACCURATELY? ..... Yes  No

*(**SHALL** REQUIREMENT)*

COMMENTS:

THE SENSOR BULB IS LOCATED IN THE ..... Retort Shell , or External Well

*(**SHALL** REQUIREMENT)*

COMMENTS:

Firm Name:

FEI Number:

DIAMETER OF OPENING FROM RETORT TO EXTERNAL WELL: \_\_\_\_\_ (OPENING **SHALL** BE AT LEAST 3/4 IN. DIAMETER.)

BLEEDER SIZE: \_\_\_\_\_ (BLEEDER **SHALL** BE AT LEAST 1/16 IN. DIAMETER.)

DOES THE BLEEDER EMIT STEAM CONTINUOUSLY DURING PROCESSING? ..... Yes  No

(**SHALL** REQUIREMENT)

IF NO, EXPLAIN (OR ANY OTHER COMMENT):

IF A MUFFLER IS USED ON BLEEDER(S), WHAT EVIDENCE DOES THE FIRM HAVE THAT IT DOES NOT RESTRICT FREE FLOW OF STEAM?

(**SHALL** REQUIREMENT – 113.87(g))

COMMENTS:

IS THE MERCURY THERMOMETER USED AS THE REFERENCED INSTRUMENT DURING PROCESSING? ..... Yes  No

(**SHALL** REQUIREMENT)

COMMENTS:

**TEMPERATURE RECORDING DEVICE (113.40(c)(2))**

IS THE RETORT EQUIPPED WITH A TEMPERATURE RECORDING DEVICE? ..... Yes  No

TYPE OF TEMPERATURE RECORDER

Round Circular Chart  Strip Chart  Other

IF OTHER, EXPLAIN:

DO THE CHART SPECIFICATIONS MEET THE REQUIREMENTS OF PART 113.40(c)(2)? ..... Yes  No

(GRADUATIONS ON THE TEMPERATURE RECORDING DEVICE **SHALL** NOT EXCEED 2°F (1°C) WITHIN A RANGE OF 10°F (5.5°C) OF THE PROCESSING TEMPERATURE. EACH CHART **SHALL** HAVE A WORKING SCALE OF NOT MORE THAN 55°F/IN. (12°C/CM) WITHIN A RANGE OF 20°F (10°C) OF THE PROCESSING TEMPERATURE – 113.40(b)(2). ALSO, SEE P. 14 OF LACF GUIDE, PART 2.)

COMMENTS:

IS THE TEMPERATURE CHART ADJUSTED TO AGREE AS NEARLY AS POSSIBLE WITH BUT NOT HIGHER THAN THE KNOWN ACCURATE MERCURY-IN-GLASS (MIG) THERMOMETER DURING THE PROCESSING PERIOD? ..... Yes  No

(**SHALL** REQUIREMENT – NOTE ANY DIFFERENCE BETWEEN THE RECORDING THERMOMETER AND THE MIG THERMOMETER AND WHICH READING IS HIGHER.)

COMMENTS:

IS THERE A MEANS FOR PREVENTING UNAUTHORIZED ADJUSTMENTS? ..... Yes  No

(A MEANS OF PREVENTING UNAUTHORIZED CHANGES IN ADJUSTMENTS **SHALL** BE PROVIDED; A LOCK OR NOTICE FROM MANAGEMENT STATING “ONLY AUTHORIZED PERSONS ARE PERMITTED TO MAKE ADJUSTMENTS,” POSTED AT OR NEAR THE RECORDING DEVICE, IS A SATISFACTORY MEANS FOR PREVENTING UNAUTHORIZED CHANGES.)

COMMENTS:

IS THE CHART DRIVE TIMING MECHANISM ACCURATE?

IF NO, EXPLAIN:

Firm Name:

FEI Number:

IS THE RECORDER COMBINED WITH A STEAM CONTROLLER? ..... Yes  No

COMMENTS:

THE TEMPERATURE RECORDER BULB IS INSTALLED IN THE..... Retort Shell  , or External Well

(THE TEMPERATURE RECORDER BULB SHALL BE INSTALLED EITHER WITHIN THE RETORT SHELL OR IN A WELL ATTACHED TO THE SHELL.)

COMMENTS:

DOES THE TEMPERATURE RECORDER BULB WELL HAVE A 1/16-IN. DIAMETER OR LARGER BLEEDER THAT EMITS STEAM CONTINUOUSLY DURING THE PROCESSING PERIOD? ..... Yes  No  N/A

(SHALL REQUIREMENT)

COMMENTS:

IF A MUFFLER IS USED ON THE BLEEDER, DOES THE FIRM HAVE DOCUMENTED EVIDENCE THAT IT DOES NOT BLOCK THE FLOW OF STEAM? ..... Yes  No  N/A

(SHALL REQUIREMENT - 113.87(g))

COMMENTS:

**PRESSURE GAGE (113.40(c)(3))**

IF A PRESSURE GAGE IS PRESENT ON THE RETORT COOKER SHELL, IS IT GRADUATED IN DIVISIONS OF 2 LBS. OR LESS? ..... Yes  No

(SHOULD REQUIREMENT)

IS THE PRESSURE COOLING SHELL EQUIPPED WITH A PRESSURE GAGE? ..... Yes  No

COMMENTS:

IF THE COOKER SHELL IS CONNECTED BY TRANSFER VALVES TO A PRESSURE COOLING SHELL, IS THE PRESSURE IN THE COOLER LESS THAN THE PRESSURE IN THE COOKER?..... Yes  No

(THE PRESSURE IN THE PRESSURE COOLER SHOULD BE AT LEAST 2 PSIG LESS THAN THE PRESSURE IN THE COOKER TO PREVENT BACKFLOW OF COOLING WATER INTO THE COOKER.)

COMMENTS:

**STEAM CONTROLLER (113.40(c)(4))**

IS THE STEAM CONTROLLER AUTOMATIC? ..... Yes  No

(EACH RETORT SHALL BE EQUIPPED WITH AN AUTOMATIC STEAM CONTROLLER TO MAINTAIN THE RETORT TEMPERATURE.)

COMMENTS:

IS THE STEAM CONTROLLER TEMPERATURE OR PRESSURE ACTUATED? .....Temp.  Press.

(THE STEAM CONTROLLER MAY BE ACTUATED BY A TEMPERATURE SENSOR POSITIONED NEAR THE MERCURY-IN-GLASS THERMOMETER; A STEAM CONTROLLER ACTIVATED BY THE STEAM PRESSURE OF THE RETORT IS ACCEPTABLE IF IT IS CAREFULLY MAINTAINED SO THAT IT OPERATES SATISFACTORILY.)

COMMENTS:

Firm Name:

FEI Number:

REPORT THE MANUFACTURER, MODEL, TYPE AND SIZE OF THE AUTOMATIC STEAM CONTROL VALVE:

IF THE TEMPERATURE (STEAM) CONTROLLER IS AIR OPERATED, DOES THE SYSTEM HAVE AN ADEQUATE FILTER TO ASSURE A SUPPLY OF CLEAN, DRY AIR? ..... Yes  No

(AIR OPERATED TEMPERATURE CONTROLLERS SHOULD HAVE ADEQUATE FILTER SYSTEMS TO ASSURE A SUPPLY OF CLEAN, DRY AIR - 113.40(c)(2).)

COMMENTS:

BLEEDERS (113.40(c)(5))

ARE BLEEDERS (EXCEPT THOSE FOR THERMOMETER WELLS) 1/8-INCH OR LARGER IN DIAMETER? ..... Yes  No

(SHALL REQUIREMENT)

COMMENTS:

ARE THESE BLEEDERS LOCATED ALONG THE TOP OF THE RETORT NO MORE THAN 8 FT APART AND WITHIN APPROXIMATELY 1 FT OF THE OUTERMOST LOCATION OF CONTAINERS AT EACH END? ..... Yes  No

(SHALL REQUIREMENT)

COMMENTS:

ARE THE BLEEDERS ARRANGED SO THAT THE OPERATOR CAN OBSERVE THAT THEY ARE OPERATING PROPERLY? ..... Yes  No

(SHALL REQUIREMENT)

COMMENTS:

ARE THE BLEEDERS WIDE OPEN DURING THE ENTIRE PROCESS, INCLUDING THE COME-UP TIME? ..... Yes  No

COMMENTS:

IF A MUFFLER IS USED ON BLEEDERS, DOES THE FIRM HAVE DOCUMENTED EVIDENCE THAT IT DOES NOT RESTRICT FREE FLOW OF STEAM?

(SHALL REQUIREMENT - 113.87(g))

COMMENTS:

VENTING AND CONDENSATE REMOVAL (113.40(c)(5 and 6))

IS THE RETORT VENTED TO REMOVE AIR PRIOR TO PROCESSING? ..... Yes  No

(SHALL REQUIREMENT)

NUMBER OF VENTS: \_\_\_\_\_ DIAMETER: \_\_\_\_\_ LENGTH: \_\_\_\_\_

LOCATION:

WHAT IS THE TYPE OF VENT VALVE? ..... Gate  Plug Cock  Other

IF OTHER, SPECIFY:

ARE VENTS FULLY OPEN DURING VENTING? ..... Yes  No

IF NO, EXPLAIN:

Firm Name:

FEI Number:

DOES THE FIRM HAVE ON FILE DOCUMENTARY PROOF DEMONSTRATING THAT ADEQUATE VENTING IS ACHIEVED? ..... Yes  No

*(SHALL REQUIREMENT – 113.40(c)(6); HEAT DISTRIBUTION DATA AND/OR A LETTER FROM A COMPETENT PROCESS AUTHORITY DOCUMENTING THE LAST HEAT DISTRIBUTION TEST PERFORMED ON THE RETORT (DATE OF TEST, WHO PERFORMED THE TEST, THE RESULTING VENT SCHEDULE, ETC.) WOULD BE ACCEPTABLE DOCUMENTATION.)*

COMMENTS:

IS A STEAM BY-PASS VALVE USED DURING VENTING? ..... Yes  No

IF YES, EXPLAIN:

*(NOTE – VENTING PROCEDURES AND ARRANGEMENTS MUST BE THE SAME AS THOSE USED DURING THE TEMPERATURE DISTRIBUTION STUDY THAT WAS CONDUCTED ON THE RETORT TO ESTABLISH THE VENT SCHEDULE.)*

IF VENTS ARE EQUIPPED WITH MUFFLERS, SPECIFY TYPE AND PERFORMANCE CHARACTERISTICS. DOES THE FIRM HAVE DOCUMENTED EVIDENCE THAT THE MUFFLER ALLOWS ADEQUATE VENTING? ..... Yes  No

*(SHALL REQUIREMENT – 113.87(g))*

COMMENTS:

WHEN THE STEAM IS TURNED ON, IS THE DRAIN OPENED FOR A TIME SUFFICIENT TO REMOVE STEAM CONDENSATE FROM THE RETORT? ..... Yes  No

*(SHOULD REQUIREMENT)*

COMMENTS:

HAS PROVISION BEEN MADE FOR CONTINUAL OR AUTOMATIC DRAINAGE OF CONDENSATE DURING RETORT OPERATION? ..... Yes  No

*(SHALL REQUIREMENT – A BLEEDER(S) LOCATED AT THE BOTTOM OF THE RETORT WOULD BE SUFFICIENT TO ASSURE CONTINUAL CONDENSATE REMOVAL.)*

DESCRIBE THE PROCEDURES USED FOR CONDENSATE REMOVAL:

IS THE RETORT EQUIPPED WITH A CONDENSATE TRAP? ..... Yes  No

COMMENTS:

IS THERE A CONDENSATE BLEEDER IN THE BOTTOM OF THE RETORT SHELL THAT SERVES AS AN INDICATOR OF CONTINUOUS CONDENSATE REMOVAL? ..... Yes  No

IF SO, IS THIS BLEEDER VISIBLE TO THE RETORT OPERATOR? ..... Yes  No

*(SHALL REQUIREMENT)*

COMMENTS:

DOES THIS CONDENSATE BLEEDER CONTINUOUSLY EMIT STEAM DURING THE THERMAL PROCESS? ..... Yes  No

*(SHALL REQUIREMENT)*

COMMENTS:

IS THE CONDENSATE BLEEDER CHECKED WITH SUFFICIENT FREQUENCY DURING RETORT OPERATION TO ASSURE ADEQUATE REMOVAL OF CONDENSATE? ..... Yes  No

*(SHALL REQUIREMENT)*

Firm Name:

FEI Number:

ARE THESE OBSERVATIONS RECORDED AT THE TIME THEY ARE MADE? ..... Yes  No

(SHALL REQUIREMENT – 113.100(a))

COMMENTS:

IF THE CONDENSATE BLEEDER IS NOT VISIBLY MONITORED, IS IT EQUIPPED WITH AN AUTOMATIC ALARM SYSTEM THAT SERVES AS A CONTINUOUS MONITOR OF CONDENSATE FUNCTIONING? ..... Yes  No

(SHALL REQUIREMENT)

COMMENTS:

IF AN AUTOMATIC ALARM IS USED TO MONITOR CONDENSATE FUNCTIONING, DOES IT WORK ADEQUATELY? ..... Yes  No

COMMENTS:

**RETORT SPEED TIMING (113.40(c)(7))**

IS THE ROTATIONAL SPEED OF THE RETORT ADJUSTED AND RECORDED WHEN THE RETORT IS STARTED, AT ANY TIME A SPEED CHANGE IS MADE AND AT INTERVALS OF SUFFICIENT FREQUENCY TO ENSURE THAT THE RETORT SPEED IS MAINTAINED AS SPECIFIED IN THE SCHEDULED PROCESS? ..... Yes  No

(SHALL REQUIREMENT)

COMMENTS:

ARE THESE ADJUSTMENTS AND RECORDINGS MADE AT LEAST ONCE EVERY 4 HOURS? ..... Yes  No

(SHOULD REQUIREMENT)

IF NO, HOW OFTEN?

IF ROTATIONAL SPEED ADJUSTMENTS AND RECORDINGS ARE NOT MADE AT INTERVALS OF SUFFICIENT FREQUENCY, DOES THE FIRM HAVE A RECORDING TACHOMETER TO PROVIDE A CONTINUOUS RECORD OF THE RETORT SPEED? ..... Yes  No

COMMENTS:

DOES THE FIRM HAVE A MEANS OF PREVENTING UNAUTHORIZED SPEED CHANGES ON THE RETORT? ..... Yes  No

(SHALL REQUIREMENT – A LOCK OR NOTICE FROM MANAGEMENT, POSTED AT OR NEAR THE SPEED ADJUSTMENT DEVICE WHICH PROVIDES A WARNING THAT ONLY AUTHORIZED PERSONS ARE PERMITTED TO MAKE ADJUSTMENTS, IS A SATISFACTORY MEANS OF PREVENTING UNAUTHORIZED CHANGES.)

Adjustment of the reel speed changes the process time and may affect the agitation of the product. The reel speed (revolutions per minute) calculated to provide the process time should be entered on the FDA 2541a (Scheduled Process Filing Form) in Part D column titled "Reel Speed." A minimum reel speed (slower than the reel speed providing adequate processing time) may be determined during process establishment to provide for adequate product agitation. This minimum reel speed should be entered on Form 2541a, Part D, in the column titled "Other" along with an explanation of "minimum reel speed." Minimum reel speeds for agitation may be less than the reel speed established for the process time. Reel speeds greater than the established reel speed for process time will shorten the process time. Reel speeds slower than the minimum reel speed for agitation may not provide for adequate agitation of the product. In cases where a minimum reel speed for agitation is not identified by the processing source, determine if agitation is critical to the process. Note some processes are established without considering agitation. If agitation is critical to the process, the firm should have information that identifies the minimum rpm required to achieve adequate product agitation in the container. This reel speed may be the same as that established to provide for process time.

Reel speed and process time can be determined using the following formulas. To use these formulas, one can enter known values into the formula to determine unknown values or to check the values supplied by the firm on the process filing form. The capacity of the retort is normally stamped on the end of the cooker reel shaft. The approximate number of reel steps for the FMC system for each container size is provided in the table below. Please be aware that some reels may be altered. In some cases, the firm may process a smaller can size in a reel designed for a larger container (e.g., 300 in a 303 x 307 reel).

Firm Name:

FEI Number:

CONTAINER SIZE                      NUMBER OF STEPS PER TURN OF REEL

211 .....	56
300-303 .....	47
303-307 .....	42
401-404 .....	35
603 .....	24

DETERMINE THE REEL SPEED BY TIMING 10 REVOLUTIONS OF THE RETORT REEL AND REPORT RESULTS (IN SECONDS): \_\_\_\_\_

CALCULATE THE ACTUAL PROCESS TIME USING THE FORMULA:

SECONDS FOR 10 REVS = (10 REVS) X (60 SEC) X (REEL STEPS) X (PROCESS TIME)/CAPACITY

ACTUAL PROCESS TIME = \_\_\_\_\_ MIN.

IS THE ACTUAL PROCESS TIME AT LEAST EQUAL TO THE MINIMUM PROCESS TIME FILED WITH FDA ..... Yes  No

CALCULATE THE PROCESS SPEED IN CONTAINERS/MIN USING THE FORMULA:

CONTAINERS PER MINUTE = CAPACITY/PROCESS TIME (MIN)

CONTAINERS PER MINUTE = \_\_\_\_\_

CALCULATE THE REEL SPEED AS REVOLUTIONS PER MINUTE (RPM) USING THE FORMULA:

RPM = CAPACITY/(REEL STEPS) X (PROCESS TIME)

REEL SPEED (RPM) = \_\_\_\_\_

IS THE REEL SPEED CALCULATED ABOVE AS CONTAINERS PER MINUTE AND/OR REVOLUTIONS PER MINUTE AT LEAST EQUAL TO THE MINIMUM REEL SPEED FILED WITH FDA? ..... Yes  No

(IF NO, THE LOT COULD BE UNDERPROCESSED AND **SHOULD** BE HANDLED AS A PROCESS DEVIATION. )

ALTERNATE FORMULAS THAT CAN BE USED TO DETERMINE SECONDS FOR 10 REVOLUTIONS OF THE REEL:

(10 REVS) X (60 SEC) X (REEL STEPS)/(CPM)

(10 REVS) X (60 SEC)/RPM

COMMENTS:

**EMERGENCY STOPS (113.40(c)(8))**

IF EMERGENCY STOPS ARE NOT OBSERVED DURING PROCESSING OR REVIEW OF RECORDS, ANSWER THE FOLLOWING QUESTIONS BY REVIEW OF WRITTEN SOPs OR INTERVIEW WITH MANAGEMENT. INDICATE HOW THIS INFORMATION WAS OBTAINED:

Processing Observation     Review of Processing Records     Review of SOPs     Interview with Management

COMMENTS:

Firm Name:

FEI Number:

IN THE CASE OF A JAM OR BREAKDOWN DURING PROCESSING OPERATIONS NECESSITATING COOLING THE RETORT, IS THE RETORT OPERATED IN A WAY WHICH ENSURES THAT THE PRODUCT IS COMMERCIALY STERILE? ..... Yes  No

(THIS CAN BE ACHIEVED BY REPROCESSING OR REPACKING AND REPROCESSING.)

IF NO, IS THE PRODUCT DISCARDED? ..... Yes  No

(SHALL REQUIREMENT)

COMMENTS:

IF OPERATED AS A STILL RETORT, ARE ALL CONTAINERS GIVEN A FULL, STILL RETORT PROCESS BEFORE THE RETORT IS COOLED? ..... Yes  No  N/A

IF SO, IS THE STILL PROCESS SCHEDULE READILY AVAILABLE TO THE RETORT OPERATOR? ..... Yes  No

(SHALL REQUIREMENT)

COMMENTS:

IF ANY CONTAINERS ARE IN THE RETORT INTAKE VALVE OR IN TRANSFER VALVES BETWEEN COOKER SHELLS AT THE TIME OF BREAKDOWN, ARE THE CONTAINERS REPROCESSED, REPACKED AND REPROCESSED, OR DISCARDED? ..... Yes  No

(SHALL REQUIREMENT - (113.40(c)(8)(i))

COMMENTS:

ARE BOTH THE TIME AT WHICH THE REEL STOPPED AND THE TIME THE RETORT WAS USED FOR A STILL RETORT PROCESS MARKED ON THE RECORDING CHART AND ENTERED ON OTHER PRODUCTION RECORDS? ..... Yes  No  N/A

(SHALL REQUIREMENT - (113.40(c)(8)(ii))

IS THE DISPOSITION OF CANS IN TRANSFER VALVES AT THE TIME OF A LINE STOPPAGE DOCUMENTED? ..... Yes  No

COMMENTS:

IF THE RETORT IS COOLED FOLLOWING AN EMERGENCY STOP, ARE SUBSEQUENT HANDLING METHODS USED FOR CONTAINERS IN THE RETORT AT THE TIME OF STOPPING AND COOLING ENTERED ON PRODUCTION RECORDS? ..... Yes  No  N/A

(SHALL REQUIREMENT - (113.40(c)(8)(ii))

COMMENTS:

DESCRIBE ANY INCIDENCES OF EMERGENCY STOPS THAT WERE NOT HANDLED ACCORDING TO 113.40(c)(8):

TEMPERATURE DROPS (113.40(c)(9))

IF TEMPERATURE DROPS ARE NOT OBSERVED DURING THE INSPECTION OR REVIEW OF PROCESSING RECORDS, ANSWER THE FOLLOWING QUESTIONS BY REVIEW OF THE FIRM'S SOPs OR INTERVIEW WITH MANAGEMENT. INDICATE HOW THIS INFORMATION WAS OBTAINED:

Processing Observation  Review of Processing Records  Review of SOPs  Interview with Management

COMMENTS:

Firm Name:

FEI Number:

IF THE TEMPERATURE OF THE RETORT DROPS BELOW THE TEMPERATURE SPECIFIED IN THE SCHEDULED PROCESS WHILE CONTAINERS ARE IN THE RETORT, IS THE REEL STOPPED PROMPTLY? ..... Yes  No

**(SHALL REQUIREMENT)**

IF YES, IS AN AUTOMATIC DEVICE USED TO STOP THE REEL? ..... Yes  No

**(SHOULD REQUIREMENT)**

COMMENTS:

BEFORE THE RETORT IS RESTARTED, ARE ALL CONTAINERS IN THE RETORT GIVEN A COMPLETE SCHEDULED STILL RETORT PROCESS IF THE TEMPERATURE DROP WAS 10°F OR MORE BELOW THE SPECIFIED TEMPERATURE? ..... Yes  No  N/A

IF YES, ARE BOTH THE TIME AT WHICH THE REEL STOPPED AND THE TIME THE RETORT WAS USED FOR A STILL RETORT PROCESS MARKED ON THE RECORDING CHART AND OTHER PRODUCTION RECORDS? ..... Yes  No  N/A

**(SHALL REQUIREMENT)**

ALTERNATIVELY, IF THE TEMPERATURE DROP IS 10°F OR MORE, IS CONTAINER ENTRY TO THE RETORT STOPPED AND THE REEL RESTARTED TO EMPTY THE RETORT? ..... Yes  No  N/A

IF YES, ARE THE DISCHARGED CONTAINERS EITHER:

Reprocessed  Repacked & Reprocessed , or Discarded  ?

ARE SUBSEQUENT HANDLING METHODS USED FOR CONTAINERS IN THE RETORT AT THE TIME OF THE TEMPERATURE DROP ENTERED ON PRODUCTION RECORDS? ..... Yes  No  N/A

**(SHALL REQUIREMENT)**

COMMENTS:

IF THE TEMPERATURE DROP IS LESS THAN 10°F, IS THE PRODUCT GIVEN AN AUTHORIZED EMERGENCY STILL PROCESS BEFORE RESTARTING THE RETORT REEL? ..... Yes  No

IS CONTAINER ENTRY INTO THE RETORT STOPPED AND AN AUTHORIZED EMERGENCY AGITATING PROCESS USED BEFORE CONTAINER ENTRY TO THE RETORT IS RESTARTED? ..... Yes  No

**(SHALL REQUIREMENT)**

COMMENTS:

DURING AN EMERGENCY AGITATING PROCESS, ARE CONTAINERS PREVENTED FROM ENTERING THE RETORT? ..... Yes  No  N/A

COMMENTS:

WHEN EMERGENCY PROCEDURES ARE USED, ARE PROCESSES AND PROCEDURES NOTED ON PRODUCTION RECORDS? ..... Yes  No  N/A

COMMENTS:

DESCRIBE ANY INCIDENCES OF TEMPERATURE DROPS THAT WERE NOT HANDLED ACCORDING TO 113.40(c)(9):

Firm Name:

FEI Number:

**RETORT PLUMBING AND EQUIPMENT ISSUES**

WHEN WAS THE LAST MAJOR OVERHAUL OR MAINTENANCE PERFORMED ON THE RETORTS?

COMMENTS:

DOES THE FIRM CONDUCT A RETORT SURVEY PERIODICALLY (YEARLY), AFTER A MAJOR RETORT OVERHAUL OR AFTER MAINTENANCE IS PERFORMED ON CRITICAL EQUIPMENT (RETORTS, FILLER, BOILER CONFIGURATION, ETC.)? A RETORT SURVEY IS NOT REQUIRED BY THE REGULATIONS, BUT IS COMMONLY USED TO DOCUMENT THAT A FIRM'S PROCESSING SYSTEM IS IN COMPLIANCE WITH FDA REGULATIONS AND THAT THE SYSTEM MEETS THE SAME CRITERIA (VALVE TYPE, STEAM SPREADER CONFIGURATION, ETC.) AS WHEN TEMPERATURE DISTRIBUTION STUDIES WERE CONDUCTED.

COMMENTS:

DO THE BOILERS SUPPLY SUFFICIENT STEAM TO THE RETORTS? IS THERE SUFFICIENT PRESSURE IN THE HEADER PIPE SUPPLYING STEAM TO THE RETORTS, ESPECIALLY WHEN MORE THAN ONE RETORT IS BEING VENTED SIMULTANEOUSLY?

COMMENTS:

**TEMPERATURE DISTRIBUTION**

HAVE TEMPERATURE DISTRIBUTION STUDIES BEEN CONDUCTED ON THE FIRM'S RETORTS? ..... Yes  No   
IF SO, WHO CONDUCTED THE STUDY, WHAT PROCEDURES WERE FOLLOWED AND WHO EVALUATED THE DATA?

IS THERE DOCUMENTATION SUCH AS A RETORT DIAGRAM AND PARAMETERS USED TO VALIDATE THE TESTS?

*(FOR AN EXPLANATION OF TEMPERATURE DISTRIBUTION, SEE P. 21 OF LACF GUIDE, PART 2. SPECIAL CONSIDERATIONS FOR CONDUCTING TEMPERATURE DISTRIBUTION STUDIES IN STEAM-AIR RETORTS ARE LISTED IN FORM 3511(h).)*

COMMENTS:

HAVE THERE BEEN ANY CHANGES TO THE RETORTS OR THERMAL PROCESSING SYSTEM SINCE THE LAST TEMPERATURE DISTRIBUTION STUDY THAT COULD AFFECT TEMPERATURE DISTRIBUTION?

*(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: