

Firm Name, City & State:

FEI Number:

Inspection Date(s):

FCE Number:

Investigators:

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. 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 DESCRIPTION

RETORT NO.	TYPE OF RETORT	LENGTH OR HEIGHT	DIAMETER
	Vertical <input type="checkbox"/> Horizontal <input type="checkbox"/>		

NUMBER OF BASKETS OR CRATES PER RETORT:

FOR VERTICAL RETORTS, ARE BOTTOM CRATE SUPPORTS PRESENT TO PROTECT THE STEAM SPREADER? Yes No

(SHALL REQUIREMENT – 113.40(b)(6))

COMMENTS:

ARE BAFFLE PLATES PRESENT IN THE BOTTOM OF THE RETORT? Yes No

(BAFFLE PLATES SHALL NOT BE USED – 113.40(b)(6).)

COMMENTS:

ARE VERTICAL RETORTS EQUIPPED WITH CENTERING GUIDES TO PROVIDE A 1.5-INCH CLEARANCE BETWEEN THE SIDE WALLS OF THE RETORT AND THE CRATE? Yes No

(SHOULD REQUIREMENT – 113.40(b)(6))

COMMENTS:

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

COMMENTS:

Firm Name:

FEI Number:

DO THE RETORTS FOLLOW THE ARRANGEMENTS IN THE DIAGRAM FOUND IN 113.40(b)(14)? Yes No

IF NO, DOES THE FIRM HAVE ON HAND HEAT DISTRIBUTION DATA OR OTHER SUITABLE INFORMATION WHICH DEMONSTRATES THAT THE HEAT DISTRIBUTION IS ADEQUATE? Yes No

(SHALL REQUIREMENT – 113.40(b)(14))

EXPLAIN, IF NECESSARY:

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

EXPLAIN:

TEMPERATURE-INDICATING DEVICES (113.40(b)(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(b)(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:

Firm Name:

FEI Number:

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(b)(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:

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; and (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 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:

Firm Name:

FEI Number:

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

DESCRIBE THE FIRM'S PROCEDURES:

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

(SHALL REQUIREMENT - 113.40(b)(1))

COMMENTS:

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 TID INSERTED DIRECTLY INTO THE RETORT SHELL IN THE SIDE AT THE CENTER? Yes No

(SHOULD REQUIREMENT)

EXPLAIN WHERE AND HOW THE TID IS POSITIONED:

IS THE TID USED AS THE REFERENCED INSTRUMENT DURING PROCESSING? Yes No

(SHALL REQUIREMENT)

COMMENTS:

Firm Name:

FEI Number:

TEMPERATURE RECORDING DEVICE (113.40(b)(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:

IS THERE A MEANS FOR 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," POSTED AT OR NEAR THE RECORDING DEVICE, IS A SATISFACTORY MEANS FOR 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:

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 THAT STEAM DOES NOT STRIKE IT DIRECTLY? Yes No

(SHALL REQUIREMENT)

COMMENTS:

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 TID? Yes No

(SHOULD REQUIREMENT – 113.40(b)(2))

COMMENTS:

Firm Name:

FEI Number:

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 THAT THERE IS NO DIRECT STEAM IMPINGEMENT ON THE CONTROL BULB?Yes No

(SHALL REQUIREMENT)

COMMENTS:

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

IF A PRESSURE GAGE IS PRESENT, IS IT GRADUATED IN DIVISIONS OF 2 LBS. (13.8 KILOPASCALS) OR LESS? Yes No

(SHALL REQUIREMENT)

COMMENTS:

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? Yes No

(SHOULD REQUIREMENT)

COMMENTS:

STEAM CONTROLLER (113.40(b)(4))

IS THE RETORT EQUIPPED WITH AN AUTOMATIC STEAM CONTROL VALVE? Yes 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/CONTROLLING INSTRUMENT? Yes No

COMMENTS:

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 - 113.40(b)(4).)

COMMENTS:

Firm Name:

FEI Number:

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

STEAM INTRODUCTION (113.40(b)(5))

IS STEAM DISTRIBUTED IN THE BOTTOM OF THE RETORT? Yes No

(STEAM **SHALL** BE DISTRIBUTED IN THE BOTTOM OF THE RETORT IN A MANNER ADEQUATE TO PROVIDE UNIFORM HEAT DISTRIBUTION THROUGHOUT THE RETORT.)

COMMENTS:

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? Yes No

COMMENTS:

ARE CONTAINERS POSITIONED IN THE RETORT AS SPECIFIED IN THE SCHEDULED PROCESS?..... Yes No

COMMENTS:

ARE DIVIDERS, TRAYS, RACKS OR OTHER MEANS OF POSITIONING FLEXIBLE CONTAINERS DESIGNED AND EMPLOYED TO ENSURE EVEN CIRCULATION OF THE HEATING MEDIUM AROUND ALL CONTAINERS? Yes No

COMMENTS:

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

ARE SCREENS USED OVER ALL DRAIN OPENINGS TO PREVENT CLOGGING OF DRAINS? Yes No

(**SHALL** REQUIREMENT)

IS THE DRAIN LINE VALVE WATER TIGHT AND NON-CLOGGING? Yes No

COMMENTS:

Firm Name:

FEI Number:

WATER LEVEL INDICATOR (113.40(b)(10))

DOES WATER COVER THE TOP LAYER OF CONTAINERS IN THE RETORT BASKETS DURING THE ENTIRE COME-UP TIME AND PROCESSING PERIOD? Yes No

DOES WATER COVER THE TOP LAYER OF CONTAINERS DURING THE COOLING PERIOD? Yes No

*(WATER **SHALL** COVER THE TOP LAYER OF CONTAINERS DURING THE ENTIRE COME-UP TIME AND PROCESSING PERIOD AND **SHOULD** COVER THE TOP LAYER DURING THE COOLING PERIODS – 113.40(b)(10).)*

COMMENTS:

IS THERE A MEANS TO DETERMINE THE WATER LEVEL IN THE RETORT DURING OPERATION?..... Yes No

IF YES, WHAT MONITORING DEVICES ARE USED? Gage Sight-glass Glass Petcock Other

IF OTHER, EXPLAIN TYPE:

IF NO MONITORING DEVICES, EXPLAIN:

*(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 ADEQUACY? Yes No

*(**SHALL** REQUIREMENT)*

COMMENTS:

PROCESSING WATER

IS THE PROCESSING WATER HEATED IN A SEPARATE VESSEL AND THEN INTRODUCED INTO THE PROCESSING VESSEL? Yes No

COMMENTS:

WAS THE TEMPERATURE OF THE PRE-HEATED WATER TAKEN INTO CONSIDERATION DURING TEMPERATURE DISTRIBUTION STUDIES? Yes No

COMMENTS:

DOES THE FIRM CONTROL THE PRE-HEATING OF PROCESS WATER AS CRITICAL TO THE THERMAL PROCESS? Yes No

COMMENTS:

Firm Name:

FEI Number:

AIR SUPPLY AND CONTROLS (113.40(b)(9))

IS AIR SUPPLIED TO THE RETORTS DURING THE COME-UP, PROCESSING AND COOLING PERIODS TO PROMOTE CIRCULATION OF WATER AND TEMPERATURE DISTRIBUTION?..... Yes No

IF YES, IS THE AIR INTRODUCED AT THE PROPER PRESSURE AND RATE? Yes No

(SHALL REQUIREMENT – 113.40(b)(9)(i))

COMMENTS:

IS THE COMPRESSED AIR SUPPLIED TO THE RETORT CONTROLLED BY AN AUTOMATIC PRESSURE CONTROL UNIT? Yes No

(SHALL REQUIREMENT – 113.40(b)(9)(i))

COMMENTS:

IS THE AIR SUPPLY LINE EQUIPPED WITH A CHECK VALVE TO PREVENT WATER FROM ENTERING THE SYSTEM? Yes No

(SHALL REQUIREMENT – 113.40(b)(9)(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? Yes No

(SHALL REQUIREMENT – 113.40(b)(9)(i))

COMMENTS:

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)(9)(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 THAT EXTENDS THE LENGTH OF THE TOP OF THE RETORT? Yes No N/A

(SHALL REQUIREMENT – 113.40(b)(11)(ii))

COMMENTS:

Firm Name:

FEI Number:

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)(11)(ii))

COMMENTS:

ARE SUCTION OUTLETS PROTECTED WITH NON-CLOGGING SCREENS TO KEEP DEBRIS FROM ENTERING THE CIRCULATING SYSTEM? Yes No
(SHALL REQUIREMENT - 113.40(b)(11)(ii))

COMMENTS:

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)(11)(ii))

COMMENTS:

IS AN ALTERNATE METHOD OF WATER CIRCULATION USED? Yes No
113.40(b)(11)(ii)
IF YES, HAS THE METHOD BEEN ESTABLISHED BY A COMPETENT PROCESS AUTHORITY? Yes No
DESCRIBE THE ALTERNATE METHOD:

COOLING WATER SUPPLY

FOR VERTICAL STILL RETORTS, IS THE COOLING WATER INTRODUCED AT THE TOP OF THE RETORT BETWEEN THE WATER AND CONTAINER LEVELS? Yes No N/A
(SHOULD REQUIREMENT - 113.40(b)(12))

COMMENTS:

FOR HORIZONTAL RETORTS, IS THE COOLING WATER INTRODUCED INTO THE SUCTION SIDE OF THE PUMP? Yes No
(SHOULD REQUIREMENT - 113.40(b)(12))

COMMENTS:

IS THE WATER COOLING LINE EQUIPPED WITH A CHECK VALVE? Yes No
(SHOULD REQUIREMENT - 113.40(b)(12))

COMMENTS:

Firm Name:

FEI Number:

RETORT HEADSPACE

IS HEADSPACE, NECESSARY TO CONTROL THE AIR PRESSURE, MAINTAINED BETWEEN THE WATER LEVEL AND THE TOP OF THE RETORT SHELL? Yes No

(**SHOULD REQUIREMENT** – 113.40(b)(13))

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.)? Yes No

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?

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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 IN 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?..... 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: