



U.S. Department of Transportation

Pipeline and Hazardous Materials Safety Administration

FEB 1 0 2016

Mr. Jay Johnson Regulatory Compliance Inmark Packaging 675 Hartman Road, Suite 100 Austell, GA 30168

Ref. No.: 15-0170

Dear Mr. Johnson:

This is in response to your August 5, 2015 email requesting clarification of the Hazardous Materials Regulations (HMR; 49 CFR Parts 171-180) concerning the testing of specification packagings. Specifically you seek confirmation of your understanding that packagings for Category A infectious substances tested with liquids can be used with a solid material.

For the purposes of testing a packaging for infectious substances, each primary receptacle must be filled with a liquid even if the package is intended to contain a solid material. In accordance with § 178.609(b) samples of each packaging must be prepared as for transport except that a liquid or solid infectious substance should be replaced by water or where conditioning at -18 °C (0 °F) is specified by water/antifreeze.

I hope this information is helpful. If you have further questions, please do not hesitate to contact this office.

Sincerely,

Duane A. Pfund

International Standards Coordinator Standards and Rulemaking Division

Duane A.

Goodall, Shante CTR (PHMSA)

Juchak 172.432

Infectious Substance

From:

Foster, Glenn (PHMSA)

Sent:

Friday, August 07, 2015 11:22 AM

To:

Dodd, Alice (PHMSA); Goodall, Shante CTR (PHMSA)

Subject:

Question about Category A infectious packaging

Attachments:

043-0125-e-ne-cd-01_2015-05-15.pdf; TC CGSB 43-125-99.pdf

Alice /Shante,

Jay Johnson replied with his missing attachment per my request below. Please use this email and the supporting documentation to create and assign a new Interp letter.

Thanks, Glenn

From: Jay Johnson [mailto:jayj@inmarkinc.com]

Sent: Friday, August 07, 2015 11:12 AM

To: Foster, Glenn (PHMSA)

Subject: RE: Question about Category A infectious packaging

Hello Glenn Here are the attachments.

Kind Regards,

Jay Johnson, DGSA | Regulatory Compliance Manager









675 Hartman Road, Suite 100 Austell GA 30168

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From: Glenn.Foster@dot.gov [mailto:Glenn.Foster@dot.gov]

Sent: Thursday, August 06, 2015 12:16 PM

To: Jay Johnson

Subject: RE: Question about Category A infectious packaging

Jay,

The scan you mentioned attaching did not come through. Can you re-send?

Thanks, Glenn

From: Jay Johnson [mailto:jayj@inmarkinc.com]
Sent: Wednesday, August 05, 2015 12:38 PM

To: Foster, Glenn (PHMSA); Stevens, Michael (PHMSA); Supko, Ben (PHMSA)

Cc: Betts, Charles (PHMSA); Frank Orvino; David Creighton; Goodall, Shante CTR (PHMSA); Dodd, Alice (PHMSA)

Subject: RE: Question about Category A infectious packaging

Hey Glenn,

Thanks for addressing this question of Canadian Approval.

I have attached a scan of the CGSB 43.125-99. I believe the section they are currently looking at is 4.2.2.1.

There is an update in the review process (also attached). The update clearly outlines the liquid/solid situation in 7.2.1.2 of the Canadian Regulations on page 17 by requiring that infectious packaging (liquid or solid) be tested with water.

"7.2.1.2 Each primary receptacle shall be filled not less than 98% of its capacity. Liquid or solid infectious substance shall be replaced by water or, where conditioning at -18°C is specified, by water/antifreeze with a minimum specific gravity of 0.95."

Best regards,

Jay

From: Glenn.Foster@dot.gov [mailto:Glenn.Foster@dot.gov]

Sent: Wednesday, August 05, 2015 12:20 PM

To: Jay Johnson; michael.stevens@dot.gov; Ben.Supko@dot.gov

Cc; charles.betts@dot.gov; Frank Orvino; David Creighton; shante.goodall.ctr@dot.gov; Alice.Dodd@dot.gov

Subject: RE: Question about Category A infectious packaging

Hello Jay,

We will have your inquiry checked in as a request for a letter of Interpretation.

Thanks, Glenn From: Jay Johnson [mailto:jayj@inmarkinc.com]
Sent: Wednesday, August 05, 2015 11:56 AM

To: Stevens, Michael (PHMSA); Supko, Ben (PHMSA); Foster, Glenn (PHMSA)

Cc: Betts, Charles (PHMSA); Frank Orvino; David Creighton **Subject:** Question about Category A infectious packaging

Good Morning,

I have a quick question about UN specification packaging. We have an infectious packaging system (STP-100) that has been UN certified in Canada for 30 plus years.

The packaging system relies on a secondary pressure canister and has been tested with a wide variety of primaries. The system successfully passed all of the test requirements with liquid inside the primaries without failure. We have been asked by a DOT Inspector in TX if our packaging system can be used to ship solid media cultures since it was tested with liquids instead of solid cultures.

I sent he following question to Transport Canada about our Division 6.2 packaging system certified in Canada:

We have been asked by a DOT inspector if the packaging system can be used to ship solid media cultures since it was tested with liquids instead of solid cultures.

The stringent requirements for Category A infectious substance packaging do not differentiate between liquid and solid on the UN specification marking for 4G so the question to you would be:

Can shippers use all the different primaries that were tested in the system with the volume limitations indicated in the packaging instructions but fill the vials with solid/semi-solid culture media instead of liquid?

Here is the response from Transport Canada:

From: Bernier, France [mailto:france.bernier@tc.gc.ca]

Sent: Wednesday, August 05, 2015 9:02 AM

To: Jay Johnson **Cc:** Garneau, Stéphane

Subject: RE: Question about Category A infectious packaging

Good morning Mr. Johnson,

Yes, it is possible. There is no prohibition in the CGSB-43.125-99 standard against using a packaging tested for liquids to transport solids.

Regards,

France Bernier

Dangerous Goods Container Specialist / Spécialiste de contenants pour les marchandises dangereuses

Ph/Tél: (613) 998-0798 france.bernier@tc.gc.ca

Transport Canada, Transport Dangerous Goods | Transports Canada, Transport des marchandises dangereuses Place de Ville tower "C" 9th floor / tour "C" 9ième étage 330 Sparks Street | 330 rue Sparks, Ottawa ON K1A 0N5



Transport Canada Transports Canada

Does this answer from Canada satisfy the question from the DOT Inspector in TX about how our infectious packaging was tested and approved in Canada for use with solids while tested with a liquid?

Do any of the US regulations contradict this answer or require us to do anything different when using this Canadian Approved UN specification packaging in the United States?

Kind Regards,

Jay Johnson, DGSA | Regulatory Compliance Manager









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CANADIAN GENERAL STANDARDS BOARD

PACKAGING OF INFECTIOUS SUBSTANCES, DIAGNOSTIC SPECIMENS, BIOLOGICAL PRODUCTS AND BIOMEDICAL WASTE FOR TRANSPORT

1. SCOPE

- 1.1 This standard contains requirements for the design, manufacturing and marking for three types of means of containment used for the transportation of Class 6.2 dangerous goods (infectious substances), diagnostic specimens, biological products and biomedical waste.
 - Type 1A (high integrity)
 - Type 1B (routine)
 - Type 1C (waste).
- 1.2 This standard includes the performance-based design criteria and marking requirements from Chapter 6.3 of the UN Recommendations on the Transport of Dangerous Goods, Model Regulations.
- 1.3 This standard does not inform shippers as to which of these packaging types must be used for their particular shipment. The IATA Dangerous Goods Regulations (for international or domestic air transport) or the TDG Regulations (for domestic transport, all modes) must be consulted to determine which packaging type (1A, 1B, 1C) is required.
- 1.4 The testing and evaluation of a product against this standard may require the use of materials and/or equipment that could be hazardous. This document does not purport to address all the safety aspects associated with its use. Anyone using this standard has the responsibility to consult the appropriate authorities and to establish appropriate health and safety practices in conjunction with any applicable regulatory requirements prior to its use.

2. REFERENCED PUBLICATIONS

- 2.1 The following publications are referenced in this standard:
- 2.1.1 Canadian General Standards Board (CGSB)

CAN/CGSB-43.150-97 — Performance Packagings for Transportation of Dangerous Goods.

2.1.2 Canadian Standards Association (CSA)

CAN/CSA-ISO 9003-94 — Quality Systems — Model for Quality Assurance in Final Inspection and Test CSA Z316.6-95 — Evaluation of Single Use Medical Sharps Containers for Biohazardous and Cytotoxic Waste.

2.1.3 Department of Transport (Transport Canada)

Transportation of Dangerous Goods Act, 1992 (including amendments)

Transportation of Dangerous Goods Regulations (including amendments).

2.1.4 Railway Association of Canada (RAC)

RAC 6000-A - Railway Packaging Standards.

2.1.5 American Society for Testing and Materials (ASTM)

D 951-94 — Standard Test Method for Water Resistance of Shipping Containers by Spray Method

D 1709-97 — Standard Test Methods for Impact Resistance of Plastic Film by the Free-Falling Dart Method

L 1922-94a — Standard Test Method for Propagation Tear Resistance of Plastic Film and Thin Sheeting by Pendulum Method

D 4991-94 — Standard Test Method for Leakage Testing of Empty Rigid Containers by Vacuum Method

D 5276-94 — Standard Test Method for Drop Test of Loaded Containers by Free Fall.

2.1.6 International Air Transport Association (IATA)

Dangerous Goods Regulations (39th edition).

