

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

Table with 4 columns: RETORT NO., TYPE OF RETORT (Vertical, Horizontal), LENGTH OR HEIGHT, DIAMETER.

NUMBER OF BASKETS OR CRATES PER RETORT:

FOR VERTICAL RETORTS, BOTTOM CRATE SUPPORTS ARE 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)(13)? 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 - 13.40(b)(13))

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:

INDICATING MERCURY-IN-GLASS THERMOMETERS (113.40(b)(1))

IS THE RETORT EQUIPPED WITH AT LEAST ONE MERCURY-IN-GLASS (MIG) THERMOMETER?..... Yes No

(SHALL REQUIREMENT)

COMMENTS:

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

IF YES, DESCRIBE THE TEMPERATURE INDICATOR:

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

(SHALL REQUIREMENT)

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 - SHALL REQUIREMENT. SEE LACF GUIDE, PART 2.)

DATE 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.)

COMMENTS:

STANDARD USED FOR THE TEST:

NAME AND TITLE OF PERSON WHO PERFORMED TEST:

Firm Name:

FEI Number:

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

WERE CALIBRATING TEST RECORDS PREPARED/MAINTAINED? Yes No

(SHOULD REQUIREMENT)

COMMENTS:

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

IS THE 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(b)(1).)

COMMENTS:

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

DESCRIBE THE FIRM'S PROCEDURES:

IS THE THERMOMETER 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 MIG THERMOMETER INSERTED DIRECTLY INTO THE RETORT SHELL IN THE SIDE AT THE CENTER? Yes No

(SHOULD REQUIREMENT)

EXPLAIN WHERE AND HOW THE MIG IS POSITIONED:

IS THE MERCURY THERMOMETER USED AS THE REFERENCED INSTRUMENT DURING PROCESSING? Yes No

(SHALL REQUIREMENT)

COMMENTS:

TEMPERATURE RECORDING DEVICE (113.40(b)(2))

IS THE RETORT EQUIPPED WITH A TEMPERATURE RECORDING DEVICE? Yes No

TYPE OF TEMPERATURE RECORDER Round Circular Chart Strip Chart Other

IF OTHER, DESCRIBE:

Firm Name:

FEI Number:

DO THE CHART SPECIFICATIONS MEET THE REQUIREMENTS OF PART 113? Yes No

(GRADUATIONS ON THE TEMPERATURE RECORDING CHART 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.)

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 – NOTE ANY DIFFERENCE BETWEEN THE RECORDING THERMOMETER AND THE MIG THERMOMETER 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 MIG THERMOMETER? Yes No

(SHOULD REQUIREMENT – 113.40(b)(2))

COMMENTS:

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:

Firm Name:

FEI Number:

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

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

(SHOULD 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)(2).)

COMMENTS:

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:

Firm Name:

FEI Number:

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:

WATER LEVEL INDICATOR (113.40(b)(9))

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 LAYERS 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)(9).)

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:

Firm Name:

FEI Number:

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:

AIR SUPPLY AND CONTROLS (113.40(b)(10))

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)(10)(i))

COMMENTS:

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

(SHALL REQUIREMENT - 113.40(b)(10)(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)(10)(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)(10)(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)(10)(i))

COMMENTS:

Firm Name:

FEI Number:

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 NA

(SHALL REQUIREMENT - 113.40(b)(10)(ii))

COMMENTS:

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 NA

(SHALL/SHOULD REQUIREMENT - 113.40(b)(10)(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)(10)(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)(10)(ii))

COMMENTS:

IS AN ALTERNATE METHOD OF WATER CIRCULATION USED? Yes No

113.40(b)(10)(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 NA

(SHOULD REQUIREMENT - 113.40(b)(11))

COMMENTS:

FOR HORIZONTAL RETORTS, IS THE COOLING WATER INTRODUCED INTO THE SUCTION SIDE OF THE PUMP? Yes No

(SHOULD REQUIREMENT - 113.40(b)(11))

COMMENTS:

IS THE WATER COOLING LINE EQUIPPED WITH A CHECK VALVE? Yes No

(SHOULD REQUIREMENT - 113.40(b)(11))

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)(12))

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?

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: