

ISTA 7 Series
Development
Test
Procedure

VERSION
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Last
TECHNICAL
Change:
MARCH 2007

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Change:
JANUARY
2013

For complete
listing of
Procedure
Changes and
Version Dates
go to
www.ista.org

Preface

ISTA, Distributing Confidence, Worldwide™

ISTA 7 Series tests are package development tests.

- Test elements may come from ISTA Series 1, 2 or 3 tests, **and**
- They may or may not evaluate the protection afforded packaged-products.

There are three sections: Overview, Testing and Report

- **Overview** provides the general knowledge required before going into the testing laboratory **and**
- **Testing** presents the specific instructions to do the testing in the laboratory **and**
- **Report** indicates what data shall be recorded to submit a test report to ISTA.

Two systems of weights and measures are presented in ISTA test procedures. They are the English system (Inch-Pound) and the international system (Metric). Inch-Pound units are shown first with Metric units in brackets, except in some tables where they are shown separately. In the case of temperatures, °C is shown first and °F is in brackets.

- Either system may be used as the unit of measure (standard units), **but**
- The standard units chosen shall be used consistently throughout the procedure.
- Units are converted to two significant figures **and**
- Not exact equivalents.

VERY IMPORTANT:

The entire document shall be read and understood before proceeding with a test.

USE OF ISTA 7E OVER PROCEDURE 7D

ISTA, in cooperation with the Pharmaceutical Cold Chain Interest Group (PCCIG), has completed an extensive survey of temperature ranges found in the U.S. parcel delivery distribution environment. This data has been used to develop **ISTA 7E**, *Testing Standard for Thermal Transport Packaging Used in Parcel Delivery System Shipment*, which should be considered for use in lieu of Procedure 7D. 7E is not available in the Resource Book but is available for a separate purchase from ISTA. Full details on ISTA 7E can be found on the ISTA website: <http://www.ista.org>

OVERVIEW FOR PROCEDURE 7D

Test Procedure 7D is a development test to evaluate the effects of external temperature exposures of individual packaged-products.

- 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 is designed to measure the relative ability of a package to protect a product when exposed to test cycles of temperature conditions.
- The product and package are considered together and not separately.
- It is not intended to evaluate the protection afforded packaged-products from shock, vibration and/or compression.

CAUTION: The cycle profiles in 7D are general simulations not intended to represent a worst case temperature exposure. The profiles listed in this procedure are not based on current data-based research. 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, therefore:

- If testing is for compliance with specific government, industry, laboratory, validation or regulatory standards or guidelines that would supplement or supersede this procedure, it is the responsibility of the user to know and understand those requirements and use the proper procedure accordingly
- ISTA strongly encourages the use of ISTA 7E over Procedure 7D. ISTA 7E was developed after a comprehensive survey of temperature ranges found in the parcel delivery system and is considered to be the best and most current simulation of the thermal environment.

Other ISTA Procedures may be appropriate for different conditions or to meet different objectives.

- It is recommended that once a package demonstrates acceptable thermal performance in a series of screening or exploratory ISTA 7D, general simulation tests in the form of a distribution test series, be conducted that simulates the extremes expected to be encountered in the transit environment.
- For packaged-products that may be transported in a small parcel delivery system consider ISTA General Simulation Performance Test Procedure 3A.
- ISTA 7E should be considered for thermal testing of insulated shipping containers in the parcel delivery system.

Refer to *Guidelines for Selecting and Using ISTA Procedures and Projects* for additional information.

Scope

Test Procedure 7D covers the thermal performance testing of packaged-products to evaluate the effects of external temperature exposure.

Product Damage
Tolerance and
Package
Degradation
Allowance

The shipper shall determine the following prior to testing:

- exact product temperature limits, high and/or low for the product **and**
- any acceptable time limits for excursions above or below the temperature limits.

For additional information on this determination process refer to *Guidelines for Selecting and Using ISTA Procedures and Projects*.

Samples

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.

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 that 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.

Number of samples required:

One sample is required for the tests in this procedure.

Replicate Testing Recommended:

To permit an adequate determination of representative performance of the packaged-product, ISTA:

- Requires the procedure to be performed one time, **but**
- Recommends performing the procedure three or more times using new samples with each test.

NOTE:

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 certified laboratories for testing must be:

- over-packaged for shipment to the laboratory **or**
- repackaged in new packaging at the laboratory.

Test Sequence

The tests shall be performed on each test sample in the sequence indicated in the following table:

Sequence #	Test Category	Test Type	Test Level	For ISTA Certification
1	Temperature Preconditioning	Temperature	Storage conditions for the product and each package element for 24 hrs. min.	Optional
2	Atmospheric	Temperature	1 st Cycle Period of selected Test Profile	Required
3	Atmospheric	Temperature	2 nd Cycle Period of selected Test Profile	Required
4	Atmospheric	Temperature	Remaining Cycle Periods of selected Test Profile	Required

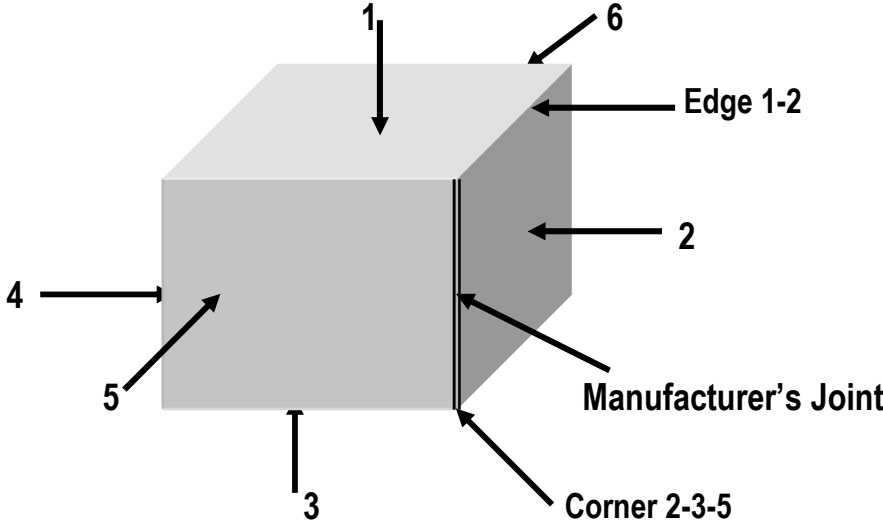
EQUIPMENT REQUIRED FOR PROCEDURE 7D

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.

Identification of
Faces, Edges
and Corners

Prior to beginning the tests identify the faces, edges and corners according to the procedure below.

Step	Action
1	Place the packaged-product in its intended shipping position as determined by shipper. If the shipping position can be variable, place the packaged-product so that the primary shipping label location is on the top face.
2	Does the packaged-product have only six faces (2 sides, 2 ends, top and bottom)? <ul style="list-style-type: none"> If Yes, then go to Step 5. If No, continue to next Step.
3	Develop a method to identify each face, edge and corner and document with a diagram.
4	All testing is now complete. Go to the Reporting an ISTA Test section at the end of this Procedure.
5	Is the package a corrugated container? <ul style="list-style-type: none"> If Yes, continue to next Step. If No, then go to Step 8.
6	Does the package have a manufacturer's joint connecting a side and an end face? <ul style="list-style-type: none"> If Yes, continue to next Step. If No, then go to Step 8.
7	Turn the packaged-product so that you are looking directly at a face with the manufacturer's joint on the observer's right and go to Step 9.
8	Position one of the smallest width faces of the packaged-product directly in front of you.
9	<p>Identify faces according to the diagram below.</p> 
10	Identify edges using the numbers of the two faces forming that edge. Example: Edge 1-2 is the edge formed by face 1 and face 2 of the packaged-product.
11	Identify corners using the numbers of the three faces that meet to form that corner. Example: Corner 2-3-5 is the corner formed by face 2, face 3, and face 5 of the packaged-product.
12	All testing is now complete. Go to the Reporting an ISTA Test section at the end of this Procedure.

**Packaged-
Product
Weight and
Size
Measurement**

**Before You
Begin
Atmospheric
Preconditioning**

You shall know the packaged-product's:

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

CAUTION:

The procedure does not address safety problems, nor the applicable safety and health practices associated with its use except for the following:

The use of solid CO₂ (dry ice) in temperature-controlled packaging must be done with great care.

Always work with dry ice in a well-ventilated area because gaseous CO₂ is the by-product of dry ice sublimation,

- over prolonged time it **will**
- displace oxygen in an airtight enclosure, **which can**
- **result in asphyxiation of testing personnel.**

Solid CO₂ has a surface temperature of -78°C (-108°F), to prevent burning of exposed tissue upon contact when handling:

- you **must** use:
- protective glasses **and**
- dry ice gloves.

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).

Any frozen refrigerant such as gel packs or foam ice packs conditioned at temperatures below freezing must also be handled with caution.

**Before You
Begin
Atmospheric
Temperature
Testing**

CAUTION:

The test profile examples included in the procedure represent some generally recognized ambient temperature and time ranges that occur, but due to continuous climatic and weather changes, delays and variations in handling practices, these test procedures do not purport to represent the extreme conditions that a package shipment might encounter. It is the responsibility of the user to determine the applicability of any cycle for individual use.

Select a **cyclic** test profile that anticipates the expected limits of heat and cold exposure that the packaged-product is likely to encounter during each segment of the transport through an expedited parcel delivery system:

Cyclic Test Profiles: For winter or summer transport conditions within the United States.

24 hour domestic small package express freight transport (Air):

WINTER PROFILE				SUMMER PROFILE			
Cold Shipping & Cold Receiving				Hot Shipping & Hot Receiving			
Temperature	Cycle Period	Cycle Period Hours	Total Time Hours	Temperature	Cycle Period	Cycle Period Hours	Total Time Hours
18°C (65°F)	1	4	4	22°C (72°F)	1	4	4
-10°C (14°F)	2	2	6	35°C (95°F)	2	2	6
10°C (50°F)	3	12	18	30°C (86°F)	3	12	18
-10°C (14°F)	4	6	24	35°C (95°F)	4	6	24

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BEFORE YOU BEGIN PROCEDURE 7D

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Cyclic Test Profiles: For winter and summer transport conditions within the United States.
48 hour domestic freight transport (Air):

WINTER PROFILE				SUMMER PROFILE			
Cold Shipping & Cold Receiving				Hot Shipping & Hot Receiving			
Temperature	Cycle Period	Cycle Period Hours	Total Time Hours	Temperature	Cycle Period	Cycle Period Hours	Total Time Hours
18°C (65°F)	1	4	4	22°C (72°F)	1	4	4
-10°C (14°F)	2	2	6	35°C (95°F)	2	2	6
10°C (50°F)	3	36	42	30°C (86°F)	3	36	42
-10°C (14°F)	4	6	48	35°C (95°F)	4	6	48

Cyclic Test Profiles: For winter and summer transport conditions for international shipments from the United States.
72 hour international expedited airfreight transport:

WINTER PROFILE				SUMMER PROFILE			
Cold Shipping & Cold Receiving				Hot Shipping & Hot Receiving			
Temperature	Cycle Period	Cycle Period Hours	Total Time Hours	Temperature	Cycle Period	Cycle Period Hours	Total Time Hours
18°C (65°F)	1	4	4	22°C (72°F)	1	4	4
-10°C (14°F)	2	6	10	35°C (95°F)	2	6	10
10°C (50°F)	3	56	66	30°C (86°F)	3	56	66
-10°C (14°F)	4	6	72	35°C (95°F)	4	6	72

Cyclic Test Profiles: For ambient conditions at both the shipping and the receiving locations that are not the same for winter and summer transport conditions for international shipments from the United States.

72 hour international expedited airfreight transport:

COLD / HOT PROFILE				HOT / COLD PROFILE			
Cold Shipping & Hot Receiving				Hot Shipping & Cold Receiving			
Temperature	Cycle Period	Cycle Period Hours	Total Time Hours	Temperature	Cycle Period	Cycle Period Hours	Total Time Hours
18°C (65°F)	1	4	4	22°C (72°F)	1	4	4
-10°C (14°F)	2	6	10	35°C (95°F)	2	6	10
10°C (50°F)	3	32	42	0°C (32°F)	3	32	42
22°C (72°F)	4	24	66	10°C (50°F)	4	24	66
35°C (95°F)	5	6	72	-10°C (14°F)	5	6	72

NOTE:

As stated in the Caution Statement, delays are possible. If experience suggests concern, the total hours of the cyclic test profiles may be extended as follows: 24 hours may be increased by 8 hours, 48 hours by 16 hours and 72 hours by 24 hours. For the 24 hour, 48 hour, 72 hour winter and the 72 hour summer cyclic test profiles add the additional time to the final cycle period. In the case of the 72 hours profiles, when the shipping and receiving ambient temperature conditions are different, add 8 hours to the second cycle period time and 16 hours to the final cycle period time.

Continued on next page

BEFORE YOU BEGIN PROCEDURE 7D

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ALTERNATIVE Ramp Test Profile Examples:

It is possible that the heat and freeze cyclic profiles may not be suitable for every situation. A ramp profile is more appropriate than a cyclic or constant temperature "soak" profile for:

- very small thermal containers, which have limited thermal mass, or
- for non-freight transport situations (e.g. car trunk transport)

In these cases a "ramp" profile should be considered selecting one of the following:

24 hour domestic freight transport (Air):

WINTER PROFILE			SUMMER PROFILE		
Temperature	Cycle/Ramp Period	Cycle/Ramp Period Hours	Temperature	Cycle/Ramp Period	Cycle/Ramp Period Hours
18°C (65°F)	1	0-6	22°C (72°F)	1	0-6
to	2	2 hr ramp	to	2	2 hr ramp
-20°C (-4°F)	3	2 hr at temp	45°C (113°F)	3	2 hr at temp
to	4	2 hr ramp	to	4	2 hr ramp
10°C (50°F)	5	12-18	30°C (86°F)	5	12-18
to	6	2 hr ramp	to	6	2 hr ramp
-20°C (-4°F)	7	2 hr at temp	45°C (113°F)	7	2 hr at temp
to	8	2 hr ramp	to	8	2 hr ramp
10°C (50°F)	9		30°C (86°F)	9	

48 hour domestic freight transport (Air):

WINTER PROFILE			SUMMER PROFILE		
Temperature	Cycle/Ramp Period	Cycle/Ramp Period Hours	Temperature	Cycle/Ramp Period	Cycle/Ramp Period Hours
18°C (65°F)	1	0-6	22°C (72°F)	1	0-6
to	2	2 hr ramp	to	2	2 hr ramp
-20°C (-4°F)	3	2 hr at temp	45°C (113°F)	3	2 hr at temp
to	4	2 hr ramp	to	4	2 hr ramp
10°C (50°F)	5	12-24	30°C (86°F)	5	12-24
to	6	2 hr ramp	to	6	2 hr ramp
-20°C (-4°F)	7	2 hr at temp	45°C (113°F)	7	2 hr at temp
to	8	2 hr ramp	to	8	2 hr ramp
10°C (50°F)	9	30-48	30°C (86°F)	9	30-48

Validate the calibration of the temperature monitoring and environmental chamber equipment.

The test blocks that follow contain tables that indicate the required steps for each test in the procedure.

TEST BLOCK 1
Atmospheric
Preconditioning

TEMPERATURE PRECONDITIONING	
Step	Action
1	Are thermocouple probes going to be used to measure the temperature of the products? <ul style="list-style-type: none"> If Yes, go to the next Step. If No, then go to Step 3.
2	Insert the thermocouple probes into the products as required.
3	Precondition all product and packaging test materials at their required storage temperatures for a minimum of 24 hours prior to testing. NOTE: In cases where frozen gel/ice pack refrigerants are used, they may require a longer staging period than 24 hours, especially if they are frozen in a shipping case and not individually.
4	Begin conditioning the draft-free room or chamber to the starting temperature from the selected temperature in Before You Begin Atmospheric Preconditioning so that the draft-room or chamber is ready at the completion of staging all materials.
5	At the completion of preconditioning assemble all preconditioned materials. Confirm that the materials have been conditioned correctly by checking the individually monitored products and refrigerants prior to testing
6	Are thermocouple probes being used to measure the temperature of the products? <ul style="list-style-type: none"> If Yes, go to the next Step. If No, then go to Step 13.
7	Without delay, load the product with the thermocouple probes and refrigerant, if used, into the container
8	Confirm that the probe or monitors are working properly.
9	Make certain that any probe wires extending out of the container (porting) do not create air leaks or gaps upon closing the lid or top of the package.
10	Insert the necessary packaging paper or dunnage and tape or secure the package closed.
11	Start the temperature recording process or activate the monitors at the pre-determined logging interval (e.g. 15 or 30 minutes).
12	Go to Step 15.
13	Without delay, load the product and refrigerant, if used, into the container.
14	Insert the necessary packaging paper or dunnage and tape or secure the package closed.
15	Temperature Preconditioning is now complete. Go to TEST BLOCK 2 (Atmospheric Testing - Cycle Period 1).

TEST BLOCK 2
Atmospheric
Testing for
Cycle Period 1

TEMPERATURE – CYCLE PERIOD 1	
Step	Action
1	Confirm that the draft-free room or chamber is conditioned correctly to the first cycle period temperature prior to testing.
2	Place the packaged-product in the environment on a pallet or open platform to permit the conditioning temperature to circulate completely around all surfaces of the packaged-product during testing. Make sure there is a minimum of a 6 in (150 mm) clearance for all packaged-product surfaces from any interior floor, wall or other package.
3	Following completion of the cycle period, remove the packaged-product from the environment.
4	Adjust the temperatures to the next specific interval manually or using a pre-programmed controller to the next cycle period of specific heat and cold cyclic/soak or ramp.
5	Go to TEST BLOCK 3 (Atmospheric Testing - Cycle Period 2).

TEST BLOCK 3
Atmospheric
Testing for
Cycle Period 2

TEMPERATURE – CYCLE PERIOD 2	
Step	Action
1	Confirm that the draft-free room or chamber is conditioned correctly to the second cycle period temperature prior to testing.
2	Place the packaged-product in the environment on a pallet or open platform to permit the conditioning temperature to circulate completely around all surfaces of the packaged-product during testing. Make sure there is a minimum of a 6 in (150 mm) clearance for all packaged-product surfaces from any interior floor, wall or other package.
3	Following completion of the cycle period, remove the packaged-product from the environment.
4	Adjust the temperatures to the next specific interval manually or using a pre-programmed controller to the next cycle period of specific heat and cold cyclic/soak or ramp.
5	Go to TEST BLOCK 4 (Atmospheric Testing - Cycle Period 3).

TEST BLOCK 4
Atmospheric
Testing for
Cycle Period 3

TEMPERATURE – CYCLE PERIOD 3	
Step	Action
1	Confirm that the draft-free room or chamber is conditioned correctly to the third cycle period temperature prior to testing.
2	Place the packaged-product in the environment on a pallet or open platform to permit the conditioning temperature to circulate completely around all surfaces of the packaged-product during testing. Make sure there is a minimum of a 6 in (150 mm) clearance for all packaged-product surfaces from any interior floor, wall or other package.
3	Following completion of the cycle period, remove the packaged-product from the environment.
4	Adjust the temperatures to the next specific interval manually or using a pre-programmed controller to the next cycle period of specific heat and cold cyclic/soak or ramp.
5	Go to TEST BLOCK 5 (Atmospheric Testing - Cycle Period 4).

TEST BLOCK 5
Atmospheric
Testing for
Cycle Period 4

TEMPERATURE – CYCLE PERIOD 4	
Step	Action
1	Confirm that the draft-free room or chamber is conditioned correctly to the third cycle period temperature prior to testing.
2	Place the packaged-product in the environment on a pallet or open platform to permit the conditioning temperature to circulate completely around all surfaces of the packaged-product during testing. Make sure there is a minimum of a 6 in (150 mm) clearance for all packaged-product surfaces from any interior floor, wall or other package.
3	Following completion of the cycle period, remove the packaged-product from the environment.
4	Adjust the temperatures to the next specific interval manually or using a pre-programmed controller to the next cycle period of specific heat and cold cyclic/soak or ramp.
5	Is there a cycle period remaining in the Test Profile? <ul style="list-style-type: none"> • If Yes, go to TEST BLOCK 6 (Atmospheric Testing - Additional Cycle Periods). • If No, all testing is now complete. Go to the Reporting an ISTA Test section at the end of this Procedure

TEST BLOCK 6
OPTIONAL
Temperature -
Additional

TEMPERATURE – ADDITIONAL	
Step	Action
1	Place the packaged-product back in the environment on a pallet or open platform to permit the conditioning temperature to circulate completely around all surfaces of the packaged-product during testing. Make sure there is a minimum of a 6 in (150 mm) clearance for all packaged-product surfaces from any interior floor, wall or other packaged-product.
2	Is there a cycle period remaining in the Test Profile after the completion of this current cycle period? <ul style="list-style-type: none"> • If Yes, go to next Step. • If No, go to Step 5.
3	Following the cycle period, adjust the temperatures to the next specific interval manually or using a pre-programmed controller to the next cycle period of specific heat and cold cyclic/soak or ramp.
4	Following completion of the cycle period go to Step 2.
5	Following completion of the cycle period, remove the packaged-product from the environment.
6	All testing is now complete. Go to the Reporting an ISTA Test section at the end of this Procedure

Reporting an
ISTA Test:
Completing and
Submitting
an ISTA
Test Report

ISTA Test Report Forms may be downloaded by members through the online ISTA Member Center (www.ista.org). Custom forms are also acceptable, but information on an official ISTA Report Form is considered to be the minimum required for any test report submission and consideration. Test report forms should be submitted to ISTA Headquarters by mail, fax or electronically. Test reports should be detailed enough for accurate repeatability of the test.

The packaged-product has satisfactorily passed the test if, upon examination, it meets the Product Damage Tolerance and Package Degradation Allowance determined prior to testing.

ISTA Certified Testing Laboratories:

- Should file a test report on all ISTA Test Procedures or Projects conducted.
- Shall file a test report on all ISTA Test Procedures or Projects conducted to obtain Transit Tested Package Certification or Acknowledgement.

To submit a test report form:

- Email to ista@ista.org
- Mail to address shown below
- Fax to +1 517-333-3813.

ISTA Transit Tested Program: Packaged-Product Certification

The ISTA Transit Tested Certification Mark as shown:

- is a registered certification mark **and**
- can only be printed on certified packages **and**
- can only be used by license agreement **and**
- by a Shipper member of the International Safe Transit Association.



When a Shipper member prints this certification mark on a packaged-product, with their manufacturer's license number, they are showing their customer, vendors and carriers that it has passed the requirements of ISTA preshipment testing.

To obtain initial certification of a packaged-product:

- the product manufacturer must be a Shipper member of ISTA in good-standing and with a valid License Agreement on file
- the testing laboratory must be a member of ISTA in good-standing and have a valid lab certification date
- a test report must be submitted by the laboratory to ISTA Headquarters.

In order to maintain its certified status and eligibility for identification with the Transit Tested Certification Mark, each packaged-product must be re-tested whenever a change is made in the:

- Product or
- Process or
- Package.

If corrugated packaging is used, it is recommended that the basis weights of the constituent papers/paperboards be determined after testing and documented to provide the best indicator of equivalence or change.

As a quality control procedure, packaged-products should be re-tested frequently, for example, yearly.

For additional information, refer to *Guidelines for Selecting and Using ISTA Test Procedures and Projects*.

ISTA Membership information is available at www.ista.org.

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