

Firm Name:

FEI Number:

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

HAVE PROCESS ESTABLISHMENT TESTS DETERMINED THAT RETORT CRATE POSITION IS CRITICAL TO THE COME-UP OR THERMAL PROCESS? Yes No

EXPLAIN:

WAS THE RECOMMENDED CRATE POSITION BEING USED DURING THE INSPECTION? Yes No

COMMENTS:

HOW DOES THE FIRM DETERMINE CRATE POSITION?

RETORT SPEED TIMING (113.40(e)(5))

IS THE ROTATIONAL SPEED OF THE RETORT SPECIFIED IN THE SCHEDULED PROCESS? Yes No

(SHALL REQUIREMENT)

COMMENTS:

IS THE ROTATIONAL SPEED OF THE RETORT ADJUSTED, AS NECESSARY, TO ENSURE THAT THE SPEED IS AS SPECIFIED IN THE SCHEDULED PROCESS? Yes No

(SHALL REQUIREMENT)

COMMENTS:

IS THE ROTATIONAL SPEED OF THE RETORT AND THE PROCESS TIME RECORDED FOR EACH RETORT LOAD PROCESSED?

Process Time Yes No

Rotational Speed Yes No

(SHALL REQUIREMENT)

IF NO, IS A RECORDING TACHOMETER USED TO PROVIDE A CONTINUOUS RECORD OF THE SPEED? Yes No

(SHALL REQUIREMENT)

IF NO TO THE ABOVE 2 QUESTIONS, DOES THE FIRM MONITOR AND RECORD THE RETORT SPEED AND PROCESS TIME OF EACH RETORT LOAD PROCESSED? Yes No

COMMENTS:

Firm Name:

FEI Number:

DOES THE FIRM HAVE A MEANS OF PREVENTING UNAUTHORIZED SPEED CHANGES ON THE RETORT?

(SHALL REQUIREMENT - A LOCK OR NOTICE FROM MANAGEMENT, POSTED AT OR NEAR THE SPEED ADJUSTMENT DEVICE THAT PROVIDES A WARNING THAT ONLY AUTHORIZED PERSONS ARE PERMITTED TO MAKE ADJUSTMENTS, IS A SATISFACTORY MEANS OF PREVENTING UNAUTHORIZED CHANGES.)

COMMENTS:

PROCESSING WATER

METHOD USED TO HEAT PROCESS WATER:

- A. Steam Injection into Process Water B. Heat Exchanger C. Steam Spreader D. Other

IF OTHER, EXPLAIN:

WATER DRAINS

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

COMMENTS:

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

COMMENTS:

WATER DISTRIBUTION

WATER DISTRIBUTION SYSTEM:

- Manifold Plate? Spray Nozzle Heads? Manifold Pipe? Other? Yes No Yes No Yes No Yes No

IF OTHER, EXPLAIN:

DESCRIBE HOLE SIZE AND DISTRIBUTION IN MANIFOLD/SPRAY NOZZLES:

HAVE HOLE SIZES BEEN ALTERED BY PRODUCT OR MINERAL BUILD-UP? Yes No

IF YES, DESCRIBE:

DOES FIRM HAVE A CLEANING PROGRAM FOR WATER DISTRIBUTION SYSTEM? Yes No

DESCRIBE:

HOW DOES THE FIRM ENSURE THAT WATER FLOW IS CONSTANT?

- A...Visual Checks B...Water Flow Measurement C...Flow Meter Yes No Yes No Yes No

HOW OFTEN IS WATER FLOW CHECKED?

Firm Name:

FEI Number:

WHAT IS THE WATER FLOW RATE? _____

DESCRIBE THE PROCEDURE TO ENSURE WATER FLOW IS MAINTAINED:

PROVIDE THE WATER FLOW METER, MODEL NUMBER AND LOCATION:

AT WHAT POINT DOES WATER ENTER THE RETORT DISTRIBUTION SYSTEM?

- Back Top Yes No
- Back Bottom Yes No
- Front Top Yes No
- Front Bottom Yes No
- Center Yes No
- Multiple Yes No

EXPLAIN WATER DISTRIBUTION SYSTEM:

DESCRIBE WATER RETURN SYSTEM:

ARE WATER RETURN INLETS SCREENED? Yes No

COMMENTS:

IS THE PROCESSING WATER REUSED? Yes No

COMMENTS:

IF WATER IS REUSED DURING THERMAL PROCESSING, WHAT IS THE RECIRCULATION RATE? _____

WHAT IS THE CAPACITY OF THE WATER PUMP (GPM/LPM)?

IS WATER FLOW IDENTIFIED AND CONTROLLED AS A FACTOR CRITICAL TO THE THERMAL PROCESS? Yes No

COMMENTS:

ARE WATER FLOW PROBLEMS HANDLED AS PROCESS DEVIATIONS? Yes No

EXPLAIN:

DURING THE INSPECTION, WAS THERE ANY EVIDENCE OF LOW WATER FLOW? Yes No

EXPLAIN:

COOLING WATER SUPPLY

IS PROCESSING WATER USED TO COOL CONTAINERS DURING THE COOLING CYCLE? Yes No

EXPLAIN HOW COOLING WATER IS INTRODUCED INTO THE SYSTEM:

Firm Name:

FEI Number:

IF WATER IS INTRODUCED FROM AN EXTERIOR SOURCE DURING COOLING, IS THE WATER COOLING LINE EQUIPPED WITH A CHECK VALVE? Yes No

COMMENTS:

MIG 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

NO. OF DEGREES F OR C/IN. OF GRADUATED SCALE: (TEMP. RANGE MUST NOT EXCEED 17°F PER INCH (4°C PER CM) OF GRADUATED SCALE - 113.40(a)(1). ALSO, SEE LACF GUIDE , P. 14.)

COMMENTS:

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:

Firm Name:

FEI Number:

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

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 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:

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 CONTROLLER

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).)

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 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:

Firm Name:

FEI Number:

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?

IS THERE DOCUMENTATION SUCH AS A RETORT DIAGRAM AND PARAMETERS USED TO VALIDATE THE TESTS? Yes No

(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:

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

COMMENTS:

Firm Name:

FEI Number:

HAS A TEMPERATURE DISTRIBUTION STUDY BEEN PERFORMED ON EACH INDIVIDUAL PRODUCT OR PRODUCT TYPE (E.G., SEAFOOD SOUP VERSUS CANNED TUNA)? 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

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

RETORT CRATES AND RACKS

DESCRIBE THE RETORT CRATES.

DIMENSIONS:

NUMBER OF HOLES:

SIZE OF HOLES:

LOCATION OF HOLES:

Firm Name:

FEI Number:

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 THE 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?

WAS CONTAINER NESTING EVALUATED AS PART OF THE PROCESS ESTABLISHMENT? Yes No

COMMENTS:

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 –

RIGID PLASTIC –

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

Firm Name:

FEI Number:

FOR POUCHES, ARE TRAYS ADEQUATELY DESIGNED WITH POCKETS TO CONTAIN AND RESTRAIN INDIVIDUAL POUCHES DURING 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:

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

COMMENTS:

EXPLAIN HOW PRESSURE IS CONTROLLED IN THE RETORT:

HAS OVER-PRESSURE BEEN IDENTIFIED AS CRITICAL TO THE THERMAL PROCESS?..... Yes No

COMMENTS:

ARE PRESSURE DROPS CONSIDERED TO BE PROCESS DEVIATIONS? Yes No

COMMENTS:

OTHER CONCERNS AND OBSERVATIONS

PLEASE EXPLAIN OTHER CONCERNS NOTED REGARDING THERMAL PROCESSING IN THIS FIRM: