DEPARTMENT OF HEALTH AND HUMAN SERVICES FOOD AND DRUG ADMINISTRATION

PROCESSING IN WATER 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. Report all pipe sizes as inside diameter (ID). Cross-sectional area = $3.14r^2$ (r = $\frac{1}{2}$ diameter).

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.	TYPE OF RETOR	Т	LENGTH OR HEIGHT	DIAMETER	
	Vertical	Horizontal			
NUMBER OF BASKETS OR	CRATES PER RET	ORT:			
FOR VERTICAL RETORTS, (<u>SHALL</u> REQUIREMENT, 1 COMMENTS:		UPPORTS ARE PRE	SENT TO PROTECT THE ST	EAM SPREADER. Yes 🗌	No 🗌
ARE BAFFLE PLATES PRES (BAFFLE PLATES SHALL N COMMENTS:				Yes 🗌	No 🗌
	ORT AND THE CRAT		O PROVIDE A 1.5-INCH CLE		THE No 🗌
			ETORT DOOR CASING WHI		No 🗌
IF NO, DOES THE FIRM HA	VE ON HAND HEA E HEAT DISTRIBUT	T DISTRIBUTION DA	AM FOUND IN 113.40(b)(13) A OR OTHER SUITABLE INI	FORMATION THAT	No 🗌

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 VALIDATED?	1 HAS BEEN	
EXPLAIN:	Yes	No 🗌
IS RECORD KEEPING PART OF THE COMPUTER FUNCTION?	Yes 🗌	No 🗌
IF YES, DOES THE RECORD KEEPING COMPLY WITH 21CFR PART 11?	Yes 🗌	No 🗌
INDICATING MERCURY IN-GLASS THERMOMETERS (113.40(b)(1))		
IS THE RETORT EQUIPPED WITH AT LEAST ONE MERCURY-IN-GLASS (MIG) THERMOMETER (SHALL REQUIREMENT) COMMENTS:	Yes 🗌	No 🗌
IS THE RETORT EQUIPPED WITH ANOTHER TYPE OF TEMPERATURE INDICATOR?	Yes 🗌	No 🗌
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 E INCH (4°C/ CM) OF GRADUATED SCALE – SHALL REQUIREMENT. SEE LACF GUIDE-PART 2.)	XCEED 17°F (8°C PER
DATE LAST TESTED FOR ACCURACY:		
(THERMOMETERS SHALL BE TESTED FOR ACCURACY AGAINST A KNOWN ACCURATE STANDARD TH INSTALLATION AND AT LEAST ONCE A YEAR THEREAFTER; RECORDS OF ACCURACY CHECKS THAT STANDARD USED, METHOD USED, AND PERSON PERFORMING THE TEST SHOULD BE MAINTAINED. SHOULD HAVE A TAG, SEAL, OR OTHER MEANS OF IDENTITY THAT INCLUDES THE DATE IT WAS LA ACCURACY.) COMMENTS:	SPECIFY DATE EACH THERMO	<u>=,</u> DMETER
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) COMMENTS:
DESCRIBE THE FIRM'S ACTIONS REGARDING MIG THERMOMETERS WHICH WERE OUT OF CALIBRATION:
IS THE MERCURY UNDIVIDED?
WHEN MIG THERMOMETERS ARE FOUND TO BE PROVIDING READINGS ABOVE THE ACTUAL TEMPERATURES, DOES THE FIRM EVALUATE PRODUCTS PRODUCED USING THOSE THERMOMETERS?
IS THE THERMOMETER LOCATED WHERE IT IS EASY TO READ ACCURATELY?
IS THE SENSOR BULB POSITIONED SO THAT IT EXTENDS DIRECTLY INTO THE WATER A MINIMUM OF AT LEAST 2 INCHES WITHOUT A SEPARABLE WELL OR SLEEVE AND IS BENEATH THE SURFACE OF THE WATER DURING THE COMPLETE PROCESS?Yes No ((SHALL REQUIREMENT) COMMENTS:
ON HORIZONTAL RETORTS, IS THE MIG THERMOMETER INSERTED DIRECTLY INTO THE RETORT SHELL IN THE SIDE AT THE CENTER?Yes No ((<i>SHOULD REQUIREMENT</i>) EXPLAIN WHERE AND HOW THE MIG IS POSITIONED:
IS THE MERCURY THERMOMETER USED AS THE REFERENCED INSTRUMENT DURING PROCESSING? Yes No ((SHALL REQUIREMENT) COMMENTS:

TEMERATURE RECORDING DEVICE (113.40(b)(2))
IS THE RETORT EQUIPPED WITH A TEMPERATURE RECORDING DEVICE?
DO THE CHART SPECIFICATIONS MEET THE REQUIREMENTS OF PART 113?
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?
IS THERE A MEANS FOR PREVENTING UNAUTHORIZED ADJUSTMENTS?
IS THE CHART DRIVE TIMING MECHANISM ACCURATE?Yes No I No I IF NO, EXPLAIN:
IS THE RECORDER COMBINED WITH A STEAM CONTROLLER TO FUNCTION AS A RECORDING/CONTROLLING INSTRUMENT?
FOR VERTICAL STILL RETORTS EQUIPPED WITH A TEMPERATURE RECORDING/CONTROLLING DEVICE, IS THE TEMPERATURE SENSOR PROBE LOCATED AT THE BOTTOM OF THE RETORT BELOW THE LOWEST CRATE SUPPORT SO STEAM DOES NOT STRIKE IT DIRECTLY?
FOR RETORTS OTHER THAN VERTICAL STILL RETORTS EQUIPPED WITH A RECORDING/CONTROLLING INSTRUMENT, IS THE RECORDING THERMOMETER BULB LOCATED ADJACENT TO THE BULB OF THE MERCURY-IN-GLASS THERMOMETER?

FOR HORIZONTAL STILL RETORTS EQUIPPED WITH A TEMPERATURE RECORDING/CONTROLLING DEVICE, IS THE
TEMPERATURE RECORDING/CONTROLLING BULB LOCATED BETWEEN THE WATER SURFACE AND THE HORIZONTAL
PLANE PASSING THROUGH THE CENTER OF THE RETORT SO THERE IS NO DIRECT STEAM IMPINGEMENT ON THE
CONTROL BULB?
(SHALL REQUIREMENT)

COMMENTS:

PRESSURE GAGE (113.40(b)(3)(i))

PRESSURE RELIEF VALVE (113.40(b)(3)(ii))

IS THE RETORT EQUIPPED WITH AN ADJUSTABLE PRESSURE RELIEF OR CONTROL VALVE INSTALLED IN THE	
OVERFLOW LINE?	No 🗌

(**SHOULD** REQUIREMENT) COMMENTS:

STEAM CONTROLLER (113.40(b)(4))

IS THE RETORT EQUIPPED WITH AN AUTOMATIC STEAM CONTROL VALVE?	No 🗌
(EACH RETORT SHALL BE EQUIPPED WITH AN AUTOMATIC STEAM CONTROLLER TO MAINTAIN THE RETORT TEMPERATURE.)	
COMMENTS:	

IS THE CONTROLLER COMBINED WITH A TEMPERATURE RECORDER TO FUNCTION AS A RECORDING/CONTROLL	ING
INSTRUMENT?	10 🗌
COMMENTS:	

IF THE TEMPERATURE (STEAM) CONTROLLER IS AIR OPERATED, DOES THE SYSTEM HAVE AN ADEQUATE FILTER	r to
ASSURE A SUPPLY OF CLEAN, DRY AIR?	No
(AIR OPERATED TEMPERATURE CONTROLLERS SHOULD HAVE ADEQUATE FILTER SYSTEMS TO ASSURE A SUPPORT OF	'LY OF
COMMENTS:	

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

STEAM INTRODUCTION (113.40(b)(5))

(STEAM SHALL BE DISTRIBUTED IN THE BOTTOM OF THE RETORT IN A MANNER ADEQUATE TO PROVIDE UNIFORM HEAT DISTRIBUTION THROUGHOUT THE RETORT.) FOR HORIZONTAL STILL RETORTS, IS THERE A STEAM DISTRIBUTION PIPE THAT RUNS THE LENGTH OF THE BOTTOM OF THE RETORT WITH PERFORATIONS DISTRIBUTED UNIFORMLY ALONG THE UPPER PART OF THE PIPE? Yes No

(**SHALL** REQUIREMENT)

DESCRIBE THE SHAPE AND DIMENSIONS OF THE STEAM SPREADER PIPE:

STACKING EQUIPMENT AND CONTAINER POSITION (113.40(b)(7))

ARE CRATES, TRAYS, ETC. FOR HOLDING CONTAINERS MADE OF STRAP IRON OR OTHER ADEQUATELY PERFORATED	
MATERIAL?	
COMMENTS:	

ARE CONTAINERS POSITIONED IN THE RETORT AS SPECIFIED IN THE SCHEDULED PROCESS?	No 🗌
COMMENTS:	

ARE DIVIDERS, TRAYS, RACKS OR OTHER MEANS OF POSITIONING FLEXIBLE CONTAINERS DESIGNED AND EMP	LOYED
TO INSURE EVEN CIRCULATION OF HEATING MEDIUM AROUND ALL CONTAINERS?	No 🗌
COMMENTS:	

DRAIN LINE AND VALVE (113.40(b)(8))

ARE SCREENS USED OVER ALL DRAIN OPENINGS TO PREVENT CLOGGING OF DRAINS?	No 🗌
(SHALL REQUIREMENT)	
IS THE DRAIN LINE VALVE WATER TIGHT AND NON-CLOGGING?	No 🗌
COMMENTS:	

WATER LEVEL INDICATOR (113.40(b)(9))

DOES WATER COVER THE TOP LAYER OF CONTAINERS IN THE RETORT BASKETS DURING THE ENTIRE COME-UP TIME AND PROCESSING PERIOD?	
DOES WATER COVER THE TOP LAYERS OF CONTAINERS DURING THE COOLING PERIOD?	
(WATER <u>SHALL</u> COVER THE TOP LAYER OF CONTAINERS DURING THE ENTIRE COME-UP TIME AND PROCESSING PERIOD AND <u>SHOULD</u> COVER THE TOP LAYER DURING THE COOLING PERIODS – 113.40(b)(9).)	
COMMENTS:	
IS THERE A MEANS TO DETERMINE THE WATER LEVEL IN THE RETORT DURING OPERATION?	

IF YES, WHAT MONITORING DEVICES ARE USED?	Sight-glass	Glass	Petcock	Other
IF OTHER, EXPLAIN TYPE:				

IF	NO	MONITORING	DEVICES,	EXPLAIN:
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(THERE SHALL BE A MEANS OF DETERMINING THE WATER LEVEL IN THE RETORT DURING OPERATION.)

DOES THE OPERATOR CHECK AND RECORD THE WATER LEVEL AT INTERVALS SUFFICIENT TO ENSURE ITS ADE	QUACY?
(SHALL REQUIREMENT)	
COMMENTS:	
PROCESSING WATER	
IS THE PROCESSING WATER HEATED IN A SEPARATE VESSEL AND THEN INTRODUCED INTO THE PROCESSING V	
Yes	No
COMMENTS:	
WAS THE TEMPERATURE OF THE PREHEATED WATER TAKEN INTO CONSIDERATION DURING TEMPERATURE	
DISTRIBUTION STUDIES?	No 🗌
COMMENTO.	
DOES THE FIRM CONTROL THE PREHEATING OF PROCESS WATER AS CRITICAL TO THE THERMAL PROCESS?	
Yes 🗌	No 🗌
COMMENTS:	
AIR SUPPLY AND CONTROLS (113.40(b)(10))	
IS AIR SUPPLIED TO THE RETORTS DURING THE COME-UP, PROCESSING AND COOLING PERIODS TO PROMOTE	
CIRCULATION OF WATER AND TEMPERATURE DISTRIBUTION?	No 🗌
IF YES, IS THE AIR INTRODUCED AT THE PROPER PRESSURE AND RATE?	No 🗌
(SHALL REQUIREMENT – 113.40(b)(10)(i))	
COMMENTS:	
COMMENTS.	
IS THE COMPRESSED AIR SUPPLIED TO THE RETORT CONTROLLED BY AN AUTOMATIC PRESSURE CONTROL UP	NIT?
Yes	No 🗌
(<u>SHALL</u> REQUIREMENT – 113.40(b)(10)(i))	
COMMENTS:	
IS THE AIR SUPPLY LINE EQUIPPED WITH A CHECK VALVE TO PREVENT WATER FROM ENTERING THE SYSTEM?	_
Yes	No 🗌
(<u>SHALL</u> REQUIREMENT – 113.40(b)(10)(i))	
COMMENTS:	

HAS THE ADEQUACY OF THE AIR OR WATER CIRCULATION FOR UNIFORM HEAT DISTRIBUTION WITHIN THE RETORT BEEN ESTABLISHED IN ACCORDANCE WITH PROCEDURES RECOGNIZED BY A COMPETENT PROCESS AUTHORITY?
Yes No ARE RECORDS OF THE ESTABLISHMENT OF UNIFORM HEAT DISTRIBUTION KEPT ON FILE?
IF AIR IS USED TO PROMOTE WATER CIRCULATION IN THE RETORT, IS IT INTRODUCED INTO THE STEAM LINE AT A POINT BETWEEN THE RETORT AND THE STEAM CONTROL VALVE AT THE BOTTOM OF THE RETORT? Yes No (SHALL REQUIREMENT – 113.40(b)(10)(i)) COMMENTS:
WHEN A WATER CIRCULATING SYSTEM IS USED FOR HEAT DISTRIBUTION, IS IT INSTALLED IN SUCH A MANNER THAT WATER WILL BE DRAWN FROM THE BOTTOM OF THE RETORT THROUGH A SUCTION MANIFOLD AND DISCHARGED THROUGH A SPREADER WHICH EXTENDS THE LENGTH OF THE TOP OF THE RETORT?
FOR WATER CIRCULATING SYSTEMS, ARE THE HOLES IN THE WATER SPREADER UNIFORMLY DISTRIBUTED AND DO THEY HAVE AN AGGREGATE AREA NOT GREATER THAN THE CROSS-SECTION AREA OF THE OUTLET LINE FROM THE PUMP?
Yes No N/A (SHALL/SHOULD REQUIREMENT) – 113.40(b)(10)(ii)) COMMENTS:
ARE SUCTION OUTLETS PROTECTED WITH NONCLOGGING SCREENS TO KEEP DEBRIS FROM ENTERING THE CIRCULATING SYSTEM?
IS THE WATER PUMP EQUIPPED WITH A PILOT LIGHT OR OTHER SIGNALING DEVICE TO WARN THE OPERATOR WHEN IT IS NOT RUNNING?Yes No ((SHALL REQUIREMENT – 113.40(b)(10)(ii)) COMMENTS:
IS AN ALTERNATE METHOD OF WATER CIRCULATION USED?
IF YES, HAS THE METHOD BEEN ESTABLISHED BY A COMPETENT PROCESS AUTHORITY?

COOLING WATER SUPPLY	COOLING WATER SUPPLY			
FOR VERTICAL STILL RETORTS, IS THE COOLING WATER INTRODUCED AT THE TOP OF THE RETORT BETWEEN TH WATER AND CONTAINER LEVELS?				
(<u>SHOULD</u> REQUIREMENT - 113.40(b)(11))				
COMMENTS:				
FOR HORIZONTAL RETORTS, IS THE COOLING WATER INTRODUCED INTO THE SUCTION SIDE OF THE PUMP?				
Yes 🗌 No				
(<u>SHOULD</u> REQUIREMENT 113.40(b)(11))				
COMMENTS:				
IS THE WATER-COOLING LINE EQUIPPED WITH A CHECK VALVE?				
(<u>SHOULD</u> REQUIREMENT – 113.40(b)(11))				
COMMENTS:				
RETORT HEADSPACE				
IS HEADSPACE, NECESSARY TO CONTROL THE AIR PRESSURE, MAINTAINED BETWEEN THE WATER LEVEL AND THE TO OF THE RETORT SHELL?	_			

(SHOULD REQUIREMENT) - 113.40(b)(12)) COMMENTS: