

ISTA, Distributing Confidence, Worldwide™**Preface:**

5B is a focused simulation guide intended to provide basic test procedures for the individual or comparative performance analysis of insulated transport packages. The test results can be used to determine the effectiveness of temperature controlled packaging and to measure the relative ability of a specific thermal package design to maintain internal temperatures within a desired range when exposed to test cycles that simulate ambient exposure.

These thermal-testing procedures should be considered as a general starting point for thermal analysis due to the many variables that can affect the thermal and distribution performance of a package. These procedures are not intended to evaluate the protection afforded packaged-products, nor the shipping containers from other conditions such as shock, vibration, moisture, corrosion, contaminating odors, etc.; packaged-products are considered separately for these conditions.

There are no distribution testing standards or guidelines for shock, vibration and compression that are written specifically for thermal packages. Internal changes normally occur in transit when using crushed ice, frozen ice packs (e.g. thawing) or dry ice (e.g. sublimation, reduction in volume). Shock and vibration conditioning should be a part of the test cycle. Distribution testing using an ISTA test procedure at a point midway through the transport cycle is another possibility to confirm the stability of the packing configuration. ISTA certification of the package can be done at this point for testing that confirms non-thermal protection of the internal products or material. It is recommended that once a package demonstrates acceptable thermal performance in a series of screening or exploratory such as ISTA 7D development tests, a distribution test series be conducted that simulates the extremes expected to be encountered in the transit environment. Following successful completion of the distribution testing, final thermal qualification can be conducted. With experience, the dynamics of the internal package will be understood and distribution testing and certification can be conducted following thermal qualification and certification. Refer to *Guidelines for Selecting and Using ISTA Procedures and Projects* for additional information.

Thermal testing should be conducted in accordance with a documented protocol by an ISTA certified laboratory, or a laboratory that has established procedures and calibrated equipment adequate to demonstrate reproducibility of methods of thermal analysis.

Determining the need for compliance with certain specific government, industry, laboratory, validation or regulatory standards that would supplement or supersede this procedure is the responsibility of the user.

NOTE:

In order to assure reproducibility of testing, the test laboratory should develop procedures that comply with the U.S. Code of Federal Regulations, Title 21, Good Manufacturing Practices (GMP's) in all laboratory practices. Alternately, in lieu of GMP's, the test laboratory should have a complete set of standard operating procedures (SOP's), conduct formal staff training and have regularly scheduled (e.g. quarterly) calibration of test equipment.

The procedure does not address safety problems, or the applicable safety and health practices associated with its use.

CAUTION:

The use of solid CO₂ (dry ice) in temperature controlled packaging must be done with great care. Gaseous CO₂, which is the by-product of dry ice sublimation, over prolonged time will displace oxygen in an airtight enclosure, which can result in asphyxiation of testing personnel. Always work with dry ice in a well-ventilated area. In addition, handling of solid CO₂, which has a surface temperature of -78°C (-108°F), must be done using protective glasses and dry ice gloves to prevent burning of exposed tissue upon contact. Packages containing dry ice must be designed to allow the positive vapor pressure of the sublimating CO₂ to vent to the outside. The use of liquid nitrogen as a refrigerant in specific shipping systems designed for this purpose (e.g. dry nitrogen - vapor shippers, liquid nitrogen storage tanks, etc.) should follow the same cautions due to the oxygen displacement characteristics of the gaseous phase of liquid nitrogen and its extreme cold temperature of -195°C (-319°F).

Guide 5B covers the thermal performance testing of temperature controlled packaging to evaluate the effects of external exposure temperatures on internal materials (e.g. packaged-product temperatures). The Focused Simulation Guide confines its testing activities to the temperature-controlled packaging and its internal packaged-products only. It is suitable for testing analysis of packaged-products with and without temperature stabilizers (e.g. refrigerants, eutectic solutions), and with or without external packaging (e.g. insulated containers).