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| <b>PERFORMANCE, QUALITY &amp; SAFETY (PQS)<br/>STANDARD OPERATING PROCEDURE</b>           |                                       |  |
| <b>SOP N°:</b> MHP/RPQ/PQT/VAX/PQS/001  | <b>Version n°:</b> 01.06              | <b>Page:</b> 1 of 20                               |
| <b>HOW TO DEVELOP AND PUBLISH A<br/>PQS PRODUCT PERFORMANCE SPECIFICATION</b>             |                                       |  |
| <b>1<sup>st</sup> edition:</b> 08/07/2004<br><i>(For details see revision table)</i>      | <b>Effective date</b><br>08/07/2004   | <b>Revision dates</b><br>06/01/2007;<br>27/01/2017 |
| <b>2<sup>nd</sup> edition:</b> 06/04/2018<br><i>Authorised by:</i><br><i>Reviewed by:</i> | 06/04/2018<br>I. Gobina<br>P. Mallins | 01/04/2020   |
| <b>Prequalification Team (PQT)</b>  |                                       |  |



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## 1. Purpose

A PQS product performance specification is a published standard which sets out the detailed performance requirements for an immunization-related [product](#). All immunization products in the following categories require a PQS product performance specification, with the exception of syringes<sup>1</sup>:

- E001: [Cold rooms, freezer rooms, and related equipment](#)
- E002: [Refrigerated vehicles](#)
- E003: [Refrigerators and freezers](#)
- E004: [Cold boxes and vaccine carriers](#)
- E005: [Coolant-packs](#)
- E006: [Temperature monitoring devices](#)
- E007: [Cold chain accessories](#)
- E010: [Waste management equipment](#)

A performance specification defines the functional requirements of a product and describes the environment within which it must operate. It also describes any interface and inter-changeability requirements. Although it should set out clear verification criteria, it must not attempt to describe *how* the functional requirements are to be met. Rather, stimulating the device manufacturer to determine how the functional requirements may be best met creates room for innovation.

[Manufacturers](#) who are interested in offering products for PQS assessment must submit a dossier that includes independent test results against the specification requirements and all requirements of the relevant [verification protocol](#). Successful applicants will be included in the PQS database. In the form of a catalogue of products, the PQS database is a resource that enables member governments and donor agencies to compare compliant products on a like-for-like basis before purchasing.

The procedures set out in this SOP will be followed by the PQS Secretariat (Secretariat), the PQS Working Group (WG) and by all Technical Specialists (TS) commissioned by the Secretariat.

## 2. Scope

This SOP is applicable to all performance specifications prepared under the PQS initiative, with the exception of syringes.

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<sup>1</sup> Syringes are prequalified on the basis of ISO standards, as described in the World Health Organization document: “*Pre-qualification of single-use injection devices under the PQS system: Guidelines for manufacturers*”.



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### 3. Responsibility

Responsibilities and tasks will be assigned as follows.

The *PQS Working Group (WG)*<sup>2</sup> (at the direction or request of the *PQS Secretariat*):

- Gathers and documents programme needs that are identified by national immunization programmes to incorporate into new performance specifications;
- May prepare draft design criteria for the required product or [device](#);
- Sends the proposal to the *PQS Secretariat* (this may take place at any time);
- Where requested by the *Secretariat*, solicits information and input from country EPI that may inform the prioritisation of specification development; and
- Reviews draft specification and provides input to TS.

The *PQS Secretariat (Secretariat)*<sup>3</sup>:

- Examines the proposal and, if satisfied of the need, directs that a new performance specification be commissioned;
- Commissions a *Technical Specialist* to develop the draft specification;
- Reviews draft specification and provides input to TS;
- Requests WG to review(s) of the draft specification;
- Arranges for peer review and manufacturer review of the draft specification;
- Takes the decision for final approval of the document; and
- Publishes the final specification to the PQS website and circulates it to the relevant members of staff of WHO, UNICEF and manufacturers.

A *Technical Specialist (TS)*:

- Completes the proposed design criteria and drafts the performance specification in consultation with the WG; and
- Revises the draft performance specifications based on the WG, peer and manufacturer reviews and submits a final draft to the Secretariat.

