ISTA 7E Usage Modes

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ISTA 7-Series tests have historically been a combination of thermal profile "simulations" and procedure protocols.

This new **7E** is different. It is a set of standard profiles based on exhaustive "real world" measurements made in the parcel shipping environment. 7E is specifically designed to be used with a companion testing procedure, Standard 20.

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- 7E may be used as a standalone profile set for proprietary testing procedures.
- If the user desires the tested package to be certified by ISTA in the context of 7E, Standard 20 must be acquired and followed in testing.

This document presents the 7E Standard Profile set in graphic and digital format. No testing procedures are a part of this 7E Profile document.

OVERVIEW OF STANDARD 7E & STANDARD 20

Use of 7E with proprietary testing procedures

Standard 7E is designed to evaluate the effects of external temperature exposures of individual packaged-products shipped through a parcel delivery system. It can be used as a "standalone" profile standard. As such, it is useful for general testing and qualification of insulated shipping containers.

Standard 20 + Standard 7E = ISTA Certification of a Thermal Transport Package

When it is used in conjunction with **ISTA Standard 20**, its usefulness is enhanced:

- It can be used for the development of temperature controlled transport packages made of any material.
- It can be used for individual or comparative performance analysis of standard or insulated transport packages against normally encountered conditions.
- It can provide a measure of the relative ability of a package to protect a product when exposed to test cycles that simulate both the range and time of exposure to ambient temperature conditions.
- It allows the testing laboratory to submit results to ISTA for certification that the package conforms to testing according to Standard 20 using the 7E standard profiles. Packages so certified can legally bear the *ISTA 7E Thermal Certification Mark.*

Standard 20

ELEMENTS OF STANDARD 20:

Qualification of a design and testing operation to certify packages to 7E requires all three of the elements of Standard 20:

- **Training** – At least *one* Certified Thermal Professional Level I and *one* Certified Thermal Professional at Level II must be active in the performance and reporting of tests. ISTA provides testing and training procedures for this element.
- **Laboratory Protocols** – Documentation of testing protocols, data packages and reports in a specified format is required. The Standard 20 document provides everything needed for this aspect of compliance.
- **Laboratory Audit** – Successful completion of an onsite laboratory audit by Certified ISTA Thermal Transport Lab Auditor is required.

Important Notes

IMPORTANT NOTES ABOUT STANDARD 20:

- Standard 20 is not intended to evaluate the protection afforded packaged-products from shock, vibration and/or compression. While physical testing is called for, the results are intended to evaluate physical impact on thermal performance.
- The cycle profiles in 7E are general simulations not intended to represent the worst case thermal exposure in the small parcel shipment environment. Many variables affect the thermal and distribution performance of a package and the ambient exposure profile extremes found in the distribution environment for each distribution situation can vary. ISTA profiles for all of the lanes used in the averaging procedures for the generation of the 7E profile set are available. Contact ISTA as indicated below for the availability of these lane-specific profiles.
- If testing is for compliance with specific government, industry, laboratory, validation or regulatory standards or guidelines that would supplement or supersede this procedure or if the value of the product or the liability of damage is significant, other ISTA Procedures may be appropriate for different conditions or to meet different objectives.

Applicability and Use

APPLICABILITY AND USE:

Applicability: The ISTA documents outlined here, **7E**, **Standard 20** and **Standard 14** are recommended for use in supporting an FDA regulated organization's compliance activities relative to the Center for Drug Evaluation and Research (**CDER**) guidelines on process validation as applied to an insulated shipping container (ISC) thermal performance. Reference the following compliance documents:

- "Guidance for Industry, Q7A Good Manufacturing Practice Guidance for Active Pharmaceutical Ingredients" ICH, 2001.
- CDER website, http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/ucm079645.pdf

Use: ISTA documents provide the means to comply with both internal and external quality system requirements through individual (Certified Thermal Professional) certification, thermal transport laboratory certification (Standard 14), and ISC design qualification (Standard 20).

The ISTA documents provide the user with a standardized methodology for demonstrating the performance of an insulated shipping container against a real world set of shipping lane temperature data, which has been statistically analyzed to create a robust thermal profile.

Benefits

Benefits to Industry of a new thermal profile and ISC qualification process:

- What it is--- A **complete insulated shipping container (ISC) qualification tool** for industry application and subsequent regulatory submission, as required.
- What it is not—
  - customized shipping lane data
  - customized worst case shipping qualification
- Who benefits—
  - End user, purchaser of ISC designs and products
    - Off the shelf, independently certified packaging solution that meets industry requirements with the requisite qualification data to support high value pharmaceutical/biopharmaceutical manufacturers and global regulators.
    - Supply chain optimization through selection of the most competitive ISC solution(s) for the most economical shipping lanes.
    - Reduction in cost and time to market by selecting pre-qualified ISC designs. Internal resource demands are minimized and focused on product development activities.
    - Internal laboratories benefit from improved efficiency in executing thermal performance testing.
  - Supplier of ISC designs and products
    - Supply markets will open up and provide a more level playing field by providing designs which can be compared based on performance data, cost and service levels.
    - Facilitates and encourages new product development and innovation as there will exist an industry accepted methodology to demonstrate benchmark thermal performance for new ISC products.
  - Contract test laboratories
    - Industry standardization via ISTA 7E and Standard 20 deployment will increase the demand for independent test laboratories certification activities (Standard 14); and the resultant value of the independent test laboratory within the marketplace is increased.
    - Standardization and supporting qualification documentation greatly improves the laboratory's efficiency in completing high quality work for their clients.

End Result

End result: ISTA reviews ISC qualification results and issues the Standard 20 certification mark for the ISC design. A complete ISC qualification documentation package is achieved and ready for regulatory submission, as required. Additionally, laboratories are certified for thermal performance testing via Standard 14 and qualified ISC designs can be listed on the ISTA.org website, readily available for purchasers of ISC's for commercial use.

An essential element of Standard 20 is the consistency of approach and the consistency of documentation.

Certification

CERTIFICATION USING STANDARD 20:

Users seeking ISTA 7E Certification for their packages must employ 7E Profiles according to the requirements and all of the specific procedures set forth in Standard 20. Using 7E Profiles without acquiring and complying with Standard 20 will not qualify any tested package for certification. Contact ISTA for specifics of Standard 20: pricing, acquisition and necessary steps for certification. Go to www.ista.org or contact ISTA at (+1) 517.333.3437