PQS performance specification

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TITLE: Ice-packs, cool-packs and warm-packs

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1. Scope:

This specification defines the requirements for ice-packs, cool-packs and warm-packs to be used to maintain safe temperatures inside the cold boxes, vaccine carriers and specimen carriers specified in PQS section **E04**. Three sizes are covered – 0.3 litre, 0.4 litre and 0.6 litre.

2. Normative references:

EMAS: *European Union Eco-Management and Audit Scheme.*
ISO 9001: 2000: *Quality Management Systems – Requirements*.
ISO 14001: 2004: *Environmental management systems - Requirements with guidance for use.*
ISO/IEC 17025: 2000: *General requirements for the competence of testing and calibration laboratories.*

3. Terms and definitions:

Cool-pack: A pack pre-cooled to a temperature between + 2°C to +8°C before use.
Ice-pack: A 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.
Montreal Protocol: Montreal Protocol on Substances that Deplete the Ozone Layer.
Pack: As in ice-pack, cool-pack or warm-pack. A flat, leak proof, plastic container, filled with tap water, complying with this specification.
Rated water content: The volume of water, in cubic centimetres measured at 21.0°C, which the pack is designed to hold and which is defined by a fill line permanently marked on the face of the pack.
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.
Warm-pack: A 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.

4. Requirements:

4.1 *General:*

A robust container designed to store water which, when frozen, cooled or warmed to an appropriate temperature, provides the thermal inertia needed to maintain safe storage conditions for vaccines and biological specimens when carried inside a cold box, vaccine carrier or specimen carrier.

4.2 *Performance:*

Sizes:

Three pack sizes may be offered: **Type 1**: 0.3 litre; **Type 2**: 0.4 litre, and **Type 3**; 0.6 litre nominal capacity. Refer to clause 4.4.1.

Water filling requirements:

Packs must be supplied with a removable filling cap and delivered empty.

Either: The recommended level for filling the pack must be clearly visible on the outside of the container and it must be possible to check the water level inside with the cap in place.

Or: The pack must be designed in such a way that it cannot be over-filled.

Deformation:

The pack must have effective reinforcement to restrain the walls against swelling. When frozen solid and laid flat on a flat surface, the pack must not exceed the unfrozen thickness by more than 25%. Deformation caused by ice expansion must be reversible – when the pack thaws its thickness must return to the pre-frozen measurement.

Robustness:

Packs must be able to withstand a one meter drop onto every face, edge, and corner when frozen to -20°C. After thawing they must then pass a leakage test. Packs must also be able to withstand a one meter drop onto every face, edge, and corner with the contents in the liquid state, at +5°C. They must then pass a leakage test.

Leakage:

Unfrozen packs, including the cap must be able to resist a lateral force of 80 kg applied to either of the two main faces without leaking.

Pack colour:

Packs must be constructed using uncolored translucent material.

4.3 *Environmental requirements:*

Ambient temperature range during transport, storage and use:

-30°C to +55°C.

Ambient humidity range during transport, storage and use:

5% to 95% RH.

4.4 *Physical characteristics:*

Overall dimensions and weights:

The three pack types must conform to the dimensional and weight restrictions shown in the table below:

Type	Nominal size	Water content (litres) **	Length (mm) ***	Width (mm) ***	Thickness (mm) ***	Max empty weight (g) ****	Max weight filled with water (g) ****
1	0.3 L	0.25 to 0.30	173	120	26	70	420
2*	0.3 L	0.25 to 0.30	163	90	34	80	380
3	0.4 L	0.35 to 0.40	163	94	34	100	500
4	0.6 L	0.55 to 0.60	190	120	34	120	720

Tolerances:

* "Type 2" 0.3 L pack is the preferred size.

** Water content: Within range.

*** Dimensions: ± 2.0mm.

**** Weight: Not exceeding the defined maxima.

4.5 *Interface requirements:*

Compatibility with cold boxes, vaccine carriers and specimen carriers:

Cold boxes, vaccine carriers and specimen carriers to PQS specifications **E04/CB01**, **E04/VC01**, **E04/SC01** and **E04/SC02** are required to be dimensionally compatible with any of the packs covered by this specification. However, it is acceptable for these products to achieve their full designated performance using only one of the three pack types.

4.6 *Human factors:*

Generally:

When packs are stacked and frozen in bulk they must not bond together.

4.7 *Materials:*

Pack and cap materials must resist UV degradation, must be easy to clean and must be selected with environmentally safe end-of-life disposal in mind. Manufacturers must use materials that are known to be non-toxic when incinerated at any temperature between 650°C and 1,200°C. Chlorinated plastics and composites containing epoxy resins are not permitted.

4.8 *Warranty:*

The product is to be covered by a two year replacement warranty in the event of any failure arising from defective design, materials or workmanship.

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 and the requirement to fill the packs with tap water.

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 must state the rated water content of the pack, up to the fill line.

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 **E05/IP01-VP**

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. On-site installation:
Packs will be filled with tap water by the purchaser or end user.

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.
- Full specifications of the product being offered, covering all the requirements set out in this document, including details of product marking and traceability.
- Certified photocopies of all type-approvals obtained for the product, including CE marking and the like.
- Certified photocopies of the legal manufacturer's ISO 9001 2000 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.
- Provide one sample for preliminary inspection.
- Indicative cost of the product per 100 units, per 1,000 units and per 10,000 units EXW (Incoterms 2000).

8. On-site maintenance:

The product is to be designed to be maintenance-free apart from initial filling with tap water.

9. Change notification:

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

10. Defect reporting:

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

Revision history:			
Date	Change summary	Reason for change	Approved
24.04.2008	No changes following industry review.	Version for final approval.	UK
03.11.2008	• 4.2.2: Second option added • 4.4.1: Dimensions and tolerances changed	Response to further industry comment.	UK
08.12.2008	• 4.4.1 *Overall dimensions and weights: A new category for 0.3 L packs is added with a preference on the type 2.*	Response to further industry comment.	UK