

Firm Name, City & State:

FEI Number:

Inspection Date(s):

FCE Number:

Investigators:

DEPARTMENT OF HEALTH AND HUMAN SERVICES

FOOD AND DRUG ADMINISTRATION

PROCESSING IN OTHER UNIQUE RETORT SYSTEMS (Retort Survey)

INSTRUCTIONS

Complete the question blocks below. Draw a diagram of the retort or obtain one from the firm. Attach the diagram to the EIR as an exhibit. Measure and verify retort plumbing – record on this form. Report all pipe sizes as inside diameter (ID). Cross-sectional area = $3.14r^2$ ($r = 1/2$ diameter). **This report is designed to capture information about unique retort systems that are not specifically mentioned in Part 113.40. These retorts must meet the requirements found in applicable sections of 113.40. The retorts and operating procedures must be carefully evaluated to ensure that they comply with Part 113.** Some of the questions in this form are designed to capture information useful in evaluation of the retort system and may not indicate a deviation from LACF Regulations, Part 113. The FDA “Guide to Inspections of Low Acid Canned Foods, Part 2,” should be used as a guide when conducting inspections of unique retort systems. Photographs are an excellent means of enhancing the description of a retort system.

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"/> Other <input type="checkbox"/>		

RETORT MANUFACTURER:

RETORT MODEL:

IDENTIFY THE PROCESSING MEDIUM:

Steam Water Other

EXPLAIN:

Firm Name:

FEI Number:

TEMPERATURE RANGE OF THERMAL PROCESS (E.G., 245/250/260 DEGREES F):

NUMBER OF BASKETS OR CRATES PER RETORT:

PROCESSING MODE:

Static Still Continuous Batch Agitating – End-over-End Axial Rocking Other

DESCRIBE OPERATION:

COMPUTER CONTROLS

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

EXPLAIN:

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:

AGITATION

IS THE AGITATING RETORT OPERATED IN THE STILL MODE? Yes No N/A

COMMENTS:

IS THE POSITION OF THE CRATE IN THE RETORT CRITICAL TO THE COME-UP AND/OR THERMAL PROCESS? Yes No N/A

EXPLAIN:

Firm Name:

FEI Number:

EXPLAIN HOW THE RETORT CRATE POSITION WAS DETERMINED:

EXPLAIN HOW THE RETORT ROTATION SPEED IS DETERMINED:

EXPLAIN HOW THE RETORT ROTATION SPEED IS RECORDED:

TEMPERATURE-INDICATING DEVICES

IS THE RETORT EQUIPPED WITH A TEMPERATURE-INDICATING DEVICE (TID) THAT ACCURATELY INDICATES THE TEMPERATURE DURING PROCESSING? Yes No
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:

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

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 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:

DATE THE TID LAST TESTED FOR ACCURACY: _____ .

STANDARD USED FOR THE TEST: _____

NAME AND TITLE OF PERSON WHO PERFORMED TEST: _____

IS THE LAST TEST DATE IDENTIFIED ON THE TID? Yes No

COMMENTS:

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

Firm Name:

FEI Number:

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

COMMENTS:

THE INDICATOR SENSOR BULB IS LOCATED IN THE SYSTEM

Retort Shell

External Well

After the Heat Exchanger

Before the Heat Exchanger

DESCRIBE THE LOCATION OF THE INDICATOR SENSOR(S):

HOW DOES THE FIRM ENSURE THAT THE TEMPERATURE INDICATED IS REPRESENTATIVE OF THE ACTUAL PROCESSING TEMPERATURE?

TEMPERATURE RECORDER

TYPE OF TEMPERATURE RECORDING:

Analog

Digital

COMMENTS:

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 – 113.40(b)(2). NOTE ANY DIFFERENCE BETWEEN THE RECORDING THERMOMETER AND THE TID 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,” POSTED AT OR NEAR THE RECORDING DEVICE, IS A SATISFACTORY MEANS OF PREVENTING UNAUTHORIZED CHANGES – 113.40(b)(2).)

COMMENTS:

IS THE CHART DRIVE TIMING MECHANISM ACCURATE? Yes No

COMMENTS:

IS THE RECORDER COMBINED WITH A STEAM CONTROLLER? Yes No

COMMENTS:

Firm Name:

FEI Number:

THE TEMPERATURE RECORDER SENSING BULB IS INSTALLED IN THE

Retort Shell

External Well

After the Heat Exchanger

Before the Heat Exchanger

EXPLAIN:

TEMPERATURE (STEAM) CONTROLLER

IS THE STEAM CONTROLLER AUTOMATIC? Yes No

COMMENTS:

HOW IS TEMPERATURE CONTROLLED IN THE RETORT?

Recorder Controller

Cam Controller

Manual Switching

Computer

Other

EXPLAIN:

WHERE IS THE CONTROLLER SENSOR LOCATED?

Retort Shell

External Well

After the Heat Exchanger

Before the Heat Exchanger

EXPLAIN:

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 113.40(a)(4).)

COMMENTS:

DURING THE INSPECTION, WAS THERE ANY EVIDENCE OF TEMPERATURE DROPS? Yes No

EXPLAIN:

Firm Name:

FEI Number:

COME-UP PROCEDURE

DESCRIBE THE FIRM'S PROCEDURE TO BRING THE RETORT UP TO PROCESSING TEMPERATURE. INCLUDE TIME, TEMPERATURE, REMOVAL OF AIR FROM THE SYSTEM AND NUMBER OF STEPS:

CAN THE FIRM DOCUMENT ALL STEPS OF THE COME-UP PROCEDURE?Yes No

COMMENTS:

DOES THE FIRM IDENTIFY PROCESS COME-UP STEPS AS CRITICAL ON THE PROCESSING FILING FORMS?....Yes No

(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 F₀.)

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:

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:

Firm Name:

FEI Number:

HEAT/TEMPERATURE DISTRIBUTION

HAVE TEMPERATURE DISTRIBUTION STUDIES BEEN PERFORMED ON THE FIRM'S RETORTS? Yes No
EXPLAIN AND PROVIDE COPIES OF SUPPORTING DOCUMENTS:

DATE OF LAST TEMPERATURE DISTRIBUTION STUDY: _____

HAS A TEMPERATURE DISTRIBUTION STUDY BEEN PERFORMED ON EACH INDIVIDUAL RETORT? Yes No
COMMENTS:

HAS A TEMPERATURE DISTRIBUTION STUDY BEEN PERFORMED ON EACH CONTAINER SIZE? Yes No
COMMENTS:

HAS A TEMPERATURE DISTRIBUTION STUDY BEEN PERFORMED ON EACH CONTAINER TYPE (E.G., GLASS, METAL, PLASTIC)? Yes No
IF NO, IDENTIFY THOSE WHICH WERE TESTED:

HAS A TEMPERATURE DISTRIBUTION STUDY BEEN PERFORMED ON EACH INDIVIDUAL PRODUCT OR PRODUCT TYPE (E.G., SEAFOOD SOUP VERSUS CANNED TUNA)? IF NO, IDENTIFY THOSE TESTED Yes No
COMMENTS:

DID EACH TEMPERATURE DISTRIBUTION STUDY IDENTIFY A COLD SPOT IN THE RETORT? Yes No
PROVIDE LOCATION AND EXPLAIN:

Firm Name:

FEI Number:

HAVE TEMPERATURE DISTRIBUTION STUDIES BEEN PERFORMED TO DETERMINE THE EFFECTS OF TEMPERATURE DROPS DURING COME-UP AND PROCESSING? Yes No

REPORT RESULTS:

HAVE TEMPERATURE DISTRIBUTION STUDIES BEEN PERFORMED TO DETERMINE THE EFFECTS OF LOW WATER FLOW? Yes No N/A

REPORT RESULTS:

ARE PARTIAL LOADS PROCESSED IN THE FIRM'S RETORTS? Yes No

COMMENTS:

ARE BAFFLE PLATES OR DUMMY LOADS USED DURING THE PROCESSING OF PARTIAL LOADS? Yes No

EXPLAIN:

HAVE TEMPERATURE DISTRIBUTION STUDIES BEEN PERFORMED WITH PARTIAL LOADS? Yes No

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:

Firm Name:

FEI Number:

RETORT CRATES AND RACKS

DESCRIBE THE RETORT CRATES.

DIMENSIONS: _____

NUMBER OF HOLES: _____

SIZE OF HOLES: _____

LOCATION OF HOLES: _____

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 HEATING MEDIUM AROUND ALL CONTAINERS? Yes No

COMMENTS:

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? Yes No

DESCRIBE DIFFERENCES:

ARE CONTAINERS PROCESSED WITHOUT DIVIDER PLATES? Yes No

DESCRIBE STACKING ARRANGEMENT (E.G., BRICK, OFFSET, JUMBLE):

IS CONTAINER NESTING POSSIBLE? Yes No

HOW DOES FIRM CONTROL NESTING OF CONTAINERS?

DOES THE FIRM PROCESS?

Metal Cans Yes No

Glass Jars Yes No

Pouches Yes No

Rigid Plastic Yes No

COMMENTS:

Firm Name:

FEI Number:

DOES THE FIRM PROCESS MORE THAN ONE CONTAINER SIZE? Yes No

LIST ALL CONTAINER SIZES:

METAL CANS: _____

GLASS JARS: _____

POUCHES: _____

SEMI-RIGID PLASTIC: _____

IF MORE THAN ONE CONTAINER SIZE OR TYPE IS PROCESSED AT ONE TIME, DESCRIBE PROCEDURE USED:

FOR RETORT POUCHES, ARE TRAYS ADEQUATELY DESIGNED WITH POCKETS SUFFICIENT TO CONTAIN AND RESTRAIN INDIVIDUAL POUCHES DURING COME-UP AND PROCESSING? Yes No

COMMENTS:

ARE TRAYS OR DIVIDER PLATES IN GOOD CONDITION WITH NO SHARP OR ROUGH POINTS THAT COULD PUNCTURE CONTAINERS? Yes No

COMMENTS:

PRESSURE CONTROL

ARE PRODUCTS PRODUCED USING OVER-PRESSURE? Yes No

LIST THE OVER-PRESSURES USED (E.G., 30 PSI AT 140°C, 36 PSI AT 150°C):

IS THE RETORT EQUIPPED WITH A PRESSURE GAGE? Yes No

COMMENTS:

DESCRIBE THE LOCATION WHERE COMPRESSED AIR ENTERS THE RETORT:

IS THE COMPRESSED AIR USED FOR OVER-PRESSURE HEATED PRIOR TO INTRODUCTION INTO THE RETORT? Yes No

COMMENTS:

IS A DIFFUSER USED ON THE COMPRESSED AIR ENTRY LINE TO ENSURE RAPID MIXING OF THE AIR IN THE RETORT ATMOSPHERE? Yes No

COMMENTS:

Firm Name:

FEI Number:

HAS THE POINT WHERE AIR ENTERS THE RETORT BEEN IDENTIFIED AS A COLD SPOT IN THE RETORT?..... Yes No
COMMENTS:

DESCRIBE HOW PRESSURE IS CONTROLLED IN THE RETORT DURING THERMAL PROCESSING:

HAS OVER-PRESSURE BEEN IDENTIFIED AS A FACTOR CRITICAL TO THE THERMAL PROCESS? Yes No
COMMENTS:

ARE PRESSURE DROPS CONSIDERED TO BE PROCESS DEVIATIONS? Yes No
WHY?/WHY NOT?

CONTAINER COOLING

CONTAINERS ARE COOLED BY: Air Water
EXPLAIN CONTAINER COOLING:

TYPE OF VALVE ON WATER COOLING LINES: _____

WERE WATER COOLING LINES NOTED TO BE LEAKING? Yes No
COMMENTS:

DRAIN LINES

ARE SCREENS USED OVER ALL DRAIN LINES TO PREVENT CLOGGING? Yes No
COMMENTS:

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

Firm Name:

FEI Number:

OTHER CONCERNS AND OBSERVATIONS

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