distributing confidence, worldwide.

ISTA 7E + Standard 20 =

The First Global Method for Standardizing the Establishment of Insulated Shipping Container Performance

1 Designing, building, and maintaining a cGMP-compliant biopharmaceutical supply chain is one of the greatest challenges facing the biopharmaceutical industry. Part of the challenge is figuring out how to ship these temperature-sensitive pharmaceuticals (TSPs) safely and compliantly around the world, meeting the standards required of each regions regulatory bodies. Regulatory requirements include proving a selected Insulated Shipping Container (ISC) can repeatedly hold designed product loads in acceptable temperature range throughout its supply chain. Up to now, the level performance testing was up to the individual organization to determine, leading to the use of different testing profiles, protocols, and differing proofs of performance.

2 Feedback from Industry and Regulatory bodies over the past 10 years has underlined the need for one global standard which details the minimum thermal and physical testing and ISC should undergo to determine "Proof of Performance". ISTA has responded to this feedback and invested, over a 4 year period, in the development of not only one standard, but also one certification process through which the ISCs can be certified - ISTA Standard 20.

3 ISTA Standard 20 details the process and procedure for ISC Thermal Testing Laboratories to be certified to perform the design, testing, and validation of ISCs to be certified by ISTA as "ISTA 7E Certified" ISCs. Standard 20 also contains the new ISTA 7E Thermal Profiles that have been developed in a 3 year study of real shipping-lane data and have been independently statistically validated.

ISTA Standard 20: Trusted | Repeatable | Performance

ISTA Standard 20 has been in research, development and validation for over 4 years. It is the culmination of the investment of a consortium of ISTA, Industry, Supplier, and University representatives, allowing unbiased and independent critique and affording demonstrated 'real-world' applicability.

ISTA Standard 20 removes the subjectivity from ISC qualification process. Now there is one standard for thermal and physical testing of ISC which will allow 'apples-to-apples' comparison of ISC performance, making the selection of regulatory-compliant shipping solutions easier for the Industry.

Once an ISC has been designed and tested in accordance to Standard 20 by an ISTA Certified Thermal Testing Laboratory, the results are submitted to ISTA for independent review and performance certification. If the documentation and results are approved, a certification mark for that ISC will be issued for display on the ISC.

ISTA Standard 20 Process:
An Overview

Step 1. ISTA Standard 20 is purchased from ISTA.

Step 2. Standard 20 Laboratory Certification application is submitted to ISTA.

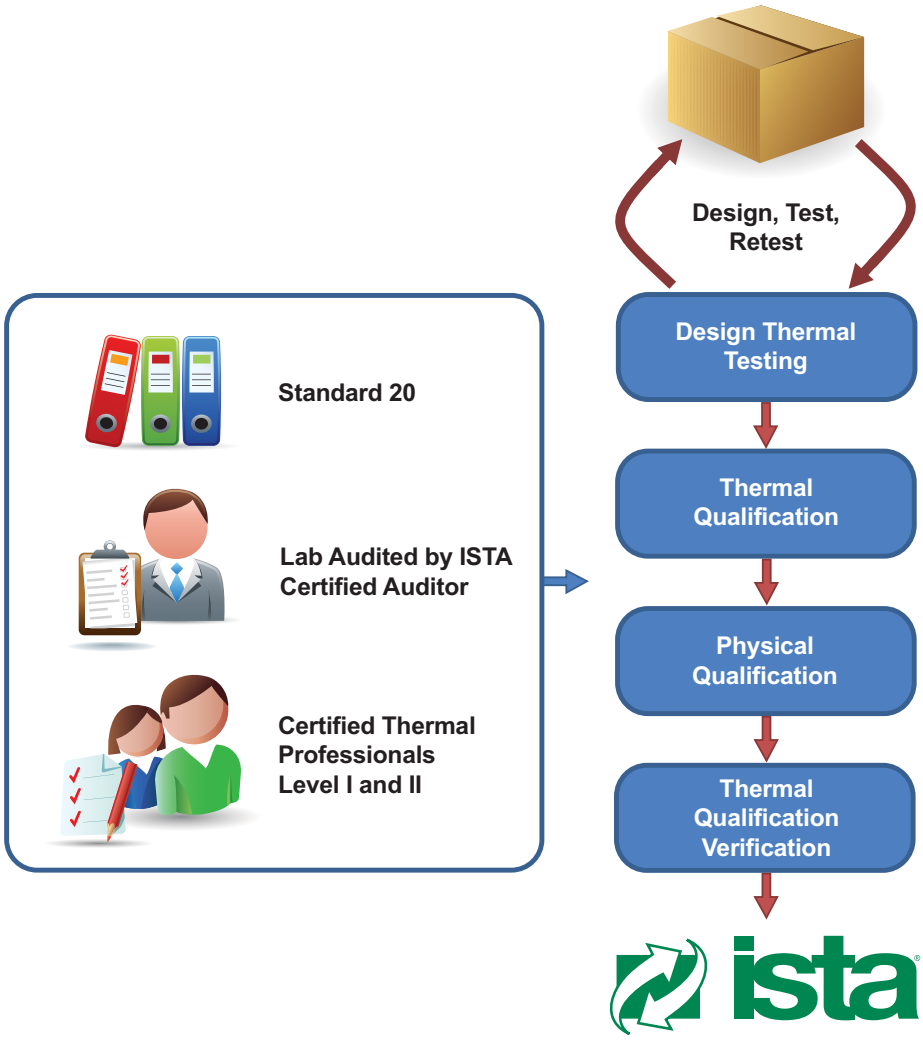
Step 3. 1-2 key laboratory personnel become certified thermal professionals level I and II.

Step 4. Laboratory is audited and approved by ISTA Certified Auditors.

Step 5. ISC is tested in accordance to ISTA Standard 20.

Step 6. ISC testing results and documentation submitted to ISTA.

Step 7. ISTA review results and issue Standard 20 certification mark for ISC.



Question and Answers about Standard 20

How long did it take to collect the data? Gathering the data was a 12 month process. A total of 83 lanes were selected and data from these lanes under both, outbound and inbound scenarios were gathered, processed and statistically processed for Summer and Winter months.

How did you select the sites? Since the plan was to create a profile relevant to parcel shipping, a central point at Louisville, Kentucky was the origination point. In the star pattern distribution scheme, destinations close to known pharmaceutical distribution hubs were chosen.

How can you call this a global profile? The profile is not intended to be geographically-specific. The ISTA 7E profiles have been developed by mapping the temperatures experienced in the 'shipping lanes' and not the temperature a particular geography was experiencing during those months. They are two very distinct things. We were interested only in the shipping lane temperatures during those months as that is the temperature the ISCs will experience. Because of this, these profiles have global applicability.

How can users be confident that the temperature values in the profile are severe enough? Experts in thermal shipping have agreed that these profiles encompass perhaps well over 90% of the shipping thermal challenge encountered in all seasons. No standard thermal profile will cover 100%, since that would require so severe a profile as to render is useless as a data set for characterizing the thermal performance of shippers.
Severe or special conditions can be treated differently from the main body of shipping instances. ISTA shipper certification is not intended to be a replacement for logical cold chain strategy. ISTA is releasing the whole body of the lane data which may well be useful for evaluation of exceptions.

How much time will the user save by purchasing coolers that bear the ISTA 7E Certification Mark? ISTA has asked many users of shipper design and validation services. In every instance, it has been cited that the current process takes from six months to a year. With a spectrum of choices of ISTA Certified shippers from a variety of vendors, users will be able to make appropriate choices in days to weeks.

Do the users have any further testing to perform once they adopt a package with the ISTA 7E Certification Mark? No. The documentation is complete for any purpose since the testing is comprehensive. Users with internal SOP's calling for further testing can follow those, but no further testing is required to comply with Standard 20. Users with known exceptions (see question above) can perform field testing to determine which Certified shippers are appropriate in those instances.

Are you sure that these 7E Certified shippers will be appropriate on other continents, like Europe or South America? Yes. The benefits of standardization of profile, process and documentation are universal.

Does ISTA intend to execute the protocol in these other markets? Yes.

What are the features of the final data package? Full data, including raw data, reports and detailed packout specifications are part of the package. In addition, Standard 20 provides a science-based method for using air temperatures monitored at specific location in the payload space as an indicator of product temperature.

What are the benefits of the data package? Regulators can be supplied the package with full confidence. Pack-out procedures are fully illustrated and documented. The data specifies parameters of QAT (Qualified Air Temperature) QAT data tables specify air temperature excursions that are "out of range when the product is in range" These allow acceptance of certain excursions with confidence that the product has not exceeded its thermal specification.

What are the cost factors for the lab/manufacturer? At the end of this section, there is a cost listing for acquisition of Standard 20 to prepare shippers for ISTA Certification.

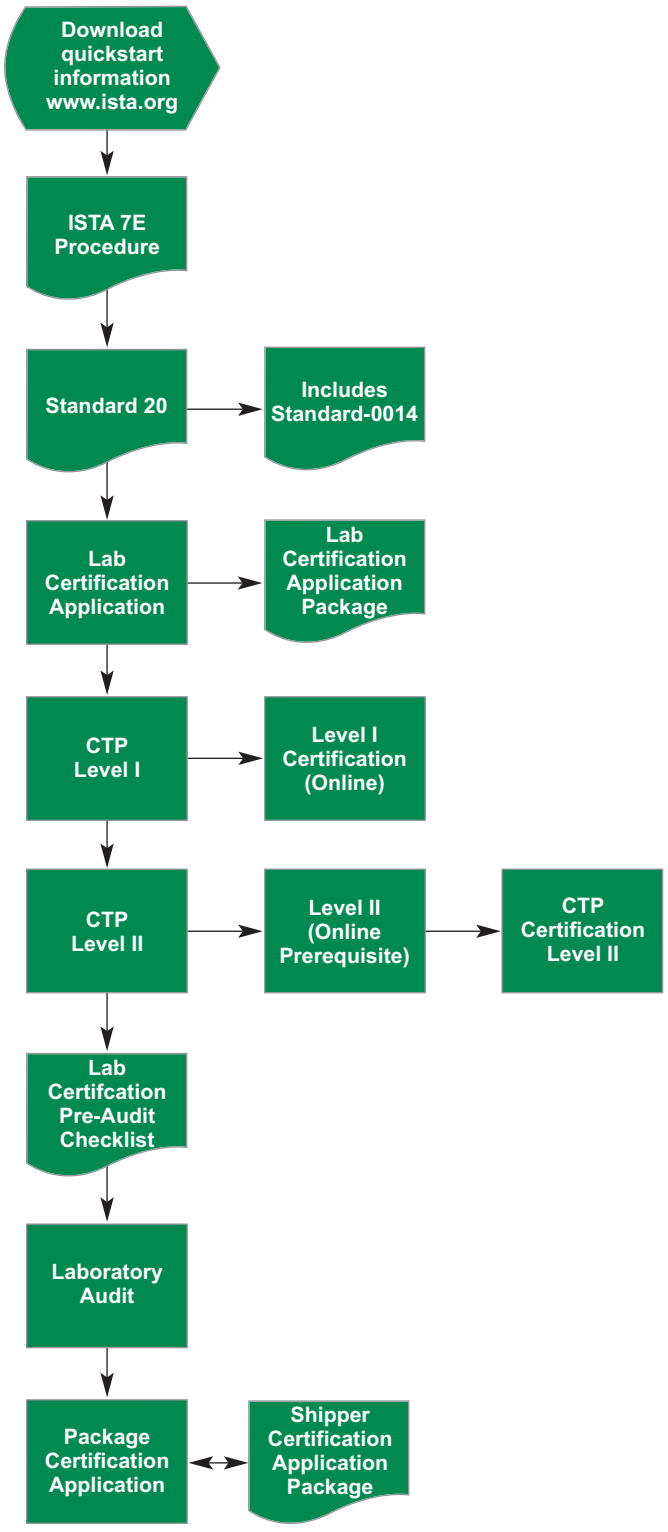
What are the cost factors for the user? There are two cost factor "categories". First, the cost of shippers. Interviews with manufacturers confirm that there will not likely be a mark-up for ISTA Certification of a shipper. The market is competitive, so cost increases are not likely. Second, there are substantial savings in store for users in their shipper acquisition. No more expense for custom qualification. Less time spent in reviewing choices is a significant cost factor. Internal engineering expense is likely to be substantially reduced. Overall, there are clear cost reductions in view.

How long will it take to become Standard 20 ready? The time to readiness can be a matter of weeks. The timing depends on two factors: (1) how well your lab is set up to pass an audit and how experienced your personnel are to pass certification as Thermal Professionals Level I and II (2) how aggressive you are in pursuing onsite audit scheduling and whether you elect to send your Thermal Professional Level II candidate to a group training session or elect to have an Auditor travel to your locations for personal training.

Looking at the 7E profiles, they seem to be less "severe" that what climate data would suggest. The 7E profiles are based on exposures of parcels in the hub and spoke shipping environment during the coldest/warmest parts of the year. The test packages were not “outdoors” but in transit in trucks and planes, and in sort and storage facilities at the transit points. While seasonal effects are clearly apparent from the data collected, it is just as clear that the packages are buffered from the ambient extremes, so a reliance on data from the weather services to use in building profiles is not a recommended practice.

While users are waiting for labs to become certified, is ISTA going to offer anything as a bridge to compliance? Yes. ISTA is offering an online modeling tool-the 7e Converter. This tool allows you to model ISC performance against ISTA 7E using performance data you already have now.
www.7econverter.com

How to Start Up with Standard 20 ISTA 7E Roadmap



**Certification requires ISTA membership.

The 7E Thermal Profiles are the only standard Industry-defined global thermal profiles available for performance testing of ISCs in accordance with ISTA Standard 20. The standard includes heat and cold profiles developed from data gathered in real world transport. All the lane data and protocols on how data was gathered are available for purchase through ISTA. **Price: $10,000**

Standard 20 is a design and qualification process for insulated shipping containers. It is a comprehensive set of requirements to achieve a certified package according to ISTA 7E. The companion document, STN-0014, details specifics of audit requirements for thermal transport lab certification. **Price: $10,000**

Each lab seeking to become an ISTA Certified Thermal Transport Lab must make application to ISTA. **Price: $500**

Each lab seeking certification based on ISTA 7E shall have a Certified Thermal Professional Level I. Lab personnel can achieve Level I certification by passing an online test. Each lab shall have at least one CTP Level I. **Price: $295**

Each lab seeking certification based on ISTA 7E shall have a Certified Thermal Professional Level II. Level II status is a two step process, including an online “pre-test” and an in-person training session with a Certified ISTA Thermal Transport Auditor. The CTP Level I and II can be the same person. **Price: $1,295**

Each lab seeking to become an ISTA Certified Thermal Transport Lab must then apply for an audit. Submission of a pre-audit checklist is required to schedule an audit. After successful review, an on-site audit is scheduled. **Price: No Charge**

The Certified ISTA Thermal Transport Auditor conducts the audit based on the requirements of STN-0014. The possible audit results are: (1) Certified, (2) Not Certified – pending remedial actions, or (3) Not Certified. **Price: $2,500**

Thermal Transport Package Certification requires an application filing. A certified package signified that the shipper has been qualified to all the requirements of ISTA 7E. The ISTA Thermal Transport certification mark can then be applied to the shipper and marketed as an ISTA 7E certified package. **Price: $500**

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