WHO/PQS/E004/CB01.3
Original: English
Distribution: General

PQS performance specification

TITLE: Vaccine cold box

Specification reference:	E004/CB01.3
Product verification protocol:	E004/CB01-VP.3
Issue date:	17.12.2012
Date of last revision:	27.08.2018

Contents:

1. Scope:

This specification defines the requirements for thermally insulated cold boxes. These are typically used to maintain the cold chain when vaccines are transported in bulk from one fixed vaccine store to another. Two types of cold box are described:

- **Short range:** With a minimum cold life of 48 hours.
- **Long range:** With a minimum cold life of 96 hours.

2. Normative references:

EMAS: *European Union Eco-Management and Audit Scheme.*
IEC 60529: Consolidated Edition 2.1 (incl. am1): *Degrees of protection provided by enclosures (IP Code).*
ISO 9001: *Quality Management Systems – Requirements.*
ISO 14001: 2004: *Environmental management systems - Requirements with guidance for use.*
ISO/IEC 17025: 2005: *General requirements for the competence of testing and calibration laboratories.*
ISO 20282-1: 2006: *Ease of operation of everyday products - Part 1: Context of use and user characteristics.*

3. Terms and definitions:

Cold life: The empty container is stabilized at +43°C and loaded with ice-packs. Cold life is measured from the moment when the container lid is closed until the temperature of the warmest point in the vaccine storage compartment first reaches +10°C, at a constant ambient temperature of +43°C.

Cool life: The empty container is stabilized at +43°C and loaded with cool-packs which have been stabilized at + 5°C for a minimum of 24 hours. Cool life is measured from the moment when the container is closed, until the temperature of the warmest point inside the vaccine storage compartment first reaches +20°C, at a constant ambient temperature of +43°C.

Cool-pack: A water-pack pre-cooled to a temperature between + 2°C to +8°C before use.

Ice-pack: A water-pack frozen to a temperature between -5°C and -20°C before use. Ice-packs are used for the transport of oral polio vaccine (OPV) or stool specimens.

In writing: means communication by letter, fax or email.
Legal Manufacturer: The natural or legal person with responsibility for the design, manufacture, packaging and labelling of a product or device before it is placed on the market under his own name, regardless of whether these operations are carried out by that person himself or on his behalf by a third party.
Phase change material (PCM): A material, other than water, which changes state between solid and liquid or changes between two different solid crystallization states over a defined temperature range, absorbing or releasing heat during the phase change. This process is reversible and can be useful for thermal control in cold chain devices and products.
Montreal Protocol: Montreal Protocol on Substances that Deplete the Ozone Layer.
Reseller: A commercial entity, licensed to act on behalf of a Legal Manufacturer, and which carries product liability and warranty responsibilities no less onerous than those carried by the Legal Manufacturer.
Secondary packaging: A carton which contains a number of individual vaccine vials or vial pairs. Most countries store and distribute vaccines in these cartons.
Vaccine storage capacity: The total volume of the vaccine storage compartment, in litres. The measurement is equal to the volume of the largest rectilinear object that can be inserted into the compartment with all the manufacturer's specified packs in place.
Vaccine storage compartment: The zone within an insulated container which is designated by the manufacturer as suitable for storing vaccine when the container is loaded with the full number of water-pack required to achieve the cold life specified in this document.
Warm life: The empty container is stabilized at +18°C and loaded with warm-packs which have been stabilized at the same temperature for a minimum of 24 hours. Warm life is measured from the moment when the container is closed, until the temperature of the coldest point inside the vaccine storage compartment first reaches 0°C at a constant ambient temperature of -20°C.
Warm-pack: A water-pack typically stabilized at room temperature, up to a recommended maximum of +24°C. Warm-packs are used for the transport of freeze sensitive vaccines in countries where sub-zero temperatures are common.
Water-pack: A flat, leak proof, plastic container, filled with tap water, complying with specification **PQS/E005/IP01**.

4. Requirements:

4.1 *General:*

Short range or long range insulated cold box, with hinged and insulated lid, designed for transporting vaccines.

4.2 *Performance:*

4.2.1 Vaccine storage capacity:

- **Short range:** 5.0 to 25.0 litres.
- **Long range:** 5.0 to 25.0 litres.

4.2.2 Cold life:

- **Short range:** minimum 48 hours.
- **Long range:** minimum 96 hours.

4.2.3 Cool life:

No standard set; however performance data will be published.

4.2.4 Warm life:

No standard set; however performance data will be published.

4.2.5 Shape:

Containers must be substantially square or rectangular in plan and section. Rounded corners are permitted.

4.2.6 Design principles:

The design of the container, including the placement of the packs and of the load, must promote the free circulation of air within the container to ensure minimum temperature stratification. Container design should seek to minimize the weight of water-packs required to meet the cold life requirement.

4.2.7 Lid seal:

The lid of the container must be fitted with a captive labyrinth seal which engages with the container walls when the lid is closed so as to minimize cold bridging and maximize structural strength.

4.2.8 Hinges:

The lid of the container must be fitted with a robustly constructed hinge mechanism. The lid must open beyond 90° to give full access to the interior of the cold box. The hinges must be recessed so that they are fully protected against damage during transport and storage. Hinges must be maintenance-free, without need for lubrication and must be secured to the container in a manner which prevents loosening due to vibration.

4.2.9 Lid stay:

The container must be fitted with a stay device designed to prevent damage caused by over-stressing the lid when open. The stay device must be designed to prevent it becoming trapped between the lid seal and the body of the container when the lid is closed and it must be secured to the container in a manner which prevents loosening due to vibration.

4.2.10 Catches:

The lid of the container must be secured in the closed position by a catch or catches and it must not be possible for a catch to open accidentally once engaged. Catches must be recessed so that they are fully protected against damage during transport and storage. Catches must be maintenance-free, without need for lubrication and must be secured to the container in a manner which prevents loosening due to vibration.

4.2.11 Carrying handles:

The body of the container must be fitted with at least two moulded-in or hinged handles designed so that they can be used to lift and carry the container comfortably when it is fully loaded. Hinge mechanisms must restrain the handle in a near-horizontal position when the container is lifted and the handles must automatically drop back into the vertical position when they are released. Preferably the handles should be recessed so that they are fully protected against damage during transport and storage. Handles must be maintenance-free, without need for lubrication and must be secured to the container in a manner which prevents loosening due to vibration. The handle arrangement must not prevent stable stacking of the boxes.

4.2.12 Vaccine storage advice:

Cold boxes must carry factory-fitted non-removable labels designed to last the lifetime of the appliance. Labels should be in the UN language most appropriate to the country of use (Arabic, English, French, Mandarin Chinese, Russian or Spanish, or other language, by special order) and should carry the following information.

- **On the outside of the lid, and/or on the front face of the cold box:** As Annex 1.
- **On the inside of the lid:** As Annex 2.

4.2.13 Stacking and handling:

The design of the base and lid of the container should include moulded features that allow multiple units of the same model to be stacked on top of one another in a safe and stable manner. The base of the container must be designed to withstand repeated dragging across hard rough floor surfaces.

4.2.14 Corrosion resistance:

All metallic components and their fixings must be constructed in stainless steel or a suitable non-ferrous metal.

4.2.15 Chemical resistance:

The external and internal surfaces of the container must be resistant to chemicals used for disinfecting (e.g. sodium hypochlorate, 5.25% in water).

4.2.16 IP rating:

Protection of the container with lid closed and latched not less than IEC 60529: IP55.

4.2.17 Robustness:

The container must withstand a one meter drop onto each face, edge, and corner at its rated fully-loaded weight. At the end of the test there must be no damage that affects the performance of the product and the lid must still close and latch correctly.

4.3 *Environmental requirements:*

4.3.1 Ambient temperature range during transport, storage and use:

-30°C to +55°C.

4.4 *Physical characteristics:*

4.4.1 Overall dimensions:

In conformity with clauses 4.5.1 to 4.5.3.

4.4.2 Weight:

The weight of the container must not exceed the following figures:

- **Short range:** Maximum loaded weight, inclusive of the recommended number of water filled water-packs: 35.0 kg
- **Long range:** Maximum loaded weight, inclusive of the recommended number of water filled water-packs 50.0 kg.

4.5 *Interface requirements:*

4.5.1 Dimensional compatibility with packs:

The internal dimensions of the container must be compatible with any of the three standard types of water-pack specified in **E005/IP01**. However, it is acceptable for the product to achieve its designated cold life at its designated vaccine storage capacity using only one of these three types.

4.5.2 Dimensional compatibility with vaccine packaging:
Cold boxes are generally used to transport vaccine in secondary packaging. The net dimensions of the storage compartment (length, breadth and height, with water-packs in place) should accommodate the widest possible range of standard immunization vaccines in this form of packaging, with the vials arranged upright in the container[1].

4.5.3 Dimensional compatibility with transport mode:
Short range cold boxes must be designed so that they can safely be carried upright inside cars, light vans or 4WD vehicles, strapped to the luggage rack of a small motorcycle or moped or carried by a single porter or a pack animal.
Long range cold boxes must be designed so that they can safely be carried upright inside cars, light vans, 4WD vehicles or boats, or carried by two porters or a pack animal.

4.6 *Human factors:*

4.6.1 Generally:
The product must be designed in accordance with the general usability principles laid out in ISO 20282-1: 2006.

4.7 *Materials:*

4.7.1 Casing material selection:
Internal and external casing materials must resist UV degradation and all joints between the moulded components must be water and vapour proof, must be easy to clean and must be selected with environmentally safe end-of-life disposal in mind. Chlorinated plastics and composites containing epoxy resins are not permitted.

4.7.2 Thermal insulation foaming agents:
Any gas complying with the limitations and deadlines set by the Montreal Protocol on the elimination of ozone-depleting chemicals. Cyclopentane and similar foaming agents with a low global warming potential (GWP) are preferred.

4.7.3 PCM:
Integrated thermal buffer materials may be used to prevent freezing temperatures from propagating to the vaccine storage compartment or for other thermal purposes. The buffer material may be PCM-based but if so, must comply with WHO/PQS/E005/PCMC0.1– PCM specification for Phase-change material containers.

4.8 *Warranty:*
The product is to be covered by a two-year replacement warranty in the event of any component failure arising from defective design, materials or

[1] Definitive guidance on secondary packaging is not available and there are no fixed standards. However, a survey of a sample of 20 vaccines from 16 manufacturers in 74 presentations gives the following statistics:

	Length	**Width**	**Height**
Maximum:	25.3 cm	16.4 cm	14.5 cm
Minimum:	6.1 cm	2.9 cm	1.7 cm
95th percentile:	19.5 cm	14.8 cm	11.0 cm

workmanship. The manufacturer must state the time period over which the rated cold life is assured.

4.9 *Servicing provision:*
The product is to be designed to achieve a maintenance-free life of not less than 5 years, apart from routine cleaning.

4.10 *Disposal and recycling:*
The manufacturer is to provide information to the buyer on any hazardous materials contained within the product and suggestions for resource recovery/recycling and/or environmentally safe disposal.

4.11 *Instructions:*
User and maintenance instructions in Arabic, English, French, Mandarin Chinese, Russian and Spanish. The instructions need not repeat the information shown on the permanent labels, but must include guidance on how to repair minor damage.

4.12 *Training:*
No requirement. Training on prevention of vaccine freeze damage and correct use of ice-packs, cool-packs and warm-packs is the responsibility of the purchaser.

4.13 *Verification:*
In accordance with PQS Verification Protocol **E004/CB01-VP.3**.

5. Packaging:

Materials used for packaging the finished product are to be free of ozone-depleting compounds as defined in the Montreal Protocol. The general specification of shipping containers will be subject to agreement with the individual procurement agencies.

6. In-coming inspection:

A random visual inspection of each batch of cold boxes will be conducted by purchasing agencies. This inspection will generally be based upon **E004/CB01-VP.3** clause 5.3.1 (Test 1: Type examination), but may include other tests.

7. Product dossier:

The legal manufacturer or reseller is to provide WHO with a pre-qualification dossier containing the following:

- Dossier examination fee in US dollars.
- General information about the legal manufacturer, including name and address.
- Unique identification reference for the product type.
- Brand name of the product.
- Full specifications of the product being offered, covering all the requirements set out in this document, including details of product marking and traceability.

- A set of digital photographs showing a three-quarter view of the unit with the lid closed, and three-quarter view with the lid fully opened and a top view of the interior with the full compliment of water-packs in place.
- Certified photocopies of all type-approvals obtained for the product.
- Certified photocopies of the legal manufacturer's current ISO 9001 quality system certification.
- Where relevant, certified photocopies of the legal manufacturer's ISO 14001:2004 certification, EMAS registration or registration with an equivalent environmental audit scheme. Conformity with an environmental audit scheme is not mandatory; however preference will be given to manufacturers who are able to demonstrate compliance with good environmental practice.
- Where available, laboratory test report(s) proving conformity with the product specifications.
- Indicative cost of the product per unit, per 10 units and per 100 units, including water-packs, EXW (Incoterms 2000).

8. On-site maintenance:

The product is to be designed to be maintenance-free apart from repair of minor impact damage caused by dropping and the like.

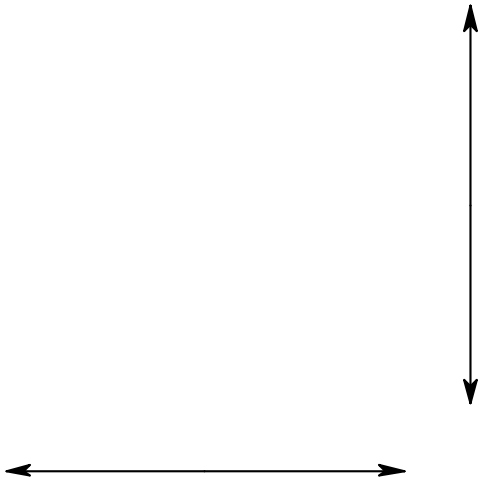
9. Change notification:

The legal manufacturer or reseller must advise WHO in writing of any changes in form, fit or function which may affect the performance of the product after PQS pre-qualification has taken place.

10. Defect reporting:

The legal manufacturer or reseller must advise WHO and the UN purchasing agencies in writing in the event of safety-related product recalls, component defects and other similar events.

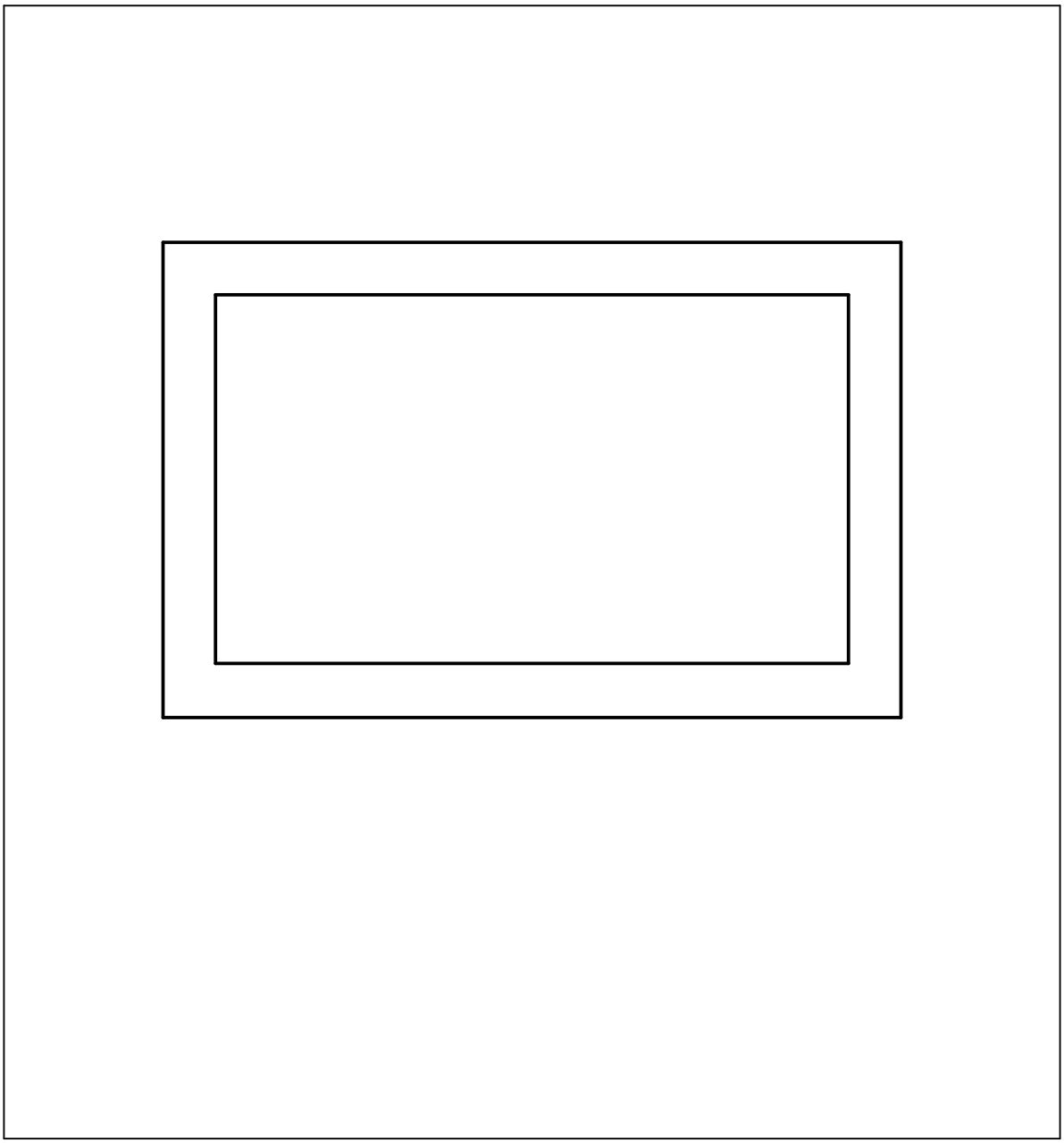
Annex 1 – Label on outside of the lid, and/or front face of cold box



Notes:

1. Language: As required – see clause 4.11.

Annex 2 – Label on inside of lid



Notes:

1. The layout of the label must suit the shape of lid in order to ensure maximum legibility.
2. Language: As required – see clause 4.11.
3. Optionally, the manufacturer's name, model number and date of manufacture/serial number may be permanently fixed elsewhere on the container instead of inside the lid.

Revision history:			
Date	Change summary	Reason for change	Approved
23.04.2008	4.2.6: Minimization of icepack weight added. 4.2.13: Stacking and handling amendment.	Version for final approval	UK
04.09.2008	Minor editions for consistency of terminology used	Comments received from Steering Committee	UK
03.11.2008	4.2.11: Moulded-in handle option added. 4.7.3: omitted. 7: 'including CE marking and the like' omitted. Annex 2: Note 3 added.	Manufacturer's further review comments	UK
08.12.2008	4.2.16 IP rating has been changed to IEC 60529: IP55	Manufacturer's further review comments	UK
21.05.2010	2: Normative references updated. 3. Vaccine storage compartment definition changed. 4.3.2: Clause omitted. 4.7.1: Requirement added 6. Incoming inspection added. 7. ISO 9001 wording amended. Annex 1: Minor change to label wording.	 Comments received. Comments received. Comments received. Comments received. Comments received.	DM
17.12.2012	Vaccine storage capacity	redefined	DM
27.08.2018	Clause 3 (Terms and definitions) PCM definition edited in line with other specs	Reflect change to allowance of water-based and PCM-based buffers	IG
27.08.2018	Section 4.7 edited to include a definition of PCM	Reflect change to allowance of water-based and PCM-based buffers	IG