FEI Number: FCE Number:

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 DESC	RIPTION	
RETORT NO.	TYPE OF RETORT		LENGTH OR HEIGHT	DIAMETER
	Vertical 🗌	Horizontal 🗌		
FOR VERTICAL RETORTS, B	BOTTOM CRATE SUF	PORTS ARE PRESE	NT	Yes 🗌 No 🗌
(SHALL REQUIREMENT)				
COMMENTS:				
ARE BAFFLE PLATES PRESI	ENT IN THE BOTTOM	I OF THE RETORT?		Yes 🗌 No 🗌
	ETORTS BECAUSE 1		3.40(a)(6)) – BAFFLE PLATES AF E FLOW OF STEAM FROM STEA	
COMMENTS:				
ARE THERE ANY PROTRUSI THAT COULD DAMAGE CON COMMENTS:			ORT DOOR CASING GOF CRATES?	Yes 🗌 No 🗌
		COMPUTER CO	NTROLS	
DOES A COMPUTER CONTR COMMENTS:	ROL ANY OF THE RE	TORT FUNCTIONS?		Yes 🗌 No 🗌

Firm Name:	FEI Number:
DOES THE FIRM HAVE DOCUMENTATION ON HAND WHICH INDICATES THAT THE COMPUTER SYSTEM HAS BEEN VALIDATED? EXPLAIN:	
IS RECORD KEEPING PART OF THE COMPUTER FUNCTION?	
COMMENTS:	
INDICATING MERCURY-IN-GLASS THE	ERMOMETER (113.40(a)(1))
IS THE RETORT EQUIPPED WITH AT LEAST ONE MERCURY-IN-GLASS ((<u>SHALL</u> REQUIREMENT) COMMENTS:	MIG) THERMOMETER? Yes 🗌 No 🗌
IS THE RETORT EQUIPPED WITH ANOTHER TYPE OF TEMPERATURE II IF SO, DESCRIBE THE INDICATOR:	NDICATOR DEVICE? Yes No
ARE SCALE DIVISIONS EASILY READABLE TO 1°F (.5°C)? (<u>SHALL</u> REQUIREMENT) COMMENTS:	Yes 🗌 No 🗌
NO. OF DEGREES FOR C/IN. OF GRADUATED SCALE:	—
(TEMP. RANGE MUST NOT EXCEED 17°F (8°C) PER INCH (4°C/CM) OF G	
DATE LAST TESTED FOR ACCURACY: (THERMOMETERS SHALL BE TESTED FOR ACCURACY AGAINST A KNOW INSTALLATION AND AT LEAST ONCE A YEAR THEREAFTER; RECORDS O USED, METHOD USED AND PERSON PERFORMING THE TEST SHOULD TAG, SEAL OR OTHER MEANS OF IDENTITY THAT INCLUDES THE DATE I	WN ACCURATE STANDARD THERMOMETER UPON OF ACCURACY CHECKS THAT SPECIFY DATE, STANDARD BE MAINTAINED. EACH THERMOMETER SHOULD HAVE A
COMMENTS:	
STANDARD USED FOR THE TEST:	
NAME AND TITLE OF PERSON WHO PERFORMED THE TEST:	
IS THE LAST TEST DATE IDENTIFIED ON THE THERMOMETER?	
WERE CALIBRATING TEST RECORDS PREPARED/MAINTAINED?	Yes 🗌 No 🗌

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

Firm Name:	FEI Number:
	LUMN OR THAT CANNOT BE ADJUSTED TO THE STANDARD <u>SHALL</u>
IF EVALUATION OF PRODUCTION LOTS REVEALS PRO	TS PRODUCED USING THOSE THERMOMETERS?
IS THE THERMOMETER LOCATED WHERE IT IS EASY T (<u>SHALL</u> REQUIREMENT) COMMENTS:	O READ ACCURATELY? Yes No
THE SENSOR BULB IS LOCATED IN THE	Retort Shell 🔲 , or External Well 🗌
DIAMETER OF OPENING FROM RETORT TO EXTERNAL (DIAM COMMENTS:	WELL: BLEEDER SIZE: ETER MUST BE AT LEAST 3/4 IN.) (1/16 IN. MINIMUM)
DOES THE BLEEDER EMIT STEAM CONTINUOUSLY DU IF NO, EXPLAIN (<u>SHALL</u> REQUIREMENT):	RING PROCESSING? Yes No
IF A MUFFLER IS USED ON BLEEDER(S), WHAT EVIDEN OF STEAM? – 113.87(g)	ICE DOES THE FIRM HAVE THAT IT DOES NOT RESTRICT FREE FLOW
IS THE MERCURY THERMOMETER USED AS THE REFE (<u>SHALL</u> REQUIREMENT) COMMENTS:	RENCED INSTRUMENT DURING PROCESSING?
TEMPERATURE F	RECORDING DEVICE (113.40(a)(2))
IS THE RETORT EQUIPPED WITH A TEMPERATURE REI TYPE OF TEMPERATURE RECORDER IF OTHER, DESCRIBE:	CORDING DEVICE? Yes No

Firm Name:	FEI Number:
DO THE CHART SPECIFICATIONS MEET THE REQUIREMENTS OF (GRADUATIONS ON THE TEMPERATURE RECORDING DEVICE <u>SI</u> OF THE PROCESSING TEMPERATURE. EACH CHART <u>SHALL</u> HAV WITHIN A RANGE OF 20°F (10°C) OF THE PROCESSING TEMPER.	<u>HALL</u> NOT EXCEED 2°F (1°C) WITHIN A RANGE OF 10°F (5.5°C) E A WORKING SCALE OF NOT MORE THAN 55°F/IN. (12°C/CM)
COMMENTS:	
IS THE TEMPERATURE CHART ADJUSTED TO AGREE AS NEARLY THE KNOWN ACCURATE MERCURY-IN-GLASS (MIG) THERMOMET	
(SHALL REQUIREMENT – NOTE ANY DIFFERENCE BETWEEN THE AND WHICH READING IS HIGHER.)	RECORDING THERMOMETER AND THE MIG THERMOMETER
COMMENTS:	
IS THERE A MEANS FOR PREVENTING UNAUTHORIZED ADJUST (A MEANS OF PREVENTING UNAUTHORIZED CHANGES IN ADJUS MANAGEMENT STATING "ONLY AUTHORIZED PERSONS ARE PERI RECORDING DEVICE, IS A SATISFACTORY MEANS FOR PREVENT COMMENTS:	TMENTS <u>SHALL</u> BE PROVIDED. A LOCK OR NOTICE FROM MITTED TO MAKE ADJUSTMENTS," POSTED AT OR NEAR THE
IS THE CHART DRIVE TIMING MECHANISM ACCURATE?	Yes 📋 No 📋
IS THE RECORDER COMBINED WITH A STEAM CONTROLLER TO AS A RECORDING/CONTROLLING INSTRUMENT? COMMENTS:	
THE TEMPERATURE RECORDER BULB IS INSTALLED IN THE (THE TEMPERATURE RECORDER BULB SHALL BE INSTALLED EITH THE SHELL.) COMMENTS:	
DOES THE TEMPERATURE RECORDER BULB WELL HAVE A 1/16 THAT EMITS STEAM CONTINUOUSLY DURING THE PROCESSING (<u>SHALL</u> REQUIREMENT) COMMENTS:	
IF A MUFFLER IS USED ON THE BLEEDER, WHAT EVIDENCE DOP OF STEAM? – 113.87(g)	S THE FIRM HAVE THAT IT DOES NOT RESTRICT THE FLOW
(<u>SHOULD</u> REQUIREMENT)	

COMMENTS:

Firm Name: FEI Number:
PRESSURE GAGE (113.40(a)(3))
IF A PRESSURE GAGE IS PRESENT, IS IT GRADUATED IN DIVISIONS OF 2 LBS. OR LESS?
AUTOMATIC STEAM CONTROLLER (113.40(a)(4))
IS THE STEAM CONTROLLER AUTOMATIC?
IS THE STEAM CONTROLLER TEMPERATURE OR PRESSURE ACTUATED?
REPORT THE MANUFACTURER, MODEL, TYPE AND SIZE OF THE AUTOMATIC STEAM CONTROL VALVE:
IF THE TEMPERATURE (<i>STEAM</i>) CONTROLLER IS AIR OPERATED, DOES THE SYSTEM HAVE AN ADEQUATE FILTER TO ASSURE A SUPPLY OF CLEAN, DRY AIR?
STEAM INLETS (113.40(a)(5))
IF THE RETORT IS OVER 30 FT LONG, ARE THERE 2 STEAM INLETS?
ARE STEAM INLETS LOCATED OPPOSITE THE VENT?
(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:

FEI Number:

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 SPREADER HOWEVER, IF THEY HAVE THEM, THEY SHOULD BE PERFORATED ALONG THE CENTER LINE OF THE PIPE FACING THE INTERI OF THE RETORT OR ALONG THE SIDES OF THE PIPE.)
COMMENTS:
NUMBER OF PERFORATIONS: DIAMETER OF PERFORATIONS:
LOCATION OF PERFORATIONS:
THE CALCULATED TOTAL CROSS-SECTIONAL AREA OF THE PERFORATIONS:
IS THIS AREA 1.5 TO 2 TIMES THE TOTAL CROSS-SECTIONAL AREA OF THE SMALLEST RESTRICTIONS IN THE STEAM INLET LINE?
(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.)
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?
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.)
COMMENTS:
BLEEDERS (113.40(a)(8))
NUMBER OF BLEEDERS:
LOCATION (INCLUDE DISTANCE BETWEEN BLEEDERS ON HORIZONTAL RETORTS):
COMMENTS:
ARE THEY WIDE OPEN DURING THE ENTIRE PROCESS, INCLUDING THE COME-UP TIME?

Firm Name:	FEI Number:
IF A MUFFLER IS USED OVER THE BLEEDERS, WHAT I FLOW OF STEAM? – 113.87(g)	EVIDENCE DOES THE FIRM HAVE THAT IT DOES NOT RESTRICT FREE
(SHOULD REQUIREMENT) COMMENTS:	
AIR OR WATER COOI	LING LINE VALVES (113.40(a)(10) to (11))
IS WATER OR COMPRESSED AIR USED DURING COOL COMMENTS:	ING? Water 🗌 Air 🗌
TYPE OF VALVE ON WATER COOLING LINES SUPPLYI	NG RETORT:
WERE WATER LINES OBSERVED TO BE LEAKING? COMMENTS:	Yes 🗌 No 🗌
TYPE OF VALVE ON THE AIR SUPPLY LINE TO THE RE	TORT:
WERE AIR LINES OBSERVED TO BE LEAKING?	Yes 🗌 No 🗌
VE	ENTS (113.40(a)(12))
NUMBER OF VENTS: SIZE(S) – DIA LENGTH:	METER:
WHAT IS THE VALVE TYPE? IF OTHER, SPECIFY:	
ARE VENTS FULLY OPEN DURING VENTING?	Yes No
IS A STEAM BY-PASS VALVE USED DURING VENTING? IF YES, EXPLAIN:	9Yes 🗌 No 🗌
(NOTE – VENTING PROCEDURES AND ARRANGEMENTS DISTRIBUTION STUDY THAT WAS CONDUCTED ON THE	S MUST BE THE SAME AS THOSE USED DURING THE TEMPERATURE E RETORT TO ESTABLISH THE VENT SCHEDULE.)
ARE VENTS LOCATED OPPOSITE THE STEAM INLET? IF NO, EXPLAIN:	Yes 🗌 No 🗌
(VENTS SHALL BE LOCATED OPPOSITE THE STEAM IN	NLET.)

MANIFOLD VALVE TYPE? Gate Plug Cock Other IOM A SINGLE RETORT, IT SHALL BE CONTROLLED BY A 12)) A. =
IOM A SINGLE RETORT, IT SHALL BE CONTROLLED BY A 12)) A. = IAMETER OF CONNECTING VENTS: (A = (NO. OF VENTS) X (3.14) X (r²)) RT MANIFOLD?
12)) A =
IAMETER OF CONNECTING VENTS: (A = (NO. OF VENTS) X (3.14) X (r ²)) RT MANIFOLD? Yes No CTIONAL AREA OF THE PIPE IS LARGER THAN THE TOT
(A = (NO. OF VENTS) X (3.14) X (r²)) RT MANIFOLD? Yes No CTIONAL AREA OF THE PIPE IS LARGER THAN THE TOT
RT MANIFOLD? Yes No
CTIONAL AREA OF THE PIPE IS LARGER THAN THE TOT
TO THE ATMOSPHERE? Yes 🗌 No
SEVERAL STILL RETORTS <u>SHALL</u> LEAD TO THE
VENTS/MANIFOLDS FROM ALL RETORTS VENTING
S) X (3.14) X (r²))
AL TO THIS AREA? Yes 🗌 No
CTIONAL AREA IS AT LEAST EQUAL TO THE TOTAL PIPES FROM ALL RETORTS VENTING SIMULTANEOUSL
- 113.40(a)(12).)

Firm Name:	FEI Number:
DO VENTING ARRANGEMENTS AND METHODS COMPLY WIT	TH ONE OF THE EXAMPLES IN 113.40(a)(12)? Yes No
IF NO, DOES THE FIRM HAVE TEMPERATURE DISTRIBUTION HAVE BEEN PERFORMED?	DATA OR SUITABLE DOCUMENTATION THAT APPROPRIATE TESTS
113.40(a)(12)(iii)	
COMMENTS:	
IF VENTS ARE EQUIPPED WITH MUFFLERS, SPECIFY TYPE THE FIRM HAVE THAT THE MUFFLER(S) ALLOWS ADEQUAT	AND PERFORMANCE CHARACTERISTICS. WHAT EVIDENCE DOES E VENTING (SEE 113.87(g))?
DIVIDER PLATES AND I	RETORT BASKET – 113.40(a)(9)
ARE DIVIDER PLATES USED TO SEPARATE CAN LAYERS? COMMENTS:	Yes 🗌 No 🗌
THE PLATES ARE UNIFORMLY PERFORATED?	
ARE THE PERFORATIONS AT LEAST 1-IN. HOLES ON 2-IN. C	ENTERS OR THE EQUIVALENT?
(IN COMMENTS, PROVIDE HOLE SIZE AND DISTRIBUTION (E COMMENTS:	.G., 1/4" ON 1/2" CENTERS).)
ARE RETORT BASKETS UNIFORMLY PERFORATED?	
DESCRIBE:	
DO BASKET BOTTOMS HAVE AT LEAST 1-IN. HOLES ON 2-IN	. CENTERS OR THE EQUIVALENT? Yes 🗍 No 🦷
	Y OVER THE PERFORATED STEEL BOTTOM OF THE RETORT IN THE BOTTOM PLATE AND RESTRICT THE FLOW OF STEAM TURE DISTRIBUTION IN THE RETORT.)
COMMENTS:	
DOES THE FIRM HAVE DOCUMENTATION ON FILE THAT PER USING DIVIDER PLATES AND THE CURRENT BASKET DESIG	
COMMENTS:	
	AND EQUIPMENT ISSUES
WHEN WAS THE LAST MAJOR OVERHAUL OR MAINTENANC COMMENTS:	E PERFORMED ON THE RETORTS? Yes No

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?
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 ON 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: