

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

RETORT NO. & DIMENSIONS	*CAN SIZE	COOKER CAPACITY	STEPS/REEL
		NO. OF PRECOOKERS	NO. OF PRESS 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:

Firm Name:

FEI Number:

TEMPERATURE-INDICATING DEVICES (113.40(c)(1))

IS THE RETORT EQUIPPED WITH AT LEAST ONE TEMPERATURE-INDICATOR DEVICE (TID) THAT ACCURATELY INDICATES THE TEMPERATURE DURING PROCESSING? Yes No

COMMENTS:

DOES EACH TID HAVE THE FOLLOWING:

(A) A SENSOR AND A DISPLAY? (SHALL REQUIREMENT - 113.40(c)(1)) Yes No

COMMENTS:

(B) A DESIGN THAT ENSURES THAT THE ACCURACY OF THE DEVICE IS NOT AFFECTED BY ELECTROMAGNETIC INTERFERENCE AND ENVIRONMENTAL CONDITIONS? Yes No

COMMENTS:

IS EACH TID AND EACH REFERENCE DEVICE MAINTAINED BY THE PROCESSOR TESTED FOR ACCURACY AGAINST A REFERENCE DEVICE FOR WHICH THE ACCURACY IS TRACEABLE TO A NATIONAL METROLOGY INSTITUTE, SUCH AS THE NATIONAL INSTITUTE OF STANDARDS AND TECHNOLOGY (NIST), BY APPROPRIATE STANDARD PROCEDURES UPON INSTALLATION AND AT LEAST ONCE A YEAR THEREAFTER? (SHALL REQUIREMENT - 113.40(c)(1)) Yes No

COMMENTS:

IS THE TID REPAIRED OR REPLACED WHEN FOUND DEFECTIVE OR INCAPABLE OF BEING ADJUSTED TO THE ACCURATE CALIBRATED REFERENCED DEVICE? Yes No

COMMENTS:

WHEN A MERCURY-IN-GLASS THERMOMETER IS USED AS THE TID, IS IT EQUIPPED WITH A SCALE THAT DOES NOT EXCEED 17 DEG F/INCH (4 DEG C/CM OF GRADUATED SCALE)? Yes No

COMMENTS:

IS THE TID INSTALLED WHERE IT CAN BE ACCURATELY AND EASILY READ? Yes No

COMMENTS:

IS THE TID SENSOR INSTALLED IN THE RETORT SHELL [] OR IN AN EXTERNAL WELL ATTACHED TO THE RETORT []

COMMENTS:

DATE THE TID LAST TESTED FOR ACCURACY: _____ .

DOES EACH TID AND EACH REFERENCE DEVICE MAINTAINED BY THE PROCESSOR HAVE A TAG, SEAL OR OTHER MEANS OF IDENTITY INDICATING WHEN THEY WERE LAST TESTED FOR ACCURACY? Yes No

Firm Name:

FEI Number:

ARE ACCURACY RECORDS OF THE TID AND REFERENCE DEVICE MAINTAINED BY THE PROCESSOR ESTABLISHED AND MAINTAINED IN ACCORDANCE WITH PART 113.100(c) AND (d)? Yes No

Note - To answer Yes to this question the records must contain the following information per Part 113.100(c): (1) A reference to the tag, seal or other means of identity used by the processor to identify the TID; (2) The name of the TID manufacturer; (3) The identity of the reference device, equipment and procedures used for the accuracy test and to adjust the TID; (4) If the TID accuracy test is conducted by an outside facility, a guarantee, certificate of accuracy, certificate of calibration, or other document from the facility that includes a statement or other documentation regarding the traceability of the accuracy test to a National Institute of Standards and Technology (NIST) or other national metrology institute standard; (5) The identity of the person or facility that performed the accuracy test and adjusted or calibrated the TID; (6) The date and results of each accuracy test including the amount of calibration adjustment; and (7) The date on or before which the next accuracy test must be performed.

In addition, Part 113.100(d) requires that records of accuracy of a reference device maintained by the processor shall include: (1) A reference to the tag, seal or other means of identity used by the processor to identify the reference device; (2) The name of the manufacturer of the reference device; (3) The identity of the equipment and reference to procedures used for the accuracy test and to adjust or calibrate the reference device; or (4) If an outside facility is used to conduct the accuracy test for the reference device, a guarantee, certificate of accuracy, certificate of calibration, or other document from the facility that includes a statement or other documentation regarding the traceability of the accuracy to a NIST or other national metrology institute standard; (5) The identity of the person or facility that performed the accuracy test and adjusted or calibrated the referenced device; (6) The date and results of each accuracy test including the amount of calibration adjustment; and (7) The date on or before which the next accuracy test must be performed.

COMMENTS:

STANDARD USED FOR THE TEST:

NAME AND TITLE OF PERSON WHO PERFORMED TEST:

IS THE LAST TEST DATE IDENTIFIED ON THE TID? Yes No

WERE CALIBRATING TEST RECORDS PREPARED/MAINTAINED? Yes No

(SHALL REQUIREMENT)

COMMENTS:

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

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

DESCRIBE THE FIRM'S PROCEDURES:

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

(SHALL REQUIREMENT)

COMMENTS:

Firm Name:

FEI Number:

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

(SHALL REQUIREMENT)

COMMENTS:

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 TID 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 RECORDING DEVICE Analog Digital

IF OTHER, EXPLAIN:

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

(SHALL REQUIREMENT - NOTE ANY DIFFERENCE BETWEEN THE RECORDING THERMOMETER AND THE TID 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:

Firm Name:

FEI Number:

IS THE CHART DRIVE TIMING MECHANISM ACCURATE? Yes No

IF NO, EXPLAIN:

IS THE TEMPERATURE RECORDING DEVICE 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 IN 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. (13.8 KILOPASCALS) 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:

Firm Name:

FEI Number:

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:

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? Yes No

(SHALL REQUIREMENT - 113.87(g))

COMMENTS:

Firm Name:

FEI Number:

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: _____

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.)

IS THE FIRM VENTING THE RETORTS THROUGH OTHER METHODS (VENTING THROUGH THE BLEEDERS, ETC.) AND DOES THE FIRM HAVE THE APPROPRIATE DOCUMENTATION ON FILE?..... Yes No

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: _____

Firm Name:

FEI Number:

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)

COMMENTS:

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:

Firm Name:

FEI Number:

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 whether 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).

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): _____

Firm Name:

FEI Number:

CALCULATE THE ACTUAL PROCESS TIME USING THE FORMULA:

SECONDS FOR 10 REV_s = (10 REV_s) 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 REV_s) X (60 SEC) X (REEL STEPS)/(CPM)

(10 REV_s) X (60 SEC)/RPM

COMMENTS (CALCULATIONS):

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:

Firm Name:

FEI Number:

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 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 ?

Firm Name:

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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):

RETORT PLUMBING AND EQUIPMENT ISSUES

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

COMMENTS:

Firm Name:

FEI Number:

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: