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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 as an exhibit to the EIR. Report all pipe sizes as inside diameter (ID). Cross-sectional area = $3.14r^2$ (r = ½ diameter).

If problems are found with the firm's retort equipment or processing system, refer the reader to the narrative Turbo EIR under "Objectionable Conditions and Management's Response," and include a narrative explanation of specific problems and evidence under the subheading "Supporting Evidence and Relevance." Submit the completed form as an EIR attachment.

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 retort and operating procedures must be carefully evaluated to insure 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.

RETORT DESCRIPTION

RETORT NO.	TYPE OF RETORT	LENGTH OR HEIGHT	DIAMETER
	Vertical ☐ Horizontal ☐ Other ☐		

RETORT MANUFACTURER:

RETORT MODEL:

IDENTIFY THE PROCESSING MEDIUM: ..... Steam ☐ Water ☐ Other ☐

EXPLAIN:

TEMPERATURE RANGE OF THERMAL PROCESS (E.G. 245/250/260 DEGREE 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 THAT 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 ☐

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:

MIG THERMOMETER/TEMPERATURE INDICATOR

IS THE RETORT EQUIPPED WITH A MIG THERMOMETER? ..... Yes ☐ No ☐

IS A MERCURY-IN-GLASS THERMOMETER USED AS THE REFERENCE INSTRUMENT DURING PROCESSING?

Yes ☐ No ☐

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 ☐

NO. OF DEGREES F OR C/IN. OF GRADUATED SCALE: _____. *(TEMP. RANGE MUST NOT EXCEED 17°F(8°C) PER INCH (4°/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 ☐

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).)

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 ☐

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 INSURE THAT THE TEMPERATURE INDICATED IS REPRESENTATIVE OF THE ACTUAL PROCESSING TEMPERATURE?

TEMPERATURE RECORDER

TYPE OF TEMPERATURE RECORDER: ..... Round Circular Chart ☐ Strip Chart ☐ Other ☐

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 FIELD GUIDE-PART 2.)

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

(SHALL REQUIREMENT – 113.40(B)(2). NOTE ANY DIFFERENCE BETWEEN THE RECORDING THERMOMETER AND THE MERCURY-IN-GLASS/INDICATING THERMOMETER AND WHICH READING IS HIGHER.)

IS THERE A MEANS TO PREVENT 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 – 113.40(B)(2).)

IS THE CHART DRIVE TIMING MECHANISM ACCURATE? ..... Yes ☐ No ☐

IS THE RECORDER COMBINED WITH A STEAM CONTROLLER? ..... Yes ☐ No ☐

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 ☐

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)(2).)

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

EXPLAIN:

COME UP PROCEDURE

DESCRIBE THE FIRMS 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 ☐

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 F_o.)

HEAT/TEMPERATURE DISTRIBUTION

HAVE TEMPERATURE DISTRIBUTION STUDIES BEEN PERFORMED 0N THE FIRMS 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 ☐

HAS A TEMPERATURE DISTRIBUTION STUDY BEEN PERFORMED ON EACH CONTAINER SIZE? ..... Yes ☐ No ☐

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 ☐

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 FIRMS RETORTS? ..... Yes ☐ No ☐

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 ☐

RETORT CRATES, 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 ☐

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

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 ☐

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 ☐

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

PRESSURE CONTROL

ARE PRODUCTS PRODUCED USING OVERPRESSURE? ..... Yes ☐ No ☐

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

IS THE RETORT EQUIPPED WITH A PRESSURE GAUGE? ..... Yes ☐ No ☐

DESCRIBE THE LOCATION WHERE COMPRESSED AIR ENTERS THE RETORT:

IS THE COMPRESSED AIR USED FOR OVERPRESSURE HEATED PRIOR TO INTRODUCTION INTO THE RETORT?
Yes ☐ No ☐

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

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

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

HAS OVERPRESSURE BEEN IDENTIFIED AS A FACTOR CRITICAL TO THE THERMAL PROCESS? ..... Yes ☐ No ☐

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 COOLING WATER LINES:

WERE COOLING WATER LINES NOTED TO BE LEAKING? ..... Yes ☐ No ☐

DRAIN LINES

ARE SCREENS USED OVER ALL DRAIN LINES TO PREVENT CLOGGING? ..... Yes ☐ No ☐

IS THE DRAIN VALVE WATER TIGHT AND NON-CLOGGING ..... Yes ☐ No ☐

OTHER CONCERNS AND OBSERVATIONS

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