Agenda

• ISO 11607
• Popular Test Methods (ISO 11607 Part 1 – Annex B)
• ASTM D4332
  – Standard Practice for Conditioning Container, Packages or Packaging Components for Testing
• ASTM F2825
  – Standard Practice for Climatic Stressing of Packaging Systems for Single Parcel Delivery
• ASTM D4169
  – Standard Practice for Performance Testing of Shipping Containers and Systems
• ASTM D7386
  – Standard Practice for Performance of Packages for Single Parcel Delivery Systems
What is ISO 11607?

• Guidance document for validating terminally sterilized medical devices

• Recognized by FDA

• If you have a sterilized medical device, which must perform efficiently, safely, and effectively in the hands of the users.
ISO 11607

- Packaging for terminally sterilized medical devices

  - Part 1
    - Requirements for materials, sterile barrier systems and packaging systems

  - Part 2
    - Validation requirements for forming, sealing and assembly process
## ISO 11607 Part 1 – Annex B

<table>
<thead>
<tr>
<th>Annex B</th>
</tr>
</thead>
<tbody>
<tr>
<td>Accelerated Aging</td>
</tr>
<tr>
<td>Conditioning</td>
</tr>
<tr>
<td>Integrity</td>
</tr>
<tr>
<td>Internal Pressure</td>
</tr>
<tr>
<td>Performance Testing</td>
</tr>
<tr>
<td>Puncture</td>
</tr>
<tr>
<td>Seal Strength</td>
</tr>
<tr>
<td>Visual Inspections</td>
</tr>
</tbody>
</table>
Conditioning

• Standard Practice for Conditioning Container, Packages or Packaging Components for Testing (ASTM D4332)
ASTM D4332 – Scope

• To simulate field conditions that a package may encounter during its life/testing cycle
ASTM D4332 – Revision History

- 2014 (Released January 2015)
- 2013 (Released April 2013)
- 2001 Edition 2
- 2001 Edition 1
- 2001
- 2000
- 1999
- 1989 Edition 1
- 1989
- 1984
## ASTM D4332 – 2014

<table>
<thead>
<tr>
<th>Previous Revision</th>
<th>2013</th>
</tr>
</thead>
<tbody>
<tr>
<td>Changes</td>
<td>1. Expanded scope</td>
</tr>
<tr>
<td></td>
<td>2. Clarified the word equilibrium</td>
</tr>
<tr>
<td></td>
<td>3. Introduced another standard (ASTM F2825)</td>
</tr>
</tbody>
</table>
Scope

1.1 This practice provides for standard and special conditioning and testing atmospheres that may be used to simulate particular field conditions that a container, package, or packaging component may encounter during its life or testing cycle.

1.2 This practice describes procedures for conditioning these containers, packages, or packaging components so that they approach or reach equilibrium with the atmosphere to which they may be exposed. This standard is commonly used for conditioning when conducting transit simulation tests.

1.3 Practice D685 should be used as the relevant conditioning standard when quantification of box compression strength at standard atmosphere conditions is required.
Clarify equilibrium

7.3 Place the container, package, or packaging component within the conditioning chamber and expose it to the required conditions for an amount of time specified in the particular test procedure. If no time period is specified, a period of at least 72 h or that required to reach equilibrium is recommended.

7.3 Place the container, package, or packaging component within the conditioning chamber and expose it to the required conditions for an amount of time specified in the particular test procedure. If no time period is specified, a period of at least 72 h, or that time required to reach equilibrium (which may be shorter or longer in duration than 72 h), is recommended.
Introduced another standard

\textbf{F2825 Practice for Climatic Stressing of Packaging Systems for Single Parcel Delivery}

\textbf{Not Listed in ISO 11607}
ASTM F2825 – Scope

• To evaluate the ability of a package system to withstand a range of climatic stresses that it may be exposed to during distribution throughout the world

• Designed as conditioning prior to testing for overnight or 2-day delivery system of a single parcel package system

• Does **not** cover refrigerated, frozen food storage or cryogenic storage
ASTM F2825 – Revision History

- 2010 Edition 1 (Released January 2011)
- 2010 (Initial Release Nov 2010)
Questions?
Performance Testing

- Standard Practice for Performance Testing of Shipping Containers and Systems (ASTM D4169)
ASTM D4169 – Scope

• To evaluate the ability of shipping units to withstand the distribution environment
ASTM D4169 – Revision History

