PQS performance specification

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1. Need and scope

The need for this specification stems from the possible technical benefits of using non-water phase-change materials (PCMs) in vaccine cold chain equipment (CCE) at ultra-low temperatures (ULTs), and the added potential risks that PCM brings. ULT PCM use in CCE poses potential additional material compatibility, safety, and performance issues. The scope of this performance specification is to specify requirements for containment of ULT PCM used in vaccine CCE and includes specifications for both the PCM itself and the container holding the PCM. This specification addresses removable containers that are regularly removed from the CCE by end users and contain the PCM generally used as the primary coolant materials for unpowered CCE.

Fixed containers that are not intended for removal from the CCE by end users are not addressed under this specification. Fixed containers are addressed in two other WHO-PQS documents: specification **PQS/E005/PCMC02** and the related verification protocol, **PQS/E005/PCMC02-VP.** CCE referred to in this document includes, but is not limited to, equipment prequalified in category E004 – Carriers and cold boxes.

2. Normative references

(Use the most recent version)

EMAS: European Union Eco-Management and Audit Scheme.
GHS Rev.8. United Nations: Globally Harmonized System of Classification and Labelling of Chemicals, eighth revised edition.
ISO 9001: 2015 Quality Management Systems – Requirements.
ISO 14001: 2015: Environmental Management Systems – Requirements with Guidance for Use.
WHO/PQS/E005/IP01.3: PQS performance specification: Water-packs for use as icepacks, cool-packs and warm-packs.
WHO/PQS/E005/PCM02-VP0.1: Phase-change material containers – ultra-low temperature.

3. Terms and definitions

Cold chain equipment (CCE): Equipment used to maintain the temperature of vaccines or other medical products and samples in an acceptable temperature range. This definition includes refrigerators, refrigerated rooms, freezers, combined refrigerator/freezers, support accessories, carriers, and cold boxes.
Container: A closed volume with walls designed to hold a PCM.
Fixed container: A PCM container that is an integral part of the CCE and is not expected to be regularly removed from the CCE by the end user.
In writing: 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 their own name, regardless of whether these operations are carried out by that person or on their behalf by a third party.
Montreal Protocol: Montreal Protocol on Substances that Deplete the Ozone Layer.
Nominal phase-change temperature: The nominal temperature at which the PCM changes phase as defined by the manufacturer.
Nominal ULT: A single temperature below which the equipment is able to maintain the vaccine storage compartment, designated as a multiple of 5, between -25°C and -80°C (inclusive).
Phase-change material (PCM): A material, other than pure water, which changes its 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.
Removable container: A PCM container that is expected to be regularly removed from the CCE by the end user.
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.
Ultra-low temperature (ULT): A temperature range attributed to materials that will be used at or lower than -25°C.
Water-pack: a flat, leak proof, plastic container, filled with tap water.

4. Requirements

4.1 General

A robust container designed to store PCM which, when prepared at an appropriate temperature and used according to user instructions in specified CCE, provides the thermal inertia needed to maintain safe storage conditions for vaccines and biological specimens.

4.2 Performance

4.2.1 Sizes

The PCM container is recommended to be the same dimensions as one of four types of water-packs defined in **PQS/E005/IP01** with the following nominal dimensions:

- Type 1: 173 x 120 x 26 mm
- Type 2: 163 x 90 x 34 mm
- Type 3: 163 x 94 x 34 mm
- Type 4: 190 x 120 x 34 mm

These dimensions are compatible with the dimensions of existing WHO PQS prequalified CCE and will allow for the new PCM containers to be compatible with existing CCE.

4.2.2 Filling

Containers shall be filled with PCM by the CCE manufacturer or obtained pre-filled from another entity. Containers shall be permanently and robustly sealed by the manufacturer or another pre-filling entity and designed to prevent end users from either opening or refilling the containers throughout their five-year maintenance-free lifetime.

4.2.3 Deformation

Containers shall have effective reinforcement to restrain the walls against swelling and contracting. In either fully solid or fully liquid state, and laid flat on a flat surface, the container shall not exceed the nominal thickness by more than 25%. Deformation caused by expansion and contraction throughout the operating temperature range shall be reversible.

4.2.4 Migration

Containers holding PCM shall resist migration of PCM through container walls. PCM migration through container walls shall be on average less than 0.1% per month by mass as measured over a 60-day period.

4.2.5 Compatibility

Container materials shall be compatible with the PCM used. Compatible means that the PCM will not significantly weaken the material, causing the container to fail over the life of the container and PCM. The PCM shall also be compatible with the materials in the CCE in which the container is used. The CCE manufacturer may cite existing literature to establish the compatibility of the container and CCE materials with the PCM in the container. Acceptable literature is articles from refereed scientific or engineering journals, test data from the PCM manufacturer or test data from the container manufacturer if the container manufacturer is not the CCE manufacturer.

4.2.6 Robustness

Containers shall be able to withstand the following stress tests:

- Freeze/thaw cycling – Filled containers shall not exhibit more than a 1% decrease in filled mass due to lost PCM after being subjected to 100 freeze/thaw cycles.
- Compression test – No filled containers exhibit visual leakage after being subjected to an 800 N compression load on a minimum of three combinations of container sides.
- Drop tests –
    - Filled containers shall be able to withstand a one-metre drop onto every face, edge and corner when completely frozen. After thawing to room temperature, they shall then pass a compression test.

4.2.7 Container colour and distinguishment from water-packs

Containers shall be designed and produced such that they can be clearly distinguished from uncoloured and translucent water-packs without reading any labels or text. The following distinguishments are required:

1. Colouration of the container, and/or PCM material if the container is translucent enough to distinguish the colour of the PCM.
2. Containers shall clearly indicate the nominal phase-change temperature or melting temperature of the contained PCM. The indication in the format -##°C is recommended to be a minimum of 25 mm height text and should appear on the largest face or surface of the container. The indications or markings on the surface of the PCM container shall be accomplished such that they cannot be removed. This should be achieved by any combination of moulding, pressing, forming, permanently etching, or other means as applicable per material properties of the container. Any secondarily attached or superficial markings such as adhesive labels, or paint or dye shall not be accepted under this specification.

4.3 Environmental requirements

The PCM container, PCM, seals, and closures shall be able to withstand ambient temperatures during transport, storage, and use between the nominal ULT of the CCE and +70°C.

4.4 Interface requirements

4.4.1 Compatibility with cold boxes and vaccine carriers

PCM containers that are intended and marketed for use with existing WHO PQS prequalified CCE should be dimensionally compatible with those already existing cold boxes, vaccine carriers and specimen carriers prequalified under PQS category E004. The necessary type of PCM container and dimensions should always be confirmed prior to procurement to avoid any incompatibilities between PCM containers and cold boxes, vaccine carriers, or specimen carriers.

4.5 Human factors

4.5.1 Generally

When PCM containers are stacked and frozen in bulk they shall not bond together such that they cannot be separated by hand.

4.6 Phase-change material hazards

4.6.1 Physical hazards

The PCM shall not have any of the GHS physical hazard codes (H2xx).

4.6.2 Health hazards

The PCM shall not have any of the GHS health hazard codes (H3xx) with the exception of the following:

- H304 – May be fatal if swallowed and enters airways.
- H305 – May be harmful if swallowed and enters airways.
- H316 – Causes mild skin irritation.
- H317 – May cause an allergic skin reaction.
- H320 – Causes eye irritation.

4.6.3 Environmental hazards

The PCM shall not have any of the GHS environmental hazard codes (H4xx). The PCM shall not generate toxic substances when incinerated between 650°C and 1,200°C.

4.7 Container labelling

The outside of the PCM container shall have labels indicating hazards of the PCM contained. Labels shall conform to the **GHS Rev.8. United Nations** and any additional labelling standards of the country in which the container is to be used. Labels shall be in the United Nations (UN) language most appropriate for the country of use. Labels shall be obvious, permanent and remain fixed and legible throughout the expected operating temperature range and if it contacts water or the PCM in the container. Although not explicitly required in the GHS reference, containers shall clearly indicate any applicable GHS hazard code pictograms as defined in **GHS Rev.8. United Nations** and/or other relevant hazard identification system symbol.

4.8 Materials

Containers shall be made from materials that are known to be nontoxic when incinerated at any temperature between 650°C and 1,200°C.

4.9 Warranty

Containers are to be covered by a three-year replacement warranty in the event of any failure arising from a defective design, materials, or workmanship.

4.10 Servicing provision

Containers should have a maintenance-free life of not less than five years, apart from routine cleaning.

4.11 Instructions

User instructions shall be provided in at least one of the UN languages: Arabic, English, French, Mandarin Chinese, Russian, or Spanish or other language by special order. If only one language is included, it shall be the language most

appropriate for the country of use. The instructions shall state the volume and general type of PCM with which the container is filled. In case of container failure, information on health hazards and instructions for first aid, clean-up, and disposal practices of PCM shall also be included.

4.12 Training

The PCM container manufacturer shall provide specific training, or training materials, on the safe handling and use of the filled PCM containers upon request. There is no requirement for the manufacturer to provide on-site training on the use of the PCM containers themselves. However, the manufacturer should note that training on the safe handling and use of the filled PCM containers will be included as a requirement for the CCE in which the PCM containers will be used, to be provided by the CCE manufacturer.

4.13 Disposal and recycling

The manufacturer shall provide information to the buyer on any hazardous materials contained within the PCM or PCM container and suggestions for resource recovery/recycling and/or environmentally safe disposal. Instructions for product recovery/recycling and/or environmentally safe disposal shall be included in the user instructions noted above.

4.14 Verification

In accordance with World Health Organization (WHO) Performance, Quality and Safety (PQS) Verification Protocol **E005 PCMC02-VP0.1.**

5. Packaging

Materials used for packaging the finished PCM container 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

Not required.

7. Product dossier

If the container is not a modified version of a PQS prequalified container where only the shape of the container has changed with no change to the PCM, then the legal manufacturer or reseller shall provide WHO with a prequalification 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.
- A description of the PCM with which the container is filled. This shall include at a minimum: the type of PCM or primary component of the PCM if it is a blend of chemicals; the chemical or trade name of the PCM if different from the type identified; the name of the producer of the PCM; contact information for the producer of the PCM if different from the legal manufacturer of the product.
- Certified copies of any applicable type-approvals obtained for the product (e.g., CE Mark, UL, etc.).
- Certified copies of the legal manufacturer's current **ISO 9001** quality system certification.
- Where relevant, certified copies of the legal manufacturer's **ISO 14001:2015** 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 that are able to demonstrate compliance with good environmental practices.
- 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).

If the container is a modified shape of a PQS prequalified container with the same materials, wall thickness, sealing, manufacturing techniques and PCM, then the legal manufacturer or reseller shall provide a written statement to PQS that the container is a modified shape of an approved container and identify the approved container from which the new container is derived. In such cases, submission of a complete dossier as specified above is not necessary unless subsequently requested by PQS.

8. Change notification

The legal manufacturer or reseller is to advise WHO in writing of any changes to the materials, wall thickness, sealing, manufacturing techniques or PCM of the container after PQS pre-qualification has taken place. Any change that WHO believes would alter the test results obtained against the PQS verification protocol **E005PCMC02 VP0.1** will result in a request for the container to be retested. Changes to container shape do require notification of WHO but may not require retesting of the container pending review of the notificaiton details.

9. Defect reporting

The legal manufacturer or reseller is to advise WHO and the UN purchasing agencies in writing in the event of safety-related recalls, component defects and other similar events. This reporting should occur immediately upon the legal manufacturer receiving notification of the complaint or event, and shall occur within 30 days. If requested to do so by WHO/UNICEF, the manufacturer shall

submit a report to WHO/UNICEF stating the number of affected pieces of equipment.

Revision history			
Date	**Change summary**	**Reason for change**	**Approved**
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