

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 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:

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:

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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:

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:

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:

Firm Name:

FEI Number:

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; (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 the 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:

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

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

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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 TID 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)

(SHALL REQUIREMENT)

COMMENTS:

IS THE TID 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 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:

Firm Name:

FEI Number:

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 IN 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)

(**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:

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 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))

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, NOR 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:

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WERE WATER LINES OBSERVED TO BE LEAKING? Yes No

COMMENTS:

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 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:

Firm Name:

FEI Number:

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:

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

COMMENTS:

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

Firm Name:

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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:

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 PROCESS (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:

Firm Name:

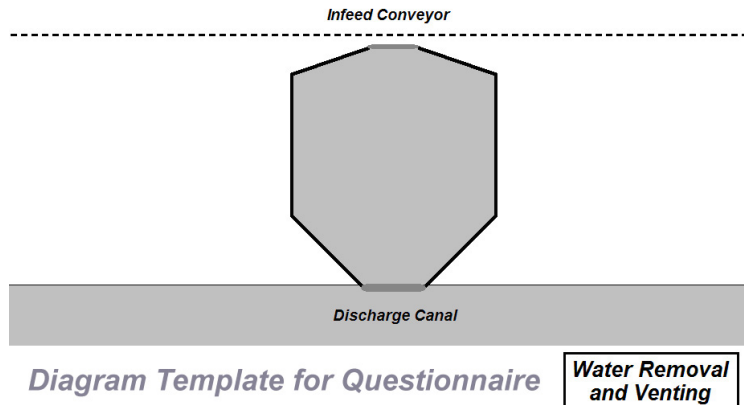
FEI Number:

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."



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

COMMENTS:

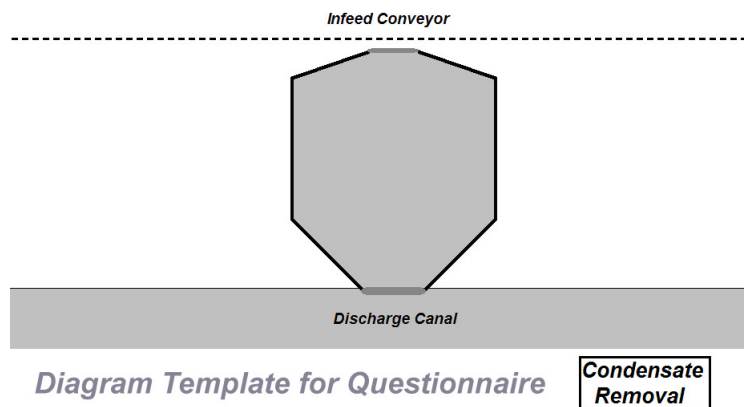
COMPLETE A HAND DRAWN SCHEMATIC OF THE CONDENSATE REMOVAL PLUMBING, STEAM TRAP AND SITE GLASS USING THE DIAGRAM TEMPLATE BELOW LABELED "CONDENSATE REMOVAL."

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:



Firm Name:

FEI Number:

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:

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:

Firm Name:

FEI Number:

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:

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:

Firm Name:

FEI Number:

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: