

**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 as an exhibit to the EIR. Report all pipe sizes as inside diameter (ID). Cross-sectional area = $3.14r^2$ ($r = \frac{1}{2}$ diameter). Refer to FDA Guide to Inspections of LACF Manufacturers, Part 2, pp 34-36 and 21CFR Part 113.40(f).

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.	NO. OF CARRIER CHAINS	NO. OF CARRIERS IN STEEL DOME
	NO. OF CNS/CARRIER	CONTAINER SIZE(S)

COMPUTER CONTROLS

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

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

COMMENTS:

IF YES, DOES THE RECORD KEEPING COMPLY WITH 21CFR 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.

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:

WHEN THE SCHEDULED PROCESS SPECIFIES MAINTENANCE OF PARTICULAR TEMPERATURES IN THE HYDROSTATIC WATER LEGS, IS A MERCURY-IN-GLASS 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 MERCURY-IN-GLASS (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 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 – 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:

THE TEMPERATURE SENSING BULB IS INSTALLED IN THE Retort Shell 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 SENSING 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 STEAMDOME, DOES THE WELL HAVE A 1/16-IN DIA. 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 IT OPERATES SATISFACTORILY 113.40(f)(5).)

COMMENTS:

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

VENTING (113.40(f)(6))

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

(SHALL REQUIREMENT)

COMMENTS:

WHAT IS 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"): _____

LOCATION:

(BLEEDER OPENINGS 1/4 INCH 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 STOP WATCH, 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 STOP WATCH AND REPORT THE RESULTS:

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 STEAMDOME 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 WHICH 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 THAT 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 CONVEYER 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: