ISTA 7E Usage Modes

ISTA, Distributing Confidence, Worldwide™

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.

- 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.

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Initial Release

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.

OVERVIEW OF STANDARD 7E & STANDARD 20

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

OVERVIEW OF STANDARD 7E & STANDARD 20

STANDARD 20 TESTING SEQUENCES:

Testing Sequence	What is being tested
Design Testing	Initial laboratory testing to affirm that the design is performing according to user requirements is performed using 7E profiles. (May be repeated to refine designs for achieving user requirements).
Thermal Qualification	Laboratory testing to affirm accuracy and repeatability of Design Testing is performed using 7E profiles.
Physical Qualification	Laboratory testing to affirm package integrity is sufficient to assure thermal performance is performed using ISTA physical testing standards.
Thermal Qualification Verification	Field testing to affirm that laboratory thermal testing results are repeatable in field conditions is performed using sensor placement determined by prior laboratory testing.

The testing sequences are set forth in detail in the documentation of Standard 20. Standard 20 is a suite of documents that provide everything that a laboratory or design team will need to get a package to the point of submission for ISTA approval and certification.

Standard 20

CONTENTS OF THE STANDARD 20 DOCUMENT:

Document	ISTA Designation	Contents
Standard 20 Main Document	STD-0020	A complete set of instructions for laboratory procedures, equipment requirements, calibration, setting of acceptance criteria, documentary standards and data handling requirements for the 7E profiles to be applied according to Standard 20
Insulated Shipper Qualification Program Worksheets	APPX-0021	This document contains all the worksheets required for testing as part of an Insulated Shipper (ISC) qualification program
Template Usage Guide	APPX-0022	How to use the included templates
Design Protocol	APPX-0023	An outline of the protocol document for Design Thermal Testing
Design Report	APPX-0024	The form and requirements for reporting results of Design Thermal Testing
Design Table of Contents	APPX-0025	A table of contents template for the Design Data Package
Design Data Package Example	APPX-0026	A complete example of illustrating the requirements of a Design Data Package
Thermal Qualification Protocol	APPX-0027	An outline of the protocol document for Thermal Qualification Testing.
Thermal Qualification Report	APPX-0028	The form and requirements for reporting results of Thermal Qualification Testing
Thermal Qualification Table of Contents	APPX-0029	A table of contents template for the Thermal Qualification Data Package

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OVERVIEW OF STANDARD 7E & STANDARD 20

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Document	ISTA Designation	Contents
Thermal Qualification Data Package Example	APPX-0030	A complete example of illustrating the requirements of a Thermal Qualification Data Package
Physical Qualification Protocol	APPX-0031	An outline of the protocol document for Physical Qualification Testing
Physical Qualification Report	APPX-0032	The form and requirements for reporting results of Physical Qualification Testing
Physical Qualification Table of Contents	APPX-0033	A table of contents template for the Physical Qualification Data Package
Physical Qualification Data Package Example	APPX-0034	A complete example of illustrating the requirements of a Physical Qualification Data Package
Thermal Verification Protocol	APPX-0035	An outline of the protocol document for Thermal Qualification Testing
Thermal Verification Report	APPX-0036	The form and requirements for reporting results of Design Thermal Testing
Thermal Verification Table of Contents	APPX-0037	A table of contents template for the Thermal Verification Data Package
Thermal Verification Data Package Example	APPX-0038	A complete example of illustrating the requirements of a Thermal Verification Data Package
Document History File Template	APPX-0039	An outline of the user document presenting the results of testing to Standard 20
Document History File Example	APPX-0034	A complete example of illustrating the requirements of a Document History File
ISC Qualification Program Worksheets	FORM-0046	A compilation of worksheets that are part of the Data Packages
Significant Figures and Rounding	SOP-0039	A thorough explanation of data handling techniques for significant figures and results that conform to quantitative user requirements
Good Documentation Practice	SOP-0044	A thorough explanation of required standards for signatures, authorities for document approval and exceptions handling.
Header and Footer Template	TPL-0042	A template showing the requirements of document notation and appearance

TESTING USING 7E STANDALONE

Used Standalone

The profile set provided here represents annual hot and cold seasonal maxima and minima for a parcel shipping environment. Users who intend to employ their own testing procedures are encouraged to consider using Standard 20 as a procedure standard for testing. If users do not determine a need for Standard 20, the following guidelines are recommended.

Testing Recommendations

Samples should be the untested actual package and product, but if one or both are not available, the substitutes shall be as identical as possible to actual items. The product and package should be considered together and not separately.

Substituted products should be as close as possible in regard to content, composition, thermal mass, consistency (e.g. liquid, powder, or paste), and other physical properties, and be packaged in the product specific primary package.

It is recommended that the simulated packaged-product tested be as close as possible in its specific heat to the actual product so hat changes in temperature of both materials would occur at the same rates.

If a refrigerant or temperature stabilizer is used, it shall be the exact type that will be used by the shipper.
To permit an adequate determination of representative performance of the packaged-product, ISTA recommends that the procedure to be performed a minimum of one time, preferably three or more times using new samples with each test.

Packages that have already been subjected to the rigors of transportation cannot be assumed to represent standard conditions. In order to insure testing in perfect condition, products and packages shipped to laboratories for testing should be:

- over-packaged for shipment to the laboratory, or
- re-packaged in new packaging at the laboratory.

Temperature Conditioning:

- Draft-free Room or Chamber and Control apparatus complying with the apparatus section of ASTM D 3103.
- Temperature Indicators complying with the apparatus section of ASTM D 3103.

It is important to measure and document the package + product:

- gross weight in pounds (kg), and
- outside dimensions of Length, Width and Height (L x W x H) in inches (mm or m) *CAUTION:*

Level of Performance

Standardization establishes a rule or measure for quality and level of performance. The 7E standard was developed by characterizing the transport environment and developing Hot and Cold profiles to test packaging configurations with a high degree of confidence. These test profiles are science-based with data to support their claim and are designed to replicate known and anticipated environmental conditions in a parcel distribution network.

The profiles are presented in Hot and Cold and for 72 hour and 144 hour durations. The user is referred to ISTA document “ISTA Report – 0043 ISTA Global Heat and Cold Profiles” for an explanation of the relationship of these profiles to the full suite of temperature measurements.

Standard 20 allows for a temperature profile tolerance of ±3.0°C (above or below the Profile value for each hourly interval). This is indicated in the graphs that follow. The average temperature of the profile used must have an average value that is ±1.0°C relative to the mean temperature for the 7E profile average value. If a programmed chamber profile test results fit within the indicated envelope, as shown in the graphs and in the tabular data, *and* it produces a mean temperature value within the limits, then it is considered to be a valid 7E profile.