Designation: D 3103 – 07

Standard Test Method for Thermal Insulation Performance of Distribution Packages[1]

This standard is issued under the fixed designation D 3103; the number immediately following the designation indicates the year of original adoption or, in the case of revision, the year of last revision. A number in parentheses indicates the year of last reapproval. A superscript epsilon (ε) indicates an editorial change since the last revision or reapproval.

1. Scope

1.1 This test method covers the determination of the thermal insulation quality of a package and the thermal stability of its contents when exposed to variable ambient temperature conditions. It is suitable for testing packages with various internal energy sources with or without product payloads.

1.2 *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.* Specific precautionary statements are given in 5.3.

2. Referenced Documents

2.1 *ASTM Standards:* [2]

D 996 Terminology of Packaging and Distribution Environments

D 4332 Practice for Conditioning Containers, Packages, or Packaging Components for Testing

2.2 *Other Standards:*

ISTA 5B Focused Simulation Guide for Thermal Performance Testing of Temperature Controlled Transport Packaging[3]

3. Terminology

3.1 *Definitions*—General definitions for packaging and distribution environments are found in Terminology D 996.

3.2 *Definitions of Terms Specific to This Standard:*

3.2.1 *data acquisition unit and associated system*—single- or multi-channel recorder and its associated software and hardware utilizing thermocouples and thermistor sensors traceable to NIST (National Institute for Standards and Technology) that collects and date stamps time and temperature.

3.2.2 *draft-free atmosphere*—an atmosphere where the test specimens are isolated from direct air currents while surrounding air temperature is maintained uniformly throughout the chamber.

3.2.3 *eutectic system*, *n*—a mixture or compound in which pure solid phases changes occur at a well-defined specific temperature.

3.2.4 *exterior atmosphere*—the atmosphere surrounding the exterior surface of a package.

3.2.5 *interior atmosphere*—the atmosphere in contact or near the packaged item.

3.2.6 *mapping*—collecting temperature data at a wide range of locations inside a package or chamber to determine the variability of temperature range in the environment.

3.2.7 *package system*—the combination of exterior package, interior packaging, refrigerants, and product payload.

3.2.8 *product payload*—the product and any associated secondary packaging that is to be temperature controlled within the insulated test package.

3.2.9 *refrigerants*—eutectic materials, gel packs, ice, or other material that serves as an energy source or buffer medium within the package system.

3.2.10 *secondary package*—the package that contains the primary container/closure system(s).

3.2.11 *thermal conductivity, homogeneous material*—the rate of heat flow, under steady conditions through unit area, per unit temperature gradient in the direction perpendicular to the area.

4. Significance and Use

4.1 This test method is intended for use for evaluating the performance of thermal insulated packaging used for high-value, high-risk materials. This test method may also be used for any product that requires accurate internal package temperature readings while being exposed to a range of external air temperatures.

4.2 Certain items, such as biological materials, pharmaceuticals, diagnostics, and blood products, must be shipped inside temperature-controlled packages. Factors affecting the rate of

[1] This test method is under the jurisdiction of ASTM Committee D10 on Packaging and is the direct responsibility of Subcommittee D10.23 on Natural Environment Test Methods.

Current edition approved May 1, 2007. Published June 2007. Originally approved in 1972. Last previous edition approved in 1999 as D 3103 – 99.

[2] For referenced ASTM standards, visit the ASTM website, www.astm.org, or contact ASTM Customer Service at service@astm.org. For *Annual Book of ASTM Standards* volume information, refer to the standard's Document Summary page on the ASTM website.

[3] Available from International Safe Transit Association (ISTA), 1400 Abbott Rd., Suite 160, East Lansing, MI 48823–1900, http://www.ista.org.

heat transfer of the package include the insulation of the exterior package, the energy source, and the product payload.

4.3 Because of the variety of factors affecting the performance of a thermally insulated package, testing should be conducted with the actual package whenever possible. When simulated packages are used, special care must be exercised so that the simulated payload and coolant will be as close as possible to the actual packages in temperature and other relevant physical properties.

5. Test Conditions and Apparatus

5.1 *Temperature Profile of Exterior Atmosphere*—The time-temperature test profile should be established prior to testing based on actual field data, compendial or regulatory requirements, or contractual requirements.

5.1.1 *Field Data Time-Temperature Profile*—It is recommended that the test profile represent actual worst case distribution conditions as closely as possible. The test profile of exterior package temperatures should be based on actual ambient air data accumulated during package handling and transit whenever possible. Any published test cycle or cycle developed using ISTA 5B may also be used as applicable. When using a method based on actual data or developed in accordance with ISTA 5B, the rate of temperature change between trip segments should reflect, as closely as possible, actual transit conditions. Should other than worst case conditions be used, indicated the percentile of the data pool that the profile represents.

5.1.2 *Regulatory Requirements*—When using a time-temperature test profile from a regulatory or compendial source, such as the WHO, cite the source and its application.

5.1.3 *Contractual Requirements*—Should the time-temperature test profile be stipulated by contract, cite the source and, where available, the rationale for the profile.

5.1.4 *Constant Temperature*—A constant temperature profile may be used, especially to determine relative performance of insulating materials. Constant temperatures do not reflect actual transit conditions but may be useful for comparative testing or for research.

5.2 *Test Chamber*—Tests must be performed in one or more rooms or cabinets (chambers) for which test samples can be individually placed with adequate space around all surfaces for air circulation at the desired temperature. An access port should be available for leading thermocouple wires out of the chamber for hook-up to the data acquisition unit (DAU). A temperature indicator should be placed 10 in. from the test package to record the temperature of the exterior atmosphere during the entire test duration.

5.3 *Test Chamber Controller*—The room or cabinet must maintain a uniform temperature around the test specimen. The test chamber control apparatus must be capable of maintaining the desired temperature to within ±3°C. It may be desirable to incorporate a programmable controller with the capability of performing temperature profiles (for example, multiple temperature changes over time). However, the temperature cabinet heating and cooling mechanisms must have the capability to change temperature at the desired ramp rates of the profile. (**Warning**—Gaseous CO_2 is colorless, odorless, and noncombustible. In well-ventilated uses they present few problems, but evaporation or sublimation in airtight enclosures for prolonged periods (for example, 12 h) can produce sprung doors and asphyxiation of operating personnel. Usually these CO_2 can be used if provisions are made to evacuate the built-up gas periodically.)

5.3.1 *Single or Multi-Channel Data Acquisition Unit (DAU)*:

5.3.1.1 The recording capability should be as an electronic datalogger by sensor number with date and time of reading that can be presented in a continuous graph form as a secondary presentation. Resolution of the device shall be 0.1°C or greater. Accuracy over the range tested should be ±0.5°C. The printer or associated computer datafile shall be activated by a voltage from an insulated copper-constantan wires, Type T, or other suitable sensor for the temperature range to be measured that are specified by the manufacturer to be accurate to 0.1°C. The wires may be single or multi-strand and should be flexible enough to be run through repeated bends in the package. Any tips or probes added to the wire should be noted and should not change the accuracy or response time of the thermocouple.

5.3.2 *Thermistor-Recorder*—A thermistor sensor may be used, instead of a thermocouple, for sensing interior temperatures of the package. The thermistor may be attached to recording equipment, as described in 5.3.1, with supplementary electrical circuitry as needed, or it may be a wireless, battery operated, computer programmable unit that stores digital temperature readings at specified time intervals. Programming and data downloading of the units is done through a suitable computer interface with appropriate software. System accuracy over the range tested should be ±0.5°C with minimum resolution to 0.1°C. Response time over range should be determined prior to use and suitable for the reading interval of the test.

5.4 *Calibration Reference Standard*—A NIST-traceable device used in conjunction with a constant temperature bath when calibrating and verifying accuracy pre- and post-test. The resolution and accuracy must be equal to or better than the sensors used in testing.

5.5 *Constant Temperature Bath*—A device or method that produces a stable and consistent reference temperature within ±1°C of a desired set point used in the calibration and verification of temperature sensors. The bath may produce the temperature reference point by means of an electronic signal or temperature controlled liquid bath (the type of liquid may vary depending of system and temperature). A bath in which the temperature is both stable and consistent within ±1°C of the desired set-point and is used in the calibration and verification of thermocouples. The bath solution may vary depending on the desired set-point.

6. Sampling

6.1 Experimental package designs (prototypes) shall be made as close to the specifications and methods as possible that will be used during actual production.

6.2 A minimum of three samples must be tested to ensure reproduceability.