2.1.7 Technical Association of Pulp and Paper Industry (TAPPI)

T802 OM-91 — Drop Test for Fibreboard Shipping Containers

T810 OM-92 — Bursting Strength of Corrugated and Solid Fiberboard

T811 OM-95 — Edgewise Compressive Strength of Corrugated Fiberboard (Short Column Test).

2.1.8 United Nations (UN)

Recommendations on the Transport of Dangerous Goods, Model Regulations (tenth revised edition).

2.1.9 United States Department of Defense

MIL-D-6055C-1970 — Drums, Metal, Reusable Shipping and Storage (Capacity from 88 to 510 Cubic Inches).

2.2 The sources of these publications are shown in the Notes section.

3. DEFINITIONS

The following definitions apply in this standard. Where there is a conflict between the definition in this standard and that of the *TDG Regulations*, the definition in the *TDG Regulations* shall apply.

Biological Product (Produit biologique)

A product derived from living organisms that is used to prevent, treat or diagnose disease in humans or animals or that is used for developmental, experimental or investigational purposes.

Biomedical Waste (Déchets biomédicaux)

Medical waste that is derived from animals or humans or from bio-research:

Combination Packaging (Emballage combiné)

A packaging consisting of one or more inner packagings contained in an outer packaging for transport.

Diagnostic Specimen (Échantillon de diagnostic)

Any human or animal material including excreta, secreta, blood and its components, tissue and tissue fluids that is being offered for transport.

Director (Directeur)

Director, Regulatory Affairs Branch, Transport Dangerous Goods Directorate, Transport Canada.

Infectious Substances (Matières infectieuses)

Substances known or reasonably expected to contain pathogens that are micro-organisms that are known or reasonably expected to cause disease in humans or animals as defined by the TDG Regulations.

Inner Packaging (Emballage intérieur)

A packaging for which an outer packaging is required for transport.

Medical Professional (Professionnel de la santé)

A doctor, scientist, veterinarian, epidemiologist, genetic engineer, microbiologist, pathologist, nurse, coroner, laboratory technologist or laboratory technician.

Outer Packaging (Emballage extérieur)

The outer protection of a combination packaging (excluding an overpack) together with any absorbent materials, cushioning and any other components necessary to contain and protect primary receptacles or inner packagings.

Package (Colis)

The complete product of the packing operation, consisting of the packaging and its contents prepared for transport.

Packaging (Emballage)

A receptacle and any other components or materials necessary for the receptacle to perform its containment function.

Package Design Type (Modèle type d'emballage)

Packaging of the same design size, materials and thickness, manner of construction (including the inner and outer packagings) and packing.

Primary Receptacle (Récipient primaire)

A receptacle in contact with the substances or articles to be shipped.

Risk Group (Groupes de risques)

A group into which infectious substances are assigned in accordance with the TDG Regulations based on their ability to cause disease, their ability to spread that disease and the severity of that disease.

Secondary Inner Packaging (Emballage intérieur secondaire)

An inner packaging that provides additional protection for the primary receptacle(s) and the absorbent material.

4. REQUIREMENTS FOR TYPE 1A

4.1 **Description** — Type 1A is used where a high integrity package is required. Type 1A is based on the design and marking requirements of Chapter 6.3 and Packing Instruction 620 of the *UN Recommendations on the Transport of Dangerous Goods, Model Regulations* and Packing Instruction 602 of the *IATA Dangerous Goods Regulations*.

4.2 Components

- 4.2.1 The package shall include:
 - a. An inner packaging comprising:
 - i. watertight primary receptacle(s)
 - ii. watertight secondary packaging
 - iii. absorbent material in sufficient quantity to absorb the entire contents of the primary receptacle(s), which is placed between the primary receptacle(s) and the secondary packaging. If multiple primary receptacles are placed in a single secondary packaging, they shall be individually wrapped or separated to prevent contact between them. The manufacturer shall notify the purchaser (user of the container) of this requirement and, where the manufacturer provides the absorbent, of its adsorption properties; and
 - an outer packaging of adequate strength for its capacity, mass and intended use of which the smallest external dimension is at least 100 mm.
- 4.2.2 Other than for exceptional consignments (e.g. whole organs that require special packaging), substances shall be packed in accordance with the following.

4.2.2.1 Liquid or Solid Substances

Substances Consigned at Ambient Temperature or Higher — The primary receptacles shall be made of glass, metal or plastics. A positive means of ensuring a leakproof seal shall be provided.

Substances Consigned Refrigerated or Frozen — Ice or dry ice shall be placed outside the secondary packaging(s). Interior supports shall be provided to secure secondary packaging(s) in position after the ice or dry ice has dissipated. If ice is used, the outer packaging shall be leakproof. If dry ice is used, the outer packaging shall permit the release of carbon dioxide gas. The primary receptacle and the secondary packaging shall maintain their integrity at the temperature of the refrigerant used.

Substances Consigned in Liquid Nitrogen — Plastic primary receptacles shall be capable of withstanding very low temperatures. The secondary packaging shall also be capable of withstanding very low temperatures. Provisions for

CAN/CGSB-43.125-99

- the consignment of liquid nitrogen shall also be fulfilled. The primary receptacle and the secondary packaging shall maintain their integrity at the temperature of the liquid nitrogen.
- 4.3 **Temperature Resistance** Whatever the intended temperature of the consignment, the primary receptacle or the secondary packaging shall be capable of withstanding temperatures in the range of -40 to +55°C¹.
- 4.4 Internal Pressure The primary receptacle or the secondary packaging shall withstand an internal air pressure or pressure differential of not less than 95 kPa without leakage when tested in accordance with ASTM D 4991-94 for rigid packaging or in accordance with par. 7.1.

4.5 Drop and Impact Resistance

4.5.1 Packages shall be subjected to the tests in Table 1, which for test purposes categorizes packagings according to their material characteristics. For outer packagings, the headings in the table relate to fibreboard or similar materials whose performance may be rapidly affected by moisture; plastics that may embrittle at low temperatures; and other materials (such as metal) whose performance is not affected by moisture or temperature. If a primary receptacle and a secondary packaging of an inner packaging are made of different materials, the material of the primary receptacle determines the appropriate test. When a primary receptacle is made of two materials, the material most liable to damage determines the appropriate test.

TABLE 1

Drop and Impact Tests for Type 1A Packages

Drop and impact resis for Type IA rackages										
Component of Combination Packaging					Requirements ¹					
i			i	Inner Packaging Drop Tests			Impact Test (par. 7.3)			
Fibre- board	Plastic	Other	Plastic	Other	(par. 7.2.2)	(par. 7.2.3)	(par. 7.2.4)	(par. 7.2.5)		
X			X		X	X	X	to be	X	
Χ.				X	X	X		conducted when dry	X	
Name Al-Ope	X		X		X		X	ice is used	X	
	X			X	X		X		X	
		X	X		X		X		X	
***************************************		X		X	X	*****	-		X	

Note:

- 4.5.2 Drop Resistance There shall be no leakage from the primary receptacle(s) which shall remain protected by absorbent material in the secondary packaging after conducting the appropriate drop sequence in accordance with par. 7.2.2.
- 4.5.3 Impact Resistance Following each impact of the steel rod, penetration of the secondary packaging is acceptable provided that there is no leakage from the primary receptacle(s) after conducting the test in accordance with par. 7.3.

4.6 Quality Assurance

- 4.6.1 The requirements of this paragraph apply to all packages manufactured after December 31, 1993.
- 4.6.2 A Package Design Report shall be completed in the form prescribed in Appendix A for each package design type meeting the requirements for a Type 1A packaging.
- 4.6.3 Every manufacturer of a Type 1A package meeting this standard shall ensure that the details of the design specified in the Package Design Report are maintained during production by having and maintaining a quality assurance

Prior to conducting the drop tests and impact test, packages shall be prepared in accordance with par. 7.2.1.

¹ It is not required to perform the tests at these temperatures.

system for each facility manufacturing the packages. The quality assurance system shall meet the requirements of CAN/CSA-ISO 9003-94.

4.7 Department of Transport (Transport Canada) Certificate of Registration

- 4.7.1 A Certificate of Registration shall be issued by the Director or a person designated by the Director, to manufacturers of packages meeting the design and production requirements for Type 1A packages. The Director may issue a provisional Certificate of Registration. Conformance with the requirements of this standard shall be assessed by Transport Canada or a competent facility designated by the Director. Requests for registration of designs shall be sent to the Director, Regulatory Affairs Branch (ASDD), Department of Transport, Ottawa, Ontario K1A 0N5.
- 4.7.2 Production of packages, other than test samples, shall not begin until the manufacturer has been issued a Certificate of Registration for the design by Transport Canada.
- 4.7.3 Production of packages shall not continue more than three years past the date of issue of the Certificate of Registration for the design unless a renewal of the certificate has been issued by the Department of Transport.
- 4.7.4 If an application for the renewal of the Certificate of Registration has been filed at least 60 days prior to its expiration, the production of packages may continue until notification is received from the Department of Transport relating to the renewal. Packages produced up to the receipt of the notice may be used up.

4.8 Variations within a Design Type

- 4.8.1 Provided that an equivalent level of performance is maintained, the following variations in the primary receptacles placed within a secondary packaging are allowed without further testing of the completed package:
 - a. Primary receptacles of equivalent or smaller size as compared to the tested primary receptacles may be used provided:
 - the primary receptacles are of similar design to the tested primary receptacle (e.g. shape: round, rectangular, etc.);
 - ii. the material of construction of the primary receptacle (glass, plastics, metal, etc.) offers resistance to impact and stacking forces equal to, or greater than, that of the originally tested primary receptacle;
 - iii. the primary receptacles have the same or smaller openings and the closure is of similar design (e.g. screw cap, friction lid, etc.);
 - iv. sufficient additional cushioning material is used to take up void spaces and to prevent significant movement of the primary receptacles; and
 - v. primary receptacles are oriented within the secondary packaging in the same manner as in the tested package.
 - b. A lesser number of the tested primary receptacles, or of the alternative types of primary receptacles identified in par. 4.8.1 a., may be used provided sufficient cushioning is added to fill the void space(s) and to prevent significant movement of the primary receptacles.
- 4.8.2 Inner receptacles of any type may be assembled within a secondary packaging and transported without testing in the outer packaging under the following conditions:
 - a. The secondary and outer packaging combination shall have been successfully tested in accordance with par. 7.3 with fragile (e.g. glass) inner receptacles;
 - b. The total combined gross mass of inner receptacles shall not exceed one half the gross mass of inner receptacles used for the test mentioned in par. 4.8.2 a.;
 - c. The thickness of cushioning between inner receptacles and between inner receptacles and the outside of the secondary packaging shall not be reduced below the corresponding thicknesses in the originally tested packaging; and if a single inner receptacle was used in the original test, the thickness of cushioning between inner receptacles shall not be less than the thickness of cushioning between the outside of the secondary packaging and the inner receptacle in the original test. When either fewer or smaller inner receptacles are used (as compared to the inner receptacles used in the drop test), sufficient additional cushioning material shall be used to take up the void;

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- d. The empty outer packaging shall have successfully passed the stacking test in par. 9.6 of CAN/CGSB-43.150-97. The total mass of identical packages shall be based on the combined mass of inner receptacles used in the test mentioned in par. 4.8.2 a.;
- e. For inner receptacles containing liquids, an adequate quantity of absorbent material to absorb the entire liquid content of the inner receptacles shall be present;
- f. If the outer packaging is intended to contain inner receptacles for liquids and is not leakproof, or is intended to contain inner receptacles for solids and is not siftproof, a means of containing any liquid or solid contents in the event of leakage shall be provided in the form of a leakproof liner, plastic bag or other equally effective means of containment.

4.9 Marking

- 4.9.1 The outer surface of a package that meets the requirements of par. 4.1 to 4.8 shall be marked with:
 - a. the United Nations packaging symbol;
 - b. the code designating the type of package in accordance with the provisions of section 8 of CAN/CGSB-43.150-97;
 - c. the text "CLASS 6.2":
 - d. the last two digits of the year of manufacture of the package;
 - e. the state authorizing the allocation of the mark (e.g. "CAN" for packages manufactured in Canada);
 - f. the name or symbol of the manufacturer and the Transport Canada Design Registration Number;
 - g. for packages meeting the requirements of par. 4.8.2, the letter "U" shall be inserted immediately following the marking required in par. 4.9.1 b.

Examples of marking:



4G/CLASS 6.2/98 (as in par. 4.9.1 a., b., c. and d.) CAN/ABC 8-999 (as in par. 4.9.1 e. and f.)

4.9.2 Symbols used shall be registered with the Department of Transport, Transport of Dangerous Goods, Ottawa, Ontario K1A 0N5.

5. REQUIREMENTS FOR TYPE 1B

5:1 Description — Type 1B is suitable for routine shipments (e.g. diagnostic specimens) and is based on Packing Instruction 650 of the IATA Dangerous Goods Regulations.

5.2 Components

- 5.2.1 The package shall consist of the following components:
 - a. watertight primary receptacle(s);
 - b. watertight secondary packaging;
 - c. absorbent material between the primary receptacle(s) and the secondary packaging. Several primary receptacles may be inside a single secondary inner packaging if each is wrapped individually or separated to prevent contact between them. Enough absorbent material, such as cotton wool, shall be used to absorb the entire contents of the primary receptacles; and
 - d. strong outer packaging.

CD-01

Draft Date: *2015-05-15*CAN/CGSB-43.125-20XX

Supersedes CAN/CGSB-43.125-2003 CGSB Committee 43/27.8

Packaging of Category A and Category B infectious substances (Class 6.2) and clinical and (bio) medical waste

ICS 13.300

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Introduction

This is the fourth edition of CAN/CGSB-43.125, Packaging of Category A and Category B infectious substances (Class 6.2) and clinical and (bio) medical waste. It supersedes the previous edition published in 2003 Design and Manufacture of Packaging for the Transportation of Infectious Substances, Diagnostic Specimens, Biological Products or (Bio) Medical Waste that has never been adopted in the Transportation of Dangerous Goods (TDG) Regulations.

This standard is intended for incorporation by reference into the TDG Regulations. Where there are differences between the requirements of the TDG Regulations and this standard, the TDG Regulations prevail, unless specified otherwise, to the extent of the difference. Until the Regulations are amended to adopt this edition of the standard, an earlier edition may be the one legally in effect in Canada.

This standard sets out requirements for designing, manufacturing, marking, testing and using means of containment for the transportation of Category A and Category B infectious substances in Class 6.2 and clinical and (bio) medical waste. It is based on the *Recommendations on the Transport of Dangerous Goods, Model Regulations*, 18th edition, published by the United Nations (UN).

FORPUBLICAEWIEWORNEY

Packaging of Category A and Category B infectious substances (Class 6.2) and clinical and (bio) medical waste

1 Scope

1.1 Organization and content

This standard sets out requirements for designing, manufacturing, marking, testing and using means of containment for the transportation of Category A and Category B infectious substances in Class 6.2 and clinical and (bio) medical waste. This standard consists of three parts and one annex.

Part I contains the requirements for the design, test and manufacture of means of containment for infectious substances of category A and category B.

Part II contains the requirements for the selection and use of means of containment for infectious substances of Category A and Category B.

Part III contains the requirements for the selection and use of standardized and non-standardized means of containment for the transport of Category A and Category B infectious substances intended for disposal as well as (bio) medical and clinical waste.

Annex A contains a design report for type P620 packagings.

1.2 Application

This standard applies to both standardized and non-standardized means of containment as defined in the TDG Regulations.

1.3 Minimum requirements

This standard sets out certain minimum requirements for designing, manufacturing, selecting, using, and testing of means of containment. It is essential to exercise competent technical and engineering judgment in conjunction with this standard.

1.4 Transportation of Dangerous Goods Act and Regulations prevalence

The TDG Act, 1992, and the TDG Regulations may call for additional requirements regarding the design, manufacture, selection, use, and test of means of containment. Where there is an inconsistency between the requirements of this standard and those of the TDG Act or TDG Regulations, the Act or Regulations prevail to the extent of the inconsistency.

1.5 Safety - The testing and evaluation of a product against this standard may require the use of materials and/or equipment that could be hazardous. This document does not purport to address all the safety aspects associated with its use. Anyone using this standard has the responsibility to consult the

CAN/CGSB-43.125-20XX CD-01

appropriate authorities and to establish appropriate health and safety practices in conjunction with any requirements prior to its use.

1.6 Units

Quantities and dimensions used in this standard are given in metric units.

1.7 Interpretation of Tables and Figures

Notes to tables and figures are considered part of the table or figure and may be written as requirements.

1.8 Classification

Dangerous goods are classified in accordance with Part 2 of the TDG Regulations and the appropriate shipping names and corresponding particulars (UN number and description) classification, division, and packing group, as applicable) selected from Schedule 1 of the TDG Regulations.

2 Normative references

The following normative documents contain provisions that, through reference in this text, constitute provisions of this National Standard of Canada. The referenced documents may be obtained from the sources noted below.

NOTE The addresses provided below were valid at the date of publication of this standard.

An undated reference is to the latest edition or revision of the reference or document in question, unless otherwise specified by the authority applying this method. A dated reference is to the specified revision or edition of the reference or document in question.

2.1 Canadian General Standards Board (CGSB)

CGSB 43.146-2016 — Design, manufacture and use of intermediate bulk containers and fuel tanks contained in equipment for the transportation of dangerous goods

2.1.1 Source

The above may be obtained from the Canadian General Standards Board, Sales Centre, Gatineau, Canada K1A 1G6. Telephone 819-956-0425 or 1-800-665-2472. Fax 819-956-5740. E-mail ncr.cgsbongc@tpsgc-pwgsc.gc.ca. Web site www.tpsgc-pwgsc.gc.ca/ongc-cgsb.

2.2 Canadian Standards Association (CSA)

CSA Z316.6-95 — Evaluation of single use medical sharps containers for biohazardous and cytotoxic waste.

2.2.1 Source

The above may be obtained from CSA Group, Standards Sales, 178 Rexdale Blvd., Toronto, Ontario M9W 1R3 Canada. Telephone 416-747-4000 or 1-800-463-6727. Fax 416-747-2473. E-mail sales@csagroup.org. Web site csagroup.org.

2.3 Transport Canada

Transportation of Dangerous Goods Act, 1992 (including amendments)

Transportation of Dangerous Goods Regulations (including amendments)

TP 14850 – Small Containers for Transport of Dangerous Goods, classes 3, 4, 5, 6, 1, 8, and 9, a Transport Canada Standard.

2.3.1 Source

The above may be obtained from the Publications page of the Transport Canada Web site tc.gc.ca/eng/publications-menu.htm. The Transport Canada publication TP 14850 may be ordered from the Transport Canada Publications Order Desk at tc.gc.ca/eng/publications-order-605.html.

2.4 ASTM International

D951-99(2010) – Standard test method for water resistance of shipping containers by spray method

D1709-15 – Standard test methods for impact resistance of plastic film by the free-falling dart method

D1922-09 – Standard test method for propagation test resistance of plastic film and thin sheeting by pendulum method

D4332-14 — Standard Practice for Conditioning Containers, Packages, or Packaging Components for Testing

D4991-07 – Standard test method for leakage testing of empty rigid containers by vacuum method

D5276- 98(2009) Standard test method for drop test of loaded containers by free fall.

2.4.1 Source

The above may be obtained from ASTM International, 100 Barr Harbor Drive, West Conshohocken, PA 19428-2959, U.S.A., Web site www.astm.org, or from IHS Global Canada Ltd., 200-1331 MacLeod Trail SE, Calgary, Alberta T2G 0K3, telephone 613-237-4250 or 1-800-267-8220, fax 613-237-4251, Web site www.global.ihs.com.

2.5 Technical Association of the Pulp and Paper Industry (TAPPI)

T802 OM-12 – Drop test for fiberboard shipping containers

T810 OM-11 – Bursting strength of corrugated and solid fiberboard

T811 OM-11 – Edgewise compressive strength of corrugated fiberboard (short column test)

T839 OM-12 – Edgewise compressive strength of corrugated fiberboard using the clamp method (short column test).

2.5.1 Source

The above may be obtained from Technical Association of the Pulp and Paper Industry, TAPPI Inc., P.O. Box 933644, Atlanta, GA 31193-3644, U.S.A., telephone 1-800-446-9431 (Canada), 1-800-332-8686 (U.S.A.), 770-446-1400 (Worldwide), fax 770-209-7206, e-mail memberconnection@tappi.org, Web site www.tappi.org/.

2.6 United Nations (UN)

Recommendations on the Transport of Dangerous Goods, Model Regulations (18th revised edition).

2.6.1 Source

The above may be obtained from distributors of United Nations Publications or from the United Nations Publications Customer Service, PO Box 960, Herndon, VA 20172, U.S.A. Telephone 1-703-661-1571. Fax 1-703-996-1010. E-mail order@un.org. Web site http://www.unece.org/trans/danger/publi/unrec/rev18/18files e.html.

3 Terms and Definitions

For the purposes of this National Standard of Canada, the following terms and definitions apply. Where there is a conflict between a term or definition in this standard and that of the TDG Regulations, the definition in the TDG Regulations shall apply.

3.1

(Bio) medical or clinical wastes

waste derived from animals or humans or from bio-research.

[SOURCE: CGSB-43.125-99]

3 2

category A

infectious substance that is transported in a form such that, when it is released outside of its means of containment and there is physical contact with humans or animals, it is capable of causing permanent disability or life-threatening or fatal disease to humans or animals.

[SOURCE: Transportation of Dangerous Goods Regulations (including amendments)]3.3 category B

infectious substance that does not meet the criteria for inclusion in Category A.

[SOURCE:Transportation of Dangerous Goods Regulations (including amendments)]

3.4

culture

result of a process by which pathogens in a specimen are intentionally propagated. This definition does not include specimens taken from a human or animal patient and that are intended to be processed in a laboratory.

[SOURCE:Transportation of Dangerous Goods Regulations (including amendments)]

3.5

combination packaging

packaging consisting of one or more inner packagings contained in an outer packaging for transport.

[SOURCE: CGSB-43.125-99]3.6

director

director, Regulatory Affairs Branch, Transport Dangerous Goods Directorate, Transport Canada.

[SOURCE: CGSB-43.125-99]

3.7

infectious substances

substance known or reasonably believed to contain viable micro-organisms such as bacteria, viruses, rickettsia, parasites, fungi and other agents such as prions that are known or reasonably believed to cause disease in humans or animals

[SOURCE:Transportation of Dangerous Goods Regulations (including amendments)]

3.8

inner packaging

packaging for which an outer packaging is required for transport.

[SOURCE: CGSB-43.125-99]

3.9

large packaging

packaging consisting of an outer packaging which contains articles or inner packagings and which:

- a) is designed for mechanical handling; and
- b) exceeds 400 kg net mass or 450 litres capacity but has a volume of not more than 3 m³.

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[SOURCE: Recommendations on the Transport of Dangerous Goods, Model Regulations (18th revised edition)]

3.10

leakproof

impermeable to liquid contents or to solids that may become liquids under normal condition of transport.

[SOURCE: N/A]

3.11

outer packaging

outer protection of a combination packaging (excluding an overpack) together with any absorbent materials, cushioning and any other components necessary to contain and protect primary receptacles or inner packagings.

[SOURCE: CGSB-43.125-99]

3.12

packaging

receptacle and any other components or materials necessary for the receptacle to perform its containment function.

[SOURCE: CGSB-43.125-99]

3.13

package design type

design specification for the prototype packaging successfully tested in accordance with this standard and as described in Annex A - Design report for type P620 packagings

[SOURCE: N/A]

3.14

primary receptacle

receptacle in direct contact with the regulated good.

[SOURCE: CGSB-43.125-99, modified – updated for clarity]

3.15

secondary inner packaging

inner packaging that provides additional protection for the primary receptacle(s) including absorbent material as required.

[SOURCE: CGSB-43.125-99]

3.16

sift-proof

impermeable to dry contents, including any fine solid material produced during transport.

[SOURCE: TP14850]

3.17

type P620 packaging

packaging intended to transport an infectious substance of Category A in a form of culture or infectious substance of Category A meeting the requirements of 2.36 (3) in the TDG Regulations

[SOURCE: N/A]

3.18

type P650 packaging

packaging intended to transport an infectious substance of Category B or an infectious substance of Category A that does not meet par. 11.1.1.

[SOURCE: N/A]

3.19

UN packaging symbol



[SOURCE: TP14850]

Part I

Design and manufacture of packagings for infectious substances of Category A and Category B

4 General requirements

4.1 Design, test and manufacture

A person shall not design, test or manufacture a packaging intended for the transportation of infectious substances of Category A or Category B unless these activities are done in accordance with Part I of this standard.

4.2 Certification safety marks

- 4.2.1 A person shall not apply a UN marking on a type P620 packaging unless:
- a) the UN markings conform to the requirements of 5.1;
- b) the packaging was designed in accordance with 4.3.1.1 and 6.1;
- c) a representative prototype of the packaging has been successfully tested in accordance with the requirements of section 7 and Table 2A;
- d) the packaging was manufactured under a quality management system in accordance with 9.1.1; and
- e) the packaging design is registered with the Director in accordance with the requirements of section 10.
- 4.2.2 A person shall not apply a marking on a type P650 packaging unless:
- a) the markings conform to the requirements of 5.2;
- b) the packaging was designed in accordance with 4.3.1.2 and 6.2;
- c) a representative prototype of the packaging has been successfully tested in accordance with the requirements of section 7 and Table 2B;
- d) the packaging was manufactured under a quality management system in accordance with 9.1.2.

4.3 Packaging Design

4.3.1 Performance

4.3.1.1 Type P620 packaging

The packaging shall conform to a registered design for which a representative prototype has been tested and found to meet the applicable performance requirements set out in section 7 and Table 2A of this standard, except for design variations permitted in section 8 or Part 2 of this standard.

4.3.1.2 Type P650 packaging

The packaging shall conform to a representative prototype that has been tested and found to meet the applicable performance requirements set out in section 7 and Table 2B of this standard, except for design variations permitted in section 8 or Part 2 of this standard.

4.3.2 Internal Pressure

4.3.2.1 Type P620 packaging

The primary receptacle or the secondary inner packaging shall be capable of withstanding without leakage a pressure differential of not less than 95 kPa in accordance with 7.5.

4.3.2.2 Type P650 packaging

For shipment by aircraft, the primary receptacle or the secondary inner packaging for liquid substances shall be capable of withstanding without leakage a pressure differential of not less than 95 kPa in accordance with 7.5.

4.3.3 Temperature resistance

Whatever the intended temperature of the consignment, the primary receptacle or the secondary inner packaging of a type P620 packaging shall be capable of withstanding temperatures in the range of -40 to +55°C.

4.3.4 Refrigerants

The primary receptacle and the secondary inner packaging of packagings intended to contain a refrigerant shall maintain their integrity at the temperature of the refrigerant used as well as at the temperatures and the pressures which could result if refrigeration were lost.

4.3.5 Net mass and maximum capacity limits

Unless otherwise specified in Table 1, the net mass shall be equal to or less than 400 kg and the maximum capacity shall be equal to or less than 450 L.

4.4 Packaging Information

- **4.4.1** When made available as a kit, the packaging manufacturer and subsequent distributor shall provide the following information to the customer in relation to each packaging design:
- a) a procedure and list of components with sufficient information to allow the user to assemble, fill and close the packaging in the same fashion as it was tested;

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- b) the maximum capacity of the tested primary receptacles; and
- c) the tare weight, maximum gross mass and maximum capacity based on the packaging and capacities used for the drop test.
- **4.4.2** The packaging manufacturer and distributor shall provide the packaging information to a packaging purchaser at each initial purchase of the corresponding packaging.
- **4.4.3** The packaging manufacturer and distributor shall provide the packaging information to a packaging user upon request.

5 Certification safety mark

5.1 Marking on a type P620 packaging

5.1.1 General

5.1.1.1 Required marking

The marking shall be durable, legible, placed in a location and of such a size as to be readily visible.

