

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 HYDROSTATIC 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 FDA Guide to "Inspections of LACF Manufacturers," Part 2, pp. 34-36, and 21 CFR Part 113.40(f).

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 2 columns and 2 rows: RETORT NO., NO. OF CARRIER CHAINS, NO. OF CARRIERS IN STEAM DOME, NO. OF CONTAINERS/CARRIER, CONTAINER SIZE(S)

COMPUTER CONTROLS

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

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 [ ]

COMMENTS:

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

COMMENTS:

MERCURY-IN-GLASS THERMOMETERS (113.40(f)(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 INDICATOR DEVICE? ..... Yes [ ] No [ ]

IF YES, DESCRIBE THE INDICATOR.

Firm Name:

FEI Number:

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

**(SHALL REQUIREMENT)**

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. ALSO, SEE LACF GUIDE, P. 14.)

COMMENTS:

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.)*

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

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:

IS THE THERMOMETER LOCATED IN THE STEAM DOME NEAR THE STEAM-WATER INTERFACE? ..... Yes  No

**(SHALL REQUIREMENT)**

COMMENTS:

Firm Name:

FEI Number:

WHEN THE SCHEDULED PROCESS SPECIFIES MAINTENANCE OF PARTICULAR TEMPERATURES IN THE HYDROSTATIC WATER LEGS, IS A MIG THERMOMETER LOCATED IN EACH HYDROSTATIC WATER LEG IN A POSITION NEAR THE BOTTOM AUTOMATIC RECORDER? ..... Yes  No  N/A

(SHALL REQUIREMENT)

COMMENTS:

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

(SHALL REQUIREMENT)

COMMENTS:

ARE TEMPERATURES INDICATED BY THE MIG THERMOMETER(S) RECORDED ON A SUITABLE FORM DURING PROCESSING OPERATIONS? ..... Yes  No

(SHALL REQUIREMENT - 113.40(f)(4))

COMMENTS:

**TEMPERATURE RECORDING DEVICE (113.40(f)(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? ..... 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. 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 OF 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 OF PREVENTING UNAUTHORIZED CHANGES - 113.40(f)(2).)

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:

Firm Name:

FEI Number:

THE TEMPERATURE RECORDING 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 – 113.40(f)(2).)

COMMENTS:

THE TEMPERATURE RECORDER BULB IS LOCATED AT THE FOLLOWING POINTS:

(1) In the Steam Chamber between the steam-water interface and the lowest container position

(2) Near the top and the bottom of each Hydrostatic Water Leg if the scheduled process specifies maintenance of particular temperatures in the legs

(SHALL REQUIREMENT – 113.40(f)(4))

COMMENTS:

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

(SHALL REQUIREMENT – 113.40(f)(2))

COMMENTS:

IF A MUFFLER IS USED ON THE BLEEDER, WHAT EVIDENCE DOES THE FIRM HAVE THAT IT DOES NOT RESTRICT THE FLOW OF STEAM? – (113.87(g))

**PRESSURE GAGE (113.40(f)(3))**

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

(SHOULD REQUIREMENT)

COMMENTS:

ARE TEMPERATURES RECORDED BY ACCURATE AUTOMATIC RECORDER(S)?..... Yes  No

COMMENTS:

**AUTOMATIC STEAM CONTROLLER (113.40(f)(5))**

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 – 113.40(f)(5).)

COMMENTS:

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

Firm Name:

FEI Number:

**VENTING (113.40(f)(6))**

IS THE RETORT STEAM CHAMBER(S) VENTED BEFORE THE START OF PROCESSING OPERATIONS?..... Yes  No

**(SHALL REQUIREMENT)**

COMMENTS:

WHAT ARE THE SIZE AND TYPE OF VENT VALVE?

WHERE IS THE VENT LOCATED?

**BLEEDERS (113.40(f)(7))**

NUMBER OF BLEEDERS: \_\_\_\_\_ SIZE(S) **(SHALL BE AT LEAST 1/4 IN.)**: \_\_\_\_\_

LOCATION:

*(BLEEDER OPENINGS 1/4 IN. OR LARGER SHALL BE LOCATED AT THE TOP OF THE STEAM CHAMBER OPPOSITE THE POINT OF STEAM ENTRY.)*

COMMENTS:

ARE THEY OBSERVABLE DURING OPERATION? ..... Yes  No

COMMENTS:

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

IF NO, EXPLAIN:

IF A MUFFLER IS USED OVER THE BLEEDERS, WHAT EVIDENCE DOES THE FIRM HAVE THAT IT DOES NOT RESTRICT FREE FLOW OF STEAM? – 113.87(g)

**RETORT SPEED (113.40(f)(8))**

IS THE SPEED OF THE CONTAINER CONVEYOR CHAIN SPECIFIED IN THE SCHEDULED PROCESS? ..... Yes  No

**(SHALL REQUIREMENT)**

COMMENTS:

IS THE SPEED OF THE CONTAINER CONVEYOR CHAIN DETERMINED AND RECORDED AT THE START OF PROCESSING AND AT LEAST ONCE EVERY 4 HOURS DURING PROCESSING? ..... Yes  No

*(THE SPEED SHALL BE DETERMINED AND RECORDED AT THE START OF PROCESSING AND AT INTERVALS OF SUFFICIENT FREQUENCY TO ASSURE THAT THE RETORT SPEED IS MAINTAINED AS SPECIFIED. THE SPEED SHOULD BE DETERMINED AND RECORDED EVERY 4 HOURS.)*

*(CARRIER CONVEYOR SPEED MAY BE MEASURED AS THE NUMBER OF FLIGHTS PER MINUTE USING A STOPWATCH, OR ELECTRONICALLY WITH A SENSING PROBE. ELECTRONIC MEASUREMENT OF THE CONVEYOR SPEED SHOULD BE VERIFIED BY USING A STOPWATCH ON A ROUTINE BASIS.)*

COMMENTS:

DETERMINE THE CARRIER CONVEYOR SPEED (TIME 50 CARRIERS) USING A CALIBRATED STOPWATCH AND REPORT THE RESULTS:

Firm Name:

FEI Number:

THE NUMBER OF DESIRED CARRIERS PER MINUTE TO MEET PROCESS TIME REQUIREMENTS IS DETERMINED BY THE FOLLOWING FORMULA:

CARRIERS PER MINUTE = NUMBER OF CARRIERS IN STEAM CHAMBER/PROCESS TIME IN MINUTES

THE ACTUAL NUMBER OF CARRIERS PER MINUTE IS DETERMINED BY USING THE FOLLOWING FORMULA:

CARRIERS PER MINUTE = 3,000/SECONDS FOR 50 CARRIERS

IS THE RETORT EQUIPPED WITH AN AUTOMATIC DEVICE DESIGNED TO STOP THE CONVEYOR CHAIN WHEN THE TEMPERATURE DROPS BELOW THAT SPECIFIED IN THE SCHEDULED PROCESS? ..... Yes  No

(SHALL REQUIREMENT)

COMMENTS:

IS THE RETORT EQUIPPED WITH A METHOD FOR DETERMINING WATER LEVEL IN THE RETORT DURING TEMPERATURE DROPS? ..... Yes  No

(NOTE - IF CONTAINERS IN THE STEAM DOME CONTACT WATER DURING TEMPERATURE DROPS, THOSE CONTAINERS MUST BE SEGREGATED FROM OTHER CONTAINERS AND HANDLED AS PART OF A PROCESS DEVIATION.)

COMMENTS:

ARE THE CARRIERS IN THE RETORT IDENTIFIED SO THAT CONTAINERS CAN BE EASILY SEGREGATED FOLLOWING TEMPERATURE DROPS TO LEVELS THAT ALLOW WATER TO CONTACT THE LOWER CONTAINERS? ..... Yes  No

COMMENTS:

IS THERE A MEANS FOR PREVENTING UNAUTHORIZED SPEED CHANGES IN THE CONTAINER CONVEYOR CHAIN? ..... Yes  No

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

COMMENTS:

DOES THE FIRM HAVE A PROCEDURE FOR HANDLING STRAY CONTAINERS FOUND UNDER OR AROUND THE FEED LINES TO THE RETORT? ..... Yes  No

(NOTE - CONTAINERS OF UNKNOWN STATUS, WHICH HAVE BEEN PLACED BACK ON CONVEYOR LINES FEEDING OR DISCHARGING HYDROSTATIC COOKERS, HAVE CAUSED SEVERAL RECALLS. THE FEED AND DISCHARGE POINTS ON THESE RETORTS MAY BE CLOSE TOGETHER. STRAY CONTAINERS FOUND IN THOSE AREAS ARE NORMALLY OF UNKNOWN STATUS AND SHOULD BE SEGREGATED FOR DESTRUCTION.)

COMMENTS:

RETORT PLUMBING AND EQUIPMENT ISSUES

WHEN WAS THE LAST MAJOR OVERHAUL OR MAINTENANCE PERFORMED?

COMMENTS:

WHEN WAS THE LAST MAJOR TEMPERATURE DISTRIBUTION STUDY CONDUCTED?

WHO EVALUATED THE DATA? WHAT PROCEDURE WAS USED?

IS THERE DOCUMENTATION SUCH AS A RETORT DIAGRAM AND PARAMETERS USED TO VALIDATE THE TESTS? ..... Yes  No

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DID THE PROCESS AUTHORITY CONDUCT THE TEMPERATURE DISTRIBUTION STUDY ON 1 UNIT OR ON ALL 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? ..... Yes  No

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

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?..... 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: