

**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. 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.

If problems are found with the firm's retort equipment or processing system, refer the reader to the narrative Turbo EIR under "Objectionable Conditions and Management's Response," and include a narrative explanation of specific problems and evidence under the subheading "Supporting Evidence and Relevance." Submit the completed form as an EIR attachment.

RETORT DESCRIPTION

RETORT NO.	*CAN SIZE	COOKER CAPACITY	STEPS/REEL
	NO. OF PRECOOKERS	NO. OF PRESS COOLERS	NO. OF AMOS. 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 THAT 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? Yes No

COMMENTS:

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:

DIAMETER OF OPENING FROM RETORT TO EXTERNAL WELL: BLEEDER SIZE:

(OPENING **SHALL** BE AT LEAST 3/4-IN. DIA.)

(BLEEDER **SHALL** BE AT LEAST 1/16-IN. DIA.)

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 FIELD 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 THERMOMETER DURING THE PROCESSING PERIOD? Yes No

(SHALL REQUIREMENT; NOTE ANY DIFFERENCE BETWEEN THE RECORDING THERMOMETER AND THE MERCURY-IN-GLASS 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? Yes No

IF NO, EXPLAIN:

IS THE RECORDER COMBINED WITH A STEAM CONTROLLER? Yes No
COMMENTS:

THE TEMPERATURE SENSING BULB IS INSTALLED IN THE Retort Shel , 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. DIA. 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 IT OPERATES SATISFACTORILY.)

COMMENTS:

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 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? Yes No N/A

(**SHALL REQUIREMENT – 113.87(G)**)

COMMENTS:

VENTING & CONDENSATE REMOVAL (113.40(c)(5&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:

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 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 CONDENSATE TRAP OR BLEEDER 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)

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 THAT 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 calculated to provide the process time would be entered on the FDA 2541a (Scheduled Process Filing Form) in Part D column titled "Reel Speed" in revolutions per minute (rpm). 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, known values can be entered 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).

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:

$$\text{SECONDS FOR 10 REVS} = (10 \text{ RVS}) \times (60 \text{ SECS}) \times (\text{REEL STEPS}) \times (\text{PROCESS TIME}) / \text{CAPACITY}$$

ACTUAL PROCESS TIME = _____ MIN.

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

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

$$\text{CONTAINERS PER MINUTE} = \text{CAPACITY} / \text{PROCESS TIME (MIN)}$$

CONTAINERS PER MINUTE = _____

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

$$\text{RPM} = \text{CAPACITY} / ((\text{REEL STEPS}) \times (\text{PROCESS TIME}))$$

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 UNDER PROCESSED AND SHOULD BE HANDLED AS A PROCESS DEVIATION.)

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

$(10 \text{ REV}) \times (60 \text{ SECS}) \times (\# \text{REEL STEPS}) / (\text{CPM})$

$(10 \text{ RVS}) \times (60 \text{ SEC}) / \text{RPM}$

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:

IN THE CASE OF A JAM OR BREAK DOWN DURING PROCESSING OPERATIONS NECESSITATING COOLING THE RETORT, IS THE RETORT OPERATED IN SUCH A WAY THAT ENSURES THAT THE PRODUCT IS COMMERCIALY STERILE?

Yes No

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

IF NO, IS THE PRODUCT DISCARDED? Yes No

(SHALL REQUIREMENTS)

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 REQUIREMENTS)

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:

IS 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))

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:

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 REQUIREMENTS)

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 REQUIREMENTS)

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 REQUIREMENTS)

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):