

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:

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:

Firm Name:

FEI Number:

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:

EXPLAIN HOW THE RETORT CRATE POSITION WAS DETERMINED:

EXPLAIN HOW THE RETORT ROTATION SPEED IS DETERMINED:

EXPLAIN HOW THE RETORT ROTATION SPEED IS RECORDED:

MERCURY-IN-GLASS THERMOMETER/TEMPERATURE INDICATOR

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

COMMENTS:

IS A MIG THERMOMETER USED AS THE REFERENCE INSTRUMENT DURING PROCESSING? Yes No

COMMENTS:

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

IF SO, DESCRIBE THE INDICATOR:

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

COMMENTS:

Firm Name:

FEI Number:

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 – 113.40(a)(1). ALSO, SEE LACF GUIDE, P. 14.)

DATE TEMPERATURE INDICATOR/MIG 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 – 113.40(a)(1).)

STANDARD USED FOR THE TEST:

NAME AND TITLE OF PERSON WHO PERFORMED TEST:

IS THE LAST TEST DATE IDENTIFIED ON THE MIG THERMOMETER/TEMPERATURE INDICATOR? Yes No

COMMENTS:

DESCRIBE THE FIRM'S ACTIONS REGARDING MIG THERMOMETERS/TEMPERATURE INDICATORS THAT WERE OUT OF CALIBRATION:

IS THE MIG THERMOMETER 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, 113.40(a)(1).)

COMMENTS:

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

DESCRIBE THE FIRM'S PROCEDURES:

IS THE THERMOMETER/TEMPERATURE INDICATOR 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?

Firm Name:

FEI Number:

TEMPERATURE RECORDER

TYPE OF TEMPERATURE RECORDER:

Round Circular Chart [] Strip Chart [] Other []

COMMENTS:

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 - 113.40(b)(2). ALSO, SEE P. 14 OF LACF GUIDE, PART 2.)

COMMENTS:

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 - 113.40(b)(2). NOTE ANY DIFFERENCE BETWEEN THE RECORDING THERMOMETER AND THE MIG/ INDICATING 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," 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:

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:

Firm Name:

FEI Number:

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)(2).)

COMMENTS:

DURING THE INSPECTION, WAS THERE ANY EVIDENCE OF TEMPERATURE DROPS?

Yes No

EXPLAIN:

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:

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:

Firm Name:

FEI Number:

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:

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?

Firm Name:

FEI Number:

DOES THE FIRM PROCESS?

Metal Cans Yes No

Glass Jars Yes No

Pouches Yes No

Rigid Plastic Yes No

COMMENTS:

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:

OTHER CONCERNS AND OBSERVATIONS

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