

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 CRATELESS RETORTS
(Retort Survey)**

INSTRUCTIONS

Complete the question blocks below. Narrative responses to each item can be entered in the item's "comments" 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 narrative 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 (Crateless) <input type="checkbox"/>		

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

COMMENTS:

COMPUTER CONTROLS

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

COMMENTS:

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:

Firm Name:

FEI Number:

INDICATING MERCURY-IN-GLASS THERMOMETER (113.40(a)(1))

IS THE RETORT EQUIPPED WITH AT LEAST ONE MERCURY-IN-GLASS (MIG) THERMOMETER? Yes No

(SHALL REQUIREMENT)

IS THERE DOCUMENTATION WHICH SHOWS THAT APPROPRIATE VALIDATION AND SECURITY MEASURES HAVE BEEN TAKEN (E.G., PROCEDURES IN NFPA BULLETIN #43-L, ETC.)? Yes No

COMMENTS:

IS THE RETORT EQUIPPED WITH ANOTHER TYPE OF TEMPERATURE INDICATOR DEVICE? Yes No

IF SO, DESCRIBE THE INDICATOR:

ARE SCALE DIVISIONS EASILY READABLE TO 1°F (.5°C)? Yes No

(SHALL REQUIREMENT)

COMMENTS:

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.)

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

WERE CALIBRATING TEST RECORDS PREPARED/MAINTAINED? Yes No

(SHOULD REQUIREMENT)

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:

Firm Name:

FEI Number:

WHEN MIG THERMOMETERS ARE FOUND TO BE PROVIDING READINGS ABOVE THE ACTUAL TEMPERATURES, DOES THE FIRM EVALUATE PRODUCTS PRODUCED USING THOSE THERMOMETERS?..... Yes No

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

DESCRIBE THE FIRM'S PROCEDURES:

IS THE THERMOMETER LOCATED WHERE IT IS EASY TO READ ACCURATELY? Yes No

(SHALL REQUIREMENT)

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 MERCURY THERMOMETER USED AS THE REFERENCED INSTRUMENT DURING PROCESSING? Yes No

(SHALL REQUIREMENT)

COMMENTS:

TEMPERATURE RECORDING DEVICE (113.40(a)(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 GUIDE, PART 2.)

COMMENTS:

Firm Name:

FEI Number:

IS THE TEMPERATURE CHART ADJUSTED TO AGREE AS NEARLY AS POSSIBLE WITH BUT NOT HIGHER THAN THE KNOWN ACCURATE MERCURY-IN-GLASS (MIG) THERMOMETER DURING THE PROCESSING PERIOD? Yes No

(SHALL REQUIREMENT – NOTE ANY DIFFERENCE BETWEEN THE RECORDING THERMOMETER AND THE MIG THERMOMETER AND WHICH READING IS HIGHER.)

COMMENTS:

IS THERE A MEANS OF 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,” AND POSTED AT OR NEAR THE RECORDING DEVICE, IS A SATISFACTORY MEANS OF 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:

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)

(SHOULD REQUIREMENT)

COMMENTS:

PRESSURE GAGE (113.40(a)(3))

IF A PRESSURE GAGE IS PRESENT, IS IT GRADUATED IN DIVISIONS OF 2 LBS. 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:

Firm Name:

FEI Number:

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 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))

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

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

STEAM SPREADER (113.40(a)(7))

DESCRIBE SHAPE AND DIMENSIONS:

NUMBER OF PERFORATIONS: _____ DIAMETER OF PERFORATIONS: _____
LOCATION OF PERFORATIONS: _____
COMMENTS:

IS THE STEAM SPREADER IN GOOD REPAIR, AND ARE PERFORATIONS CLEARLY OPEN? (FOR EXAMPLE, HOLES HAVE NOT BEEN PLUGGED BY RUST OR SEDIMENT, OR ENLARGED BY WEAR; PIPES HAVE NOT RUSTED THROUGH.)..... Yes No
COMMENTS:

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

IS WATER OR COMPRESSED AIR USED DURING COOLING? Yes No
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: _____

LENGTH: _____

WHAT IS THE VALVE TYPE? Gate Plug Cock Other

IF OTHER, SPECIFY:

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

IF NO, 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.)*

RETORT TRAFFIC CONTROL

TOP AND BOTTOM DOORS OF RETORT – CHECK TO SEE WHETHER IT IS POSSIBLE TO OPEN BOTH DOORS SIMULTANEOUSLY OR REOPEN THE TOP DOOR AFTER PROCESSING, BEFORE THE RETORT IS EMPTIED (AFTER 3/4 OF THE PROCESSED CANS HAVE DROPPED). OPENING BOTH DOORS SIMULTANEOUSLY CREATES A POTENTIAL FOR CANS TO PASS THROUGH THE RETORT WITHOUT PROCESSING. REOPENING THE TOP DOOR BEFORE EMPTYING CREATES THE POTENTIAL FOR MINGLING OF UNPROCESSED AND PROCESSED CONTAINERS THAT MAY BE EMPTIED INTO THE DISCHARGE CANAL, ONCE THE TOP DOOR IS RECLOSED. (NOTE – THIS DOES NOT REQUIRE BOTH DOORS TO BE OPEN AT THE SAME TIME, BUT STILL ALLOWS UNPROCESSED CANS TO PASS THROUGH THE RETORT TO THE CANAL BELOW.)

COMMENTS:

IF BOTH DOORS ARE OPENED SIMULTANEOUSLY OR THE TOP DOOR IS REOPENED, OUT OF THE NORMAL OPERATING SEQUENCE, IS A WRITTEN RECORD OF THE EVENT GENERATED?

COMMENTS:

EXAMINE THE OVERHEAD INFEED CONVEYORS TO CONFIRM THAT CONVEYOR RAILS AND TRAFFIC DIVERTERS (USED TO FILL RETORTS) PREVENT CANS FROM FALLING OFF THE CONVEYOR IN THE EVENT OF A BACKUP OR A LINE JAM. CONFIRM THAT IT IS NOT POSSIBLE FOR CANS THAT FALL TO DEPOSIT IN THE DISCHARGE CANAL BELOW. LOOK FOR PHYSICAL BARRIERS THAT PREVENT CANS FROM REACHING THE DISCHARGE CANAL.

COMMENTS:

Firm Name:

FEI Number:

IF THERE IS A BACKUP OR LINE JAM ON THE OVERHEAD INFEED CONVEYOR OR DIVERTOR FOR UNPROCESSED CANS, WHAT ARE THE SAFEGUARDS TO PREVENT THESE CANS FROM FALLING OFF THE CONVEYOR?

COMMENTS:

IF A CAN FALLS OFF THE CONVEYOR, WHAT PHYSICAL BARRIER IS IN PLACE TO PREVENT IT FROM DEPOSITING IN THE DISCHARGE CANAL?

COMMENTS:

ARE THESE PHYSICAL BARRIERS "ABSOLUTE" (MEANING THERE IS NO WAY TO BY-PASS THEM)? Yes No

COMMENTS:

WHAT DOES THE FIRM DO WITH CANS THAT HAVE FALLEN OFF THE OVERHEAD CONVEYOR AND ARE FOUND ON THE OPERATOR'S DECK (ABOVE THE RETORT)?

COMMENTS:

IF CANS ARE REPROCESSED, HOW DOES THE FIRM GUARANTEE THE INITIAL TEMPERATURE ("IT"). ARE THERE WRITTEN PROCEDURES?..... Yes No

BLEEDERS

*FOR RETORTS HAVING A TOP STEAM INLET AND BOTTOM VENTING, A BLEEDER **SHALL** BE INSTALLED IN THE BOTTOM TO REMOVE CONDENSATE, AND THIS BLEEDER **SHALL** BE VISIBLE TO THE RETORT OPERATOR. – 113.40(a)(8). IN ADDITION, WHEN A FALSE BOTTOM (A PERFORATED STEEL PLATE) IS EMPLOYED, IT IS USEFUL TO HAVE A 1/8-INCH BLEEDER WITH ITS OPENING AT A POINT HIGHER THAN THE CONDENSATE BLEEDER AND JUST BELOW THE FALSE BOTTOM TO FUNCTION AS AN INDICATOR OF HIGH-LEVEL CONDENSATE IN THE BOTTOM OF THE RETORT. A HIGH-LEVEL CONDENSATE SENSOR WITH ALARM COULD ALSO BE EMPLOYED AT THE SAME POSITION TO WARN THE RETORT OPERATOR OF HIGH LEVELS OF CONDENSATE. (SEE NFPA BUL 26-L, 13TH EDITION, P. 14, AND LACF GUIDE, PART 2, P. 26.)*

IS THE RETORT EQUIPPED WITH A FALSE BOTTOM TO PREVENT CONTAINERS FROM CONTACTING CONDENSATE?..... Yes No

IS CONDENSATE REMOVED BY A CONDENSATE BLEEDER AT THE BOTTOM OF THE RETORT? Yes No

WHAT IS THE DIAMETER OF THE STEAM CONDENSATE BLEEDER, AND WHERE IS IT POSITIONED? Yes No

IS THE BOTTOM BLEEDER VISIBLE TO THE RETORT OPERATOR? Yes No

COMMENTS:

IS THE RETORT EQUIPPED WITH A STEAM BLEEDER(S) BETWEEN THE FALSE BOTTOM DOOR AND THE BOTTOM OF THE RETORT? Yes No

IF SO, REPORT THE NUMBER AND DIAMETER OF THE BLEEDER(S):

DOES THE OPERATOR OBSERVE A FREE FLOW OF STEAM FROM THIS BLEEDER(S) PRIOR TO BEGINNING THE RETORT THERMAL PROCESS TIMING AND DURING THE PROCESS? Yes No

ARE THESE OBSERVATIONS RECORDED? Yes No

COMMENTS:

Firm Name:

FEI Number:

CONDENSATE ACCUMULATION

WITH A CRATELESS STILL RETORT, CONDENSATE REMOVAL DURING THE VENT AND THERMAL PROCESS (COOK) STEPS IS CRITICAL. IN MOST SYSTEMS, CUSHION WATER IS EXPELLED FROM THE VESSEL BY INTRODUCTION OF PRESSURIZED STEAM AT THE BEGINNING OF THE VENT STEP. AFTER VENTING AND THROUGHOUT THE THERMAL PROCESSIN (COOKING), CONDENSATE ACCUMULATING AT THE BOTTOM OF THE RETORT VESSEL MUST CONTINUALLY BE REMOVED. IF CONDENSATE LEVELS RISE, SUBMERGING CANS AT THE BOTTOM OF THE RETORT, A DANGEROUS POTENTIAL FOR UNDER PROCESSING CAN OCCUR.

DURING THE INITIAL STAGE WHEN "CUSHION" WATER IS BEING EXPELLED FROM THE VESSEL BY INTRODUCTION OF STEAM, LOOK TO SEE HOW THE OPERATOR CONFIRMS THAT ALL OF THE WATER HAS BEEN REMOVED. A CONTROL PANEL/MONITOR MESSAGE OR INDICATOR LIGHT **SHOULD** NOT BE CONSIDERED ADEQUATE CONFIRMATION. THERE **SHOULD** BE SOME VISIBLE CONFIRMATION IN THE FORM OF AN OUTLET THAT IS EMITTING STEAM OR A SITE GLASS OR ELECTRONIC WATER LEVELER. CHECK THE LOCATION OF WHERE THE DRAIN/VENT IS ATTACHED TO THE RETORT. IT **SHOULD** BE IMMEDIATELY ABOVE THE FALSE BOTTOM DOOR. THE DRAIN **SHOULD** BE POSITIONED SO THAT IT IS ABLE TO REMOVE WATER DOWN TO THE LOWEST POINT OF THE VESSEL WHERE FOOD CONTAINERS CAN BE LOCATED.

HOW DOES THE OPERATOR VISUALLY CONFIRM THAT ALL OF THE "CUSHION" WATER HAS BEEN EXPELLED FROM THE RETORT?

WHAT SIGNALS THE OPERATOR TO START THE VENT CYCLE?

COMMENTS:

IS THE DRAIN ATTACHED TO THE VESSEL AT THE LOWEST POSSIBLE POINT ABOVE THE DOOR? Yes No

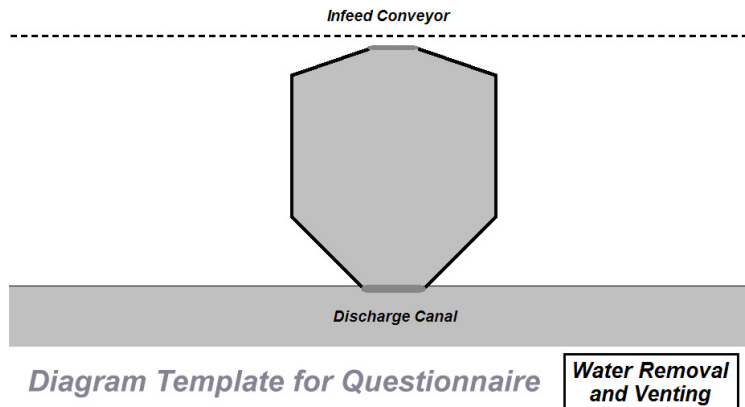
COMMENTS:

CAN THE OPERATOR SEE A STEADY FLOW OF STEAM FROM BLEEDERS (IF PRESENT, LOCATED IN THE 4-INCH DRAIN) Yes No

OR IS THERE A SITE GLASS OR ELECTRONIC LEVELING DEVICE THAT INDICATES CUSHION WATER REMOVAL?

COMMENTS:

PLEASE INCLUDE A HAND DRAWN SCHEMATIC OF THE WATER REMOVAL AND VENT PLUMBING USING THE DIAGRAM TEMPLATES BELOW LABELED "WATER REMOVAL AND VENTING."



ARE THERE WATER REMOVAL, VENT TIME AND TEMPERATURE CHART RECORDINGS? Yes No

COMMENTS:

Firm Name:

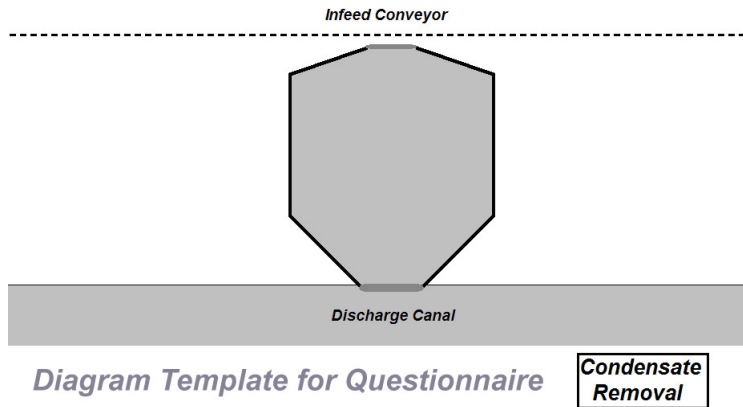
FEI Number:

COMPLETE A HAND DRAWN SCHEMATIC OF THE CONDENSATE REMOVAL PLUMBING, STEAM TRAP AND SITE GLASS USING THE DIAGRAM TEMPLATE BELOW LABELED "CONDENSATE REMOVAL."

IS THE RETORT EQUIPPED WITH A HIGH CONDENSATE LEVEL ALARM? Yes No
WHO IS AUTHORIZED TO OVERRIDE THIS ALARM (SILENCE IT)? PLEASE PROVIDE NAME AND TITLE.

WHAT DOES THE OPERATOR DO WHEN THE ALARM SOUNDS?

COMMENTS:



WHAT IS THE CONDENSATE LEVEL WHEN THE ALARM SOUNDS?

COMMENTS:

ARE CANS SUBMERGED WHEN THE ALARMS SOUND? Yes No

COMMENTS:

HOW OFTEN DOES THE FIRM TEST AND CONFIRM THE PROPER FUNCTION OF THE ALARM?

COMMENTS:

ARE THERE ANY WRITTEN PROCEDURES FOR WHAT TO DO WHEN THE ALARM SOUNDS, HOW OFTEN IT **SHOULD** BE TESTED AND WHO MAY OVERRIDE IT?

COMMENTS:

ARE RECORDS GENERATED WHEN THE ALARM SOUNDS? Yes No

COMMENTS:

IF RECORDS ARE GENERATED, DO THEY RECORD THE TIME OF THE EVENT, DURATION OF THE EVENT AND THE TEMPERATURE? Yes No

COMMENTS:

Firm Name:

FEI Number:

MANY SYSTEMS OPERATED BY COMPUTERS HAVE EVENT RECORDERS. ASSESS WHETHER THERE IS AN EVENT RECORDER THAT WOULD DOCUMENT A HIGH CONDENSATE ALARM. IF THERE IS NO EVENT RECORDER, ASK THE OPERATOR WHETHER HE/SHE MARKS IT ON THEIR WRITTEN RECORDS WHEN THE CONDENSATE ALARM TRIPS.

COMMENTS:

IS THIS SYSTEM EQUIPPED WITH AN EVENT RECORDER (FOR OCCURRENCES SUCH AS HIGH CONDENSATE)?

COMMENTS:

IF THERE IS NO EVENT RECORDER, DOES THE OPERATOR MAKE WRITTEN NOTES OF ANY ALARMS THAT SOUND DURING PROCESSING (LIST THE TYPES OF EVENTS RECORDED)?

COMMENTS:

WHAT IS THE FIRM'S PROCEDURE FOR CANS THAT ARE SUBMERGED IN CONDENSATE DURING PROCESSING?

COMMENTS:

CONFIRM THAT THE VESSEL IS EQUIPPED WITH A "FALSE" BOTTOM. THIS IS A PERFORATED PLATFORM SUPPORTED SEVERAL INCHES ABOVE THE "TRUE" BOTTOM OF THE VESSEL.

COMMENTS:

MISCELLANEOUS

CRATELESS RETORTS ARE CUSTOMARILY GROUPED IN SERIES THAT ARE CONNECTED TO A SINGLE INFEED CONVEYOR AND SINGLE DISCHARGE CANAL. ASSESS TO WHAT DEGREE THE FIRM CAN IDENTIFY PRODUCT, WITH REGARDS TO WHICH RETORT OR BATCH IT WAS PROCESSED IN (NOTE - THIS IS NOT REQUIRED BY THE REGULATION). NOTE - IF THE RECORD DOES NOT ALREADY INCLUDE A COLUMN ON THE RETORT OPERATORS LOG, SPECIFICALLY FOR "TIME OF FIRST CAN IN," SUGGEST THAT ONE BE ADDED. IF THE FIRM USES AN INKJET CODE THAT IDENTIFIES THE MILITARY TIME OF DAY, THE MILITARY TIME SHOULD BE SYNCHRONIZED WITH THE RETORT TIMING DEVICE. THIS SYNCHRONIZATION PROCEDURE WILL HELP IDENTIFY PROCESS DEVIANT LOTS AND THE RETORTS INVOLVED.

DOES THE FIRM HAVE A MEANS OF IDENTIFYING WHICH CANS (WHICH CODES) WERE PROCESSED IN EACH RETORT BATCH?..... Yes No

PLEASE DESCRIBE.

COMMENTS:

CANS LOADED INTO A RETORT ARE DROPPED INTO CUSHION WATER. CUSHION WATER MUST HAVE A HIGHER TEMPERATURE THAN THE MINIMUM "IT" DESIGNATED IN THE SCHEDULED PROCESS, OR THE CANS RISK BEING COOLED BELOW THEIR MINIMUM "IT" DURING THE LOADING PROCESS. DESCRIBE HOW THE FIRM CONFIRMS THAT THE CUSHION WATER IS OF A HIGHER TEMPERATURE THAN THE "IT" DESIGNATED IN THE SCHEDULED PROCESS.

COMMENTS:

Firm Name:

FEI Number:

RETORT PLUMBING AND EQUIPMENT ISSUES

WHEN WAS THE LAST MAJOR OVERHAUL OR MAINTENANCE PERFORMED ON THE RETORTS?

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:

DO THE BOILERS SUPPLY SUFFICIENT STEAM TO THE RETORTS? Yes No

IS THERE SUFFICIENT PRESSURE IN THE HEADER PIPE SUPPLYING STEAM TO THE RETORTS, ESPECIALLY WHEN MORE THAN ONE RETORT IS BEING VENTED SIMULTANEOUSLY? Yes No

COMMENTS:

TEMPERATURE DISTRIBUTION

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.)

COMMENTS:

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: