



Standard Guide for Use in the Establishment of Thermal Processes for Foods Packaged in Flexible Containers¹

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1. Scope

1.1 This guide contains guidelines and recommended procedures for use in the establishment of thermal processes necessary to produce commercially sterile foods packaged in hermetically sealed flexible containers. It applies to foods packaged in flexible containers that are sterilized by the application of heat from fluid heating media, particularly steam, air, water, their combinations, and their mixtures.

1.2 Specifically, this guide describes procedures for determining environmental conditions in the retort during thermal processing of foods in flexible containers and for determining heating and cooling characteristics of such products during processing. Procedures are described by which these data are used in the determination or evaluation, or both, of safe thermal processes for food packaged in flexible containers.

1.3 *Limitations*—This guide does not cover the theoretical and practical considerations that justify thermal processing as a means of rendering a packaged food product commercially sterile, nor does this guide describe methods by which thermal processes are verified or confirmed by biological methods, such as by inoculated pack and count reduction techniques.

1.4 *This standard does not purport to address all of the safety concerns, if any, associated with its use. It is the responsibility of the user of this standard to establish appropriate safety and health practices and determine the applicability of regulatory limitations prior to use.*

1.5 The sections in this guide appear in the following sequence:

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2. Terminology

2.1 Definitions of Terms Specific to This Standard:

2.1.1 *ballast container*—a filled and sealed flexible retortable container enclosing a fixed volume of nonbiological material that is approximately equal to a food-filled container of the same size and shape in terms of the rate and extent to which it will absorb thermal energy by convection and conduction.

2.1.2 *come-up time*—time required following the introduction of heating media into the retort to raise the temperature at the reference thermometer location in the retort to the process temperature.

2.1.3 *cook time*—time span during which the retort is maintained at or above the specified processing temperature (that is, time span between end of come-up and beginning of cooling, sometimes referred to as the operator's process time).

2.1.4 *cooling time*—time required following the introduction of cooling water into the retort to lower the product internal temperature to a specified value (commonly 40 to 45°C).

2.1.5 *critical factors*—physical and chemical factors that influence the thermal response of a product to thermal processing or the inhibition or inactivation of microorganisms, or combination thereof, of public health significance, and which pertain to the flexible container, the enclosed substances (including gases), the retort, and environmental conditions within and around the container from the time of product filling to the end of thermal processing.

2.1.6 *operator's process time*—time between the end of come-up and steam off.

2.1.7 *temperature stability*—the degree to which temperature remains constant at a particular location.

2.1.8 *temperature uniformity*—the degree to which temperatures are equal throughout a particular volume.

2.2 Symbols:

2.2.1 F_M —the F_o value for a hypothetical product that uniformly exhibits temperatures that are synchronously identical to that of the internal retort environment at the designated retort location during the designated process cycle, and under the designated process conditions.

2.2.2 F_o —the equivalent time in minutes at 121.1°C for product at the slowest heating point within the container under the designated process conditions to achieve the same level of destruction of bacterial spores or vegetative cells of a particular

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organism and z value as by the existence of that reference temperature at that point for that time (centerpoint lethality).

2.2.3 F_s —the equivalent time in minutes at 121.1°C for all points within the container under the designated process conditions to achieve the same level of destruction of bacterial spores or vegetative cells of a particular organism and z value as by the existence of that temperature for that time (integrated lethality).

2.2.4 z —number of Celsius degrees required for the thermal destruction to traverse one log cycle.

3. Summary of Guide

3.1 A food product is prepared and sealed within a flexible container. Information pertaining to its formulation and conditions prior to thermal processing treatment is recorded. The packaged product is subjected to a program of temperature, pressure, and other relevant conditions within a retort, comprising a come-up phase, a cook phase, and a cooling phase. Temperature measurements of the food product at its slowest heating location are made, along with measurements describing processing conditions, at regular time intervals. These data are used to obtain heating and cooling rates for the specific product-retort system, and are used in determining the processing time necessary to achieve the specified lethality (for example, F_0) for the product.

3.2 The procedures involve the following aspects:

3.2.1 Selection, assembly, and testing of the temperature measurement system,

3.2.2 Evaluation and testing of the retort system,

3.2.3 Measurement of (1) heating and cooling medium temperatures during processing, and (2) the stability and distribution of these temperatures in the retort during each phase of processing,

3.2.4 Identification of data requirements and measurement and reporting of critical factors,

3.2.5 Selection of the number of containers to be tested, the number of replicate tests, and the simulation conditions,

3.2.6 Fitting and placement of the temperature sensing element in the product,

3.2.7 Process lethality and process time determinations,

3.2.8 Verification of the process, and

3.2.9 Reporting of results and scheduled process.

4. Significance and Use

4.1 Food products processed in flexible containers carry with them the same hazard potential as any other thermally processed food product packaged in a hermetically sealed container and subjected to a thermal sterilization process. Stringent process development and control procedures must be employed and maintained to avoid a significant risk to human health from resulting products. The use of this guide in developing these procedures should help to ensure that foods packaged in flexible retort containers will be commercially sterile.

4.2 The intention of this guide is to provide standardized, reproducible, and reliable procedures leading to the establishment of safe thermal processes for foods in flexible containers. Application of this guide should not be made except by specialists competent in the commercial thermal processing of

foods and having access to all necessary facilities for making thermal process determinations.

PROCEDURES

5. Temperature Measurement

5.1 Introduction:

5.1.1 Temperature measurement within the flexible container can be made difficult by its thin profile and flexibility, and from the potential for irregularity of its thickness. The shorter process times that can be expected for products packaged in thin profile containers (thickness $\leq$ width) demand a high accuracy and precision of the temperature measuring system, since product internal temperatures change quickly, and because data must be acquired at a rapid rate.

5.1.2 Factors that can produce errors or may affect temperature measurements are:

5.1.2.1 The interaction of heat transfer media with temperature sensing devices,

5.1.2.2 Heat conduction along a temperature sensor or its support device,

5.1.2.3 Sudden or rapid changes in temperature or pressure conditions, or both, and

5.1.2.4 Stray voltages that exist between the contents of the container and its environment.

5.1.3 The acquisition of accurate time-temperature data describing the heating and cooling temperatures attained in the retort, as well as the stability and uniformity of temperature conditions in the product zone of the retort is essential for a meaningful process validation. Measurements of the temperature of the heating media are subject to many of the same precautions that apply to product temperature measurements, and these may be further affected by container racking arrangements and specific factors related to the retort design.

5.2 Thermometry Systems:

5.2.1 Thermocouples:

5.2.1.1 Thermocouples are used extensively for heat penetration studies and retort temperature distribution tests because they are simply constructed, rugged, and inexpensive. However, care must be exercised when using thermocouples to ensure that measurements result strictly from the temperature of the thermocouple junction and not from stray electrical currents, poorly constructed circuitry, or poorly designed or constructed instrumentation. Copper-constantan (Type T) thermocouple wire insulated with TFE-fluorocarbon is recommended for use in the temperature range of interest in thermal processing. This wire has the advantage of being resistant to heat and corrosion in moist environments. It is recommended that stranded thermocouple lead wire which is 22 gage or larger be used to minimize cold working effects. The effects of shunt leakage between two lead wires or connections is minimized by using a larger wire size.

5.2.1.2 Conditions inside the retort or inside the filled container necessitate special requirements and precautions in the use of thermocouples. The following are considered to be particularly important:

(a) Keep connections for thermocouple lead wires to a minimum, using plug and jack connectors designed for this purpose. Ideally, thermocouple connections should not be

made inside the retort vessel, and a continuous lead of thermocouple wire from the measuring junction to the outside of the retort should be employed. Clean connections scrupulously before each use to ensure intimate electrical contact. Exposed (for example, soldered) connections inside the retort should be hermetically and electrically insulated using a high temperature grade of silicone caulking or suitable alternative.

(b) Foods and heat exchange media (for example, steam, water) have the capacity to create or carry large electrical charges that may influence the thermocouple output, resulting in error. Stray electrical currents in the thermocouple circuit are caused by common mode voltage differences between the electrical potential at the thermocouple junction and the ground potential of the recording device. The thermocouple circuitry and instrumentation must therefore be suitably designed and constructed to isolate the true thermocouple output from stray electrical currents as discussed by Peterson & Adams (1).² Ideally, the thermocouple should be grounded at its measuring junction. Otherwise, the thermocouple should be grounded at the input terminal to the recording device. Electrical shielding of the thermocouple is desirable, but not necessary, and is often impractical.

(c) In all cases the retort and recording device(s) must be electrically grounded.

(d) Locate the thermocouple junction in such a manner as to minimize the effect of thermal conduction along the wire or its sheath. Heat transfer is potentially more rapid along the

thermocouple wire or sheath than through the food product, and may lead to large temperature measurement errors. An insertion depth of at least ten times the probe diameter is required. Probe-induced errors in temperature measurement are discussed by Kemper and Harper (2).

(e) If thermocouple lead wires are brought out of the retort by way of a packing gland, take care to prevent steam or condensate from following the leads inside the wire overwrap insulation back to the recording device. To do this, the wire overwrap may be sealed with a suitable compound. Alternatively, this can be accomplished by removing a small portion of the wire overwrap at a point along the wire between the retort and recording device (Fig. 1). Stressing (for example, bending or stretching) of the lead wire at the retort packing gland must be carefully avoided.

(f) Form the thermocouple junction by welding or soldering and trimming to a minimum size (2 mm or less).

5.2.1.3 Familiarization with suitable references on the use and calibration of thermocouples (3, 4, 5) is essential before designing and assembling thermocouple circuits.

5.2.2 *Recording Devices*—The instrument required to complete a thermocouple circuit and to measure thermocouple emf (induced voltage) is a d-c potentiometer of which various types are available, including self-balancing potentiometers, digital voltmeters, and feedback amplifiers. The modern data logger is essentially a digital voltmeter with the added capability of scanning several thermocouple circuits, producing an ice reference emf, and computing the emf-to-temperature conversion automatically at regular timed intervals. The measuring

² The **boldface** numbers in parentheses refer to the list of references at the end of this standard.

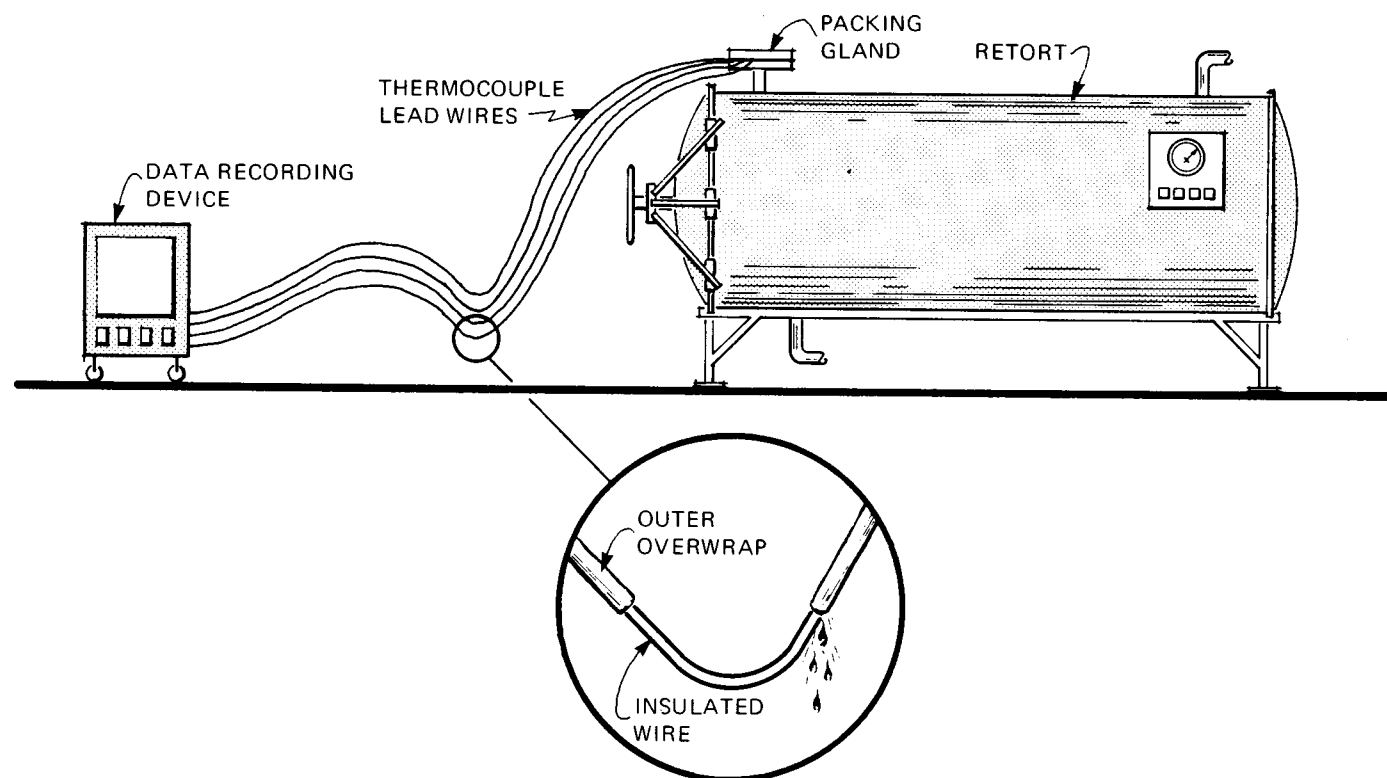


FIG. 1 Thermocouple Lead Wire Layout Showing Method for Relief of Steam/Condensate Inside Overwrap

and recording device should be designed to operate satisfactorily in a common mode voltage difference of at least 60 V dc. Also, the device should have a common mode rejection ratio of at least 140 dB.

5.2.3 Other Thermometry Systems:

5.2.3.1 Alternative temperature transducers to the thermocouple for temperature monitoring and recording are resistance temperature detectors (RTDs) and thermistors, both of which are resistance thermometers. The RTD is a highly stable and accurate temperature transducer, but also very expensive. The thermistor is more sensitive than either the thermocouple or the RTD, allowing it to detect small changes in temperature that could not otherwise be detected. Because the thermistor is a highly nonlinear device, the modern data acquisition system with computing capabilities is needed to facilitate practical signal interpretation.

5.2.3.2 The major problem in using RTDs and thermistors (especially) for temperature measurement inside retorts is the effect of steam or moisture diffusion through the insulation of their lead wires. This can cause a high resistance short circuit between the adjacent conductors, resulting in a significant error (for example, 3°C error from a 10 000 Ω shunt resistance between adjacent leads of a 100 000 Ω RTD). Consequently, a stainless steel sheath should be used to protect the conductors of resistance type thermometers used in moist environments.

5.3 Testing of Thermocouple Measuring Systems:

5.3.1 The thermocouple junction (temperature sensing), the lead wire(s), and the temperature indicating or recording device, or combination thereof, are the main components of a thermocouple measuring system. Each component plays an essential role in the overall performance of the system. The complete system should be used in any tests for accuracy and precision. The following procedure is recommended to correlate temperatures as indicated by the system with those given by an accurate standard temperature measuring device (for example, RTD, Thermistor, Mercury-in-glass standard) (see Note 1) which is certified by a recognized authority as meeting the stated accuracy according to specifications such as set out by the National Bureau of Standards (NBS).

NOTE 1—Certified thermistors and RTDs have been used in place of accurate mercury-in-glass thermometers. A 4-wire RTD is the recommended temperature transfer standard, provided that the lead wires are properly protected from the environment, as discussed above. Mercury-in-glass thermometers, although used as calibration standards for years, have little to recommend them today. Voids in the mercury inside the thermometer bulb can be created, and these are not detectable. Mercury-in-glass thermometers are not “point sensitive,” and the measurements obtained by them depend greatly upon immersion depth and the full temperature range to which they are subjected. They are more difficult to read than a digital display, due to parallax and user height considerations, and are more easily broken. If a mercury-in-glass reference thermometer is used, it should be checked with each use in a well made ice bath to ensure that its stated accuracy has not been lost.

5.3.1.1 Using an accurate (NBS-traceable) standard temperature measuring device in conjunction with a precise regulating device, establish a uniform constant temperature environment. Steam or water are suitable media. Other media (for example, oil, fine sand) could be used for calibration purposes, but thermocouples should be checked or calibrated,

or both, in the heating medium in which they are to be used. Monitor the temperature continuously throughout the media during the entire test period.

5.3.1.2 For proper standardization of the temperature measuring system, use at least three reference temperatures, one of which is within 1°C of the design temperature of the retort process.

5.3.1.3 Place each thermocouple sensing junction in the constant temperature medium in close proximity to the standard reference thermometer. Allow sufficient time for them to equilibrate with the constant temperature environment. This is usually indicated by no significant change in the temperature reading(s) of the system ($\pm 0.1^\circ\text{C}$) during a period of at least 15 min.

5.3.1.4 Record the indicated equilibrium temperature reading for each thermocouple for each reference temperature used and compare with that indicated by the standard thermometer, RTD, or thermistor.

5.3.1.5 If the difference between the reference temperature and that indicated for each thermocouple exceeds 0.5°C the thermocouple circuit and instrumentation should be checked for possible sources of error, and, if found, corrected. A calibration curve is drawn by plotting the reference temperature(s) against the indicated temperature(s) for each thermocouple. In instances where the temperature differences (errors) are not constant, such a calibration curve is used to interpolate corrections for temperatures within the range of the reference temperatures used. If the difference or error is constant for all reference temperatures used, then this can be applied to all temperature readings for the particular thermocouple in that system.

5.3.2 Changes in the thermocouple error occur over a period of time, specifically after repeated use. Therefore they should be re-tested prior to use, using at least one reference temperature as outlined above, to detect any changes. The thermocouple indicating/recording equipment should be periodically tested for proper functioning, prior to any tests for thermocouple measuring system accuracy, using procedures recommended by the manufacturer.

6. Evaluation of Retort Performance

6.1 Introduction:

6.1.1 Paramount in the consideration of retort performance is the need to provide a uniform processing environment. The critical factors affecting the ability of the heat exchange medium (fluid) to provide product heating or cooling, or both, are pressure, temperature, composition, and velocity of the heating fluid. Variation in one or a combination of factors between locations in the product zone has a direct effect on the uniformity of the sterilization treatment level achieved by the process. Another important consideration is the need to provide precise control over the retort process. Differences between processes in terms of their program of time, temperature, pressure, and fluid flow result in differences in the treatment levels attained by them. It must be established that the retort control system consistently replicates the process.

6.1.2 The temperature distribution study is intended to establish and periodically verify the uniformity and stability of