5.1.1.2 Location of marking

For packagings with a gross mass of more than 30 kg, the marking (or a duplicate thereof) shall appear on the top or side of the packaging.

5.1.1.3 Size of marking

Letters, numerals and symbols comprising the markings shall be at least 12 mm high, except that:

- a) the markings on packagings of 30 L maximum capacity or 30 kg net mass or less shall be at least 6 mm high; and
- b) the markings on packagings of 5 L maximum capacity or 5 kg net mass or less shall be at least 3 mm high.

5.1.2 Content and sequence of marking

The following markings are required and shall be displayed in the following sequence with each of the elements clearly separated from one another:

- a) the UN packaging symbol;
- b) the packaging code listed in Table 1 and, when applicable, the letter "V" or "W" assigned to the packaging code in accordance with 5.1.4;
- c) the text: "CLASS 6.2";
- the last two digits of the year of manufacture of the package;

- e) the three-letter country code "CAN.";
- the name or symbol of the manufacturer; and
- the Transport Canada Design Registration Number.

5.1.3 Examples of marking:

5.1.3.1 Solid plastic box:

4H2/CLASS6.2/15 CAN/ABC 8-9999

as in 5.1.2 a, b, c, d and e

as in 5.1.2 f and g

For a packaging with solid plastic box outer packaging, for infectious substances of Category A and manufactured in 2015. The design was registered in Canada, by the manufacturer identified as ABC under the registration number 8-9999.

5.1.3.2 Special packaging ("V" marking):

4GV/CLASS6.2/15 CAN/ABC 8-9999

For a special packaging with a fibreboard box outer packaging, for infectious substances of Category A and manufactured in 2015. The design was registered in Canada, by the manufacturer identified as ABC under the registration number 8-9999.

- 5.1.4 Letter assigned to the packaging code ("V" or "W" marking)
- **5.1.4.1** The letter "V" shall not be assigned to the packaging code unless:
- a) The rigid outer packaging has been successfully drop tested in accordance with 7.3 with fragile (e.g. glass) primary receptacles;

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- b) The total combined gross mass of primary receptacles shall not exceed one half the gross mass of primary receptacles used for the drop test in 7.3; and
- c) The rigid outer packaging has successfully passed the stacking test in accordance with 7.5 of TP14850 while empty. The stacking test load shall be based on the combined mass of the filled inner packaging(s) used for the drop test.
- **5.1.4.2** The letter "W" shall not be assigned to the packaging code unless it was assigned in accordance with 10.9.

5.2 Marking on a type P650 packaging

5.2.1 Required marking

The marking shall be durable, legible, placed in a location and of such a size as to be readily visible.

5.2.2 Location of marking

The marking shall be displayed on the external surface of the outer packaging on a background of a contrasting colour.

5.2.3 Content and size of marking

The marking shall be in the form of a square set at an angle of 45° (diamond-shaped) with each side having a length of at least 50 mm; the width of the line shall be at least 2 mm and the letters and numbers shall be at least 6 mm high.



6 Construction

6.1 Type P620 packaging

6.1.1 Components

The packaging shall consist of the following components:

- a) Inner packagings comprising:
 - i. leakproof primary receptacle(s);
 - ii. leakproof secondary packaging;
- b) a rigid outer packaging of adequate strength for its capacity, mass and intended use of which the smallest external dimension is at least 100 mm. The outer packaging shall be selected from Table 1.

Table 1— Packaging codes

Type	Material	Category	Code	Maximum capacity or		
. , , , ,	1714101141			maximum net mass		
1. Drums	A. Steel	non-removable head	1A1	450 L		
		removable head	1A2	450 L / 400 kg		
	B. Aluminum	non-removable head	181	450 L		
		removable head	1B2	450 L / 400 kg		
	D. Plywood		1D	250 L/400 kg		
10	G. Fibre		1G	400 kg		
Y	H. Plastic	non-removable head	1H1	450 L		
		removable head	1H2	450 L / 400 kg		

 $^{1 \\ \}text{ The construction requirements for these packaging codes may be found in the TP14850 standard.}$

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	N. Metal, other than steel or	non-removable head	1N1	450 L
	aluminum	removable head	1N2	450 L / 400 kg
3. Jerricans	A. Steel	non-removable head	3A1	60 L
		removable head	3A2	60 L /120 kg
	B. Aluminum	non-removable head	3B1	601
		removable head	3B2	60 L /120 kg
	H. Plastic	non-removable head	3H1	60 L
		removable head	3H2	60 L /120 kg
4. Boxes	A. Steel	0	4A	400 kg
	B. Aluminum		4B	400 kg
	C. Natural wood	ordinary	4C1	400 kg
	BY	with sift-proof walls	4C2	400 kg
	D. Plywood		4D	400 kg
0-	F. Reconstituted wood	·	4F	400 kg
/O,	G. Fibreboard		4G	400 kg
X	H. Plastic	expanded	4H1	60 kg
		solid	4H2	400 kg

6.1.2 Absorbent

Other than for solid infectious substances, an absorbent material shall be placed between the primary receptacle(s) and the secondary inner packaging and in sufficient quantity to absorb the entire content of the primary receptacle(s).

6.1.3 Primary Receptacle

Primary receptacles intended for the transportation of:

- Substances consigned at ambient temperature or at a higher temperature shall be made of glass, metal or plastic;
- b) Substances consigned in liquid nitrogen shall be made of plastic and capable of withstanding very low temperature; or
- c) Lyophilized substances may be consigned in flame-sealed glass ampoules or rubberstoppered glass vials fitted with metal seals.

6.1.4 Closures

For substances consigned at ambient or higher temperatures, positive means of ensuring a leakproof seal shall be provided, e.g. heat seal, a skirted stopper or a metal crimp seal. If screw caps are used, they shall be secured by positive means, e.g., tape, paraffin sealing tape or manufactured locking closure.

6.1.5 Multiple Primary Receptacles

If multiple fragile primary receptacles are placed in a secondary inner packaging, the primary receptacles shall be individually wrapped or otherwise separated to prevent contact between them.

6.1.6 Refrigerants

Packaging intended to contain a refrigerant such as ice, dry ice or liquid nitrogen shall conform to the following requirements:

- a) In the case of ice or dry ice, the refrigerant shall be placed
 - i. around the secondary inner packaging(s) or
 - ii...in an overpack
- b) Interior supports shall be provided to secure secondary inner packaging(s) or packages in the original position after the refrigerant has dissipated.
- c) In the case of ice, the outer packaging or overpack shall be leakproof.
- d) In the case of dry ice or liquid nitrogen, the outer packaging or overpack shall permit the release of carbon dioxide gas.

6.2 Type P650 packaging

6.2.1 Components

The packaging shall consist of the following components:

- a) Inner packagings comprising:
 - i. leakproof or siftproof primary receptacle(s);
 - ii. leakproof or siftproof secondary packaging;
- b) An outer packaging of which either the secondary or the outer packaging shall be rigid. At least one surface of the outer packaging shall have a minimum dimension of 100 mm.

6.2.2 Absorbent

Absorbent material shall be placed between the primary receptacle(s) and the secondary inner packaging. The absorbent material shall be in quantity sufficient to absorb the entire content of the primary receptacle(s) so that any release of the liquid substance will not compromise the integrity of the cushioning material or of the outer packaging. If there is any doubt as to whether or not residual liquid may be present in the primary receptacle during transport then a packaging suitable for liquids, including absorbent materials, shall be used.

6.2.3 Multiple primary receptacles

If multiple fragile primary receptacles are placed in a secondary inner packaging, the primary receptacles shall be individually wrapped or otherwise separated to prevent contact between them.

6.2.4 Refrigerants

Packaging intended to contain a refrigerant such as ice, dry ice or liquid nitrogen shall conform to the following requirements:

- a) In the case of ice, the refrigerant shall be placed
 - i. outside the secondary inner packaging(s) or
 - ii in the outer packaging or an overpack
- b) Interior supports shall be provided to secure secondary inner packaging(s) or packages in the original position after the refrigerant has dissipated.
- c) In the case of ice, the outer packaging or overpack shall be leakproof.
- d) In the case of dry ice or liquid nitrogen, the outer packaging or overpack shall permit the release of carbon dioxide gas.

7. Testing

7.1 General requirements

7.1.1 Test schedule

Packagings selected for testing shall be representative of the design intended for production. The tests required for type P620 packagings are set out in 7.2 to 7.5 and Table 2A of this standard and the tests required for type P650 packagings are set out in 7.2, 7.3, 7.5 (if applicable) and Table 2B of this standard.

7.1.2 Variations

Tests shall be repeated after each variation of the design, material or manner of construction of a packaging unless the variations are permitted in section 8. Design variations shall be documented in the design report.

7.2 Preparation for testing

7.2.1 Preparation

- **7.2.1.1** Fill and close the packagings for testing in the same manner as for transport. All closures shall be installed as specified by the closure manufacturer or container manufacturer.
- **7.2.1.2** Each primary receptacle shall be filled to not less than 98% of its capacity. Liquid or solid infectious substance shall be replaced by water or, where conditioning at -18° C is specified, by water/antifreeze with a minimum specific gravity of 0.95.



Table 2A —Test requirements — Testing required on a P620 packaging

Type of packaging ^a			Conditioning				Tests required				
			-	Special preparation							
Rigid outer packaging	Primary receptacle ^b		Ambient temperature	Water spray	Cold conditio ning	Dry ice ^c	Drop	Addition al drop ^c	Stacking ^d	Puncture	Internal pressure ^e
	Plasti c	Other	Number of samples	of	of	of	Number of samples	of 🥾	Number of samples	Number of samples	Number of samples
Fibreboard	Х		0	5	5	1	10	1	3	2	3
box		Х	0	5	0	1	5	1	3	2	3
Fibreboard	Х		0	3	3	1	6	1	3	2	3
drum		·X	0	3	0	1	3	1	3	2	3
Plastic box	Х		0	0	5	1	5	1	3	2	3
		Х	0	0	5	1	5	1	3	2	3
Plastic drum / Jerrican	Х		0	0	3	1	3	1 .	3	2	3
		Х		0	3	1	3	1	3	2	3
Box of other material Drum / Jerrican of other material	Х			0	5	1	5	1	3	. 2	3
		X	5	0	0	1	5	1	3	2	3
	Х		5	0	3	1	3	1	3	2	3
		х	5	0	0	1	3	1	3	2	3

The material of the secondary inner packagings is not taken into consideration when selecting the test or conditioning for the test.

Where a primary receptacle is made of two or more materials, the material most liable to damage determines the appropriate est.

Additional drop test required when the packaging is intended to contain dry ice (see 7.3.5.3).

Required when testing a special packaging "V" (see 11.5).

Required when testing a Type P620 packaging for solids or liquids (see 4.3.2.1).

Table 2B — Test requirements — Testing required on a P650 packaging

Type of packaging ^a		Conditioning			Tests required				
		Special preparation			1				
Rigid outer	Primary receptacle ^b		Ambient temperarute	Water	Cold conditionin g	Dry ice ^c	Drop	Additional drop ^c	Internal pressure ^d
packaging	Plastic	Other	Number of	Number of	Number of	Number of	Number of	Number of	Number of
	T lustre	Julier	samples	samples	samples	samples	samples	samples	samples
Fibreboard	Х		0	5	5	1	10	1	3
box		Х	0	5	0	1	5	1	3
Fibreboard drum	Х		0	3	3		6	1	3
		Х	0	3	0	1	3	. 1	3
Plastic box	Х		0	0	5	1	5	1	3
		Х	0	0	5	1	5	1	3
Plastic drum	Х		0	Ô	3	1	3	1	3
/ Jerrican		Х	0	0	3	1	3	1	3
Box of other	Х	<	0	0	5	1	5	1	3
material		2	5	0	0	1	5	1	3
Drum / Jerrican of			0	0	3	1	3	1	3
other (material		Х	3	0	0	1	3	1	3

The material of the secondary inner packagings is not taken into consideration when selecting the test or conditioning for the test.

Where a primary receptacle is made of two or more materials, the material most liable to damage determines the appropriate test.

Additional drop test required when the packaging is intended to contain dry ice (see 7.3.5.3).

Required when testing a Type P650 packaging for liquids (see 4.3.2.2).

7.3 Drop test

P620 and P650 packagings shall be subjected to the drop test in accordance with this section.

7.3.1 Test method

- **7.3.1.1** Perform the drop test in accordance with ASTM D5276 using the appropriate drop orientation as specified in 7.3.5 and the appropriate number of packagings in accordance with Tables 2A and 2B. Where more than one orientation is possible for a given drop test, the orientation most likely to result in failure of the container shall be used.
- **7.3.1.2** Where the packaging is intended to contain dry ice, one additional drop test (refer to Tables 2A and 2B) shall be carried out.
- **7.3.1.3** For fibreboard boxes (4G), the drop test may be conducted in accordance with TAPPI T802.
- 7.3.1.4 Except for flat drops, the centre of gravity shall be vertically over the point of impact.
- **7.3.1.5** The test containers shall be dropped on a rigid, non-resilient, flat, massive and horizontal surface.
- **7.3.1.6** The drop test shall be performed with the containers in the conditioning atmosphere, specified in 7.3.2, or within 15 min of removal from the conditioning atmosphere.

7.3.2 Conditioning

7.3.2.1 Ambient temperature conditioning

Containers requiring ambient temperature conditioning shall be conditioned in accordance with ASTM D4332.

7.3.2.2 Special preparation of test sample for the drop test

7.3.2.2.1 Fibreboard outer packagings — Water spray test

Subject the packagings to a water spray that simulates exposure to a rainfall of approximately 5 cm per hour for at least one hour in accordance with ASTM D951.

7.3.2.2.2 Primary receptacles or outer packagings made of plastic — Cold conditioning

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Subject the packaging to a temperature of -18°C or lower for a period of not less than 24 h in accordance with ASTM D4332. If the sample contains dry ice, then the conditioning period may be reduced to 4 h.

7.3.2.2.3 Packaging intended to contain dry ice

One packaging shall be stored until all the dry ice has dissipated.

7.3.3 Procedure

- 7.3.3.1 After the drop test examine each primary receptacle for evidence of leakage
- **7.3.3.2** Examine if the primary receptacle(s) remained protected by cushioning/absorbent material in the secondary inner packaging.

7.3.4 Drop Height

7.3.4.1 Type P620 packagings shall be dropped from a minimum height of 9.0 m and type P650 packagings from a minimum height of 1.2 m

7.3.5 Orientation

- **7.3.5.1** Where the samples are in the shape of a box; five shall be dropped, one in each of the following orientations:
 - box 1 flat on the bottom
 - box 2 flat on the top
 - box 3 flat on one long side
 - box 4 flat on one short side
 - box 5 diagonally on bottom corner.
- **7.3.5.2** Where the samples are in the shape of a drum; three shall be dropped one in each of the following orientations:
 - ${f box}\ {f 1}$ diagonally on the top chime, with the centre of gravity directly above the point of impact
 - box 2 diagonally on the base chime
 - box 3 flat on the side.

7.3.5.3 Sample of a packaging intended to contain dry ice

Drop one packaging in one of the orientation described in 7.3.5.1 or 7.3.5.2 which shall most likely result in failure of the packaging.

7.3.6 Criteria of a successful test

There shall be no release of the contents from the primary receptacle(s) which shall remain protected by cushioning/absorbent material in the secondary inner packaging. The secondary inner packaging shall be retained within the outer packaging. A minor exposure of the secondary inner packaging is acceptable if it is not possible to withdraw the secondary inner packaging from the outer packaging.

7.4 Puncture test

Type P620 packagings shall be subjected to the puncture test in accordance with this section.

7.4.1 Test method

7.4.1.1 Packagings with a gross mass of 7 kg or less

The packaging shall be placed on a level hard surface and the puncture device shall be dropped in a vertical free fall position and be capable of penetrating the primary receptacle(s).

7.4.1.2 Packagings with a gross mass exceeding 7 kg

The puncture device shall be set vertically in a level hard surface and the packaging shall be dropped in a vertical free fall position. The puncture device shall be capable of penetrating the primary receptacle(s).

7.4.2 Procedure

Examine the primary receptacle(s) for evidence of leakage.

7.4.3 Puncture Device

The puncture device shall be a cylindrical steel rod having a diameter of 38 mm, a mass of 8.0 ± 1.0 kg, and an impact end edge radius equal to or less than 6 mm.



Figure 1—Puncture Device (all measurements are in mm)

7.4.4 Drop height

7.4.4.1 Packaging of 7 kg or less

The puncture device shall be dropped from a height of 1 m, measured from the impact end of the device to the impact surface of the packaging.

7.4.4.2 Packaging of more than 7 kg

Packaging shall be dropped from a height of 1 m, measured from the impact surface of the packaging to the top of the puncture device.

7.4.5 Orientation

7.4.5.1 Packaging of 7 kg or less

The impact end of the puncture device shall strikes a location

- a) on the top of the first packaging; and
- b) on the side of a second packaging.

7.4.5.2 Packaging of more than 7 kg

The packaging shall be dropped on top of the puncture device so that

- a) the top face of the first packaging strikes the impact end of the puncture device; and
- b) the side of the second packaging strikes the impact end of the puncture device.
- **7.4.5.2.1** The puncture device shall protrude from the surface a distance at least equal to that between the centre of the primary receptacle(s) and the outer surface of the outer packaging with a minimum of 200 mm.

7.4.6 Criteria of a successful test

There shall be no release of the contents from the primary receptacle(s). However, penetration of the secondary inner packaging is acceptable provided that there is no leakage from the primary receptacle(s).

7.5 Internal pressure test

The primary receptacle or the secondary inner packaging of a type P620 packaging for liquids and solids and the primary receptacle or the secondary inner packaging of a type P650 packaging for liquids transported by air shall be subjected to the pressure test in accordance with this section.

7.5.1 Test method

- **7.5.1.1** Install an appropriate fitting into three containers in such manner that the performance of the container is not affected.
- 7.5.1.2 For rigid packagings, the pressure test shall be conducted in accordance with ASTM D4991.

7.5.2 Pressure gauge

The pressure shall be measured by using a gauge or other device of suitable range and accuracy.

NOTE Various means of pressure measurement calibration may be used as long as a procedure is established for ensuring that instruments are maintained and calibrated, and they operate within suitable parameters. A record shall be kept identifying the instrument, the method of calibration, its calibration frequency, and the date of its last calibration.

7.5.3 Procedure

7.5.3.1 Restrain the containers, including their closures, under the surface of water for a period of 10 min while an internal air pressure of not less than 95 kPa is applied. The restraints shall not affect the results of the test.

7.5.3.2 Examine all surfaces and seams of the containers for leakage as evidenced by the formation of bubbles while the container is under water and under constant air pressure.

7.5.3.3 Other methods, at least equally effective, may be used if written procedures properly describe the test method and there is suitable data to validate the test method. Such methods include gas leak detection (e.g. helium testers), pressure differential test or soap solution applied on the surface of the entire container. The appropriate test method shall be selected based on container type.

7.5.4 Criteria for a successful test

Tested containers shall not leak.

8 Permitted design variations

8.1 Design variation requiring no testing

Provided that an equivalent level of performance is maintained, the following variations of inner packagings within a secondary inner packaging are allowed without further testing.

8.1.1 Primary receptacles of equivalent or smaller size

Primary receptacles of equivalent or smaller size as compared to the tested primary receptacles may be used provided:

- a) the primary receptacles are of similar design to the tested primary receptacle (e.g. shape: round, rectangular, etc.);
- b) the material of construction of the primary receptacle (glass, plastic, metal, etc.) offers resistance to impact and stacking forces equal to, or greater than, that of the originally tested primary receptacle;
- the primary receptacles have the same or smaller openings and the closure is of similar design (e.g. screw cap, friction lid, etc.);
- d)sufficient additional cushioning material is used to take up void spaces and to prevent significant movement of the primary receptacles; and
- e) primary receptacles are oriented within the secondary inner packaging in the same manner as in the tested package.

8.1.2 Quantity of primary receptacles

A lesser number of the tested primary receptacles, or of the alternative types of primary receptacles identified in 8.1 a., may be used provided sufficient cushioning is added to fill the void space(s) and to prevent significant movement of the primary receptacles.

9. Quality management system

9.1 General

9.1.1 Type P620 packaging

Packagings shall be manufactured under a quality management system capable of ensuring that the packagings are in accordance with the tested and registered design specified in the design report, the requirements of this standard and the TDG Regulations.

9.1.2 Type P650 packaging

Packagings shall be manufactured under a quality management system capable of ensuring that the packagings are in accordance with the tested design specified in the design report, the requirements of this standard and the TDG Regulations.

10. Registration

10.1 General

This section applies to type P620 packagings only. Type P650 packagings are not required to be registered with the Director.

10..1.1 Registration by the Director

A person shall not manufacture a type P620 packaging under this standard unless the manufacturing facility and the packaging design have been registered by the Director.

10.1.2 Certificate of registration

A manufacturing facility is registered upon issuance, by the Director, of a certificate of registration. The certificate of registration remains valid until its indicated expiry date or its revocation for cause.

10.1.3 Design registration number

A type P620 packaging design is registered upon issuance, by the Director, of a Design Registration Number. The Design Registration Number remains valid until its revocation for cause.

10.1.4 Application for registration

10.1.4.1 Manufacturing facility

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An application for registration of a manufacturing facility shall be submitted to the Director and, at a minimum, shall include the following information:

- a. the packaging manufacturer's name and address;
- b. the manufacturing facility locations where the packaging will be produced;

10.1.4.2 Packaging design

An application to manufacture a new P620 packaging design shall be submitted to the Director and, at a minimum, shall include the following information:

- a. the packaging manufacturer's name and address;
- the manufacturing facility locations where the packaging will be produced;
- c. when different from the packaging manufacturer, the name and address of the company that has performed the performance testing;
- d. the packaging information as required in 4.4;
- e. proposed markings as required in 5.1;
- f. the design report in accordance with annex A; and
- g. a statement declaring that all requirements of this standard have been met, including the date and signature of the officer responsible for compliance to this standard on behalf of the packaging manufacturer. If the manufacturer did not perform the testing, the statement shall also be signed and dated by the responsible officer of the company that has performed the testing.

10.1.4.3 Record retention

- **10.1.4.3.1** The manufacturer shall keep a copy of every application for registration of the manufacturing facility for as long as UN standardized packagings are manufactured and at least two years thereafter.
- **10.1.4.3.2** The manufacturer shall keep a copy of every application to manufacture a packaging design for as long as UN standardized packaging is manufactured and at least two years thereafter.

10.1.5 Registration and compliance

A Certificate of Registration and Design Registration Number shall be issued by the Director, for a manufacturing facility if the Director is satisfied that:

- a. the packagings manufactured and marked are representative of the registered design;
- b. the packaging manufacturer conforms to the applicable requirements of this standard; and

c. the manufacturer is capable of consistently complying with the requirements of this standard.

10.1.6 Revocation for cause

10.1.6.1 Certificate of Registration

The Director may revoke a Certificate of Registration if the Director is satisfied that:

- a. the packagings, as manufactured, are not representative of the registered designs or do not comply to the applicable requirements of this standard;
- b. the manufacturer is not capable of complying with the requirements of this standard; or
- c. the manufacturer is not complying with the requirements of this standard.

10.1.6.2 Design Registration Number

The Director may revoke a Design Registration Number if the Director is satisfied that:

- a. the packaging, as manufactured, is not representative of the registered design as described in the Design Report; or
- b. the packaging does not comply with the requirements of this standard.

10.1.7 Renewal of Certificate of Registration

The manufacture of packagings shall not continue past the expiry date of the Certificate of Registration.

10.1.8 Application for renewal

An application for renewal of a Certificate of Registration is subject to the same process and conditions as the initial application for Certificate of Registration relating to the manufacturer. The application for renewal shall also include a list of all currently registered packaging designs identified either as actively being manufactured or to be discontinued.

10.1.9 Equivalent specification ("W" marking)

The Director may issue a Registration Number for a packaging design that, although of a type described in Table 1, is manufactured to a different specification if the Director is satisfied that the packaging is equivalent to a container that conforms to the requirements of this standard. The Director shall assign the capital letter "W" to the packaging code.

10.1.10 Design modifications

Any change in packaging design that results in the information of the previously submitted design report to no longer be accurate shall be submitted to the Director as an application to manufacture a new packaging design. If the new design is within the permitted design variations such that no new testing is

required, the application shall identify the previously tested design. If limited testing of the modified design is required, the design report shall include the relevant results.

10.1.11 Transition from CAN/CGSB-43.125-99

A Certificate of Registration issued in accordance with the CAN/CGSB-43.125-99 standard for a container design shall be deemed to be registered as a manufacturing facility and for packaging design pursuant to chapter 10 of this standard unless the certificate has expired or been revoked.

Part II

Selection and use of packagings for infectious substances of Category A and Category B

11 General requirements

11.1 Selection and use

- **11.1.1** Infectious substances that are included in Category A in a form of a culture or meet criteria 2.36 (3) in the TDG Regulations shall be handled, offered for transport or transported in a type P620 packaging.
- **11.1.2** Other infectious substances that are included in Category A but do not meet 11.1.1 may be handled, offered for transport or transported as Category B in a type P650 packaging.
- **11.2.3** Infectious substances that are included in Category B shall be handled, offered for transport or transported in a type P650 packaging.

11.2 Filling and closing

- **11.2.1** Liquids shall only be filled into packagings that have an appropriate resistance to the internal pressure that may develop under normal conditions of transport and meets the requirements set out in 4.3.2; and
- **11.2.2** A person assembling or closing a container shall assemble and close the container as instructed in the information provided by the container manufacturer or distributor in accordance with 4.4.

11.3 Air transport

A person shall not handle, offer for transport or transport by aircraft infectious substances in a packaging unless it is done in accordance with the applicable requirements set out in Part 12 of the TDG Regulations.

11.4 Marine transport

A person shall not handle, offer for transport or transport by ship infectious substances in a packaging unless it is done in accordance with the applicable requirements set out in Part 11 of the TDG Regulations.

11.5 Special packaging ("V" marking)

A person may assemble a P620 packaging, marked in accordance with 5.1.2 b and 5.1.4.1 with the letter "V", for primary receptacles of any type, for solids or liquids, if;

- a) the cushioning thickness between primary receptacles and between primary receptacle and the outside of the secondary inner packaging has not been reduced compared to the successfully tested design. If a single primary receptacle was used in the original test, the thickness of cushioning between primary receptacles shall not be less than the thickness of cushioning between the outside of the secondary inner packaging and the primary receptacle in the original test. When either a fewer number of inner packagings or smaller inner packagings are used (as compared to the inner packagings used in the drop test), sufficient additional cushioning material shall be used to take up void spaces;
- b) primary receptacles containing liquid are completely surrounded with a sufficient quantity of absorbent material to absorb the entire contents of the primary receptacles; and
- c) for an outer packaging that is not siftproof or leakproof, a leakproof liner, plastic bag, or other equally effective means is inserted in the outer packaging to contain any release of solids or liquids, as applicable, from the inner packaging.



Part III

Selection and use of containers for the transport of infectious substances of Category A and Category B intended for disposal and clinical and (bio) medical waste

12 General

- **12.1** Category A infectious substances intended for disposal and meeting the requirements of 2.36(3) in the TDG Regulations shall always be handled, offered for transport or transported in a Type P620 Packaging.
- **12.2** Substance intended for disposal and containing Category A (other than those meeting the requirements of 2.36(3) in the TDG Regulations) or Category B infectious substances or (bio) medical or clinical waste shall be transported in any of the following means of containment:
- a) UN standardized small container for packing group I or II, for liquids or solids listed in Table 3. If the container is not leakproof, a plastic bag meeting the requirements of Table 5 shall be inserted in the container to contain any possible release of liquids.

The containers associated to the UN packaging code listed in Table 3 shall be UN standardized containers that meet the requirements applicable to this type of container as set out in TP14850 or the UN Recommendations and the Regulations of the country of origin, as the case may be, and are marked accordingly.

Table 3 – Selected packaging codes for UN standardized small containers

Type	Material	Category	Packaging code
1. Drums	A. Steel	non-removable head	1A1
		removable head	1A2
	B. Aluminum	non-removable head	1B1
		removable head	1B2
	D. Plywood	-	1D
	G. Fibre	-	1G
	H. Plastic	non-removable head	1H1

		removable head	1H2
	N. Metal, other than steel or aluminum	non-removable head	1N1
	alummum	removable head	1N2
3. Jerricans	A. Steel	non-removable head	3A1
		removable head	3A2
	B. Aluminum	non-removable head	3B1
		removable head	3B2
	H. Plastic	non-removable head	3H1
		removable head	3H2
4. Boxes	A. Steel	- 1	4A
	B. Aluminum		4B
	C. Natural wood	ordinary	4C1
		with sift-proof walls	4C2
	D. Plywood	-	4D
	F. Reconstituted wood		4F
	G. Fibreboard	-	4G
	H. Plastic	expanded	4H1
	•	solid	4H2
CO_{ℓ}	N. Metal, other than steel or aluminum	-	4N
Composites	H. Plastic inner receptacle	in steel drum	6HA1
		in steel crate or box	6HA2
		in aluminum drum	6HB1
		in aluminum crate or box	6HB2

		in wooden box	6HC
		in plywood drum	6HD1
		in plywood box	6HD2
		in fibre drum	6HG1
		in fibreboard box	6HG2
,		in plastic drum	6HH1
		in solid plastic box	6HH2
	P. Glass, porcelain or stoneware inner receptacle	in steel drum	6PA1
	·	in steel crate or box	6PA2
		in aluminum drum	6PB1
		in aluminum crate or box	6PB2
	0	in wooden box	6PC
		in plywood box	6PD1
		in wickerwork hamper	6PD2
	.00	in fibre drum	6PG1
A		in fibreboard box	6PG2
		in expanded plastics outer packaging	6PH1
		in solid plastic outer	6PH2
(O'		packaging	

b) UN standardized IBC for packing group I or II, for liquids or solids listed in Table 4.

The containers associated to the UN IBC code listed in the above table shall be UN standardized IBCs that meet the requirements applicable to this type of container as set out in CAN/CGSB-43.146 or the UN Recommendations and the Regulations of the country of origin, as the case may be, and are marked accordingly.

Table 4 – Selected packaging codes for UN standardized IBCs

Туре	Type of IBC	Design characteristics	Code
Flexible (13)	Plastic (H)	Woven plastic with liner	13H3
		Woven plastic, coated and	13H4
		with liner	
	Textile (L)	Coated with liner	1314
Rigid ^a	For solids, loaded	Fitted with structural equipment	11H1
(11, 21 and 31)	by gravity (11 ^a)		
		Free-standing	11A, 11B,
			11N, 11H2
			With liners:
			11C, 11D,
	X		11F, 11G
	For liquids (31 ^a)	Fitted with structural	31H1
		equipment	
	.00	Free-standing	31A, 31B,
			31N, 31H2
Composite with	11HZ ^a	For solids, loaded or	Such as:
plastic inner		discharged	11HA1 and
receptacle		by gravity, with rigid plastic	11HH1
		inner	1111111
(11HZ and 31HZ		receptacle	
where Z is the			
placeholder for the		For solids, loaded or	Such as:
material code of		discharged	11HA2 and
the outer frame)		by gravity, with flexible plastic	11HH2
		inner receptacle	2211112

	31HZ ^a	For liquids, with rigid plastic	Such as:				
		inner receptacle	31HA1 and				
			31HH1				
		For liquids, with flexible	Such as:				
·		plastic	31HA2 and				
		inner receptacle	31HH2				
^a The single capital let	ter following the rigid IBC numeric	al codes or the letter "Z" following	ng the letter				
"H" in composite IBC	with plastic inner receptacle codes	s stands for the capital letter as sp	pecified in				
the following list that	represents the material of either t	the body of the rigid IBC or					
the outer frame body	of a composite IBC:						
A — Steel	•		·				
B — Aluminum	B — Aluminum						
C — Natural wood	C — Natural wood						
D — Plywood							
F — Reconstituted wo	pod						
G — Fibreboard	G — Fibreboard						
H — Plastic or rubber							
L — Textile							
M — Paper							
N — Metal other than steel or aluminum.							

- c) UN Standardized rigid and leakproof Large Packagings for packing group II, for liquids or solids meeting the requirements of Chapter 6.6 in UN Recommendations and the Regulations of the country of origin and marked accordingly.
- d) a non-standardized combination packaging consisting of a securely-closed plastic bag that meets the requirements of Table 5 and is contained in a securely closed outer packaging that is

- i. rigid, leakproof and designed for repeated use; or
- ii. a fibreboard box that meets the requirements of columns 1, 2 and 3 or columns 1, 2 and 4 of Table 6

12.4 Sharp objects

Packaging intended to contain sharp objects such as broken glass and needles shall:

- a. meet the requirements of CSA Z316.6, or
- b. be rigid, leakproof, puncture resistant and designed for repeated use.

Table 5 — Plastic bag

Test	Test standard	Nominal value	
Elmendorf tear strength	ASTM D1922	480 g MD	
		480 g TD	
Dart impact strength	ASTM 01709	165 g	

Table 6 — Fibreboard box

	Column 1	Column 2	Column 3	Column 4
Type of fibreboard	Maximum weight of box and contents	Maximum outside dimensions L+W+H	Minimum bursting strength ¹	Minimum edge crush² test (ECT)
	kg (lb)	cm (in)	kPa (lb/in²)	kN/m (lb/in)
Singlewall	16 (35)	190 (75)	1380 (200)	5.6 (32)
	23 (50)	216 (85)	1720 (250)	7.0 (40)
	30 (65)	241 (95)	1900 (275)	7.7 (44)
	30 (65)	267 (105)	2410 (350)	9.6 (55)

Doublewall	30 (65)	216 (85)	1380 (200)	7.4 (42)
	30 (65)	241 (95)	1900 (275)	8.4 (48)
	30 (65)	267 (105)	2410 (350)	8.9 (51)

The Minimum Bursting Strength test shall be conducted in accordance with TAPPI T810.

The Edge Crush Test (ECT) shall be conducted in accordance with TAPPI T811 or TAPPI T839.

Annex A (Normative) Design report for type P620 packagings

- **A1.** The following are the minimum requirements for the completion of test reports submitted to the Director in accordance with this standard. Information provided in the report will be confidential.
- **A2.** The report should be dated, display a unique identification number and include the following headings and information.

A2.1 Introduction

- a) The manufacturer's name, address and telephone number
- b) A general description of the package types
- c) The plant locations where the package will be produced.

A2.2 Design (Prototypes)

A2.2.1 Drawings

At least one drawing of the completed package (e.g. assembly drawing) showing assembly method and sequence, overall dimensions, materials and general construction, inner and outer packagings, liners, valves, etc., if applicable. (Photographs for clarification should be included.)

A2.2.2 Materials and construction

The materials and construction for the outer and inner packagings and any other components (e.g. absorbent material, cushioning, dividers, coatings, closures, liners, pads, gaskets).

A2.2.2.1 Materials

- a) Fibreboard The composition (nominal basis weight of solid or linerboard and corrugating medium, corrugating flute type, adhesive [i.e. regular or water resistant]), minimum burst strength, puncture strength or edge crush strength of the solid or corrugated board.
- b) Metal The material type and specification (e.g. ASTM or ISO); the nominal thickness.
- c) Plastic The resin type, density, strength properties for film.

A2.2.2.2 Construction

a) Fabrication and closure methods, fasteners, fastener spacing, closure torque, coatings, etc. As applicable.

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b) Fibreboard

- i) the box style
- ii) the drawings of liners and dividers, the boxmaker's drawing or sketch showing board inside dimensions (flat) and direction of corrugations
- iii) the type of manufacturer's joint (glued, stitched or taped)
- iv) The closure types: glued, stitched or taped
 - 1) Glued: type and coverage of glue
 - 2) Stapled: type, size, number and pattern of staples
 - 3) Taped: type, dimensions and location of tape
- c) Metal The type of seam, seaming compound and weld.

A2.2.3 The detailed material data may be provided on part lists and/or detailed drawings. These drawings may be included with the report or referenced on a list indicating the drawing revision that applies to the prototype design. If drawings are referred to but not included, copies shall be retained by the manufacturer and made available to the Director upon request. Copies of referenced specifications shall also be retained by the manufacturer.

A2.3 Qualification testing

A2.3.1 Test required

A reference to the applicable sections of the standard.

A2.3.2 Test methods and equipment

- a) A description of the type, capacity, etc. of the equipment used
- b) The test methods used
- c) Any variations, with justification, from the test methods prescribed by this standard
- d) A description of the test specimen replicates including contents, net and gross mass as tested. Include a statement that the specimens tested were randomly selected (if selected from production) and represent the package intended for manufacture.

A2.3.3 Test Results

- a) The test results in terms of the pass/fail criteria of the specific test and replicate tested. (Results may be displayed in tabular form.)
- b) A description of the damage in detail.

- c) The results listed in a sequence corresponding to "Test Required".
- d) Photographs and/or videos of the replicates should be taken during/after testing.

A2.4 Certification

- a) A statement declaring that all requirements of CAN/CGSB-43.125 have been met.
- b) Name, address, telephone number and signature of the person who conducted the tests and his employer, if different from the package manufacturer.
- c) Signature of the responsible officer for the manufacturer.

A2.5 Documentation

A copy of the packaging information in accordance with 4.4.

A2.6 Marking

An indication of the proposed marking in accordance with 5.1