IFTPS *Institute For Thermal Processing Specialists*

GUIDELINES FOR CONDUCTING THERMAL PROCESSING STUDIES

The following recommendations are to be considered voluntary guidelines. These recommendations do not preclude the application of other methods and equipment for conducting thermal processing studies. These guidelines have been developed by consensus of the Institute for Thermal Processing Specialists and should be given serious consideration for adoption as methodology by individuals performing thermal processing studies.

The Institute for Thermal Processing Specialists is a non-profit organization established exclusively for the purpose of fostering education and training for those persons interested in procedures, techniques and regulatory requirements for thermal processing of all types of food or other materials, and for the communication of information among its members and other organizations.

This document is a compilation and re-structuring of previously published IFTPS guidance documents. Prior documents were modified to follow a common format and were also updated to reflect current practices. Common sections amongst previously published documents, such as Retort Survey, were placed into separate chapters. Information was added to Chapters on Temperature Distribution, Heat Transfer Distribution, and Heat Penetration to provide recommendations regarding Data Analyses, Success Criteria, and Risks, Issues and Other Considerations.

Hyperlinks have been embedded throughout the document to assist the reader in navigating between different chapters. Hyperlinks may be identified as underlined, blue text.

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Institute For Thermal Processing Specialists
304 Stone Rd. W., Ste. 301, Guelph. ON N1G 4W4
P: 519 824 6774 F: 519 824 6642 info@iftps.org
www.iftps.org

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1 DEFINITIONS

This chapter provides definitions commonly used for thermal processing studies.

TERM	DEFINITION
Ballast Containers	These are containers used to fill the retort during thermal processing studies to simulate production conditions. Typically, ballast containers for heat penetration, temperature distribution and heat transfer distribution studies are the same type, shape and size of containers as used for the intended process. In some retort systems, e.g., multi-basket batch retorts, ballast containers may not need to be the same in baskets not containing heat penetration and heat transfer distribution probes. Material used for filling containers may be the test product, or any suitable material having heating characteristics similar to that of the test product, or in some circumstances, water (e.g., temperature distribution).
Broken Heating	Heat transfer characteristic of some foods, particularly those with starches, where the heat transfer rate changes due to a change in the product as a result of product heating. The change in heat transfer rate may represent a change from heating primarily by convection to heating by conduction.
Calibration	To check, adjust, or determine by comparison with a traceable standard the graduations of a quantitative measuring instrument.
Cassettes/Trays/Racks	A means by which filled packages are held/carried in a retort. Cassettes/trays/racks may be loaded into cubes, baskets, or other means to convey filled packages into and out of a retort.
Cold Spot – Heat Penetration	The cold spot for heat penetration studies is determined experimentally and represents the slowest heating location within the container. In the case of non-homogenous foods, the slowest heating food particle in the slowest heating location within the container would be considered to be the cold spot.
Cold Spot – Temperature Distribution	The cold-spot for temperature distribution is generally that area of the retort which is the last area in the retort to reach a minimum processing temperature during come-up.
Cold Spot – Heat Transfer Distribution	The slow/slower to heat location(s) for Heat Transfer Distribution is generally the location(s) in the retort where heat transfer into the product is the slowest. This is indicated by the location with the largest f_h value.
Come-Up Time (CUT)	Come-up time (CUT) is defined as the time requirement for the reference TID to read at or above the minimum process temperature AND all TMDs to read within 1F° (0.5°C) of minimum process temperature within 1 minute of starting the hold time.
Commercial Sterility	Commercial sterility is defined as the condition achieved by application of heat, or other treatments that renders the product free of viable microorganisms having public health significance as well as microorganisms of non-health significance capable of reproducing in food under normal non-refrigerated conditions of storage and distribution.

Computer Control System	Computer used for automation of electromechanical processes. Also referred to as a Programmable Logic Controller (PLC).
Conduction	A type of heat transfer that may be characterized as one where agitation of the package with the food does not impact the heat transfer rate.
Convection	A type of heat transfer that may be characterized as one where agitation of the package with the food does impact (positively) the heat transfer rate.
Crateless Retort	A non-agitating (i.e., still) batch retort wherein cans are sterilized in saturated steam as a "jumble pack", without baskets, trays or cassettes. Loading is by dropping cans from the retort top into a cushion of water and cans are unloaded by gravity dropping out the bottom into a water canal with a drag chain to drying and packing.
Critical Factors	US-FDA 21CFR Part 113 defines critical factors as – "any property, characteristic, condition, aspect, or other parameter, variation of which may affect the scheduled process and the attainment of commercial sterility". Critical factors may include physical and chemical aspects/parameters associated with the container, the product, the retort and processing conditions.
f_h	The time for the heat penetration curve to traverse one log cycle. Also referred to as the heating rate index.
Fill, Drained, and Net Weights	Fill Weight means the weight of solid product in the container before processing and does not include the weight of the package or cover liquid (if applicable); Drained Weight is the weight of solids after processing; and Net Weight of a product refers to the weight of all product in the container including any cover liquid minus the weight of the container.
Flow Meter	An instrument/device/sensor that measures fluid flow rate.
Heat Penetration	Studies conducted to determine and establish a Scheduled Process. Heat Penetration studies are typically conducted under "worst case" conditions for product, package, location, and retort parameters.
Heat Transfer Distribution	Heat transfer distribution studies are used to establish the ability of a retort process to uniformly mix and distribute the heat transfer medium especially when the heat transfer into product may be rate limiting.
Heat Input Unit(HIU)	Appropriate material such as a polymer, clay, or food product with repeatable/definitive thermo-physical properties, and capable of being used for heat transfer distribution studies.
Heat Penetration Curve	Plot of the logarithmic difference between either retort temperature and product temperature (heating curve) or product temperature and cooling medium temperature (cooling curve) versus time.
Hermetic Seal	The condition which excludes the ingress of microorganisms, filth or other environmental contaminants that could render the product unfit for consumption or which could reduce the quality of the product to a level less than intended.

Initial Temperature	The average temperature of the contents of the coldest container to be processed at the time the sterilization cycle begins.
Low-Acid Canned Food (LACF)	Any food, other than alcoholic beverages, with a pH >4.6 and a water activity (a_w) greater than 0.85 packaged in a hermetically sealed containers that are thermally processed and stored at ambient temperatures.
Loading Pattern/Map	A depiction showing locations of probes and/or probed containers (e.g., temperature distribution, heat penetration, and heat transfer distribution) within a retort load.
Nesting/Shingling	Condition that occurs when more than one container is stacked fully or partially on top of another container. In the case of pouches, this is referred to as shingling. Nesting/shingling may negatively impact heat transfer/heat penetration.
Overpressure	Pressure in excess of that corresponding to saturated steam vapor pressure at a given temperature and when corrected for altitude. Overpressure may be necessary to maintain package integrity during the process.
Packing Gland (Stuffing Box)	Soft rubber or other material that is used to create a tight seal around TMDs/PMDs that assists in providing a means to penetrate the retort shell without allowing process media to leak to atmosphere (if applicable).
pH	A measure of acidity or alkalinity. Chemically, pH is defined as the negative log of the hydrogen ion concentration.
Piping and Instrumentation Diagram (P&ID)	Diagram which shows the piping of the process flow together with the installed equipment and instrumentation.
Plenum/Shroud	In a steam/air retort, the plenum/shroud is the space between the retort shell and the portion of the retort holding the baskets/cassettes. The function of the plenum/shroud, usually in conjunction with a fan, facilitates movement of steam/air through the retort and retort load.
Pocket space	Space within a cassette/rack/tray to hold a package.
Pressure Control Sensing Device	Instrument used to control pressure inside the retort.
Pressure Indicating Device (PID)	Instrument used to monitor pressure inside the retort, e.g., pressure gauge or pressure transmitter with electronic display.
Pressure Measuring Device (PMD)	Pressure sensor placed within (or mounted on) the retort to accurately monitor pressures attained and maintained throughout the applied process.
Process Deviation	A change in any critical factor of the scheduled process that reduces the sterilizing value of the process, or which raises a question regarding the public health safety and/or commercial sterility of the product lot/batch.
Process Establishment	Scientific procedure to determine the adequate process time and temperatures required to produce commercially sterile canned products.
Resistance Temperature Detector(RTD)	Thermometry system based on the positive change in the resistance of a metal sensing element (commonly platinum) with increasing temperature.

Retort	Any closed vessel or other equipment used for thermal processing. May also refer to the act of applying a thermal process to a canned food in a closed pressurized vessel. May also be referred to as a "sterilizer". The terms "retort" and "sterilizer" are often used interchangeably.
Retort – Continuous Rotary/Reel and Spiral Cooker/Cooler Retorts	In Continuous Rotary/Reel and Spiral Cooker Cooler retorts, cans enter and exit the processing vessel through mechanical pressure locks. Once in the vessel, cans move through a spiral track mounted on a reel that is rotating inside a horizontal cylindrical shell. In one revolution of the reel, cans roll by gravity along the bottom part of the arc (approximately 90-120°), which provides most of the product mixing within the can. The cans are essentially static as they pass through the remainder of the arc (approximately 240-270°).
Retort –Hydrostatic	A retort in which total pressure in the sterilization section is determined and maintained by the hydrostatic pressure of inlet and outlet water columns. Packages are continuously conveyed through the machine.
Separator/Divider Sheet	Separator/divider sheets are used to separate layers of packages in a basket/crate. These typically contain perforations/holes to help facilitate free movement of the heat transfer medium. Materials of construction can vary – metal/stainless steel, rubber, plastic, and so forth.
Scheduled Process	The process defined by the processor as adequate under the conditions of manufacture for a given product to achieve commercial sterility.
Should	Should is used in this document to indicate a recommendation or option for consideration.
Simple Heating	Heat transfer characteristic of some foods where the heat transfer rate is relatively constant during product heating.
Slip Ring	A device that allows for transfer of the thermocouple voltage signal from a rotating environment to a stationary electrical contact outside of a retort.
Steam/Air Flow Indicator	Indicator located in the retort shell to determine the direction and to measure flow (cubic feet per minute - cfm) of process media.
Steam/Air Ratio	The steam/air ratio (for isothermal/isobaric conditions of the cook segment) is calculated by volume by determining the amount of steam pressure at a certain temperature plus the atmospheric pressure at sea level and dividing that value by the total absolute Total Pressure of Steam and Air/Nitrogen as indicated by the retort gauge pressure plus the atmospheric pressure. For example, using the steam tables, at 240°F (115.6°C), the absolute saturated steam pressure at sea level is 24.968 psia/1.722 bar (or 10.272 psig and 0.708 bar gauge). For a process with a gauge pressure of 15psig (1.034 bar gauge), the absolute pressure at sea level is 29.696 psia (2.048 bar). This would equate to a steam/air mixture that is 84% saturated steam (i.e., 24.968/29.696 X 100% or 1.722/2.048 X 100%) and 16% overpressure air (i.e. 29.696-24.968/29.696 X 100%). Note that the altitude of the processing facility should be considered when converting gauge pressure to absolute pressure.
Steam/Air Retort	A **steam/air** retort is a batch retort that uses air/nitrogen to provide overpressure.

Steam/Air Retort – Forced Flow Steam/Air Retort	In a forced-flow retort, a mixing fan induces a forced convection of the process heating media by drawing the steam/air mixture through the product and circulating it through a return plenum. Steam is introduced between baskets while air over-pressure is introduced into the return plenum cavity.
Steam/Air Retort – Air Make-up Steam/Air Retort	In this type of retort, small vent valves on the retort remain open after desired temperature and pressure are achieved and provide continuous venting of the retort during the heating period. Air is re-introduced into the retort as needed to satisfy over-pressure requirements while steam is simultaneously added to maintain temperature.
Steam/Air Retort – Positive Flow Steam/Air Retort	In this type of retort, a continuous flow of steam and air are passed through the vessel to create a homogeneous mixture throughout the retort. This creates an overpressure condition in the retort and results in continuous venting of the steam/air mixture thus creating flow past the containers.
Sterilizer	See definition above for Retort.
Sufficient Sampling Frequency (Data Collection)	As used in this document, sufficient sampling frequency is determined by the processor and should be frequent enough to confirm that the measured parameter is within control.
Temperature Control Sensing Device	Device used for controlling temperature in a retort.
Temperature Indicating Device(TID)	Device used for monitoring temperature, including thermometers, thermocouples, RTDs and thermistors and generally referred to as the “official” or “reference” temperature monitoring device on a retort system. A Mercury-in-Glass (MIG) thermometer is an example of a TID.
Temperature Measuring Device (TMD)	Device used for measuring temperature, including thermometers, thermocouples, RTDs, wireless data-loggers, and thermistors.
Temperature Uniformity and Stability	Verification of temperature across/within the retort load (uniformity) and over time (stability) of the process particularly during Cook/Hold.
Thermistor	TMD manufactured from semiconductor materials which exhibits large changes in resistance proportional to small changes in temperature. Thermistors are more sensitive to temperature changes than thermocouples or RTDs and are capable of detecting relatively small changes in temperature.
Thermocouple	TMD composed of two dissimilar metals which are joined together to form two junctions. When one junction is kept at an elevated temperature as compared to the other, a small thermoelectric voltage or electromotive force (emf) is generated which is proportional to the difference in temperature between the two junctions.

Temperature Distribution	Studies conducted in a sterilizer (retort)using distributed temperature measuring devices (TMD) to establish venting procedures, venting schedules, come-up requirements, and temperature stability and uniformity, which are necessary to establish heating and cooling performance (i.e., temperature uniformity) throughout the retort. Temperature distribution studies are typically performed using actual production retort conditions or parameters.
Tray/Rack	See Cassette/Tray/Rack above
Validation	There are multiple definitions of the word "validation". In the context of this guideline document, validation is assumed to mean at least two successive and successful replicate studies that meet established success/acceptance criteria.
Vent/Venting	A vent is a device/valve through which air is removed from a retort. Venting is the process by which air is removed.
Verification	In the context of this guidance document, verification is assumed to mean replicate studies that are intended to confirm a process. Verification may also be used to indicate confirmation of the calibration status of process measurement devices used to collect thermal process data.
Water Activity (a_w)	Water activity (a_w) is defined as the ratio of the partial pressure of water above a food to the water vapor pressure of pure water at a given temperature (a_w= p/p_o).
Water Cascade Retort	A **water *cascade*** retort is defined as one where a small amount of process water is drawn from the bottom of the retort by a high-capacity pump and distributed through metal plate(s) or manifold(s) in the top of the retort. This process water cascades down over the retort cassettes, cages or racks in a rainwater or "shower" fashion, passing over the product containers on the way back to the bottom of the retort where it is re-circulated through the heating and distribution system. Processing water may be heated using one or more direct or indirect heating methods including heat exchangers, direct steam injection, or via steam distribution pipes or spreaders.
Water Immersion Retort	A **water *immersion*** retort is defined as one where process water is sometimes heated in a separate vessel and once the process water reaches the desired processing temperature, is dropped into the processing vessel. Water is re-circulated during processing. Sufficient water to completely cover the packages may be used. In other cases, packages may only be partially covered with water during processing.
Water Spray Retort	A **water *spray*** retort is defined as one where a controlled amount of process water is drawn from the bottom of the retort by a high capacity pump and distributed through spray nozzles located along the top and sides of the retort. This process water is sprayed over the retort cassettes, cages or racks in a high-pressure "mist" fashion passing over the product containers on the way back to the bottom of the retort where it is re-circulated through the heating and distribution system. Processing water may be heated using one or more direct or indirect heating methods including heat exchangers, direct steam injection, or steam distribution pipes or spreaders.
	A sensor/measuring device that is self-contained (i.e., does not require wires). These

Wireless Data-logger	devices typically require programming prior to use and collected data are then downloaded or transmitted for analyses after use.
%CV	The coefficient of variance is mathematically calculated by dividing the standard deviation of a set of numbers by the average of the same set of numbers and then multiplying that quotient by 100. (%CV = standard deviation/average * 100)

2 TEST EQUIPMENT AND CALIBRATION OF TEST EQUIPMENT

SCOPE

2.1. The guidelines in this chapter apply to equipment used to collect thermal process data in any retort system. The guidelines apply to both internal and external measuring and data collection systems. Test equipment used for collecting thermal process data should be suitable for the purpose of the studies being conducted. Devices to collect temperature distribution, heat transfer distribution, and heat penetration data, in general, should be calibrated relative to the expected test conditions and ranges prior to conducting thermal process studies. Ideally, devices should also be calibrated upon completion of thermal process studies. Process efficacy and success criteria of thermal processing studies may not be met if sensors and measuring devices are inaccurately calibrated.

2.2. Biological indicators are not addressed in this chapter.

OBJECTIVE

2.3. The objective of this document is to provide guidance with regard to calibration of test equipment used to collect thermal process data.

TOOLS, EQUIPMENT, INSTRUMENTATION

2.4. *Data Acquisition System* – The data acquisition system should be calibrated prior to use. It should also be equipped with sufficient channels to accurately monitor and record temperature/pressure within the process delivery system. Manual recording of data may be used if a sufficient sampling frequency can be maintained.

2.5. *Temperature Measuring Device (TMD)* – TMDs may be thermocouples, wireless data-loggers, or other similar devices. All TMDs must be of sufficient accuracy, size, and length, and in sufficient quantity, to adequately and accurately monitor the process environment.

2.6. *Pressure Indicating Devices* – Operational gauges, electronic indicators, and/or wireless data-loggers may be used to monitor pressures associated with the retort operation during a test. These devices should be calibrated prior to the start of data collection. Typical pressure measurements could include: retort vessel pressure, steam line pressure, and other line pressures that may be critical to the process.

2.7. *Reference Temperature Indicating Device (TID)* – This may be a retort Mercury-In-Glass (MIG) thermometer or other valid reference temperature measuring device including a digital thermometer of sufficient accuracy and precision.

2.8. *Packing Gland (Stuffing Box)* – This is needed for entry of lead wires into the retort when wired data collection devices are used. Materials used should be soft enough to provide a tight seal without over-tightening and damaging the TMDs. Examples include Neoprene or other synthetic materials.

2.9. *Slip Ring* – This allows for transfer of thermocouple outputs from a rotating environment to a stationary electrical contact outside of the retort.

2.10. *Flow Meters* – Where applicable, flow meters may be used to measure flow of process water during come-up, heating, and cooling in those systems using circulating pumps. Flow meters may be used to measure volume or velocity of air flow in those systems using air for agitation of heating and cooling media.

2.11. *Stopwatch* – This is needed to verify rotation rate/speed in systems that have agitation and/or continuous container handling.

2.12. *Heat Input Unit (HIU)* – An appropriate material to simulate the product being studied in heat transfer distribution studies. Packaged product may also be used as an HIU.

METHODS FOR TEST EQUIPMENT STANDARDIZATION

2.13. *Retort Temperature Indicating Device (TID)* – The reference temperature measurement device must conform to applicable regulations. For example, US-FDA regulation 21 CFR Part 113 establishes the requirement that temperature indicating devices and reference devices must be tested against a reference device for which the accuracy is traceable to a National Institute of Standards and Technology (NIST), or other metrology institute. The reference device is typically calibrated for accuracy against a known certified reference device at least annually. The preference is to have the Retort TID calibrated near to the time data are collected. The last calibration check date should be included in the study documentation.

2.14. *Measurement System(s)* – Measurement systems include as applicable: thermocouples/TMDs (with extension wires as applicable), data acquisition system, pressure measurement devices, and flow meters. The recommendations of the datalogging equipment manufacturer should be followed or an instrument professional should be consulted regarding the correct grounding technique to use.

TMD Standardization/Calibration

2.14.1. Prior to conducting thermal process studies, standardization or calibration of test equipment should be performed. Thermocouples ideally would be calibrated in the test retort(s). All thermocouples, extensions, connections and the specific data logger should be assembled as they will be used under the actual test conditions. Consideration for conducting duplicate calibration studies prior to conducting critical thermal processing studies is recommended.

2.14.2. An acceptable method of calibration is to bundle all TMDs and locate them in close proximity to the known accurate reference TID, taking care not to inhibit flow of the heat transfer medium across the reference TID. The retort is brought up to the same sterilization set-point temperature and pressure as defined for the test and the retort is allowed to equilibrate. Equilibration time may be dependent upon the specific retort and/or retort type. The temperature differences between the reference TID and TMDs are then calculated and documented. These differences may be applied as correction factors for each TMD. A typical range of correction factors for thermocouples is usually not more than 1-2F° (0.6 – 1.2C°). Large correction factors may indicate an issue with the TMD that merits investigation and corrective actions prior to use in thermal processing studies. Non-thermocouple TMDs such as wireless data-loggers should be within manufacturer's specifications at the time of their use provided those specifications are consistent with conditions of intended use of the TMD.

2.14.3. Alternatively, TMDs may be calibrated off-line in an established calibration program within the temperature range to be used during data collection. The difference between the TMDs against the known accurate reference device should be calculated and documented as part of the study data. This difference may be applied as correction factors for each TMD.

2.14.4. Verification of the calibration of all TMDs after completing thermal processing studies is recommended. Off-sets which are substantially different than the pre-study values should be evaluated relative to the data that were collected.

Pressure Measurement Devices – Various methods are available to calibrate pressure measurement devices. Traditional calibrated and traceable dead weight testers (or their electronic analogs) are recommended to be used as the primary reference standard against which pressure gauges, transmitters and data logging devices should be calibrated. Regardless of method used, standardization results should be documented as part of the overall study data package where pressure is part of the process. Accuracy of pressure measurement systems should preferably be ≤1% of the calibrated and traceable pressure reference standards used, in the planned working or operating pressure range of the processes in which they are to be used. In addition, the accuracy should satisfy the applicable following considerations:

2.14.5. For steam/air retort processes, the accuracy of pressure measurements should not result in calculated intrinsic (unsafe) Steam Air Ratios ≥1% (i.e. richer in steam) for the actual process value.

2.14.6. For non-overpressure retort systems (primarily saturated steam), the accuracy of pressure measurements should not result in an overestimate (unsafe) error of the equivalent saturated steam temperature (corrected for sea level) of ≥0.2F° (0.1C°), if process temperatures are planned to be calculated from pressure values for any evaluation or consideration.

Flow Meters – A number of methods may be used to calibrate flow meters. Regardless of method used, standardization results should be documented as part of the overall study data package.

2.14.7. Fluid flow rates are often determined by flow meters or indirectly by revolutions per minutes (RPM) of fans, pumps or motors for known/fixed cross section flow areas.

2.14.8. Flow meters (usually mechanical or electronic), direct contact or non-contact, have become increasingly specialized and complicated and manufacturers have set up specialized flow test benches to provide calibration services for their flow meters.

2.14.9. Periodically (e.g., annually), factory electronic flow sensor output should be verified with volumetric, gravimetric or other approaches (e.g., tachometers, velocity meters, current or voltage draw) and results compared to calibration data. Re-calibration would be needed if the verification results are not consistent with the calibration data.

2.14.10. Based on the way flow is measured or imputed, process fluid flow sensor accuracy should be calibrated for use in production or validation in the operating range of the process and validations should factor in known off-sets, errors and calibration inaccuracies. Process efficacy and success criteria of thermal processing studies may not be met if flow meters are inaccurately calibrated.

Stopwatches – Stopwatches typically are received calibrated with an expiration date from the stopwatch equipment supplier.

Non-product based Heat Input Units (HIU) – Each HIU used in heat transfer distribution studies must have a unique identity.

2.14.11. Using either a pilot scale retort or the test retort, a standardization test for a complete set of HIU (e.g., 12-24 separate units) should be made using expected operating parameters (i.e., temperature and pressure) to establish a baseline for the heating performance as measured by the heating rate index (i.e., f_h) prior to use and periodically during their life expectancy.

2.14.12. All HIUs within a set should be in close proximity to one another during the standardization/calibration study.

2.14.13. All TMDs used in conjunction with HIUs must be calibrated prior to calibrating the HIU.

2.14.14. A reasonable means of determining acceptable standardization for the use of a set of HIUs in heat transfer distribution studies at any time during their life expectancy is to utilize the statistical measure of coefficient of variance of the f_h of the HIUs (%CV = standard deviation/average * 100%). A value of less than or equal to 1% would be acceptable for a set of HIUs to be used to collect heat transfer distribution data.

2.14.15. In addition, each individual non-product based HIU within a set should always be within 1% of its historical performance as measured by f_h for the same standardization/calibration process. Once the %CV exceeds 1% for a given HIU relative to its established baseline, consideration for removing it from service should be made. A rationale for using an HIU that falls outside of this recommendation could be based on its performance in a specific study provided the data collected meet the success criteria established (i.e., f_h %CV ≤5% in a heat transfer distribution study).

Product-based HIU – Product should be representative of the product heating type (e.g., conduction, convection) to be studied during heat transfer distribution tests.

RISKS, ISSUES, AND OTHER CONSIDERATIONS

2.15. To meet the calibration criteria noted above (section 2.14) and to ensure accuracy of test results, consideration should be given to minimizing errors inherent in any component of the temperature measuring system. For example, use of special limits of error (SLE) wire or premium grade thermocouple wire should be used to make thermocouples. The use of 3 or 4 wire high accuracy RTD can help to reduce intrinsic error.

2.16. ***Thermocouple Calibration:*** Thermocouples should be calibrated against a traceable calibration standard (e.g., thermometer, RTD, thermistor). Inaccuracies in temperature measurements may result in errors in thermal process studies; hence, frequent calibration is essential to provide reliable data. Factors affecting calibration include: worn or dirty slip-rings, improper junctions, metal oxidation, multiple connectors on one thermocouple and inadequate data acquisition system cold junction compensation. As a consequence, thermocouples should be calibrated in place as part of the complete data acquisition system. Some precautions when using thermocouple-based data acquisition systems include: minimizing multiple connections on the same wire, cleaning all connections, grounding the thermocouples and recording device, slitting thermocouple outer and inner insulation outside the retort to prevent flooding of data-logger or data recording device (4, 8), and using properly insulated thermocouple wires.

2.17. ***HIU*** **–**The considerations discussed below apply to HIUs other than packaged product.

2.17.1. Inherent variations associated with any HIUs must be considered when selecting the specific type of HIU, e.g., polymer-based solid material, bentonite suspensions, and oils. In addition, the design and geometry of an HIU must also be considered.

2.17.2. The nature of the process environment (temperature and pressure) may dictate the HIU material. The material selected must withstand the operating conditions repeatedly and reliably.

2.17.3. The geometric design of the HIUs should consider the package(s) general shape in all dimensions and placement within the package holding system (e.g., rack, trays, baskets) in order to mimic potential flow restrictions of the process media. Typically, the HIUs should be designed to conform to the shape of containers forming the ballast.

2.17.4. The thermal properties of the HIUs should be verified before and after their last use to ensure that their properties remain unchanged. Since material thermal diffusivity relates indirectly to heating rate index (i.e., f_h), thermal property verification could be in the form of heating rate determination of all HIUs under specific heating conditions before and after a test.

2.17.5. Factors that can influence standardization/calibration of the HIU materials include: machining tolerances, seals, air and water residues in the TMD wells, and heat degradation of the HIU upon repeated use.

2.17.6. HIUs such as bentonite suspensions at different concentrations exhibit different heating characteristics resulting in convection and conduction (simple or broken heating) profiles. Preparation steps should be consistent from batch to batch to minimize inherent errors (13, 14).

2.18. When actual packaged product is being used to collect heat transfer distribution or heat penetration data, a critical assumption is that it is uniform across all test packages. Any intrinsic variability in the product would be built into the data collected during its use in specific thermal processing studies such as heat penetration or heat transfer distribution tests. This intrinsic variability would/could eventually affect Process Establishment or meeting Heat Transfer Distribution Success Criteria.

DOCUMENTATION

Calibration or standardization results should be included in study documentation. A listing of records required by US-FDA regarding calibration records for temperature indicating and reference devices can be found in 21 CFR Part 113.100.

3 DOCUMENTING PROCESSING EQUIPMENT AND TEST CONDITIONS

It is important to establish proper documentation regarding the processing equipment used for thermal processing studies including: temperature distribution, heat transfer distribution, and heat penetration. While processing equipment surveys are not a part of data collection per se, they are important in identifying retorts that are used for thermal processing studies, documenting study test conditions, as well as helping plant management realize that projects outside the retort room may have an effect on processing operations.

Surveys should be periodically performed on all retorts to ensure that they remain consistently and properly installed to previously documented conditions. These may also be an important part of a plant's change control program. Note that USDA requires annual surveys or audits of retort systems.

SCOPE

The guidelines in this chapter are applicable to any retort system. The listed items for a processing room survey should not be considered as being "all inclusive". Some listed items may not be applicable to the particular retort/processing system being documented.

OBJECTIVES

The objectives of conducting a retort/processing survey include:

3.1. Documentation of test retort(s).

3.2. Providing documentation to aid in the identification and sometimes the selection of retorts for temperature distribution, heat transfer distribution, and heat penetration studies.

3.3. Documentation of "as existing" conditions that may then be used as part of an overall change control program.

ITEMS TO INCLUDE IN THE SURVEY

Retort

3.4. Shell – Physical dimensions of the retort and capacity (e.g., number of baskets, cassettes, dividers, etc.). Secure if possible, the retort manufacturer's or factory blueprints of the retort and all attendant piping, as well as, any alterations since the retort was originally installed.

3.5. Controls- Process controls and installation variations from one retort to another (if any) in the selected test retort group

3.6. Location of Instrumentation including instrument wells – Size, shape and location of well(s) used to locate sensors.

3.7. Reference Temperature Indicating Device (TID) – Type, location and calibration status.

3.7.1. Where used, Mercury-in-glass (MIG) thermometer location, temperature range and increments, length of scale, calibration date, and length of insertion, i.e., the length of the sensing bulb that is inside either the retort shell or instrument well.

3.7.2. Electronic TID type (e.g., RTD, thermocouple, thermistor, etc.), range, response time, location, and length of insertion. If applicable, record if the reference TID is located directly in the heat transfer medium.

3.8. Temperature Control Sensing Device – Type and location of the temperature control sensing device. Describe location of control sensor in relation to the TID sensor and to the steam distributor. If applicable, record if the temperature control sensor is located directly in the heat transfer medium.

3.9. Pressure Control Sensing Device – Type and location of the pressure control sensing device.

3.10. Overflow/purge/vents (air removal)

3.10.1. Valve type and size

3.10.2. Pipe size and connections to drain headers or channels

3.10.3. Vents – location and size of pipes, type and size of valves

3.10.4. Vent manifold or manifold headers – location and size of all pipes and connecting pipes

3.10.5. Bleeders, mufflers – location, number, size and construction

3.10.6. Safety valves – size, type and location

3.10.7. Additional piping or equipment such as condensate removal systems, etc.

3.11. Pressure Indicating Device/Sensor – Note type, range and location of pressure sensors and gauges.

3.12. Drains including water level dumps, overflows, condensate removal

3.12.1. Valve type and size

3.12.2. Pipe size and length

3.12.3. Note if check valves are used

3.12.4. Note location of the condensate removal system in relation to critical zones, e.g., relation of condensate drain to the bottom of the cook shell in a continuous rotary/reel and spiral cooker.

3.13. Steam supply to the retorts

3.13.1. Boiler capacity (horsepower, BTU rating), pressure, and method of firing (gas, oil, coal, dual capacity).

3.13.2. Header pressure. This is important to determine that adequate steam pressure and volume is available for the retorting system. This part of the survey should be performed during both peak use and off-load hours.

3.13.3. Pipe size and length, valve size and types, pressure regulators or reducers, pipe fittings including steam by-pass pipes, from the main steam line to the test retort(s)

3.13.4. Size of all connecting steam pipes to the main line, noting all equipment using steam (e.g., blanchers, exhaust boxes, etc.).

3.14. Steam Introduction into the Retort –

3.14.1. Type and specifications for the steam distribution system including configuration (e.g., fishtail, cross, in-line, etc.), steam flow piping, size, number and location of steam injection perforations

3.14.2. Steam injection chamber (if applicable)

3.14.3. Steam injection points – size, type and location

3.14.4. Steam spreader or nozzle – shape, size, location and configuration, number, size and location of holes in pipe, size of "T", or any other pipe fittings.

3.14.5. Describe the heating medium (e.g., steam, hot water) and temperature.

3.14.6. Describe the cooling medium (e.g., re-circulated refrigerated water, ambient well water, evaporative cooling towers or ponds in re-circulating cooling water circuits).

3.15. Air or nitrogen supply to and into the retorts

3.15.1. Compressor type, capacity and operating pressure

3.15.2. Type and size of filter, dryer and tank

3.15.3. Line size, pressure, filters and dryers for instrument air

3.15.4. Process air header line size(s), pressure and pressure regulation, if used

3.15.5. Entry location and inlet size, control valve size and type, pressure setting and flow rate during testing. Availability to supply instruments. Indicate if air is heated or air lines are in close proximity to steam or water lines.

3.15.6. For Overpressure Retorts - Location and size of pipes and valves (type and size) and method of control.

3.16. Water supply to and into the retorts

3.16.1. Process water supply source, quality, temperature, and controls, if applicable

3.16.2. Cooling water supply source, quality (including microbial control methods), temperature, and controls, if applicable

3.16.3. Use of any alternate methods of heating processing water

3.16.4. Describe the method used to heat and cool the processing water including type (e.g., heat exchanger, cooling tower, etc.)

3.16.5. Location and size of pipes, valve size and type, pump and/or spreader size, type and location (if applicable)

3.16.6. Water level indicators – where applicable, type (e.g., sight glass, petcock, electronic, etc.) and location

3.17. Depending upon the retort system, document the following:

3.17.1. Where applicable, water recirculation system including pump type and capacity, location and sizes and filters of inlet/outlet ports, recirculation line size, flow meter type and capacity, output rates at operating conditions (e.g., gpm or L/min), rpm, pipe diameter for pump inlet and outlet and horsepower rating, impeller size

3.17.2. Air flow, orifice size, pressure setting and flow rate, if applicable

3.17.3. Pressure and/or flow switches type, location, and trip point setting, if applicable

3.18. For Steam/Air Retorts

3.18.1. Type and description of circulation and mixing system for steam/air mixing; bleeder(s) size, type and location

3.18.2. **[Air Plenum and fan shroud]** **(if applicable)**

3.18.3. Distance (length) from retort shell to plenum material if designed as a “shell in shell”.

3.18.4. Details on fan shroud design and connection to the plenum

3.19. For [Water Spray] and [Water Cascading] Retorts

3.19.1. Water spreader(s) size, type and location

3.19.2. Water recirculation system – pump type and capacity, impeller size, motor size, location and sizes and filters of inlet/outlet ports, recirculation line size, type and capacity of flow meter

3.19.3. Steam injection points – size, type and location

3.19.4. Heat exchanger – use, size and type

3.19.5. Water distribution Plate(s) (Water Cascade)

3.19.6. Location of water inlet pipe to manifold (e.g., top/center of retort shell, top/rear of retort shell)

3.19.7. Dimensions of manifold and material of construction

3.19.8. Number, size and location (hole pattern) of holes in water distribution plate; percent open area of the holes in the water distribution plate should be calculated (Water Cascade)

3.19.9. Water distribution pipes (Water Spray Retorts)

3.19.10. Entrance location of entrance of water inlet pipe into retort shell

3.19.11. Location of water distribution pipes in relation to circumference of retort interior

3.19.12. Length of pipes, do they extend the length of the retort?

3.19.13. Number, size and location of holes in pipes

3.19.14. If connected to nozzles, describe the nozzle type. Are nozzles fixed or capable of oscillation? Describe if nozzles restrict diameter of the openings.

3.19.15. Describe water flow rate, e.g., liters per minute, gallon per minute, etc.

3.19.16. Process water retention channel or trough in bottom of retort

3.19.17. Note if and how process water is retained for cooling or re-use

3.19.18. Length, width and depth of water channel or trough

3.19.19. Amount of water (liters or gallons) at start of process and how it is controlled and measured.

3.19.20. If applicable, location of steam distributors or spreaders in relation to channel or trough.

3.20. Rotational Equipment – rotational speed indicator and drive system

3.21. Recording Device – Recorder or recorder/controller type and description including: resolution, parameters recorded, and calibration status.

3.22. Retort Loading Considerations/Loading Equipment

3.22.1. Container information to include material, size and dimensions, orientation for processing (vertical, horizontal, jumbled), and loading configuration (e.g., layered, nested, compartmented, offset, etc.)

3.22.2. Maximum number of containers per layer

- **3.22.3.** Maximum number of cassettes, baskets, or racks per retort
- **3.22.4.** Cassette, basket or rack dimensions, hole size, configuration and spacing in the base plate and sides of cassettes, baskets or racks
- **3.22.5.** Separator sheet dimension, hole size including open area, configuration, and spacing
- **3.22.6.** Partial load arrangement, if permitted
- **3.22.7.** Water displacement requirements (ballast)
- **3.22.8.** Distance between cassettes, baskets or racks, where applicable
- **3.22.9.** Orientation of the cassettes, baskets or racks in the retort during processing
- **3.22.10.** Percent open area of the cassettes, baskets or racks, if used
- **3.22.11.** Describe basket clamping devices, where applicable
- **3.22.12.** Describe top and bottom plates holding baskets, where applicable

3.23. Other Equipment – Other control or functional equipment installed that might affect the thermal process study being conducted. Examples of other types of equipment that should be noted include:

- **3.23.1.** Sampling ports
- **3.23.2.** Water or condensate level dump valves
- **3.23.3.** Initial charge and make-up water systems
- **3.23.4.** Insulation and/or jacketing of retort shell

DOCUMENTATION

Results and observations made should be documented and retained for future reference. The use of digital images may prove useful.

4 CONDUCTING TEMPERATURE DISTRIBUTION TESTS

Temperature distribution studies are conducted in a sterilizer (retort) using distributed temperature measuring devices (TMDs) to establish venting procedures, venting schedules, come-up requirements, temperature stability and uniformity, all of which are necessary to establish reproducible and reliable heating and cooling performance throughout the retort. Temperature distribution studies are typically performed using estimated production retort operating conditions or parameters.

SCOPE

4.1. The guidelines in this chapter are applicable to conducting temperature distribution studies in batch saturated steam, steam/air, water immersion, water spray, and water cascade retorts operating in both still and agitated modes.
4.2. Crateless retorts are excluded from the guidelines provided in this document.
4.3. Continuous Rotary/Reel and Spiral and Hydrostatic retorts are excluded from the guidelines in this document.

OBJECTIVES

4.4. The objectives of conducting temperature distribution studies include:
  4.4.1. Establishing venting procedures and schedules (where applicable), come-up requirements, identifying the existence (if any) of slowest to come to process temperature location(s), as well as temperature stability and uniformity during the Cook.
  4.4.2. Temperature distribution data may also provide insight into the impact of changes made to processing equipment, utilities, and other identified critical factors (e.g., package size, type, loading configuration, etc.).

INTRODUCTION and BACKGROUND

4.5. Acceptable temperature distribution is a requirement for process establishment.
4.6. New retorts require temperature distribution studies. Similarly, retorts that have undergone extensive repair re-design, or relocation can be expected to require temperature distribution studies.
4.7. Consideration should be given to testing all retorts on a regular basis to confirm they continue to perform as previously tested and documented. The replacement or normal wear of components associated with maintaining acceptable temperature distribution also warrant consideration for performing temperature distribution studies. These components may include, but are not limited to: water circulating pumps, valves and pipes associated with steam/water flow, steam injectors (fishtails), air orifices, overflow/pressure regulating valves, spray nozzles, heat exchangers, water distribution plates, and control system changes.

4.8. Temperature distribution can vary with individual installations of identical equipment at the same location. Consideration should be given to performing temperature distribution in each individual retort to document variation within individual retorts.

4.9. If appropriate, information taken in the processing equipment survey and an understanding of plant change control processes, validation, and operation procedures may be used to develop a reduced testing plan.

4.10. Demonstration of adequate temperature distribution is usually a prerequisite for conducting heat transfer distribution (where applicable).

MATERIALS, TOOLS, EQUIPMENT

4.11. See Chapter 2 – Test Equipment and Standardization of Test Equipment

METHODS

4.12. Test Retort Selection

4.12.1. Consideration should be given to testing all retorts in a system.

4.12.2. When appropriate, a reduced testing plan can be developed based on the information taken in the processing equipment survey (see – Chapter 3, Documenting Processing Equipment and Test Conditions). The reasons for retort selection should be documented in testing records. The retort(s) selected should represent the one(s) identified as having the greatest potential for diminished delivery of the critical process utilities such as steam, air, and water. Factors that may help identify the test retort (s) include: retort position (e.g., at the beginning or end of a line of retorts, furthest from steam header), container configuration, divider sheet style, type of heat transfer medium, and processing partial loads.

4.12.3. The results of the processing equipment survey should be verified for completeness and accuracy prior to the start of tests.

4.13. Test Retort Documentation

4.13.1. Test retort documentation may include photographs, diagrams, and a description of the operation, condition, and calibration status of sensors/measurement devices.

4.14. Location of Temperature Measuring Devices in the retort

TMDs should be placed in the following locations:

4.14.1. Attached or in close proximity to the reference TID probe.

4.14.2. Attached or in close proximity to the temperature control device, unless the reference TID and the controller probe are located together.

4.14.3. Located in at least two containers filled with test medium for the purpose of determining initial product temperatures. These containers should be located in the positions that are representative of the potential worst case locations in the retort load.

4.14.4. The lowest of initial temperatures to be encountered during normal commercial operation should be taken into account in establishing temperature distribution. The initial temperature measured should be considered in the context of retort shell and basket/crate/rack temperatures which may be lower or higher than the product temperatures and could have an effect on the total heat load.

4.14.5. An adequate number of TMDs are needed to ensure that the slowest to come-up to temperature locations are identified. A minimum of five (5) TMDs per basket/crate are typically used. These should be located in different layers or otherwise separated in each basket/crate in the initial phase of the temperature distribution study. The intent is to determine the slowest to come-up to temperature location in each basket/crate. Note that additional studies with a higher concentration of TMDs in a particular area or zone may be required to verify that the slowest come-up to temperature location(s) within the retort load have been identified.

4.14.6. TMDs should be placed so those measuring junctions are not in direct contact with containers or other surfaces. All TMDs must be securely fastened in place to prevent damage and unplanned movement during the process (particularly in agitating systems).

4.14.7. In subsequent studies, where no changes have been made to the equipment and previous studies have indicated consistency of cold spot location(s), a reduced number of TMDs per basket/crate/rack may be sufficient.

4.15. Location of pressure sensor(s)

4.15.1. At least one pressure sensor should be located in the retort shell. If the operational pressure sensor has been recently calibrated, it can be used in place of a test device. Pressure gauges should also be used to monitor line pressures of steam, air, and cooling water during a test.

4.16. Location of flow meter(s)

4.16.1. A calibrated flow meter (or alternate method) should be located in a manner to provide an accurate record of the water circulation flow during the process cycle in systems using circulation pumps.

4.16.2. A calibrated flow meter (or alternate method) should be located in a manner to provide an accurate record of the air flow during the process cycle in systems using air for agitation and mixing of process water.

4.16.3. For steam/air retorts – a calibrated flow meter (or alternative method) may be located in the return air plenum to provide an accurate record of the steam/air mixture during the process cycle. If the circulating fan is equipped with a directional/rotational and rpm sensing ability of the fan shaft, then the details of the fan motor from the retort survey will suffice.

4.17. Record of Monitored Locations (TMD Map)

4.17.1. A schematic drawing to show the placement of all monitoring devices within the retort should become part of the documentation for the temperature distribution tests.

4.18. Preparing Retort with Containers

4.18.1. Container Size – The container size and load density that are likely to be the most difficult to achieve temperature uniformity are typically selected for temperature distribution studies. In many cases this will be the smallest container and/or the densest load in use.

In some cases, multiple container sizes, types, configurations and orientations will need to be tested.

4.18.1.1. Since temperature distribution may vary widely with some systems depending upon container and type, it may be necessary to study each different container/ type and loading condition to develop a different come-up profile for each size/type and loading condition.

4.18.2. Container Contents – Containers may be filled with water, or the fastest heating product, for studying retorts that process convection heating products. For conduction heating products, the containers should be filled with product, starch suspensions, or other material that simulates the product. Regardless of material chosen, caution should be exercised when heating characteristics may change with multiple heating cycles. For water immersion, water spray, or water cascade retorts that use a temperature "overshoot" in the come-up profile to help temperature uniformity, use of conduction heating containers is often the worst case situation, and should be carefully considered. Note that stabilization periods at the end of come-up are not considered to be overshoots.

4.18.2.1. For saturated steam retorts, water may be used for conduction heating products; however the come-up times may be somewhat longer than what will occur with product.

4.18.2.2. Document the reasons for ballast container content selection in test documentation.

4.18.3. Container Placement Considerations – Containers are placed in the basket/crate in a manner that is equivalent to the worst-case situation as seen in the commercial operation. The worst-case may be the maximum number of containers per layer, actual number of layers, maximum load density, loading pattern, maximum fill of pocket space, and other conditions that result in the densest load. Where vertical channelling is possible, this condition should be considered in the temperature distribution test design. These aspects may need to be evaluated through additional testing to ensure that the worst-case has been defined.

4.18.4. Container Organization – This includes aspects related to baskets, divider sheets, trays, racks, and other means of holding or configuring packages in the retort.

4.18.4.1. The separator or divider sheets should be the same as those to be used in production. If more than one type of separator or divider sheet is used in production, then the dividers with the smallest percent open area should be used. If additional dividers are used on either the top or the bottom of the container load, this procedure must be duplicated for the test.

4.18.4.2. For a tray or rack that is used to hold and/or separate containers, the design of the tray or rack that will be used in production must be used for temperature distribution studies.

4.18.4.3. Variations in basket/crate/rack loading configuration and design expected in production may need to be tested to determine which yields the worst-case situation. The smallest anticipated partial load and location of the partial load should be compared to full load conditions noting the uniformity and temperature control and stability throughout the retort.

4.19. Conducting the Test

Data Collection/Monitoring Points – Depending upon the retort system, the following should be monitored and recorded during temperature distribution studies.

All Retorts

4.19.1. Temperature and Pressure Controller set point(s), including if there is an overshoot set point for come-up and a lower set point for processing

4.19.2. Product or Ballast Initial Temperature

4.19.3. Time process cycle starts, Time = 0 (time zero)

4.19.4. Times when the end of come-up, start of thermal processing/cook step has been achieved, as indicated by either the step change in a control program or the achievement of process set-point temperature at both the reference TID and the recorder/controller

4.19.5. Reference TID readings at sufficient intervals during the entire cycle, including the point in time it reaches the process temperature set point.

4.19.6. Monitor rotation or agitation rate at sufficient intervals using an accurate calibrated stopwatch or calibrated device including any points where rotation rate changes during processing or on a continuous chart where rotation or agitation is used.

4.19.7. Time at the end of thermal process, and start of cool.

4.19.8. Actual basket/crate/rack orientation in the retort.

4.19.9. Operating activity of other retorts including the number of retorts entering come-up during the study.

4.19.10. Numbers and descriptions of other equipment using steam (e.g., blanchers) at the time of the study and before, during, and after come-up.

In addition to the above, these items should be monitored and recorded based on the retort being studied:

Steam/Air

4.19.11. Temperature of air supply entering the retort.

4.19.12. Water level in relation to spreaders and lowest level of containers in the retort, if applicable.

4.19.13. Time when the pressure set-point(s) is achieved.

4.19.14. Time and temperature when the drain is closed, if it is open during a portion of the vent if applicable.

4.19.15. Time and temperature taken from the reference TID when the vent closes.

4.19.16. Air flow in scfm or liters per minute, if applicable and available.

4.19.17. Line steam pressure at the time of the test and before, during, and after come-up, if possible.

4.19.18. Retort pressure, throughout the test cycle at sufficient intervals or on continuous chart.

Saturated Steam

4.19.19. Water level in relation to spreaders and lowest level of containers in the retort.

4.19.20. Time and temperature when the drain is closed, if it is open during a portion of the vent.

4.19.21. Time and temperature taken from the reference TID when the vent closes.

4.19.22. Line steam pressure at the time of the test and before, during, and after come-up, if possible.

4.19.23. Time steam bypass valve closes.

Water Spray and Water Cascade

4.19.24. Temperature of initial process water.

4.19.25. Water level in relation to spreaders and lowest level of containers in the retort.

4.19.26. Flow or recirculation rate of water as determined by flow meter or other acceptable means.

4.19.27. Time when the pressure set-point(s) is achieved.

4.19.28. Retort pressure, throughout the test cycle at sufficient intervals or on continuous chart.

Water Immersion

4.19.29. Temperature of initial process water.

4.19.30. Fill time (displacement) in those systems dropping water from a storage drum or tank into the working processing vessel.

4.19.31. Water level in process vessel in relation to the top surface of containers, stated as a minimum or an actual level throughout the process.

4.19.32. Flow or recirculation rate of water as determined by flow meter or other acceptable means.

4.19.33. Time when the pressure set-point(s) is achieved.

4.19.34. Air flow in scfm or liters per minute, if applicable and available.

4.19.35. Line air pressure at the time of the test and before, during, and after come-up, if possible.

4.19.36. Retort pressure, throughout the test cycle at sufficient intervals or on continuous chart.

4.20. Data-logger

4.20.1. The data-logger should record the temperature of each TMD at sufficient sampling frequencies, typically 10-30seconds, throughout the length of the study.

4.20.2. The data-logger should record the temperature from cycle start through completion of cooling.

4.21. Other critical data collection point frequencies

4.21.1. Assumed or potential process-related critical factors should be recorded at intervals of sufficient frequency to describe and verify retort operating parameters during the test. Recordings are part of the permanent test records and should include the temperature recording chart, the pressure readings/chart, flow rate records, reference TID readings, and other data gathered that were identified as critical data collection points.

4.22. Study time duration

4.22.1. The test should extend for at least as long as needed for the retort control system to stabilize, establish a definite temperature profile, and all monitoring and TMDs have reached a steady-state condition.

4.22.2. If desired, retort cooling phase temperatures may be recorded through the entire cooling cycle. This is particularly important if product cooling lethality will be based on actual retort cooling profiles in developing scheduled processes.

4.23. Retort Test Conditions

Operating Procedures – Normal commercial operating procedures testing the extremes of allowable ranges to examine the effects of loading, overpressure, and agitation should be followed.

4.23.1. Temperature distribution studies should be run at the maximum retort temperature to be used for commercial processing. For example, one should **not** run temperature distribution studies at 250°F (121°C) if the product is processed at 266°F (130°C). Generally, temperature distribution studies should not be run any higher or lower than 5F° (~2.5C°) from the temperature at which product will be processed.

4.23.2. Minimum vent temperature and time is a critical factor for steam retorts. The temperature and time at which the vent is closed become the minimum vent schedule for the process.

4.23.3. Partial loading conditions should be studied in addition to the full load where permitted.

4.23.4. Basket rotation should be studied at or below the expected Scheduled Process value.

Where applicable, the following additional conditions may be tested at the standard retort processing temperature used for commercial production:

Steam/Air

4.23.5. High steam to air ratio (Low Overpressure).

4.23.6. Low steam to air ratio (High Overpressure).

Water Spray, Water Cascade, and Water Immersion Retorts

4.23.7. Low flow of the heat transfer medium.

4.24. Replication – To demonstrate reproducibility**,** at a minimum duplicate temperature distribution studies should be performed for each situation (e.g., container size, container type, operating temperature, basket/crate/rack system) with uniform and comparable results obtained from each test.

4.25. Post-test inspection

4.25.1. The condition of the measuring sensors, the test containers, and other attributes of the retort load should be examined after the completion of the entire set of studies to determine if the test results may have been affected by movement or other changes to the desired test setup.

DATA ANALYSES

4.26. Plot or tabulate the minimum and maximum measured temperatures for all TMDs within the retort load at each scan/time interval. The TID, Controller, and Chart temperatures at specific time points should be evaluated relative to the TMD's temperature.

4.27. Evaluate the difference between the minimum measured temperature and the programmed or set-point minimum process temperature at specific time points to establish or confirm temperature off-sets and to establish come-up time.

4.28. Identify the location of the TMD that was the slowest to achieve come-up criteria. Identify the time this TMD achieved come-up criteria.

4.29. Identify the minimum Initial Temperature.

SUCCESS CRITERIA

4.30. Come-Up –

4.30.1. The TID should be at or above minimum process temperature at the end of come-up.

4.30.2. All TMDs should be within 1F° (0.5C°) of minimum process temperature at the end of come-up.

4.30.3. All TMDs should be at or above the minimum process temperature within 1 minute of starting the hold time.

4.31. Cook/Hold –

4.31.1. After the start of Hold, the TID should not fall below the minimum process temperature.

4.31.2. After the first minute of the Hold phase, the uniformity and stability of temperatures is confirmed by having no TMD temperature fall below minimum process temperature once that TMD has reached the minimum process temperature.

4.32. Cooling – If specific cooling profiles are critical to the process delivery, the temperature distribution during cooling must support those profiles.

4.33. Other –

4.33.1. The location of all TMDs must be confirmed at the end of all studies. Any TMD that shifted during data collection should be evaluated for impact on study outcomes.

4.33.2. The integrity of test packages/ballast should be confirmed to be acceptable.

4.33.3. All critical retort operating parameters (e.g., Temperature, Rotation, Pressure, Flow, Water Level, and Fan Speed) were achieved as planned and/or programmed.

4.33.4. Situations or conditions that do not meet these criteria should be critically evaluated.

4.33.5. Identify the minimum Initial Temperature for which the temperature distribution is valid.

4.33.6. Identify all other aspects of the product, package, ballast, loading pattern, and so forth for which the temperature distribution is valid.

DOCUMENTATION

Temperature distribution findings should be summarized in a report. Supporting items that should be included are:

4.34. Reason(s) for retort selection.
4.35. Results from the retort survey and test retort documentation.
4.36. Schematic showing placement of all measuring devices in the retort.
4.37. Reason(s) for product selection.
4.38. Retort charts, operator logs, retort control program, and control system reports.
4.39. Critical point observations to include Initial Temperature.
4.40. Calibration information for all sensors/devices used.
4.41. Data-logger data for both retort and product.
4.42. Graphical depictions of minimum/maximum data.

5 CONDUCTING HEAT TRANSFER DISTRIBUTION TESTS

This Guideline covers the scientific basis and fundamentals for conducting Heat Transfer Distribution Studies with emphasis on critical elements to be considered. This Guideline provides rationale for considerations to be used by an end user in deciding when Heat Transfer Distribution Studies are needed in addition to Temperature Distribution Studies.

SCOPE

5.1. The guidelines in this chapter are applicable to conducting Heat Transfer Distribution Studies in steam/air retorts and may be applied to water spray, water cascade, and water immersion retorts where air overpressure in excess of the saturated steam pressure (corrected for altitude) at process temperature is used. These guidelines are applicable to retorting systems operating in both still and agitated modes.

OBJECTIVES

The objectives of Heat Transfer Distribution Studies include:

5.2. Identification of the slowest to heat location in a retort to the extent that it impacts process delivery within the retort load when using the same process, product, package, and load conditions. Load Conditions include: Partial loading of baskets (e.g., less than a full basket of trays), less than a full retort load (e.g., 4 baskets in a 5-basket retort), tray/racks loading (e.g., not all package locations filled with a package), and density and/or percentage of open volume/void volume.

5.3. Identification of the repeatability of those relatively slower to heat locations across retorts and studies using the same process, product, package, and load conditions.

5.4. Identification of recommended locations to place Heat Penetration containers for Process Establishment.

5.5. Verification of the adequate delivery of the thermal process over time for a given product/package combination and loading condition(s).

INTRODUCTION and BACKGROUND

5.6. Temperature Distribution testing usually focuses on come-up and cook portions of the retort cycle. Temperature uniformity in these portions of the retort cycle may not always correlate to adequate heat transfer into packages throughout the retort, hence the need for Heat Transfer Distribution studies. Acceptable Temperature Distribution is recommended prior to conducting Heat Transfer Distribution Studies.

5.7. Heat Transfer Distribution testing may be recommended when:

5.7.1. A non-condensable gas such as nitrogen or air is introduced into the heat transfer medium to provide overpressure in excess of the saturated steam pressure (corrected for altitude) at the Cook Temperature.

5.7.2. For heating medium delivery systems (including type, flow, rack, package, etc.) whenever it is possible that in certain areas of the retort load the rate of heat energy supplied to the package is not in excess of the rate at which the package can absorb the heat energy.

5.7.3. For new retorts, new retort programs/controls, new product/package/closure combinations including trays/racks/load configurations requiring overpressure air in excess of the saturated steam pressure at Cook Temperature.

5.7.4. As part of an overall Change Control Program.

5.7.5. When partial loads may be processed during manufacturing.

5.7.6. Any time there are concerns that heat transfer delivery may be impacted by the retort's heating medium mixing and distribution system such as the presence of a fan, nozzles, shrouds/plenum, racking/tray design, and so forth.

5.8. Heat Transfer Distribution data may assist in conducting deviation analyses provided data are collected using actual product and package.

5.9. Heat Transfer Distribution data can be used as part of an overall ongoing program to verify retort operations over time.

5.10. The effects of package location along the radius of rotating loads are often not considered in Temperature Distribution testing, nor are effects of fastest to heat packages compared to those that are fastest to cool. Heat Transfer Distribution Studies may provide insight into potential effect of location along the radius of rotating loads as well as effects of faster to heat and cool packages within the retort load. In addition, insight may be gained on retort fan position, heating medium/air inlet design and shroud design, and their influence on the flow and mixing of the heating medium.

5.11. If desired, lethality data collected using actual packaged product (vs. non-product based HIUs) may be separated into that achieved during come-up and cook versus that achieved in cool. This information may be valuable in assessing the effects on nutrients and the product's physical stability throughout the retort load. Modifications to the retort, package, loading configurations, trays/racks, processing cycle, etc. to reduce or minimize the lethality differential throughout the load may be then possible. <u>Note that Heat Transfer Distribution data are not used for Process Establishment</u>.

5.12. As part of an overall Change Control program, Heat Transfer Distribution data collection should be considered whenever:

5.12.1. Changes are made to packaged product loading such as new or modified trays, baskets, etc. are introduced.

5.12.2. Changes are made to load density, flow rate of heat transfer medium, and shroud design.

5.12.3. Changes are made to the primary package (e.g., heavier bottle), change to package fill volume and/or headspace volume, etc.

5.12.4. New formulations are introduced.

5.12.5. Changes are made to utilities or the retort such as those done as part of upgrades to equipment or significant repairs.

5.12.6. The amount of air overpressure in excess of saturated steam pressure (when corrected for altitude) at Cook Temperature is modified.

5.12.7. Partial loads are to be processed.

5.13. Heat Transfer Distribution studies, in contrast to Heat Penetration studies, must always be conducted in the production retort(s). Pilot Plant Retorts or Research Simulators should not be used for studying or extrapolating Heat Transfer Distribution performance.

5.14. Microbiological techniques are not recommended for Heat Transfer Distribution studies.

5.15. Temperature and pressure must be independently controlled and recorded.

MATERIALS, TOOLS, EQUIPMENT

5.16. See IFTPS Guidelines for Conducting Thermal Processing Studies, Chapter 2 – Test Equipment and Calibration of Test Equipment.

5.17. Heat Transfer Distribution measurements may be obtained from instrumented/probed:-

5.17.1. Product-filled packages; or

5.17.2. Non-product based HIUs made from polymer-based materials such as Teflon, clays such as bentonite suspensions, and oils. Please refer to, Section 2.14.11 for criteria regarding use of non-product based HIUs.

5.18. A sufficient number of instrumented/probed samples to ensure that all areas of the retort load are being studied and to support statistically valid analyses must be included in each study.

METHODS

Test Retort Selection

5.19. In general, all of the information taken in the processing equipment survey should be used to select the retort(s) that will be used for Heat Transfer Distribution Studies. The reasons for retort selection should be documented in testing records or all retorts should be studied.

5.20. The retort(s) selected should represent the one(s) identified as having the greatest potential for diminished mixing and delivery of the heat transfer medium.

5.21. Heat Transfer Distribution Studies must be conducted using production retorts under expected production and operating conditions.

Test Retort Documentation

5.22. Information based on data from the processing equipment survey and from Temperature Distribution Studies should be included in study documentation.

5.23. The specific process, product, package, and load conditions being studied must be documented.

Ballast Retort Load

5.24. The ballast used may be product-filled packages of the type and size being evaluated. Alternatively, other materials may be used provided their heating characteristics are consistent with the product being studied.

5.25. Ballast packages should retain their heating and physical characteristics if they are to be re-used. Re-use of ballast packages should be documented in a Test Report.

5.26. Note that water-filled packages generally should not be used as ballast for Heat Transfer Distribution Studies to allow the retort controls to perform representatively for heating media, delivery and its replenishment within the load.

Baskets/Trays and Loading Considerations

5.27. The loading conditions used or expected to be permitted during manufacture of packaged product must be studied. This includes using the baskets, trays/racks, dividers, cassettes, etc. that will hold/carry product-filled packages.

5.28. Load density may have a dramatic impact on Heat Transfer Distribution. This is due to inhibition or retardation of distributing the heat transfer medium throughout the retort load. Therefore, optimization with respect to the specific retort's heat transfer medium mixing and distribution should be considered wherever possible. Optimization factors to consider include the design of:

- **5.28.1.** Trays/racks/baskets,
- **5.28.2.** Package,
- **5.28.3.** Number of packages per layer/rack/basket, and
- **5.28.4.** Retort operating parameters such as temperature and pressure values and ramps, timing of air introduction, any venting at the start of the retort cycle, or pre-heating of the overpressure air.

Locations of Probed Packaged Product/HIU in the retort

5.29. Heat Transfer Distribution test units are placed in suspected or known slower to heat locations within the retort load. Multiple studies may be required to confidently identify the slower to heat locations within the retort load.

- **5.29.1.** TMDs to measure temperatures surrounding the test packages should be located in proximity to those test packages. These TMDs are to be used to accurately calculate f_h values of adjacent test packages.

5.30. TMDs to measure product/HIU temperatures to be used for data analyses should be securely fastened inside the test package so that the measuring junction/tip is held in the test package cold spot.

5.31. At a minimum, five (5) probed product packages/HIUs should be located in separate suspected or known slower to heat areas of each basket. Symmetry and rotation effects should also be considered when determining locations for Heat Transfer Distribution test units.

5.32. All baskets in the retort should contain test units**.**

Location of pressure sensor(s)

5.33. Independent verification of total retort pressure during Heat Transfer Distribution Studies is recommended when possible and practical.

Location of flow meter(s)

5.34. Independent verification of flow rates of the heating medium is recommended when possible and practical.

Record of Monitored Locations (Loading Pattern/Map)

5.35. A schematic drawing to show the placement of all monitoring devices within the retort should become part of the documentation for Heat Transfer Distribution Studies.

Retort Control and Process Conditions

5.36. Heat Transfer Distribution Studies should be conducted using the process parameter conditions such as temperature, pressure, mixing and distributing the heat transfer medium, and rotation set-points used during normal production or manufacture of the packaged food being studied.

5.36.1. Since f_h and the associated %CV are used as the primary measures to assess adequacy of Heat Transfer Distribution, data do not necessarily need to be collected at the highest allowed overpressure permitted for the product/package being evaluated. This is in contrast to Heat Penetration studies where all "worst case" retort conditions and parameters must be used.It is important that the amount of overpressure used during Heat Transfer Distribution Studies be representative of the expected production condition for the product/package being studied.

Conducting the Test

5.37. Data Collection/Monitoring Points – Heat Transfer Distribution test units must be located in suspected or known slower to heat locations within the retort load. Independent verification of parameters such as controlling temperature, pressure, heat transfer medium flow rates, etc. is recommended. Location of independent sensors is at the discretion of the persons responsible for the study design.

5.38. Scan Frequency for Measurement Devices

5.38.1. Where possible, measurement devices should be set to a scan frequency sufficient to accurately determine heating parameters (i.e., f_h).

5.39. Study time duration

5.39.1. Cook durations should be of sufficient length to adequately determine f_h values and to confirm that Temperature Distribution success criteria were satisfied (See Temperature Distribution success criteria).

5.40. Replication

5.40.1. At a minimum, duplicate Heat Transfer Distribution Studies should be performed for each situation (e.g., package size, package type, operating temperature, basket/tray/rack system, etc.) with uniform and comparable results obtained from each test. Success Criteria must be met in all replicate studies.

5.40.2. Replicates should be true replicates in all respects, including Initial Temperature, Retort Temperature, Pressure, rpm, and so forth.

5.41. Pre- and Post-test inspections

5.41.1. See Chapter 2 –Test Equipment and Calibration of Test Equipment.

5.41.2. The fabrication, accuracy, condition of the HIUs, the product-filled test packages, and other attributes of the retort load should be examined before Heat Transfer Distribution are initiated to determine if they are acceptable for use and Heat Transfer Distribution results using them will not be adversely affected by the testing sub-systems.

5.41.3. The condition of the measuring sensors, the HIU/product-filled test packages, and other attributes of the retort load should be examined after the completion of the test to determine if the test results may have been affected by movement of these sensors or other changes to the desired test setup.

5.41.4. Comparison of pre- and post-test fill weights to ensure test packages have not leaked during testing. Consideration should be given to discarding data from leaking packages.

DATA ANALYSES

5.42. Calculate f_h values and the associated % CV

5.43. Identify the slower to heat locations within the retort load, e.g., f_h distribution within the retort.

5.44. Confirm adequate Temperature Distribution including come-up time.

5.45. Confirm that retort control and process conditions were achieved as designed.

5.46. If HIUs/product-filled test packages have also been placed in faster to heat locations, the f_h differential between slow and fast to heat locations may also be compared.

5.47. Determine product slower and faster to heat locations for the HIUs/product-filled test package combination. The slowest to heat location is determined based on the largest f_h value.

5.48. All subsequent process determination studies, i.e. Heat Penetration, should be conducted placing test packages in the known slowest to heat locations determined from Heat Transfer Distribution studies.

5.49. If desired, determine product slowest and fastest to cool locations.

SUCCESS CRITERIA

Heat Transfer Distribution may be considered acceptable when:

5.50. Temperature Distribution success criteria have been met during each Heat Transfer Distribution Study.

5.50.1. Note that demonstration of adequate Temperature Distribution is recommended prior to conducting Heat Transfer Distribution Studies.

5.51. Retort control and process conditions achieved/met as designed.

5.52. f_h % CV ≤ 5% within and across replicate studies. When this condition is met, uniform heat transfer conditions have been confirmed and Heat Penetration probes may be located anywhere in the retort.

5.52.1. In the event the f_h CV is found to be>5%, it should first be confirmed that the sensors used were consistent with accuracy stipulations (see Chapter 2 – HIU). Additional Heat Transfer Distribution studies need to be conducted to ascertain that the slowest to heat locations have been reliably and consistently determined, with appropriate confidence and rigor. Thereafter, all Process Establishment Heat Penetration Studies for the test (i.e. product, package, process, retort and load) combination need to be conducted at the identified slowest to heat locations.

5.52.2. Alternatively, when the %CV is >5%, iterative changes could be made to the retort, retort control, load density, rack design, etc. in an attempt to achieve an f_h % CV ≤ 5%. Once changes have been completed, replicate Heat Transfer Distribution studies should be conducted. Note that temperature distribution studies are a pre-requisite to conducting heat transfer distribution studies. The need to collect temperature distribution data after making changes should be evaluated prior to conducting additional heat transfer distribution studies.

5.53. Verified that the retort is uniform in terms of heat transfer media distribution and delivery and/or the slowest to heat location(s) within the retort load that may be used for Heat Penetration studies for Process Establishment have been identified.

5.54. If product-filled packages are used, product functionality and seal integrity are within accepted parameters.

RISKS, ISSUES, AND OTHER CONSIDERATIONS

5.55. HIU geometry should not interfere with the normal flow pattern and mixing of the heat transfer medium within the retort load.

5.56. Heat Transfer Distribution data are not used for Process Establishment.

5.57. f_h values determined from HIU other than actual the product/package may not be used for deviation evaluations.

5.58. Sufficient quantity of probed packages/HIU to conduct a valid statistical evaluation of the f_h variability within a test is required. Typically this will require that more than 6 values are used to calculate a mean f_h and the associated standard deviation and %CV. In general, a larger number of values will provide more robust values.

5.59. Replicate studies are recommended. The number of replicate studies will depend upon the number of retorts being evaluated and whether you are studying a new retort/process/package/formulation or if this is part of a periodic (e.g., annual) re-verification program. When replicate studies fail to meet Success Criteria for Heat Transfer Distribution, additional studies are needed.

5.60. Since f_h and the associated % CV are used as the primary measures to assess adequacy of Heat Transfer Distribution, data do not necessarily need to be collected at the highest allowed overpressure for the product/package being studied. This is in contrast to Heat Penetration studies where the "worst case" retort conditions as defined by the Scheduled Process must be used. It is important that the amount of overpressure used during Heat Transfer Distribution Studies be representative of the expected production condition for the product/package being studied.

5.61. Non-product based HIUs may be a preferred option to product-filled packages when the food being studied heats primarily by conduction.

DOCUMENTATION

Documentation of heat transfer distribution studies should include:

5.62. Reason(s) for retort selection.

5.63. Results from the retort survey and test retort documentation including digital photos showing the heating media delivery system including fans, pumps, nozzles, spreaders, shrouds, and so forth.

5.64. Schematics and/or digital photos showing placement of all monitoring devices in the retort.

5.65. Reason(s) for use of the specific HIU selected, i.e., packaged product vs. non-product based HIU.

5.66. Reason(s) for use of the specific Ballast selected, i.e., packaged product, packaged water or HIU.

5.67. Schematics and digital photos or packages, HIUs, Racks, Trays and Loads used for testing.

5.68. Retort charts, operator logs, retort control program, and control system reports

5.69. Critical factor records.

5.70. Calibration information for all sensors/devices used.

5.71. Raw data for both Temperature and Heat Transfer Distribution probes and that for any other monitoring devices such as pressure sensors that were used during the study.

5.72. Data and statistical analyses, re-tests, results and discussion as part of a Heat Transfer Distribution Testing Report, documenting testing deviations, findings, success criteria and recommendations for additional/subsequent work.

6 CONDUCTING HEAT PENETRATION STUDIES

SCOPE

The guidelines in this chapter apply to conducting heat penetration studies in any retort system including saturated steam, steam/air, water spray, water cascade, water immersion, and crateless. Batch retorts may be operated in either the still or agitating mode. Considerations for collecting heat penetration data in continuous rotary/reel and spiral and hydrostatic retorts are included. The intent of this document is to provide guidance in regards to the preparation and execution of heat penetration studies. Suggestions regarding data analysis of heat penetration data are also provided.

OBJECTIVES

6.1. The purpose of a heat penetration study is to determine the heating and cooling behavior of a product/package combination in a specific retort system for the establishment of safe thermal processes to deliver commercially sterile products and to assist in evaluating process deviations.

6.2. The study must be designed to adequately and accurately examine all critical factors associated with the product, package and process which affect heating rates.

6.3. Before commencing a heat penetration study, where applicable, an evaluation of retort temperature distribution and heat transfer distribution should have been completed.

6.4. A goal in conducting these studies is to identify the worst case temperature response expected to occur in commercial production as influenced by the product, package and process.

INTRODUCTION and BACKGROUND

Several product, process, package and measurement related factors can contribute to variations in the time-temperature data gathered during a heat penetration test. Establishment of a process requires expert judgment and sound experimental data for determining which factors are critical and the effect of changing those factors both within and beyond established critical limits. The list of items addressed in this section is extensive, but should not be assumed to cover all possible factors. Quantitative data on variability should be recorded where appropriate and all pertinent data should be documented to better understand and account for possible variations in heat penetration behavior.

6.5. Product

6.5.1. Product formulation and weight variation of ingredients should be consistent with worst case production values. Changes in formulation may necessitate a new heat penetration study.

6.5.2. Fill weight used for heat penetration studies should not be less than the maximum declared on the process schedule. Excess product may be expressed as percent overfill.

6.5.3. Solids content should be measured for nonhomogeneous products both before and after processing. Solids content deposited in a sieve should be weighed and expressed as a percentage of total weight. Note: Addition of compressed or dehydrated ingredients may result in increased drained weight.

6.5.4. Note that solids content may be considered a critical factor for homogeneous products and should be measured before processing.

6.5.5. Consistency or viscosity of semi-liquid or liquid components should be measured before and after processing. Flow behavior will change with type and concentration of thickening agents (e.g., starch, gums, etc.), temperature and shear rate. Changes may be reversible or irreversible which may be important when reprocessing product.

6.5.6. Size, shape and weight of solid components should be measured before and after processing, when appropriate. For example, measuring size and shape of cooked rice in product may not be possible or useful.

6.5.7. Integrity and size of solid component clusters may change during processing and affect temperature sensor placement in the product and cold spot location.

6.5.8. Methods of product preparation prior to filling should simulate commercial practice. For example, blanching may cause swelling, matting or shrinkage which could influence heat penetration characteristics.

6.5.9. Product matting or clumping may change heat penetration characteristics and influence cold spot location. Also, caution should be exercised with sliced products which may stack together during processing.

6.5.10. Rehydration of dried components, either before or during processing, is a critical factor which may influence heat penetration behavior, as well as process efficacy with respect to spore inactivation. Details of rehydration procedures should be recorded during the heat penetration study.

6.5.11. Product may heat by convection, conduction or mixed convection/conduction depending on its physical properties. Heating properties may also be influenced by presence/absence of agitation during processing, headspace volume, etc.

6.5.12. Some foods exhibit complex (broken) heating behavior. Product may initially heat by convection, then due to a physical change in the product, change to conduction heating behavior. For example, for products such as soups which contain starch, a change in heating behavior may be due to starch gelatinization at a particular temperature. Small variations in product formulation or ingredients may cause the transition from convection to conduction heating to occur at a different temperature and related time. Special care should be taken to identify and control specific product and process variables related to the heating rates of these products.

6.5.13. Additional product characteristics such as salt content, water activity, pH, specific gravity, concentration of preservatives, and methods of acidification may influence heat transfer or microbiological resistance and should be recorded.

6.6. Container

6.6.1. Manufacturer and brand name information for the container should be recorded in case information related to filling, sealing or processing is required.

6.6.2. Container type (metal cans, glass jars, retort pouches, semi-rigid containers); size and dimensions should be recorded.

6.6.3. Nesting of low profile packages can influence heating behavior. Heat penetration studies where nesting can occur, including jumbled loads, should include tests conducted on stacks of packages as well as non-nested packages.

6.6.4. Container vacuum and headspace should be recorded for rigid containers. For flexible and semi-rigid containers, the volume of residual gases in the container should be determined. Entrapped and dissolved gases may create an insulating layer in the container causing a shift in the cold spot location and a decrease in the heating rate. Controlled overpressure during processing has been found to reduce these effects.

6.6.5. Maximum thickness of flexible packages (pouches) has a direct relationship to the cold spot temperature history with thicker packages heating more slowly. Heat penetration studies should be carried out at the maximum specified and permitted package thickness.

6.6.6. Container orientation (vertical, horizontal, and specific location of top/bottom of the package) within the retort may be a critical factor for some product/package combinations and should be studied, where appropriate. Changes in container orientation may also influence vent schedules and come-up time as well.

6.6.7. Post-processing examination of test containers for abnormalities should be conducted with special emphasis on the slowest and fastest heating containers. It is strongly recommended that flexible packages be carefully examined following processing to identify the thermocouple junction location. If the intended sensing location has shifted, it is likely that heat penetration data collected are not reliable.

6.7. Method of Fill

6.7.1. Fill temperature of the product should be controlled. It will affect the initial temperature which may influence some heat penetration parameters (lag factor, retort come-up period). This may constitute a critical factor for a process, particularly for products which exhibit broken heating behavior.

6.7.2. Fill and net weights may influence heating rates both in still and rotary cooks. Information on variability may be found in statistical process control and product quality control records.

6.7.3. In most cases, controlling headspace by determining net weight is not sufficient due to possible variations in the specific gravity of the food product. Care should be taken to avoid incorporation of air which would affect the headspace vacuum. In rotary processes, container headspace is a critical factor since the headspace bubble helps mix the product during agitation.

6.8. Closing or Sealing

6.8.1. Closing or sealing equipment should provide a strong, hermetic seal which is maintained during the thermal process.

6.8.2. Vacuum is affected by variables such as: headspace, product temperature, entrapped air, and vacuum efficiency of the closing equipment.

6.8.3. Some products such as vegetables vacuum-packed in cans may have a minimum vacuum as a critical factor. For others packed in flexible or semi-rigid containers, vacuum setting will influence the residual air content in the package, also constituting a critical factor.

6.9. Retort System - The type of retort system used may have a significant influence on the heating rates of products processed in the retort. Results from a heat penetration test should be reported with reference to the retort type, heat transfer medium, agitation, and other pre-defined conditions existing at the time of testing.

6.9.1. When testing convection and conduction heating products, retort come-up time should be as short as possible consistent with obtaining satisfactory temperature distribution. Results will be conservative when using laboratory size retorts or simulators as these tend to have shorter come-up times and cool more quickly than production retorts. However, caution should be exercised when processing broken heating products where the length of the come-up period may affect the time at which the product heating characteristics change from convection to conduction. This may also be of concern where come-up times are longer in production than defined by the designed process.

6.9.2. Laboratory size retorts or simulators may be used for development work on heat penetration behavior. After development, the thermal process should, if physically possible, be verified in an appropriate production retort.

6.9.3. Heat transfer distribution studies should be conducted prior to conducting heat penetration studies for overpressure retort systems.

6.9.4. Racking systems may be used to separate layers of cans or jars; constrain the expansion of semi-rigid and flexible containers; provide support and circulation channels for thin profile containers; and ensure maximum pouch thickness is not exceeded. Care should be taken to understand the influence of a specific rack design on retort performance and heat transfer to containers.

6.9.5. Still batch retort systems vary in operation based on: type of heating medium(e.g., steam, steam/air, water); orientation of the retort (vertical, horizontal); method of heating medium agitation (fans, pumps, air injection); and other factors which may influence the heating behavior.

6.9.6. Rotational batch retort systems (e.g., axial, end-over-end) are designed to rotate (or oscillate) entire baskets of product during processing. Container agitation may provide faster rates of heat penetration to the container cold spot as compared to still cooks.

6.9.7. It is recommended that data be collected at small time increments (e.g., 15-seconds or less) particularly for low viscosity fluids where the cold spot may move in relationship to a fixed TMD during rotation, producing erroneous results. Short time intervals are important with low viscosity liquids and broken heating products that change from convection to conduction. Slightly longer time intervals (e.g., 30-seconds) may be acceptable for conduction heating products. 1 minute is adequate for most conduction heating products, and 3 minutes may be adequate for large containers of conduction heating products where the process time is longer. In general, 50 to 100 data points collected over the collection time may be sufficient for many conduction heating products.

6.9.8. Slip-ring connectors should be cleaned and TMD calibration verified at regular intervals. Critical factors for rotational batch retorts may include: headspace, product consistency, solids to liquid ratio, initial temperature, container size, rotational speed and radius of rotation.

6.9.9. Continuous retort systems move containers through the processing vessel along a spiral track located at the outside circumference of a horizontal retort shell or may be carried through a hydrostatic retort in chain driven flights. Regardless of the configuration, it becomes difficult or impossible to use thermocouples to collect heat penetration data in these systems. Data may be obtained using simulators and then confirmed using wireless data-loggers in the commercial vessel.

6.9.10. Heat penetration data, in some cases can be collected using process simulators. An understanding of scaling or other differences between commercial vessels and the process simulator and the impact on heat penetration is needed and should be documented.

MATERIALS, TOOLS, EQUIPMENT

6.10. See Chapter 2 – Test Equipment and Calibration of Test Equipment

METHODS

6.11. ***Positioning of Temperature Measuring Devices (TMDs) in the Container***

6.11.1. The method of inserting a TMD into a container should result in an airtight, watertight seal which should be verified after testing. Verification may be accomplished through comparison of container weights recorded pre-and post-testing.

6.11.2. TMD sensing junctions should be positioned in the cold-spot of the package.

6.11.3. During insertion of the TMD, caution must be taken to avoid physical changes to the product components such as creating a conduction pathway to the particulate center. Care should also be taken to address potential agitation created by the probe, which can occur in rotation processes if the probe acts as a stirrer.

6.11.4. The method employed for mounting the TMD into the container should not affect the container geometry which could influence heat penetration characteristics.

6.11.5. Flexible or rigid TMDs may be inserted into rigid, flexible or semi-rigid containers using compression fittings or packing glands. For flexible containers, NFPA (4) provides illustrations of thermocouple positioning into a solid particulate and several thermocouple positioning devices to ensure the thermocouple remains in a fixed position within the container.

6.11.6. The most appropriate TMD device for a particular application will depend upon the product, racking system, container type and sealing equipment.

6.11.7. Leakage may be detected by weighing the container before and after processing to determine changes in gross weight. If there is leakage caused by improperly mounted TMDs or the failure of a hermetic seal, data collected for that container should be discarded.

6.12. ***Type and Placement of Containers***

6.12.1. The type and size of container used in the heat penetration study should be the same as that used for the commercial product.

6.12.2. The racking and loading of rigid (e.g., cans), semi-rigid (e.g., plastic bottles, trays and cups) and flexible (e.g., pouches) containers should simulate commercial practice.

6.12.3. Test containers should be placed at the slowest heating location(s) in the retort, as determined by temperature and heat transfer distribution studies.

6.13. ***Temperature of the Heating Medium***

6.13.1. TMDs to measure the heating medium should be positioned so as to prevent direct contact with racks or containers and identified according to their specific locations in the retort.

6.13.2. A minimum of two TMDs are recommended for retort temperature measurement: one situated close to the sensing bulb of the retort reference TID, the other located near the test containers.

6.13.3. In addition, at least one TMD should be placed near the sensor for the temperature controller when that location is remote from the location of the reference TID.

6.14. ***Retort Pressure*** - Worse case overpressure conditions should be used when collecting heat penetration data.

6.14.1. Overpressure conditions during processing will influence package expansion by constraining the expansion of headspace gases. This may be beneficial by improving heat transfer to food in flexible and semi-rigid containers or detrimental by restricting the size of the headspace bubble in rotary processes.

6.14.2. Cooling without overpressure may result in depressurization within a container at the end of a process, leading to accelerated decreases in temperature for fluid foods. Glass packages may also break if overpressure is not properly maintained during cooling.

6.15. ***Cold Spot Determination***

6.15.1. The location of the slowest heating or cold spot in a container is critical to establishing a process and should be determined experimentally. A cold spot location study should be completed to determine the slowest heating location for a specific product/package/process combination. Usually, the cold spot location will be determined from a series of heat penetration tests employing several containers with TMDs inserted at different locations. Alternatively, more than one TMD per container may be used; however, multiple TMDs may influence heating behavior, especially for products in smaller containers (6). Care and judgement based on a number of preliminary experiments, must be exercised to ensure the cold spot location has been identified.

6.16. ***Initial Product Temperature***

6.16.1. Measurement of initial product temperature should be taken immediately prior to testing.

6.17. ***Number of Containers per Test Run***

6.17.1. A heat penetration test should evaluate at least 10 working TMDs for each test run (6). If the retort cannot accommodate this quantity, the number of replicate test runs should be increased.

6.18. ***Number of Test Runs***

6.18.1. Replication of heat penetration test runs is important in order to obtain results which account for run-to-run, product, container and process variability.

6.18.2. After initial cold spot determination tests are completed and all critical factors have been determined, at least two full replications of each test are recommended. Should results from these tests show variation, a minimum of a third test is recommended.

6.18.3. Variation in the results is expected and quite common, especially for products which are non-homogeneous or exhibit complex heating behavior. Variability is generally evaluated based on plots of the heating and cooling curves and/or lethality calculations and should be considered when identifying or predicting the slowest heating behavior of a process.

DATA ANALYSES

6.19. Various methods are available for analyzing heat penetration data (4, 6, 7, and 8). Regardless of the method used, awareness of the potential pros/cons for each method should be understood and addressed.

RISKS, ISSUES AND OTHER CONSIDERATIONS

6.20. Use of self-contained (i.e., wireless data-loggers) TMDs should be evaluated for accuracy, reliability, and applicability prior to use as the product temperature measuring devices for heat penetration studies. In some cases these devices may provide benefits over using wired thermocouples, e.g., in agitating retorts such as continuous rotary sterilizers, batch retorts operated in an agitating mode, and hydrostatic retorts.

6.21. Ecklund (5) reported correction factors for heat penetration data to compensate for errors associated with the use of non-projecting, stainless steel receptacles. While not reported in the literature, this may also be a concern with other fittings.

6.22. **Type of Connectors and Associated Errors:** Connectors used in a thermocouple circuit are fittings attached to a thermocouple within which electrical connections are made. Several types of connectors are available for specific applications and thermocouple type. Caution must be exercised to avoid certain sources of error which may be associated with the use of connectors and extension wires. These include: disparity between thermocouples, connectors and extension wires; temperature differences between two wire junctions; and reversed polarity at the thermocouple-extension wire junction. Thermocouple connectors should be cleaned frequently to remove oxidation from contacts to assure good electrical contact and prevent errors in thermocouple readings. Similar concerns should be addressed when using RTDs and thermistors.

DOCUMENTATION

The following provides a summary of details which may be incorporated in a checklist and documented in their entirety or partially as deemed appropriate for a specific study. Other factors not listed in this section may also be relevant.

6.23. Pre-test Documentation
- **6.23.1.** Product characteristics
- **6.23.2.** Product name, form or style and packing medium
- **6.23.3.** Net weight and volume
- **6.23.4.** Consistency of viscosity of the liquid component
- **6.23.5.** Size, shape and weight of solid components
- **6.23.6.** Size of solid component clusters
- **6.23.7.** pH of solid and liquid components
- **6.23.8.** Methods of preparation prior to filling (ingredient mixing methods, special equipment, etc.)
- **6.23.9.** Matting tendency
- **6.23.10.** Rehydration of components
- **6.23.11.** Acidification procedures
- **6.23.12.** Other characteristics (e.g., % solids, density, etc.)

6.24. Container Description
- **6.24.1.** Container material (brand name and manufacturer)
- **6.24.2.** Type, size and inside dimensions
- **6.24.3.** Container test identification code
- **6.24.4.** Maximum thickness (flexible container)
- **6.24.5.** Gross weight of container
- **6.24.6.** Container nesting characteristics
- **6.24.7.** Slowest heating or cold spot location in container

6.25. Data Acquisition Equipment and Methodology
- **6.25.1.** Identification of data logging system
- **6.25.2.** TMDs and connector plug maintenance
- **6.25.3.** TMDs and connectors numbered
- **6.25.4.** Electrical ground checked (using thermocouples)
- **6.25.5.** Calibration of TMDs placed in heating medium
- **6.25.6.** Type, length, manufacturer and identification code of TMDs and connectors

6.25.7. TMD location in container

6.25.8. Positioning technique for TMDs

6.26. Fill Method

6.26.1. Fill temperature of product

6.26.2. Fill weight of product

6.26.3. Headspace

6.26.4. Filling method (comparison to commercial process)

6.26.5. Sealing operations

6.26.6. Type of sealing equipment

6.26.7. Time, temperature, pressure and vacuum settings (if applicable0

6.26.8. Gas evacuation method

6.26.9. Can vacuum

6.26.10. Volume of residual gases (i.e., flexible containers)

6.27. Retort System

6.27.1. Retort system – still or rotary, type of agitation (end-over-end, axial, oscillatory, none)

6.27.2. Retort identification number

6.27.3. Reel diameter (number of container positions) and rotational speed

6.27.4. Heating medium (steam, steam/air, water immersion, water spray/cascade) and flow rate

6.27.5. Circulation method for water or overpressure media

6.27.6. Temperature distribution records

6.27.7. Where applicable, heat transfer distribution records

6.27.8. Retort venting schedule

6.27.9. Package position study data for batch rotary retorts

6.28. Loading of Retort

6.28.1. Loading or racking system details

6.28.2. Container orientation

6.28.3. Location of thermocouples for retort temperature

6.28.4. Use of ballast containers to ensure fully loaded retort (applicable to some retort systems)

6.28.5. Selected time interval for data logging system

6.28.6. Location of test containers in retort (slowest heating zone)

6.29. Additional Information

6.29.1. Date

6.29.2. Test identification

6.29.3. Processor and location

6.29.4. Individual(s) performing heat penetration test

6.30. Test-Phase Documentation

6.30.1. Test run identification

6.30.2. Initial temperature of product at the start of heating

6.30.3. Rotation speed (if applicable)

6.30.4. Time heating starts
6.30.5. Time vent closed and temperature, if applicable
6.30.6. Time retort reaches set point temperature (t_c)
6.30.7. Temperature indicated on reference TID and when cook starts
6.30.8. Pressure from a calibrated pressure gauge or transducer
6.30.9. Time process begins
6.30.10. Time cooling begins (pressure cooling, if applicable)
6.30.11. Cooling water temperature
6.30.12. Time cooling ends
6.30.13. Any process irregularities or inconsistencies

6.31.Post-Test Documentation

6.31.1. Container location and orientation
6.31.2. Container net and gross weight check for leakage
6.31.3. Thickness of container (flexible pouches)
6.31.4. Measurement of container vacuum or residual air content (if applicable)
6.31.5. Location of the TMD and whether or not it is impaled in a food particle
6.31.6. Post-processing product characteristics (e.g., syrup strength, appearance, viscosity, headspace, drained weight, pH, consistency, shrinkage, matting, clumping, etc.)

APPENDIX A – SELECTED BIBIOGRAPHY

The following references represent a selection of publications that may provide more insight and information regarding thermal processing studies.

1. Pflug, I. J and Berry M. R. 1987. Using Thermocouples to Measure Temperature during Retort or Autoclave Validation. J. Food Protection. Vol 50 (11): 975-981.
2. Tung, M. A and Britt, I. J. 1995. Food Material Science and Food Process Engineering: Keys to Product Quality and Safety. Food Research International. Vol 28 (1): 101 – 108.
3. Tung, M. A. Britt, I. J. and Ramaswamy, H. S. 1990. Food Sterilization in Steam/Air Retorts. Food Technology. 44(12) 105 -109.
4. NFPA 1985. Guidelines for Thermal Process Development for Foods Packaged in Flexible Containers. National Food Processors Association, Washington, DC.
5. Ecklund, O.F. 1956. Correction factors for heat penetration thermocouples. *Food Technol.* 10(1): 43-44.
6. Pflug, I.J. 1975. Procedures for Carrying Out a Heat Penetration Test and Analysis of the Resulting Data. University of Minnesota, Minneapolis, MN.
7. CFPRA 1977. Guidelines for the Establishment of Scheduled Heat Processes for Low-Acid Foods. Technical Manual No. 3. Campden Food Preservation Research Association, Chipping Campden, Gloucestershire, UK.
8. ASTM. 1988. Standard Guide for Use in the Establishment of Thermal Processes for Foods Packaged in Flexible Containers. F 1168-88. American Society for Testing and Materials, Philadelphia, PA.
9. Bee, G.R. and Park, D.K. 1978. Heat penetration measurement for thermal process design. *Food Technol*. 32(6): 56-58.
10. Ball, C.O. 1923. Thermal Process Time for Canned Food, Bulletin of the National Research Council, Washington, DC. Vol. 7, Part 1, Number 37.
11. Ball, C.O. 1927. Theory and practice in processing. The Canner, 64 (5), 27.
12. Ball C.O. and Olsen F.C.W. 1957. Sterilization in Food Technology. Theory, Practice and Calculation. New York, McGraw-Hill Book Co.
13. Jackson, J.M. and Olson, F.C.W. 1940. Thermal processing of canned foods in tin containers. IV. Studies of the mechanisms of heat transfer within the container. Food Research. 5(4): 409-420.
14. Niekamp, A., Unklesbay, K., Unklesbay, N., and Ellersieck, M. 1984. Thermal properties of bentonite-water dispersions used for modelling foods. J. Food Science. 49(1): 28-31.

APPENDIX B - Documenting Processing Equipment and Test Conditions Worksheet

Where possible, drawings, schematics, pictures of the retort and associated equipment could be beneficial to include when documenting test retorts and test retort conditions. The following table is an example of a worksheet that may be used to document processing equipment and test conditions. This example may be modified as needed.

Survey Information

Date ________________ Location _________________ Done by _____________________

Altitude ___________________ Height above sea level _____________________

TYPE OF RETORT

' Continuous Reel ' Hydrostat – Saturated Steam ' Batch – Steam/Air ' Batch – Water Spray ' Batch – Water Cascade

' Batch – Water Immersion ' Batch – Crateless ' Other (Describe) ___________________________

PRODUCT INFORMATION (optional)

Product Name __________________________

Product Heating ' Simple, Convection ' Simple, Conduction ' Broken ' Other (describe) _______________

Container – Material ________ Dimensions _________ Orientation for processing ' Vertical ' Horizontal ' Jumbled

Fill/Net/Drained Weight _____________________

List product critical factors, targets, and limits ____

PACKAGE INFORMATION (optional)

Type of package - ' Rigid ' Semi-Rigid ' Flexible ' Paperboard ' Other, describe ____________________________

Material of construction (describe) - ____

For metal cans - ' 2pc ' 3pc Side seam construction ___________________________________

Loading Patterns - ' Jumble Pack ' Arrayed ' Other (describe) _____________________________________

Package Information, continued

Seal/Closure – Type ________________

Container Vacuum - ' Yes ' No If yes, allowed limits _____________________________________

RETORT OPERATION

Throughput (CPM) _____________________________________ Containers/load ________________________

Cook Temperature Set-point _________________ Pressure Set-point during Cook _______________________

Rotation Set-point _______________________________

Partial Loads ' Yes ' No If yes, describe allowed conditions ____

____

Where applicable, include retort control program.

For Water Immersion - ' Full Immersion ' Partial Immersion Water recirculation rate __________________

For Water Spray – Number and type of nozzles _________________________________ Flow Rate ____________________

For Water Cascade – Number and type of spreader/manifold __________________________ Flow Rate ________________

For Steam/Air – Fan location ____________________ Fan RPM __________________ Shroud - ' Yes ' No

Pre-heating of overpressure air/nitrogen - ' Yes ' No If yes, describe how heated, how controlled, and to what temperature
____

Steam/Air Ratio ____________________ Is venting part of the process - ' Yes ' No If yes, when is vent closed ________________

LOADING CONSIDERATIONS (where possible secure drawings, schematics, pictures)

Loading Configuration - ' Layered ' Nested ' Compartmented ' Offset ' Other (describe) _________________________________

Loading considerations, continued
Water displacement requirements (ballast) ____

Cassette, Basket, or Rack - Dimensions ____________________ Distance between (if applicable) _____________________

Orientation in retort during processing ________________________ Percent open area _______________

Separator/Divider Trays – Material of construction __________________________ Hole Size (if applicable) _______________

Percent open area _____________________________

Hole Open Area, Spacing and Pattern – Base plate _______________ Sides of cassettes/baskets/rack __________________________

Separator/divider Sheets ________________________

RETORT SPECIFICS (where possible secure factory blueprints/schematics of the retort and all attendant piping as well as any alterations since the retort was installed)

Manufacturer _______________________ Date Installed ______________ Physical Dimensions of shell _______________

Capacity – Continuous Reel: Zone 1 _________ Zone 2 __________ Zone 3 _________ Zone 4 ________ Cooker _________
Cooler _________ Pressure Cooler __________ Total _________

Capacity – Hydrostatic: Preheat ______________ Sterilization ______________ Cooling _____________ Total __________

Number of flights _______________________

Capacity – Batch: No. of Baskets/Crates per Retort ___________ No. of packages per load _______________

Capacity – Crateless: Maximum number of containers per load _________________________________

Heat Transfer Medium: ' Saturated Steam ' Steam/Air ' Water ' Other ________________

Method of Heating Heat Transfer Medium (describe) - ____

Retort specifics, continued

Cooling Medium : ' Ambient well water ' Chilled water ' Other (describe) ______________________________________

Method of process water microbial control ____

Method of distributing/mixing heat transfer medium: ' Fan ' Pump(s) ' Air plenum/shroud ' Nozzles ' Not Applicable

' Other (describe) _________________________________

Controls (e.g., PLC, Computer Control, etc.) - (Describe):

____

Note any differences between retorts in the test group.

List of all controlling/sensing devices (note that ideally a schematic/drawing should be available): _____________________________

____

Rotation: ' Yes ' No Continuous Reel – RPM _____________________________ Hydrostatic – CPM __________________________

Batch – RPM _________________________________ Batch – Oscillatory ___________________________

Vents – Type ___________________________ Size __________________________ Location ____________________________________

Pipe size and connection to drain headers or channels ______________________________________

Vent manifold/manifold header – Location ___________________ Pipe size(s) including connecting pipes ________________________

Bleeders/Mufflers – Number ___________ Size(s) _________________________ Location(s)____________________________________

Construction ____

Drains – Valve Type ___________________ Valve Size _________________ Pipe size ____________ Pipe Length _______________

Connections to drain headers or channels ______________________________________ Location(s) _____________________________

Retort specifics, continued

Condensate Removal System(s) – Type _________________________ Size ________________________ Location ________________

Check Valves ' Yes ' No If yes, Size _______________________ Type ______________________ Location(s) ___________________

Safety Valves – Size ___________________ Type ___________________________ Location(s) ______________________________

Centering guides or baffles present ' Yes ' No If yes, indicate location ____

Water re-circulation system (if applicable) – Pump type ______________ Pump Size ____________ Pump Capacity ________________

Inlet/outlet port – Locations ___________________ Size ________________ Filters ______________________ Recirculation line size _________

Flow meter (if applicable) – type ___________________ Capacity _______________

Horsepower _________ Pipe diameter for pump inlet ___________ and for pump outlet _____________

UTILITIES TO/FROM RETORT

Steam Supply

Boiler Capacity _____________ Method of Firing _____________________ Pressure ________________

Steam header pressure (peak usage) ______________________ Pipe Size _______________ Length ____________________

Steam header pressure (off-load hour usage) ______________________

Steam injection chamber (if applicable) _________________________________

Valve Type ____________ Valve Size _________________

Pipe fittings including steam by-pass pipes from main line to retort (presence, type, size) ____

Size of all connecting steam pipes to the main line ____

Note all equipment using steam from same supply line ____

Utilities to/from retort, continued
Pressure Reducing Valve/Regulator ' Yes ' No If yes, type and pressure into retort ____

Size and Type of Valve for Steam entry into Retort ____

Steam distribution system in retort – Number, location and size of steam spreaders/distributors _______________________________________

Steam injection points – Size ___________ Type _______________________ Location(s) __________________________________

Steam spreader or nozzle – Shape ________________ Size ______________ Location(s) ________________________________

Configuration ___________________________ Number of _________________ Size and location in pipe _________________________

Size of "T" _____________________ Size of other pipe fittings ____

Water Supply (where possible, attach a P&ID)
Water pressure to retort _______________________________________ Water temperature to retort _____________

Water distribution system in retort – Number, size and location of water spreaders/manifolds _______________________________________

____

Process Water Supply – Source __________________ Quality ____________ Temperature _______ Controls (if any) ____________________

Cooling water supply – Source _____________ Quality ______________ Temperature _______ Controls (if any) ________________________

Method of heating processing water (describe) ____

Heat exchanger – Size ______________ Type __________________

Pump – Size ________ Type __________ Location ____________________

Air/Nitrogen Supply
Compressor Type ______________________________ Capacity __________________ Operating Pressure ____________________________

Utilities to/from retort, continued

Filter Type __________________________ Filter Size _____________________ Dryer Type ____________________ Dryer Size _________________

Tank Type _______________________ Tank Size _________________________________

Line – Size _____________ Pressure ____________ Filters and dryers for instrument air ____

Process air header – Line size ______________ Pressure ________________ Regulation (if applicable) _________________

Entry – Location _______________________ Inlet Size __________________

Control Valve – Size _____________________ Type _______________________ Pressure setting _____________ Flow rate ________________

Indicate availability to supply instruments ____

Air heated ' Yes ' No Indicate if air lines are in close proximity to steam or water lines ____

For Overpressure – Pipe location(s) ________________ Pipe size _________________ Valve type _______________ Valve size _______________

Method of control (describe) ____

SENSORS

<u>Temperature</u>

Type of Reference TID ______________________________ Model of TID ________________________ Location(s) ___________________________

Range ________________________________ Response time ___________________ Length of insertion ___________________________

Length of scale (MIG) _________________________________ Increments (MIG) _____________________________________

Calibration status – Date last calibrated __________________ Next calibration date _______________________

Size, shape, location of wells ____

Sensors, continued

Temperature Control Sensing Device – Type ___________________ Location __________________ Relationship to TID _____________________

For Water Spray and Water Cascade – Is this device in the water spray/cascade ' Yes ' No

For Steam/Air – Is this device in the retort or in the air (return) plenum - ' Retort ' Air return/plenum

Pressure

Type of PID ___________________________________ Model of PID _____________________________ Location(s) ___________________________

Range ______________________________________ Calibration status – Date last calibrated ______________

Next calibration date _____________________

Water

Water level indicator type (if applicable) _______________________________________ Location(s) _________________________________

Other

Rotation sensor Type ____________________________ Location ______________________________ Drive system _______________________

Throughput/speed sensor Type ______________________________ Location __________________________

Type and size of flow meter ___________________________________ Location(s) ________________________________

RECORDING DEVICES

Recorder/Recorder Controller – Type _________________________ Resolution ____________________________

Parameters recorded ____ Calibration status _____________________________

List Process critical factors and their associated limits - ____

____

WATER SPRAY AND WATER CASCADE RETORT – These are items that may not be covered in other areas of the survey.

Water Spreader(s) – Type ______________ Size _________________ Location ___________________________

Water recirculation system – Pump Type _______________ Pump Capacity _________________ Pump Impeller Size _______________

Pump Motor size ____________________

Inlet/Outlet port Location ____________________ Size _______________________

Water flow rate - ________________________________

Process water retention channel or trough in bottom of retort ' Yes ' No If yes, Length ________ Width ______ Water depth ________

Process water retained for cooling - ' Yes ' No

Process water retained for re-use - ' Yes ' No

Amount of process water at start of process - _____________ Controlled by _____________________ Measured by ______________________

Steam distributors (if applicable) – Location in relation to channel or trough ____

Water Distribution Plate(s) – Water Cascade only – Inlet pipe to manifold location : ' Top/center of retort shell ' Top/rear of retort shell

Dimensions of manifold ____________________________ Material of Construction __________________________________

Number of holes _____________ Size of holes ___________ Location (hole pattern) ____

Percent open area __________________________________

Water distribution pipes (Water Spray only) – Location of water inlet pipe to retort shell ____

Location of water distribution pipes in relation to circumference of interior of retort ____

Water spray/cascade retorts, continued
Length of pipes (do they extend length of shell) ____

Number of holes _____________ Size of holes __________________ Location of holes ______________________________

Nozzles – Type (if applicable) ____________________________ ' Fixed ' Oscillatory ' Other (describe) __________________________

Restrict hole opening ' Yes ' No If yes, how much ____

STEAM/AIR RETORTS –

Air plenum and fan shroud – Distance (length) from retort shell to plenum if designed as a "shell in shell" ____________

If not designed as "shell in shell", describe: ____

Fan shroud details (describe) ______________________________

APPENDIX C – Temperature Distribution Data Collection/Monitoring Points

The following table is a compilation of suggested data collection/monitoring points when collecting temperature distribution data in different types of retorts.

	Retort Type				
Data Collection/Monitoring Points	**ST**	**SA**	**WS**	**WC**	**WI**
Temperature and Pressure Controller set point(s), including if there is an overshoot set point for come-up and a lower set point for processing	(	(	(	(	(
Product or Ballast Initial Temperature.	(	(	(	(	(
Time process cycle starts, Time 0.	(	(	(	(	(
Time when the end of come-up, start of thermal processing/cook step has been achieved, as indicated by either the step change in a control program or the achievement of process set-point temperature at both the reference TID and the recorder/controller.	(	(	(	(	(
Reference TID readings at sufficient intervals during the entire cycle, including the point in time it reaches the process temperature set point.	(	(	(	(	(
Monitor rotation or agitation rate at sufficient intervals using an accurate calibrated stopwatch or calibrated device including any points where rotation rate changes during processing or on a continuous chart where rotation or agitation is used.	(	(	(	(	(
Time at the end of thermal process and start of cool.	(	(	(	(	(
Actual basket/crate/rack orientation in the retort.	(	(	(	(	(
Operating activity of other retorts including the number of retorts entering come-up during the study.	(	(	(	(	(
Numbers and descriptions of other equipment using steam (e.g., blanchers) at the time of the study and before, during, and after come-up.	(	(	(	(	(
Temperature of air supply entering the retort.		(			
Water level in relation to spreaders and lowest level of containers in the retort.	(	(	(		
Time when the pressure set-point(s) is achieved.		(	(	(	(
Time and temperature when the drain is closed, if it is open during a portion of the vent.	(	(			
Time and temperature, if or when the vent closes, taken from the reference TID.	(	(			
Air flow in scfm or liters per minute, if applicable and available.		(			(
Line steam pressure at the time of the test and before, during, and after come-up, if possible.	(	(			
Retort pressure, throughout the test cycle at sufficient intervals or on continuous chart.		(	(	(	(
Time steam bypass valve closes.	(				
Temperature of initial process water.			(	(	(
Flow or recirculation rate of water as determined by flow meter or other acceptable means.			(	(	(
Fill time (displacement) in those systems dropping water from a storage drum or tank into the working processing vessel.					(
Water level in process vessel in relation to the top surface of containers, stated as a minimum or an actual level throughout the process.					(
Line air pressure at the time of the test and before, during, and after come-up, if possible.					(

ST – Saturated Steam **SA** – Steam/Air **WS** – Water Spray **WC** – Water Cascade

WI – Water Immersion

APPENDIX D – Heat Penetration Documentation Checklist

The following table is an example of a checklist that may be used for Heat Penetration Studies. This example may be modified as needed.

Pre-Test Documentation		
Item/Parameter	**Data**	**Done By**
Product characteristics		
Product name, form, style, packing medium		
Net weight and volume		
Consistency or viscosity of the liquid component		
Size, shape, and weight of solid components		
Size of solid component clusters		
pH of solid and liquid components		
Methods of preparation prior to filling (e.g., ingredient mixing methods, special equipment, etc.)		
Matting tendency		
Rehydration of components		
Acidification procedures		
Other characteristics (e.g., % solids, density, etc.)		

Container Description		
Container material (brand name and manufacturer)		
Type, Size, and Inside dimensions		
Container test identification code		
Maximum thickness (flexible container)		
Gross weight of container		
Container nesting characteristics		
Slowest heating or cold spot location in container		

Data Acquisition Equipment and Methodology		
Identification of data logging system		
TMD type and where applicable, connector plug maintenance		
Type, length, manufacturer and identification code of TMDs and connectors		
Electrical ground checked (using thermocouples)		
Calibration of TMDs placed in heating medium		
TMD location in container		
Positioning technique for TMDs		
Fill Method		
Fill temperature of product		
Fill weight of product		
Headspace		
Filling method (comparison to commercial process)		
Sealing operations		
Type of sealing equipment		
Time, temperature, pressure, and vacuum setting (if applicable)		
Gas evacuation method		
Can vacuum		
Volume of residual gases (i.e., flexible container)		

Retort System		
Retort system – still or rotary, type of agitation (end-over-end, axial, oscillatory, none)		
Retort identification number		
Reel diameter (number of container positions) and rotational speed		
Heating medium (steam, steam/air, water immersion, water spray/cascade, hydrostatic) and flow rate		
Circulation method for water or overpressure media		
Temperature distribution records		
Heat transfer distribution records (if applicable)		
Retort venting schedule		
Package study position for batch retorts		
Loading of Retort		
Loading or racking system details		
Container orientation		
Location of TMDs for retort temperature		
Use of ballast containers to ensure fully loaded retort (applicable for some retort systems)		
Selected time interval for data logging system		
Location of test containers in retort		

Additional Information		
Date		
Test identification		
Processor and location		
Individuals performing test		
Test Phase Documentation		
Test run identification		
Initial temperature of product at the start of heating		
Rotation speed (if applicable)		
Time heating starts		
Time vent closed and temperature, if applicable		
Time retort reaches set point temperature (t_c)		
Temperature indicated on reference TID when cook starts		
Pressure from a calibrated pressure gauge or transducer		
Time process begins		
Cooling water temperature		
Time cooling begins (pressure cooling, if applicable)		
Time cooling ends		
Any process irregularities or inconsistencies		

Post-Test Documentation		
Container location and orientation		
Container net and gross weight check for leakage		
Thickness of container (i.e., flexible pouches)		
Measurement of container vacuum or residual air content (if applicable)		
Location of the TMD and whether or not it is impaled in a food particle (if applicable)		
Post-processing product characteristics (e.g., syrup strength, appearance, viscosity, etc.)		