- 2014 (Released Jan 2015)
- 2009 (Released Nov 2009)
- 2008 (Released Jan 2009)
- 2005
- 2004a
- 2004
- 2001 Edition 1
- 2001
- 1999 Edition 1
- 1999
- 1998
- 1996 Edition 1
- 1996
- 1994
- 1993
- 1992A
- 1990
- 1989
- 1986
- 1986 Edition 1
# ASTM D4169 – 2014

<table>
<thead>
<tr>
<th>Previous Revision</th>
<th>2009</th>
</tr>
</thead>
</table>
| Changes           | 1. Changes to Schedule G and H  
2. Affecting distribution cycles 1, 2, 7, 8, 9, 10, and 11 |

Designation: D4169 – 09 D4169 – 14
Schedule G – Simulated Rail Switching

• To determine the ability of the shipping unit to withstand the acceleration levels and compressive forces that might occur during rail switching operations

• ASTM D5277
  – Incline impact tester

• ASTM D4003 Test Method A
  – Programmable horizontal impact
Schedule G – Simulated Rail Switching
Schedule G – Simulated Rail Switching

Special Instructions—Three impacts shall be performed. For railcars with standard draft gear, shock durations of 40 ± 10 ms shall be used, as measured on the floor of the carriage. For railcars with long–travel draft gear, shock durations of 300 ± 50 ms shall be used.

Special Instructions—Four impacts shall be performed. For railcars with standard draft gear, shock durations of 40 ± 10 ms shall be used, as measured on the floor of the carriage. For railcars with long–travel draft gear, shock durations of 300 ± 50 ms shall be used. Reference Association of American Railroads, General Information Bulletin No. 2.
14.3 Test Levels—Allow the carriage to impact a cushioned barrier in accordance with the following assurance levels:

14.3 Test Levels—Allow the carriage to impact a cushioned barrier in accordance with the following table. Assurance Level I shall be used for open-top rail car load tests. Assurance Level II shall be used for boxcar load tests for non-hazardous materials and for TOFC/COFC load tests for non-hazardous materials. There is no Assurance Level III for this Test Schedule.
Schedule G – Simulated Rail Switching

<table>
<thead>
<tr>
<th>Assurance Level</th>
<th>Number of Impacts</th>
<th>Impact Velocity (mph)</th>
<th>Impact Velocity (m/s)</th>
</tr>
</thead>
<tbody>
<tr>
<td>I</td>
<td>2</td>
<td>8</td>
<td>(3.58)</td>
</tr>
<tr>
<td></td>
<td>1</td>
<td>6</td>
<td>(2.68)</td>
</tr>
<tr>
<td>II</td>
<td>2</td>
<td>6</td>
<td>(2.68)</td>
</tr>
<tr>
<td></td>
<td>1</td>
<td>4</td>
<td>(1.79)</td>
</tr>
<tr>
<td>III</td>
<td>1</td>
<td>6</td>
<td>(2.68)</td>
</tr>
<tr>
<td></td>
<td>2</td>
<td>4</td>
<td>(1.79)</td>
</tr>
</tbody>
</table>
14.3.1 If known, container impact surfaces should be the same as occur in actual shipment. If the shipping orientation is not known, or if more than one orientation is possible, the first three impacts should be on that test specimen surface which is deemed to be most sensitive to damage. For the fourth impact, rotate the specimen 180° on the carriage.

<table>
<thead>
<tr>
<th>Assurance Level</th>
<th>Impact Number</th>
<th>Velocity</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>mph</td>
</tr>
<tr>
<td>I</td>
<td>1</td>
<td>4 (± 0.5)</td>
</tr>
<tr>
<td></td>
<td>2</td>
<td>6 (± 0.5)</td>
</tr>
<tr>
<td></td>
<td>3</td>
<td>8 (± 0.5)</td>
</tr>
<tr>
<td></td>
<td>4 (rotate 180°)</td>
<td>8 (± 0.5)</td>
</tr>
<tr>
<td>II</td>
<td>1</td>
<td>4 (± 0.5)</td>
</tr>
<tr>
<td></td>
<td>2</td>
<td>6 (± 0.5)</td>
</tr>
<tr>
<td></td>
<td>3</td>
<td>6 (± 0.5)</td>
</tr>
<tr>
<td></td>
<td>4 (rotate 180°)</td>
<td>6 (± 0.5)</td>
</tr>
</tbody>
</table>

No Assurance Level III

Cannot be used on inclined impact tester (Conbur)
ASTM D4169 – 2014 (cont.)

Schedule G – Simulated Rail Switching
Schedule G – Simulated Rail Switching

Click here to find & view the HITS video (near bottom of our webpage)
Schedule G – Simulated Rail Switching
Schedule G – Simulated Rail Switching
Schedule G – Simulated Rail Switching
Schedule G – Simulated Rail Switching
Schedule H - Environmental Hazard

• To provide for anticipated and rapid changes in ambient conditions associated with military distribution of material

• To determine the susceptibility of the total pack to the effects of cyclic exposure
### Schedule H - Environmental Hazard

<table>
<thead>
<tr>
<th>Assurance Level</th>
<th>Temperature, °F (°C)</th>
<th>Water Spray</th>
<th>Duration, h</th>
</tr>
</thead>
<tbody>
<tr>
<td>I</td>
<td>160 ± 5 (71 ± 2)</td>
<td>X</td>
<td>16</td>
</tr>
<tr>
<td></td>
<td>55 ± 5 (13 ± 2)</td>
<td>X</td>
<td>2</td>
</tr>
<tr>
<td></td>
<td>−10 ± 5 (−23 ± 2)</td>
<td>X</td>
<td>2</td>
</tr>
<tr>
<td></td>
<td>160 ± 5 (71 ± 2)</td>
<td>X</td>
<td>2</td>
</tr>
<tr>
<td></td>
<td>55 ± 5 (13 ± 2)</td>
<td>X</td>
<td>2</td>
</tr>
<tr>
<td></td>
<td>32 ± 5 (0 ± 2)</td>
<td>X</td>
<td>4</td>
</tr>
<tr>
<td></td>
<td>160 ± 5 (71 ± 2)</td>
<td>X</td>
<td>2</td>
</tr>
<tr>
<td></td>
<td>55 ± 5 (13 ± 2)</td>
<td>X</td>
<td>2</td>
</tr>
<tr>
<td></td>
<td>−65 ± 5 (−54 ± 2)</td>
<td>X</td>
<td>2</td>
</tr>
<tr>
<td></td>
<td>160 ± 5 (71 ± 2)</td>
<td>X</td>
<td>16</td>
</tr>
<tr>
<td></td>
<td>55 ± 5 (13 ± 2)</td>
<td>X</td>
<td>2</td>
</tr>
<tr>
<td></td>
<td>−65 ± 5 (−54 ± 2)</td>
<td>X</td>
<td>2</td>
</tr>
<tr>
<td></td>
<td>40 ± 5 (4 ± 2)</td>
<td>X</td>
<td>3</td>
</tr>
<tr>
<td></td>
<td>160 ± 5 (71 ± 2)</td>
<td>X</td>
<td>16</td>
</tr>
</tbody>
</table>
### ASTM D4169 – 2014 (cont.)

#### Schedule H - Environmental Hazard

<table>
<thead>
<tr>
<th>Assurance Level</th>
<th>Temperature, °F (°C)</th>
<th>Water Spray</th>
<th>Duration, h</th>
</tr>
</thead>
<tbody>
<tr>
<td>I</td>
<td>160 ± 5 (71 ± 2)</td>
<td>X</td>
<td>16</td>
</tr>
<tr>
<td></td>
<td>55 ± 5 (13 ± 2)</td>
<td>X</td>
<td>2</td>
</tr>
<tr>
<td></td>
<td>−5 ± 5 (−21 ± 2)</td>
<td>X</td>
<td>2</td>
</tr>
<tr>
<td></td>
<td>125 ± 5 (52 ± 2)</td>
<td>X</td>
<td>2</td>
</tr>
<tr>
<td></td>
<td>55 ± 5 (13 ± 2)</td>
<td>X</td>
<td>16</td>
</tr>
<tr>
<td></td>
<td>32 ± 5 (0 ± 2)</td>
<td>X</td>
<td>4</td>
</tr>
<tr>
<td></td>
<td>160 ± 5 (71 ± 2)</td>
<td>X</td>
<td>2</td>
</tr>
<tr>
<td></td>
<td>55 ± 5 (13 ± 2)</td>
<td>X</td>
<td>2</td>
</tr>
<tr>
<td></td>
<td>−65 ± 5 (−54 ± 2)</td>
<td>X</td>
<td>16</td>
</tr>
<tr>
<td></td>
<td>160 ± 5 (71 ± 2)</td>
<td>X</td>
<td>2</td>
</tr>
<tr>
<td></td>
<td>55 ± 5 (13 ± 2)</td>
<td>X</td>
<td>2</td>
</tr>
<tr>
<td></td>
<td>−65 ± 5 (−54 ± 2)</td>
<td>X</td>
<td>2</td>
</tr>
<tr>
<td></td>
<td>40 ± 5 (4 ± 2)</td>
<td></td>
<td>3</td>
</tr>
<tr>
<td></td>
<td>160 ± 5 (71 ± 2)</td>
<td></td>
<td>16</td>
</tr>
</tbody>
</table>
### Distribution Cycles

<table>
<thead>
<tr>
<th>DC</th>
<th>Distribution Cycle</th>
<th>First</th>
<th>Second</th>
<th>Third</th>
<th>Fourth</th>
<th>Fifth</th>
<th>Sixth</th>
<th>Seventh</th>
</tr>
</thead>
<tbody>
<tr>
<td>2</td>
<td>Specially defined distribution system, user specified (see Appendix X2)</td>
<td>select from Schedules A through I</td>
<td>Schedule A Handling</td>
<td>Schedule D Stacked Vibration</td>
<td>Schedule G Rail Switching</td>
<td>Schedule A Handling</td>
<td>Schedule A Handling</td>
<td>Schedule A Handling</td>
</tr>
<tr>
<td>7</td>
<td>Rail only, bulk loaded</td>
<td>Schedule A Handling</td>
<td>Schedule D Stacked Vibration</td>
<td>Schedule G Rail Switching</td>
<td>Schedule A Handling</td>
<td>Schedule A Handling</td>
<td>Schedule A Handling</td>
<td>Schedule A Handling</td>
</tr>
<tr>
<td>8</td>
<td>Rail only, unitized</td>
<td>Schedule A Handling</td>
<td>Schedule D Stacked Vibration</td>
<td>Schedule G Rail Switching</td>
<td>Schedule A Handling</td>
<td>Schedule B Warehouse Stacking</td>
<td>Schedule A Handling</td>
<td>Schedule A Handling</td>
</tr>
</tbody>
</table>
Distribution Cycles

18. Non-Commercial Government shipments per MIL-STD-2073-1
Questions?
ASTM D4169 – Revision History

- 2014 (Released January 2015)
- 2009 (Released November 2009)
- 2008
- 2005
- 2004a
- 2004
- 2001 Edition 1
- 2001
- 1999 Edition 1
- 1999

- 1998
- 1996 Edition 1
- 1996
- 1994
- 1993
- 1992A
- 1990
- 1989
- 1986
- 1986 Edition 1
ASTM D7386

- Standard Practice for Performance Testing of Packages for Single Parcel Delivery Systems
- Performance Testing

Not Listed in ISO 11607
ASTM D7386 – Scope

• To provide a uniform basis of evaluating, in a laboratory, the ability of shipping units, weighing up to but not exceeding 150 lb (68 kg), intended for the single parcel delivery system to withstand the hazards associated with the distribution environment.

• Single parcel delivery system packages
  – Not listed in the Standard for Terminology (ASTM D996)
ASTM D7386 – Revision History

• 2012
• 2008 (Initial Release)
ASTM D7386 – Test Plans

EXAMPLES

Small Packaged Product Bagged (TS-1)
12" x 10" x 4"
- 520 cu. in. < 800 cu. in. (less)
- 9 lb < 16 lbs. (pkg. wt.)
- 13 in. < 14 in. (long dim.)

Large Flat Packages (TS-2)
30" x 25" x 6"
- 6 in. <= 8 in. (shortest dim.)
- 26 in. / 6 in. = 4.33
- 4680 cu. in. > 600 cu. in.

Long Narrow Packages (TS-3)
38" x 7" x 7"
- 38 in. >= 36 in.
- 7.0 in. < (38 in. x 0.20 = 7.6 in.)

All others not meeting TS-1, TS-2, or TS-3 criteria
EXAMPLES

Small Packaged Product Bagged (TS-1)
13" X 10" X 4"

520 cu. in. < 800 cu. in. (vol.)
9 lb < 10 lbs (pkg wt.)
13 in. < 14 in. (long dim.)

Large Flat Packages (TS-2)
30" X 26" X 6"

6 in. < 8 in. (shortest dim)
26 in./6 in. = 4.33
4680 cu. in. > 800 cu. in.
ASTM D7386 – Test Plans

TS-3

sec. 9.1.3
Longest dimension \( \geq 36 \) in. & other two dimensions are 20% or less of longest dimension

NO – go to sec. 9.1.3

YES

NO

TS-4

Long Narrow Packages (TS-3)

38” x 7” x 7”

38 in. \( \geq \) 36 in.

7.0 in < (38 in. x 0.20 = 7.6 in.)

All others not meeting T-1, TS-2, or TS-3 criteria
ASTM D7386 – Test Plans

EXAMPLES

Small Packaged Product Bagged (TS-1)
15" x 10" x 4"
520 cu. in. < 800 cu. in. (less)
9 lb < 10 lbs (pkg wt.)
13 in. < 14 in. (long dim.)

Large Flat Packages (TS-2)
30" x 25" x 6"
8 in. <= 8 in. (shortest dim)
26 in/6 in. = 4.33
4660 cu. in. > 800 cu. in.

Long Narrow Packages (TS-3)
38" x 7" x 7"
38 in. >= 36 in.
7.0 in. (< 38 in. x 0.20 = 7.6 in.)

All others not meeting TS-1, TS-2, or TS-3 criteria

TS1

YES

sec 9.1.1
<800 cu. in. & < 10 lbs. & Long Dimension <= 14 in.

NO-go to sec. 9.1.2

TS-2

YES

sec. 9.1.2
Shortest Dimension <= 8 in. & Next shortest dimension at least 4X larger than shortest dimension & >800 cu. in.

NO-go to sec. 9.1.3

TS-3

YES

sec. 9.1.3
Longest dimension >= 36 in. & other two dimensions are 20% or less of longest dimension

TS4

NO-go to sec. 9.1.1

NO-go to sec. 9.1.2
ASTM D4169

VS

ASTM D7386
ASTM D4169 vs ASTM D7386

- 6 Step testing procedure to optimize protective packaging (quantitative testing)
- Need for package integrity testing (qualitative)
- Developed ASTM D4169 to bring distribution environment in the lab
- Focus on medical or pharmaceutical industry
- Similar to ISTA 3A
ASTM D4169 vs ASTM D7386

- 20 revisions total
- 18 distribution cycles (DC)
- Listed in ISO 11607

- 2 revisions total
- 4 test schedules (TS)
- Not in ISO 11607
ASTM D4169 vs ASTM D7386 (cont.)

- Broader scope to include packages and pallets
- Narrow scope – single parcel shipment packages

13

Air (intercity) and motor freight (local, single package up to 150 lb (61.8 kg). Consider using Practice D7386 for single parcel carrier shipments.
• Distribution Cycle 13
  – Manual handling
  – Vehicle stacking
  – Loose load vibration
  – Low pressure (altitude)
  – Vehicle vibration
  – Concentrated impacts
  – Manual handling

• Test Schedule (TS) 1, 2, 3, and 4
  – Drops
  – Vibration with top load
  – High altitude
  – Drops
  – Tip over (TS 2 & 3)
  – Rotational edge drop (TS 2 & 3)
  – Hazard drop (TS 2 & 3)
  – Vibration without top load
  – Drops
  – Concentrated impact
How do I choose?

- ISO 11607 Part 1 – Annex B
- Many test standards (ASTM D4169, ASTM D7386, ISTA series, etc)
- Don’t change your testing procedure if field failures are minimal to non existent
Conclusions

• ASTM D4332-14
• ASTM D4169-14
Questions?
Next Webinar: Packaging Dynamics Series

#1: Overview and Definition of Terms – Jan 2015 DONE!

#2: Defining & Quantifying the Distribution Environment Through Which All Products Must Travel – March 2015

#3: Determining the Vibration Sensitivity & Shock Fragility of Products; Test Methods, End Results, and Significant Insights – May 2015


#5: Design and Testing of the Protective Package System; How We Know When the Job Was Done Correctly– Oct 2015
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Contact Us
THANK YOU!

Please feel free to Contact Us with any questions, suggestions, or requests for testing assistance!

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Laboratory Manager
Presenter

Wil Caday
Engineering Services
Presenter