

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 DISCONTINUOUS 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. Attach the diagram 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(d) and p. 31 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. Includes a row for PROCESSING MODE with options: Axial, End-over-End, Rocking.

* 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(d)(1))

IS THE RETORT EQUIPPED WITH AT LEAST ONE MERCURY-IN-GLASS (MIG) THERMOMETER? Yes No

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

IF SO, DESCRIBE THE INDICATOR:

Firm Name:

FEI Number:

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: _____ .

COMMENTS:

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)

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

IS THE MERCURY UNDIVIDED? Yes No

(A THERMOMETER WHICH 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 THERetort 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. DIAMETER) (BLEEDER SHALL BE AT LEAST 1/6-IN. MINIMUM)

COMMENTS:

DOES THE BLEEDER EMIT STEAM CONTINUOUSLY DURING PROCESSING? Yes No

(SHALL REQUIREMENT):

IF NO, EXPLAIN:

Firm Name:

FEI Number:

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?

(SHALL REQUIREMENT)

COMMENTS:

TEMPERATURE RECORDING DEVICE (113.40(d)(2))

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

TYPE OF TEMPERATURE RECORDER Round Circular Chart Strip Chart Other

IF OTHER, DESCRIBE:

DO THE CHART SPECIFICATIONS MEET THE REQUIREMENTS OF PART 113.40(d)(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? Yes No

IF NO, EXPLAIN:

IS THE RECORDER COMBINED WITH A STEAM CONTROLLER TO FUNCTION AS A RECORDING/CONTROLLING INSTRUMENT? 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:

Firm Name:

FEI Number:

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(d)(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:

STEAM CONTROLLER (113.40(d)(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 ACTIVATED 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(d)(2).)

COMMENTS:

BLEEDERS (113.40(d)(5))

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

(SHALL REQUIREMENT)

COMMENTS:

Firm Name:

FEI Number:

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

(SHALL REQUIREMENT)

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 AND CONDENSATE REMOVAL (113.40(d)(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(d)(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.)

Firm Name:

FEI Number:

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:

IS PROVISION MADE FOR CONTAINING DRAINAGE OF CONDENSATE DURING THE RETORT OPERATION? Yes No

(SHOULD REQUIREMENT - IN RETORTS HAVING TOP STEAM INLET AND BOTTOM VENTING, A BLEEDER SHALL BE INSTALLED IN THE BOTTOM OF THE RETORT TO REMOVE CONDENSATE - 113.40(d)(5).)

(NOTE - A CONDENSATE TRAP OR BLEEDER LOCATED AT THE BOTTOM OF THE RETORT WOULD BE SUFFICIENT TO ASSURE CONTINUAL CONDENSATE REMOVAL.)

COMMENTS:

DESCRIBE THE PROCEDURES USED FOR CONDENSATE REMOVAL:

IF A CONDENSATE BLEEDER IS PRESENT AT THE BOTTOM OF THE RETORT,
IS IT VISIBLE TO THE RETORT OPERATOR? Yes No

DOES IT CONTINUOUSLY EMIT STEAM DURING THE COME-UP AND THERMAL PROCESS? Yes No

COMMENTS:

IS THE CONDENSATE BLEEDER CHECKED WITH SUFFICIENT FREQUENCY DURING THE
PROCESSING OF EACH RETORT LOAD TO ASSURE ADEQUATE REMOVAL OF CONDENSATE? Yes No

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

(SHALL REQUIREMENT - 113.100(a))

COMMENTS:

RETORT SPEED TIMING (113.40(d)(7))

*IS THE ROTATIONAL SPEED OF THE RETORT ADJUSTED, AS NECESSARY, TO ENSURE
THAT THE SPEED IS AS SPECIFIED IN THE SCHEDULED PROCESS? Yes No

(SHALL REQUIREMENT)

COMMENTS:

IS THE ROTATIONAL SPEED OF THE RETORT AND THE PROCESS TIME
RECORDED FOR EACH RETORT LOAD PROCESSED? Yes No

(SHALL REQUIREMENT)

IF NO, IS A RECORDING TACHOMETER USED TO PROVIDE A CONTINUOUS RECORD OF THE SPEED? Yes No

IF NO, HOW DOES THE FIRM MONITOR AND RECORD THE RETORT SPEED AND PROCESS TIME OF EACH RETORT LOAD PROCESSED?

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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.)

*THE REEL SPEED IS ADJUSTED TO PROVIDE FOR A SPECIFIC PROCESS TIME. MINIMUM REEL SPEEDS ARE NORMALLY DETERMINED DURING PROCESS ESTABLISHMENT TO PROVIDE FOR ADEQUATE PRODUCT AGITATION. REEL SPEEDS THAT ARE GREATER THAN THE MINIMUM ESTABLISHED PROCESS MAY SHORTEN THE PROCESS TIME. REEL SPEEDS THAT ARE SLOWER THAN THE MINIMUM REEL SPEED MAY NOT PROVIDE FOR ADEQUATE AGITATION OF THE PRODUCT. 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 (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:

$SECONDS\ FOR\ 10\ REVs = (10\ REVs) \times (60\ SEC) \times (REEL\ STEPS) \times (PROCESS\ TIME) / CAPACITY$

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:

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

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:

$(10\ REVs) \times (60\ SEC) \times (REEL\ STEPS) / (CPM)$

$(10\ REVs) \times (60\ SEC) / RPM$

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), OR 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 PERFORMED 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? Yes No

(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:

OTHER CONCERNS AND OBSERVATIONS

EXPLAIN ANY OTHER CONCERNS WITH THE OPERATION OF THIS RETORT SYSTEM: