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. 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 DES	CRIPTION	
RETORT NO.	TYPE OF RETORT	LENGTH OR HEIGHT	DIAMETER
	Vertical Horizontal		
	Vertical (Crateless)		
FOR VERTICAL RETORTS, E <i>(SHALL REQUIREMENT)</i> COMMENTS:	30TTOM CRATE SUPPORTS ARE PRE	SENT	Yes 🗌 No 🗌
ARE BAFFLE PLATES PRES (SHALL NOT BE USED IN TH THE BOTTOM OF STILL STE PERFORATED STEAM DIST COMMENTS:	ENT IN THE BOTTOM OF RETORT? HE BOTTOM OF STEAM STILL RETOF FAM RETORTS BECAUSE THEY CAN I RIBUTOR PIPES.)	RTS (113.40(a)(6)) – BAFFLE PLA MPEDE THE FLOW OF STEAM F	TES ARE UNDESIRABLE IN ROM STEAM INLETS OR
ARE THERE ANY PROTRUS CONTAINERS DURING LOAI COMMENTS:	IONS INSIDE THE RETORT OR THE R DING/UNLOADING OF CRATES?	ETORT DOOR CASING WHICH C	OULD DAMAGE
	COMPUTER (CONTROLS	
DOES A COMPUTER CONTR COMMENTS:	ROL ANY OF THE RETORT FUNCTION	IS?	Yes 🗌 No 🗌
DOES THE FIRM HAVE DOC	UMENTATION ON HAND THAT INDICA	TES THAT THE COMPUTER SYS	TEM HAS BEEN VALIDATED? Yes 🗌 No 🗌
IS RECORD KEEPING PART	OF THE COMPUTER FUNCTION?		Yes 🗍 No 🗍
IF YES, DOES THE RECORD	KEEPING COMPLY WITH 21CFR PAR	Т 11?	Yes No 🗌

IF CRATE POSITION HAS BEEN DETERMINED CRITICAL TO THE PROCESS, WHAT IS THE RECOMMENDED POSITION AND HOW WAS IT DETERMINED? (FOR EXAMPLE, PROCESS ESTABLISHMENT TESTS MAY HAVE DETERMINED THAT AN ANGLED CRATE POSITION RESULTS IN FASTER HEAT PENETRATION.)

PROCESSING WATER	
METHOD USED TO HEAT PROCESS WATER: A. Steam Injection Into Process Water D B. Heat Exchanger C. Steam Spreader D. Other IF OTHER, EXPLAIN:	r 🗌
WATER DRAINS	
ARE SCREENS USED OVER ALL DRAIN OPENINGS TO PREVENT CLOGGING OF DRAINS?	No 🗌
IS THE DRAIN LINE VALVE WATER TIGHT AND NON-CLOGGING	No 🗌
WATER DISTRIBUTION	
WATER DISTRIBUTION SYSTEM: Manifold Plate?	
HAVE HOLE SIZES BEEN ALTERED BY PRODUCT OR MINERAL BUILD-UP?	No 🗌
DOES THE FIRM HAVE A CLEANING PROGRAM FOR THE WATER DISTRIBUTION SYSTEM?	No 🗌
HOW DOES THE FIRM INSURE THAT WATER FLOW IS CONSTANT? Visual Checks No Water Flow Measurement Yes Flow Meter No Flow Meter Yes No PAGE 2	

COMMENTS:	
HOW OFTEN IS WATER FLOW CHECKED?	
WHAT IS THE WATER FLOW RATE?	
DESCRIBE THE PROCEDURE TO INSURE WATER FLOW IS MAINTAINED:	
PROVIDE THE WATER FLOW METER MODEL NUMBER AND LOCATION:	
AT WHAT POINT DOES WATER ENTER THE RETORT WATER DISTRIBUTION SYSTEM?	
Back Top Yes No	
Back Bottom Yes No	
Front Top	
EXPLAIN THE WATER DISTRIBUTION SYSTEM:	
DESCRIBE THE WATER RETURN SYSTEM:	
ARE WATER RETURN INLETS SCREENED?	
IS THE PROCESSING WATER REUSED?	
IF WATER IS REUSED DURING THERMAL PROCESSING, WHAT IS THE RECIRCULATION RATE?	

IS WATER FLOW IDENTIFIED AND CONTROLLED AS A FACTOR CRITICAL TO THE THERMAL PROCESS?	
ARE WATER FLOW PROBLEMS HANDLED AS PROCESS DEVIATIONS? Yes No COMMENTS:	
DURING THE INSPECTION, WAS THERE ANY EVIDENCE OF LOW WATER FLOW? Yes Yes No COMMENTS:	
COOLING WATER SUPPLY	
IS PROCESSING WATER USED TO COOL CONTAINERS DURING THE COOLING CYCLE?	
IF WATER IS INTRODUCED FROM AN EXTERIOR SOURCE DURING COOLING, IS THE WATER COOLING LINE EQUIPPED WITH A CHECK VALVE?	
INDICATING MERCURY IN-GLASS THERMOMETERS (113.40(e)(1))	
IS THE RETORT EQUIPPED WITH AT LEAST ONE MERCURY-IN-GLASS (MIG) THERMOMETER? Yes I No COMMENTS:]
IS THE RETORT EQUIPPED WITH A TEMPERATURE INDICATING DEVICE OTHER THAN A MERCURY-IN-GLASS THERMOMETER?	
ARE SCALE DIVISIONS EASILY READABLE TO 1°F (.5°C)?	 ER
STANDARD USED FOR THE TEST:	
NAME AND TITLE OF PERSON WHO PERFORMED TEST:	

IS THE LAST TEST DATE IDENTIFIED ON THE THERMOMETER?
WERE CALIBRATING TEST RECORDS PREPARED AND MAINTAINED?
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?
IS THE THERMOMETER LOCATED WHERE IT IS EASY TO READ ACCURATELY?
THE SENSOR BULB IS LOCATED IN THE Retort Shell , or External Well (SHALL REQUIREMENT) COMMENTS:
IS THE MERCURY THERMOMETER USED AS THE REFERENCED INSTRUMENT DURING PROCESSING? Yes No (SHALL REQUIREMENT) (SHALL REQUIREMENT) COMMENTS:
TEMERATURE RECORDER (113.40(e)(2))
TYPE OF TEMPERATURE RECORDER Other Difference of the Content Difference of the Content Difference of the Difference of the Difference of the Content Difference of the
DO THE CHART SPECIFICATIONS MEET THE REQUIREMENTS OF PART 113.40(e)(2)?

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?
IS THE RECORDER COMBINED WITH A TEMPERATURE (STEAM) CONTROLLER TO FUNCTION AS A RECORDING/ CONTROLLING INSTRUMENT?
TEMPERATURE CONTROLLER
HOW IS TEMPERATURE CONTROLLED IN THE RETORT? Recorder Controller CAM Controller Manual Switching Computer 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?
COME-UP PROCEDURE
DESCRIBE THE FIRM'S PROCEDURE TO BRING THE RETORT UP TO PROCESSING TEMPERATURE. INCLUDE TIME, TEMPERATURE AND NUMBER OF STEPS:
CAN THE FIRM DOCUMENT ALL STEPS OF THE COME-UP PROCEDURE?

DOES THE FIRM IDENTIFY PROCESS COME-UP STEPS AS CRITICAL ON THE PROCESSING FILING FORMS?	
Yes \Box No \Box (NOTE: PROCESSING STEPS ARE REQUIRED ON THE PROCESS FILING FORM WHEN THEY HAVE BEEN IDENTIFIED AS CRITICAL TO THE THERMAL PROCESS. THIS IS ALWAYS THE CASE WHEN THE GENERAL METHOD IS USED TO CALCULATE THE ${\rm F_o.}$)	
AIR PURGE	
IN SOME SYSTEMS AN AIR PURGE (VENT VALVE) IS USED TO ENHANCE WATER ENTRY INTO THE PROCESSING VESSEL; IS AN AIR PURGE VALVE USED ON THE PROCESSING VESSEL?	
HAS TIMING OF THE AIR PURGE VALVE (TIME OPEN) BEEN IDENTIFIED AS CRITICAL TO ADEQUATE TEMPERATURE DISTRIBUTION IN THE RETORT?	
HEATED PROCESS WATER	
IS THE WATER TEMPERATURE OF THE PREHEATED WATER CRITICAL TO TEMPERATURE DISTRIBUTION IN THE RETORT?	
Yes 🗌 No 🗌	
COMMENTS:	
DESCRIBE THE TEMPERATURE REQUIREMENTS FOR PREHEATED WATER:	
DID THE FIRM MEET THE REQUIREMENTS FOR PREHEATING WATER DURING THIS INSPECTION?	
TEMPERATURE DISTRIBUTION	
HAVE TEMPERATURE DISTRIBUTION STUDIES BEEN PERFORMED ON THE FIRM'S RETORTS?	
DATE OF LAST TEMPERATURE DISTRIBUTION STUDY:	
HAS A TEMPERATURE DISTRIBUTION STUDY BEEN PERFORMED ON EACH INDIVIDUAL RETORT?	

HAS A TEMPERATURE DISTRIBUTION STUDY BEEN PERFORMED ON EACH CONTAINER SIZE?	
HAS A TEMPERATURE DISTRIBUTION STUDY BEEN PERFORMED ON EACH CONTAINER TYPE? (E.G., GLASS, METAL, PLASTIC)	
COMMENTS:	
HAS A TEMPERATURE DISTRIBUTION STUDY BEEN PERFORMED ON EACH PRODUCT OR PRODUCT TYPE?	
Yes 🗋 No	
HAVE TEMPERATURE DISTRIBUTION STUDIES BEEN PERFORMED TO DETERMINE THE EFFECTS OF TEMPERATURE DROPS DURING COME-UP AND PROCESSING?)
ARE PARTIAL LOADS PROCESSED IN THE FIRM'S RETORTS?	•
RETORT CRATES & RACKS	
DESCRIBE THE RETORT CRATES:	
DIMENSIONS:	
NUMBER OF HOLES:	
SIZE OF HOLES:	
LOCATION OF HOLES:	
CRATES/BASKETS NOT USED	
ARE CONTAINERS POSITIONED IN THE RETORT AS SPECIFIED IN THE SCHEDULED PROCESS?)
ARE DIVIDERS, TRAYS, RACKS OR OTHER MEANS OF POSITIONING FLEXIBLE CONTAINERS DESIGNED AND EMPLOYED INSURE EVEN CIRCULATION OF HEATING MEDIUM AROUND ALL CONTAINERS?	D TO
ARE DIVIDER PLATES USED? Yes 🗌 No	

DESCRIBE NUMBER OF HOLES AND DISTRIBUTION IN DIVIDER PLATES:
IS THE SAME TYPE OF DIVIDER PLATE USED FOR ALL CONTAINERS?
ARE CONTAINERS PROCESSED WITHOUT DIVIDER PLATES?
CONTAINER NESTING WHERE ONE CONTAINER OR MORE ARE POSITIONED ONE INSIDE ANOTHER TO REPRESENT A MUCH LARGER CONTAINER MAY OCCUR WITH PRODUCTS DESIGNED TO STACK ON STORE SHELVES E.G. TUNA, SARDINES.
IS CONTAINER NESTING POSSIBLE?
WAS CONTAINER NESTING EVALUATED AS PART OF THE PROCESS ESTABLISHMENT
WHICH OF THE FOLLOWING CONTAINER TYPES ARE PROCESSED? Metal Cans Glass Jars Pouches Rigid Plastic COMMENTS:
DOES THE FIRM PROCESS MORE THAN ONE CONTAINER SIZE?
FOR POUCHES, ARE TRAYS ADEQUATELY DESIGNED WITH POCKETS TO CONTAIN AND RESTRAIN INDIVIDUAL POUCHES DURING PROCESSING?
ARE TRAYS OR DIVIDER PLATES IN GOOD CONDITION WITH NO SHARP OR ROUGH POINTS THAT COULD PUNCTURE CONTAINERS?

PRESSURE CONTROL	
ARE PRODUCTS PRODUCED USING OVERPRESSURE?	
IS THE RETORT EQUIPPED WITH A PRESSURE GAGE? Yes No COMMENTS:	
IS A MEANS PROVIDED FOR INTRODUCING COMPRESSED AIR OR STEAM AT THE PROPER PRESSURE AND RATE? Yes 🗌 No	
COMMENTS:	
IS THE PRESSURE IN THE RETORT CONTROLLED BY AN AUTOMATIC PRESSURE CONTROL UNIT?	
IF A PRESSURE GAGE IS PRESENT ON THE RETORT COOKER SHELL, IS IT GRADUATED IN DIVISIONS OF 2 LBS. OR LE	SS?
(NOTE: THIS IS A RECOMMENDATION – " SHOULD " REQUIREMENT – 113.40(e)(3).) COMMENTS:	
DESCRIBE THE LOCATION WHERE COMPRESSED AIR OR STEAM ENTERS THE RETORT:	
IS COMPRESSED AIR USED FOR OVERPRESSURE HEATED PRIOR TO INTRODUCTION INTO THE RETORT? Yes No N/A COMMENTS:	
IS A DIFFUSER USED ON THE COMPRESSED AIR ENTRY LINE TO INSURE RAPID MIXING OF THE AIR IN THE RETORT ATMOSPHERE?	
HAS THE POINT WHERE AIR ENTERS THE RETORT BEEN IDENTIFIED AS A COLD SPOT IN THE RETORT? Yes No N/A COMMENTS:	
EXPLAIN HOW PRESSURE IS CONTROLLED IN THE RETORT:	

HAS OVERPRESSURE BEEN IDENTIFIED AS CRITICAL TO THE THERMAL PROCESS?
ARE PRESSURE DROPS CONSIDERED PROCESS DEVIATIONS?
RETORT SPEED TIMING (113.40(e)(5))
IS THE ROTATIONAL SPEED OF THE RETORT SPECIFIED IN THE SCHEDULED PROCESS?
IS THE ROTATIONAL SPEED OF THE RETORT ADJUSTED, AS NECESSARY, TO ENSURE THAT THE SPEED IS AS SPECIFIED IN THE SCHEDULED PROCESS?
IS THE ROTATIONAL SPEED OF THE RETORT AND THE PROCESS TIME RECORDED FOR EACH RETORT LOAD PROCESSED?
ROTATIONAL SPEED
IF NO, IS A RECORDING TACHOMETER USED TO PROVIDE A CONTINUOUS RECORD OF THE SPEED? Yes No (SHALL REQUIREMENT) (SHALL REQUIREMENT) IF NO TO THE ABOVE 2 QUESTIONS, HOW DOES THE FIRM MONITOR AND RECORD THE RETORT SPEED AND PROCESS TIME OF EACH RETORT LOAD PROCESSED?
OTHER COMMENTS:
DOES THE FIRM HAVE A MEANS OF PREVENTING UNAUTHORIZED SPEED CHANGES ON THE RETORT? Yes 🗌 No 🗍
(SHALL REQUIREMENT; A LOCK OR NOTICE FROM MANAGEMENT POSTED AT OR NEAR THE SPEED ADJUSTMENT DEVICE THAT PROVIDES A WARNING THAT ONLY AUTHORIZED PERSONS ARE PERMITTED TO MAKE ADJUSTMENTS, IS A SATISFACTORY MEANS OF PREVENTING UNAUTHORIZED CHANGES.) COMMENTS:
EXPLAIN HOW THE RETORT ROTATIONAL SPEED IS MONITORED AND RECORDED.

OTHER CONCERNS AND OBSERVATIONS

EXPLAIN ANY OTHER CONCERNS WITH THE OPERATION OF THIS RETORT SYSTEM: