

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 STILL 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).

**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.	TYPE OF RETORT	LENGTH OR HEIGHT	DIAMETER
	Vertical <input type="checkbox"/> Horizontal <input type="checkbox"/>		

FOR VERTICAL RETORTS, BOTTOM CRATE SUPPORTS ARE PRESENT. .... Yes  No

*(SHALL REQUIREMENT)*

COMMENTS:

ARE BAFFLE PLATES PRESENT IN THE BOTTOM OF THE RETORT? ..... Yes  No

*(SHALL NOT BE USED IN THE BOTTOM OF STEAM STILL RETORTS (113.40(a)(6)) – BAFFLE PLATES ARE UNDESIRABLE IN THE BOTTOM OF STILL STEAM RETORTS BECAUSE THEY CAN IMPEDE THE FLOW OF STEAM FROM STEAM INLETS OR PERFORATED STEAM DISTRIBUTOR PIPES.)*

COMMENTS:

ARE THERE ANY PROTRUSIONS INSIDE THE RETORT OR THE RETORT DOOR CASING THAT COULD DAMAGE CONTAINERS DURING LOADING/UNLOADING OF CRATES? ..... Yes  No

COMMENTS:

**COMPUTER CONTROLS**

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

COMMENTS:

Firm Name:

FEI Number:

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:

**TEMPERATURE-INDICATING DEVICES (113.40(a)(1))**

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

(SHALL REQUIREMENT)

COMMENTS:

DOES EACH TID HAVE THE FOLLOWING:

(A) A SENSOR AND A DISPLAY? (SHALL REQUIREMENT – 113.40(a)(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(a)(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:

Firm Name:

FEI Number:

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

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 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:

Firm Name:

FEI Number:

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

DESCRIBE THE FIRM'S PROCEDURES WHEN THE TIDs ARE FOUND TO BE PROVIDING TEMPERATURE READINGS ABOVE THE ACTUAL TEMPERATURE:

IF EVALUATION OF PRODUCTION LOTS REVEALS PROCESS DEVIATIONS, ARE THE DEVIATIONS HANDLED PER PART 113.89? ..... Yes  No

DESCRIBE:

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

(SHALL REQUIREMENT - 113.40(a)(1)(v))

COMMENTS:

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

COMMENTS:

DIAMETER OF OPENING FROM RETORT TO EXTERNAL WELL: \_\_\_\_\_ BLEEDER SIZE: \_\_\_\_\_  
(DIAMETER MUST BE AT LEAST 3/4 IN.) (1/16 IN. MINIMUM)

COMMENTS:

DOES THE BLEEDER EMIT STEAM CONTINUOUSLY DURING PROCESSING? ..... Yes  No

IF NO, EXPLAIN (SHALL REQUIREMENT):

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

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

(SHALL REQUIREMENT)

COMMENTS:

Firm Name:

FEI Number:

**TEMPERATURE RECORDING DEVICE (113.40(a)(2))**

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

TYPE OF TEMPERATURE RECORDING DEVICE ..... Analog  Digital

DESCRIBE:

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:

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:

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:

Firm Name:

FEI Number:

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)

(SHALL REQUIREMENT)

COMMENTS:

**PRESSURE GAGE (113.40(a)(3))**

IF A PRESSURE GAGE IS PRESENT, IS IT GRADUATED IN DIVISIONS OF 2 LBS. (13.8 KILOPASCALS) OR LESS?.....

Yes  No

(SHOULD REQUIREMENT)

COMMENTS:

**AUTOMATIC STEAM CONTROLLER (113.40(a)(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 TID; 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.)

COMMENTS:

**STEAM INLETS (113.40(a)(5))**

IF THE RETORT IS OVER 30 FT LONG, ARE THERE 2 STEAM INLETS? ..... Yes  No  N/A

IF NO, HOW MANY? \_\_\_\_\_

(SHOULD REQUIREMENT)

COMMENTS:

Firm Name:

FEI Number:

ARE STEAM INLETS LOCATED OPPOSITE THE VENT? ..... Yes  No   
IF NO, EXPLAIN.

(STEAM **SHALL** ENTER THE PORTION OF THE RETORT OPPOSITE THE VENT.)

THE ID OF THE SMALLEST RESTRICTION IN THE STEAM INLET LINE – DESCRIBE WHERE THE SMALLEST RESTRICTION IS LOCATED (INCLUDE THE TEMPERATURE (STEAM) CONTROL VALVE AS A RESTRICTION):

CALCULATED CROSS-SECTIONAL AREA OF SMALLEST RESTRICTION: \_\_\_\_\_

( $A = 3.14(r)^2$ )

COMMENTS:

**STEAM SPREADER (113.40(a)(7))**

DESCRIBE SHAPE AND DIMENSIONS:

(NOTE – STEAM SPREADERS ARE REQUIRED FOR HORIZONTAL STILL RETORTS. THE SPREADER PIPE **SHOULD** BE PERFORATED ALONG THE TOP 90° OF THE PIPE. VERTICAL STILL RETORTS ARE NOT REQUIRED TO HAVE STEAM SPREADERS. HOWEVER, IF THEY HAVE THEM, THEY **SHOULD** BE PERFORATED ALONG THE CENTER LINE OF THE PIPE FACING THE INTERIOR OF THE RETORT OR ALONG THE SIDES OF THE PIPE.)

COMMENTS:

NUMBER OF PERFORATIONS: \_\_\_\_\_ DIAMETER OF PERFORATIONS: \_\_\_\_\_

LOCATION OF PERFORATIONS: \_\_\_\_\_

COMMENTS:

THE CALCULATED TOTAL CROSS-SECTIONAL AREA OF THE PERFORATIONS: \_\_\_\_\_

(NO. OF PERFORATIONS) X (3.14) X ( $r^2$ )

IS THIS AREA 1.5 TO 2 TIMES THE TOTAL CROSS-SECTIONAL AREA OF THE SMALLEST RESTRICTIONS IN THE STEAM INLET LINE? ..... Yes  No

(THE NUMBER OF PERFORATIONS **SHOULD** BE SUCH THAT THE TOTAL CROSS-SECTIONAL AREA OF THE PERFORATIONS IS EQUAL TO 1.5 TO 2 TIMES THE CROSS-SECTIONAL AREA OF THE SMALLEST RESTRICTION IN THE STEAM INLET LINE.)

Firm Name:

FEI Number:

IF THE TOTAL CROSS-SECTIONAL AREA OF ALL PERFORATIONS IN THE STEAM SPREADER PIPE IS NOT 1.5 TO 2 TIMES THE CROSS-SECTIONAL AREA OF THE SMALLEST RESTRICTION IN THE STEAM INLET LINE, DOES THE FIRM HAVE DOCUMENTATION OF A TEMPERATURE DISTRIBUTION STUDY SUPPORTING THE EXISTING NUMBER AND SIZE OF PERFORATIONS IN THE SPREADER PIPE? ..... Yes  No

COMMENTS:

IS THE STEAM SPREADER IN GOOD REPAIR AND ARE THE PERFORATIONS CLEARLY OPEN? (FOR EXAMPLE, HOLES HAVE NOT BEEN PLUGGED BY RUST OR SEDIMENT, NOR ENLARGED BY WEAR; PIPES HAVE NOT RUSTED THROUGH.) ..... Yes  No

COMMENTS:

**BLEEDERS (113.40(a)(8))**

NUMBER OF BLEEDERS: \_\_\_\_\_ SIZE(S): \_\_\_\_\_

LOCATION (INCLUDE DISTANCE BETWEEN BLEEDERS ON HORIZONTAL RETORTS):

COMMENTS:

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

*(SHALL REQUIREMENT)*

IF NO, EXPLAIN (OR ANY OTHER COMMENTS):

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)

*(SHALL REQUIREMENT)*

COMMENTS:

**AIR OR WATER COOLING LINE VALVES (113.40(a)(10) to (11))**

IS WATER OR COMPRESSED AIR USED DURING COOLING? ..... Water  Air

COMMENTS:

TYPE OF VALVE ON WATER COOLING LINES SUPPLYING RETORT:

WERE WATER LINES OBSERVED TO BE LEAKING? ..... Yes  No

COMMENTS:



Firm Name:

FEI Number:

TYPE OF VALVE ON THE AIR SUPPLY LINE TO THE RETORT:

WERE AIR LINES OBSERVED TO BE LEAKING? ..... Yes  No

COMMENTS:

**VENTS (113.40(a)(12))**

NUMBER OF VENTS: \_\_\_\_\_ SIZE(S) – DIAMETER: \_\_\_\_\_

WHAT IS THE VALVE TYPE? ..... Gate  Plug Cock  Other

IF OTHER, SPECIFY:

ARE VENTS FULLY OPEN DURING VENTING? ..... Yes  No

IF NO, EXPLAIN:

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.)*

ARE VENTS LOCATED OPPOSITE THE STEAM INLET? ..... Yes  No

IF NO, EXPLAIN:

*(VENTS **SHALL** BE LOCATED OPPOSITE THE STEAM INLET.)*

IF VENTS ARE CONNECTED TO A RETORT MANIFOLD, WHAT IS THE MANIFOLD VALVE TYPE?

Gate  Plug Cock  Other

IF OTHER, SPECIFY:

(WHERE A RETORT MANIFOLD CONNECTS SEVERAL VENT PIPES FROM A SINGLE RETORT, IT **SHALL** BE CONTROLLED BY A GATE, PLUG COCK OR OTHER ADEQUATE TYPE VALVE. – (113.40(a)(12))

RETORT MANIFOLD DIAMETER AND CROSS-SECTIONAL AREA: DIA. = \_\_\_\_\_ A = \_\_\_\_\_

(CROSS-SEC. AREA = (3.14) X (r<sup>2</sup>))

NUMBER OF VENTS CONNECTING TO MANIFOLD: \_\_\_\_\_ DIAMETER OF CONNECTING VENTS: \_\_\_\_\_

THE CROSS-SECTIONAL AREA OF ALL CONNECTING VENTS: \_\_\_\_\_ (A = (NO. OF VENTS) X (3.14) X (r<sup>2</sup>))

IS THIS LARGER THAN THE CROSS-SECTIONAL AREA OF THE RETORT MANIFOLD? ..... Yes  No

(THE RETORT MANIFOLD **SHALL** BE OF A SIZE THAT THE CROSS-SECTIONAL AREA OF THE PIPE IS LARGER THAN THE TOTAL CROSS-SECTIONAL AREA OF ALL CONNECTING VENTS. – (113.40(a)(12))

COMMENTS:

Firm Name:

FEI Number:

DOES THE VENT, RETORT MANIFOLD OR MANIFOLD HEADER BREAK TO THE ATMOSPHERE? ..... Yes  No

IF YES, WHERE?

IF NO, EXPLAIN:

(A MANIFOLD HEADER CONNECTING VENTS OR MANIFOLDS FROM SEVERAL STILL RETORTS **SHALL** LEAD TO THE ATMOSPHERE – 113.40(a)(12).)

DIAMETER AND CROSS-SECTIONAL AREA OF MANIFOLD HEADER (IF APPLICABLE):

DIAMETER = \_\_\_\_\_ AREA = \_\_\_\_\_

DIAMETERS AND TOTAL CROSS-SECTIONAL AREA OF CONNECTING VENTS/MANIFOLDS FROM ALL RETORTS VENTING SIMULTANEOUSLY:

DIAMETERS = \_\_\_\_\_

AREA = \_\_\_\_\_ (A = (NO. OF CONNECTING MANIFOLDS) X (3.14) X (r<sup>2</sup>))

IS THE MANIFOLD HEADER CROSS-SECTIONAL AREA AT LEAST EQUAL TO THIS AREA? ..... Yes  No

(THE MANIFOLD HEADER **SHALL** BE OF A SIZE THAT THE CROSS-SECTIONAL AREA IS AT LEAST EQUAL TO THE TOTAL CROSS-SECTIONAL AREA OF ALL CONNECTING RETORT MANIFOLD PIPES FROM ALL RETORTS VENTING SIMULTANEOUSLY – 113.40(a)(12).)

COMMENTS:

IS THERE A VALVE ON THE MANIFOLD HEADER? ..... Yes  No

(THE MANIFOLD HEADER **SHALL** NOT BE CONTROLLED BY A VALVE – 113.40(a)(12).)

COMMENTS:

DO VENTING ARRANGEMENTS AND METHODS COMPLY WITH ONE OF THE EXAMPLES IN 113.40(a)(12)?..... Yes  No

(THE GENERIC VENTING ARRANGEMENTS OUTLINED IN 113.40(a)(12) WERE ESTABLISHED WITH CONTAINERS BEING JUMBLE-FILLED INTO THE BASKETS/CRATES. ANY OTHER CONTAINER ARRANGEMENT IN THE BASKETS WILL NOT MEET THE VENTING REQUIREMENTS OF 113.40(a)(12).)

IF NO, DOES THE FIRM HAVE TEMPERATURE DISTRIBUTION DATA OR SUITABLE DOCUMENTATION THAT APPROPRIATE TESTS HAVE BEEN PERFORMED? ..... Yes  No

113.40(a)(12)(iii)

COMMENTS:

IF VENTS ARE EQUIPPED WITH MUFFLERS, SPECIFY TYPE AND PERFORMANCE CHARACTERISTICS. WHAT EVIDENCE DOES THE FIRM HAVE THAT THE MUFFLER(S) ALLOWS ADEQUATE VENTING (SEE 113.87(g))?

Firm Name:

FEI Number:

**DIVIDER PLATES AND RETORT BASKET (113.40(a)(9))**

ARE DIVIDER PLATES USED TO SEPARATE CAN LAYERS? ..... Yes  No

COMMENTS:

THE PLATES ARE UNIFORMLY PERFORATED? ..... Yes  No

ARE THE PERFORATIONS AT LEAST 1-IN. HOLES ON 2-IN. CENTERS OR THE EQUIVALENT?

(IN COMMENTS, PROVIDE HOLE SIZE AND DISTRIBUTION (E.G., 1/4 IN. ON 1/2 IN. CENTERS).)

COMMENTS:

ARE RETORT BASKETS UNIFORMLY PERFORATED? ..... Yes  No

DESCRIBE:

DO BASKET BOTTOMS HAVE AT LEAST 1-IN. HOLES ON 2-IN. CENTERS OR THE EQUIVALENT? ..... Yes  No

(NOTE – PERFORATED DIVIDER PLATE(S) PLACED DIRECTLY OVER THE PERFORATED STEEL BOTTOM OF THE RETORT BASKETS CAN COVER THE HOLES (IN WHOLE OR IN PART) IN THE BOTTOM PLATE AND RESTRICT THE FLOW OF STEAM THROUGH THE BASKET(S). THIS COULD AFFECT TEMPERATURE DISTRIBUTION IN THE RETORT.)

COMMENTS:

DOES THE FIRM HAVE DOCUMENTATION ON FILE THAT PERMITS VENTING USING DIVIDER PLATES AND THE CURRENT BASKET DESIGN? ..... Yes  No

COMMENTS:

**RETORT PLUMBING AND EQUIPMENT ISSUES**

WHEN WAS THE LAST MAJOR OVERHAUL OR MAINTENANCE PERFORMED ON THE RETORTS? ..... Yes  No

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:

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Firm Name:

FEI Number:

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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:

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**TEMPERATURE DISTRIBUTION**

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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?

*(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:

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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:

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