WHO/PQS/E005/PCMC0.1
Original: English
Distribution: General

PQS performance specification

TITLE: Phase-change material containers

Specification reference: E005/PCMC0.1
Issue date: 01 June 2018
Date of last revision: New

Contents

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) designs and the added potential risks that PCM brings. PCM use in CCE poses additional material compatibility, safety and performance issues, and there is little existing data on their longterm performance in CCE. The scope of this performance specification is to specify requirements for containment of PCM used in vaccine CCE and includes specifications for both the PCM itself and the container holding the PCM. This specification addresses fixed containers that are not intended for removal from the CCE by end users.

Removable containers that are regularly removed from the CCE by the end user are not permitted under this specification. CCE includes equipment prequalified in categories: E001 – Cold rooms, freezer rooms, and related equipment; E003 – Refrigerators and freezers; and E004 – Carriers and cold boxes.

2. Normative references

EMAS: European Union Eco-Management and Audit Scheme.
Global Harmonized System (GHS) Rev 5. United Nations: Globally Harmonized System of Classification and Labelling of Chemicals.
International Organization for Standardization (ISO) 9001:2015 Quality Management Systems – Requirements.
ISO 14001:2004: Environmental Management Systems – Requirements with Guidance for Use.

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, 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 her/his own name, regardless of whether these operations are carried out by that person or on her/his behalf by a third party.
Montreal Protocol: Montreal Protocol on Substances that Deplete the Ozone Layer.
Phase-change material (PCM): A material, other than 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.

4. Requirements

4.1 General

A robust container designed to store PCM which, when conditioned to an appropriate temperature, provides the thermal inertia needed to maintain safe storage conditions for vaccines and biological specimens. The container must be a fixed container. The fixed container must be produced as a separable component of the CCE that is later integrated or affixed into the CCE to avoid removal by end users. Removable containers are not permitted under this specification.

4.1 Performance

4.1.1 Filling

Containers must be filled with PCM by the CCE manufacturer or obtained pre-filled from another entity. Containers must be permanently and robustly sealed by the manufacturer or this other entity.

4.1.2 Migration

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

4.1.3 Compatibility

Container materials must 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 must also be compatible with the materials in the CCE in which the PCM container is used. The CCE manufacturer may cite existing literature to establish the compatibility of the PCM 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 PCM container manufacturer if the PCM container manufacturer is not the CCE manufacturer.

4.1.4 Robustness

Containers must be able to withstand the following stress tests:

- Freeze/thaw cycling – 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.

4.2 Environmental requirements

Ambient temperature range during transport, storage and use: –30°C to +55°C.

4.3 Phase-change material hazards

4.3.1 Physical hazards

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

4.3.2 Health hazards

The PCM must 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.

4.3.3 Environmental hazards

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

4.4 Container labelling

The outside of the PCM container must have labels indicating hazards of the PCM. Labels must conform to the Globally Harmonized System for Classification and Labelling of Chemicals and any additional labelling standards of the country in which the container is to be used. Labels must be in the United Nations (UN) language most appropriate for the country of use. Labels must be obvious, permanent and remain fixed and legible if it comes into contact with water or the PCM in the container.

4.5 Materials

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

4.6 Warranty

Fixed containers will have the same warranty as the CCE in which the PCM container is installed.

4.7 Servicing provision

Fixed containers should have a maintenance-free life at least as long as the CCE in which the PCM container is installed.

4.8 Instructions

User instructions must 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 must be the language most appropriate for the country of use. The instructions must state the volume and general type of PCM with which the container is filled. Instructions for clean-up of PCM and disposal in case of container failure must also be included.

4.9 Training

No requirement. Training on prevention of vaccine freeze damage and correct use of PCM is the responsibility of the purchaser.

4.10 Disposal and recycling

The manufacturer is to 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 must be permanently affixed to the outside of the equipment in which the container is installed and permanently affixed to the outside of the container.

4.11 Verification

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

5. Packaging

Materials used for packaging the finished PCM container or CCE 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 approved container where only the shape of the container has changed, then the legal manufacturer or reseller must 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 of 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 must 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 photocopies of any applicable type-approvals obtained for the product (e.g. CE Mark, UL, etc.).
- 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 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 approved 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.

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 prequalification has taken place. Any change that WHO believes would alter the test results obtained against the PQS verification protocol **E005PCMC VP0.1** will result in a request for the container to be retested. Changes to container shape do not require notification of WHO or retesting of the container.

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.

Revision history			
Date	**Change summary**	**Reason for change**	**Approved**
June 2018	Document created	N/a	N/a