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<sup>2</sup> The PQS Working Group (WG) is comprised of the WHO (PQS and Expanded Programme on Immunization), the United Nations Children's Fund (UNICEF) Supply and Programme Divisions, the Gavi, the Vaccine Alliance Secretariat, specialist agencies, partner organizations and other key stakeholders. In an advisory capacity through the WG structure, these actors offer a wide range of programmatic and technical expertise that supports the development, introduction and advancement of technologies that will meet countries' EPI needs for high-quality cold chain equipment and devices.

<sup>3</sup> The WHO PQS Secretariat is responsible for sharing up-to-date information on prequalified immunization devices and products, as well as product alerts. It ensures that the standards that apply to equipment maintenance, manufacturing and product testing are current. The Secretariat also coordinates product feedback reports and learnings from product field monitoring. The Secretariat holds ultimate responsibility for the PQS process and takes all final PQS decisions, including the decision to award prequalified status to a product or device.



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#### 4. Associated reference documentation

- SOP No MHP/RPQ/PQT/VAX/PQS/002: *How to review and revise a PQS product performance specification.*
- SOP No MHP/RPQ/PQT/VAX/PQS/003: *How to withdraw a PQS product performance specification.*
- SOP No MHP/RPQ/PQT/VAX/PQS/004: *How to develop and publish a PQS product verification protocol.*
- SOP No MHP/RPQ/PQT/VAX/PQS/005: *How to review and revise a PQS product verification protocol.*
- SOP No MHP/RPQ/PQT/VAX/PQS/006: *How to withdraw a PQS product verification protocol.*

#### 5. Procedure

##### 5.1 Introduction

A performance specification must be comprehensive, unambiguous and written in a consistent manner, in a 'neutral' style. This helps to avoid favouring products from a particular manufacturer or from a particular country or geographical region. Wherever possible it must cite any relevant ISO or other published normative references that are directly applicable to the specified product or to its component parts. Finally, it must comply fully with WHO immunization policies and guidelines current at the time of publication.

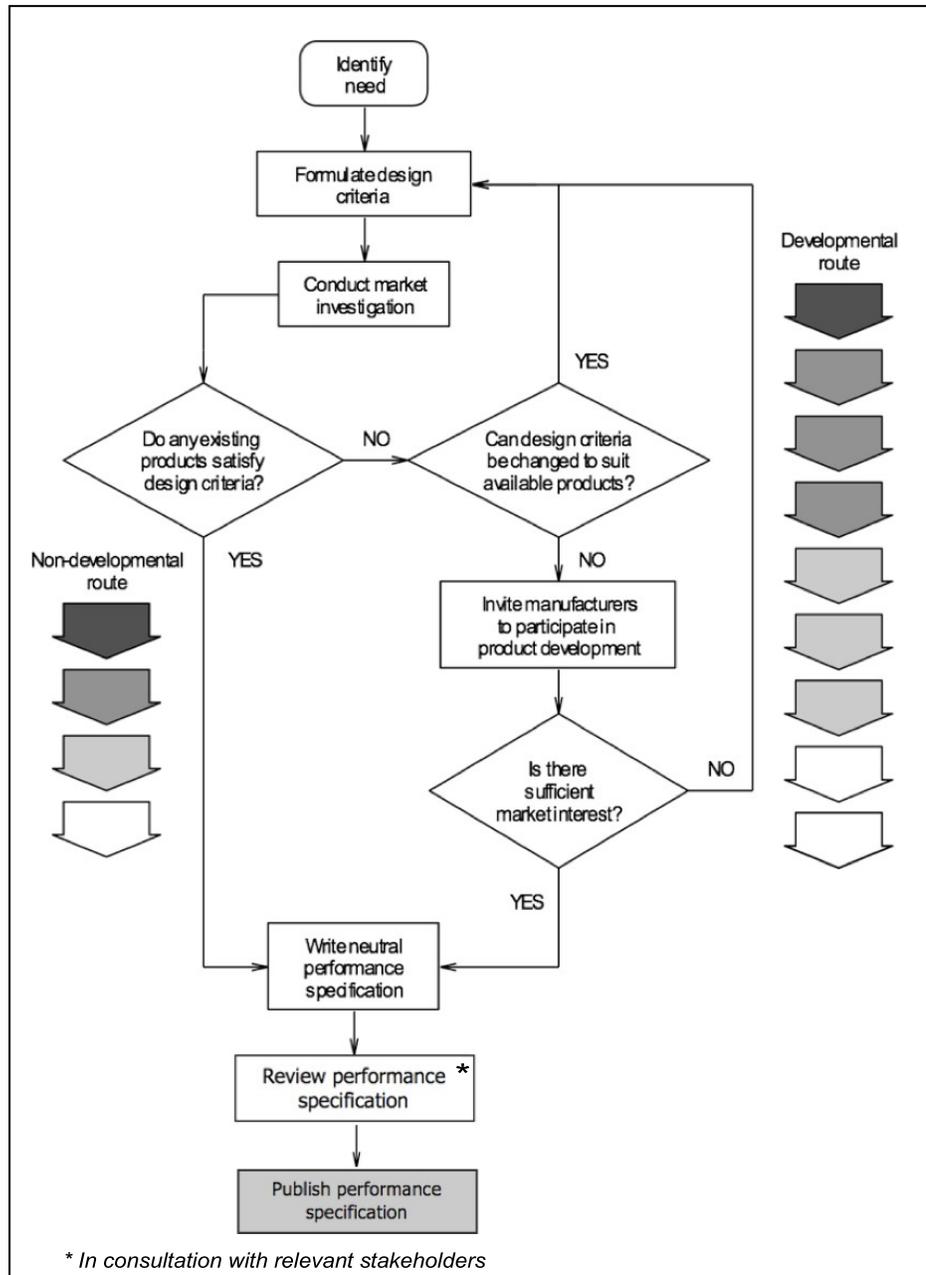
Figure 1 provides an overview of the various stages in the development of a performance specification, which are described in more detail in the following paragraphs. Each of the task headings below includes (in brackets) a description of the person or group responsible for the task.

A performance specification and all its subsequent revisions must be reviewed and signed off by the PQS Secretariat. All revisions must be accurately recorded in the *revision history form* (found at the end of this document).



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**Figure 1 – Developing a performance specification**





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## 5.2 Approaches to product prequalification

(All responsible staff)

There are two approaches to product prequalification:

- The *non-developmental approach* invites manufacturers to offer compliant items from their existing product range;
- The *developmental approach* identifies selected manufacturers who are prepared to modify an existing product or to develop a new one.

The Secretariat, WG and/or TS must ensure that the list of manufacturers contacted is as inclusive and wide as possible. As a minimum, this list should include all prequalified manufacturers, developers, inventors etc. known to PQS in the category. A performance specification which targets commercially-available products is likely to attract the widest and most economically competitive range of compliant devices; this *non-developmental approach* must be the first choice. The *developmental approach* should be taken only when market investigation has established that no existing products can meet the design criteria and that the design criteria themselves cannot be further modified.

## 5.3 Maintain background market surveillance

(All responsible staff)

All staff responsible for preparing and/or reviewing performance specifications must keep themselves up to date with product information and technological developments relevant to their own area of expertise.

## 5.4 Identify need

(WG)

A performance specification is developed in response to an identified need. Understanding genuine EPI programme needs is the critical first step. The WG must ensure that all relevant stakeholders are consulted and that the relevance and extent of the needs they identify are assessed. Most often these needs arise from the field; e.g. a requirement for low-temperature protection for refrigerators in cold climates, driven by field observation of freeze-sensitive vaccines subjected to temperatures below freezing. In other instances, the need may be driven by broader programme development issues; e.g. the introduction of Hepatitis B vaccine triggers the need for more effective freeze indicator devices. PQS should have documented information about the need and/or interest of the country-level EPI for a new product before beginning work on the performance specification. Manufacturer promotion is not enough to justify this work.

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5.5 Formulate design criteria  
(WG, TS)

After a need has been identified by relevant stakeholders, and assesses together with the WG, formulate a brief description of the proposed design criteria that are required to meet it. This document begins with a statement of the need and also lists desired performance criteria for the proposed product. The document may outline possible approaches to meet the need, but this is not its main purpose; given that the core principle of PQS performance specifications is to define the ‘what’ and not the ‘how’ of new product needs. Overall, the design criteria document provides a focused brief for the initial market investigation phase, and it is very likely that it will be further changed by this process. Figure 2 provides an example.

**Figure 2 - Sample design criteria**

|   |
|---|
| <b>FREEZE INDICATOR DEVICE</b>  |
| <p><b>Need</b><br/>A device to enable store staff and health workers to see whether vaccines have been exposed to temperatures below 0°C, during storage in a fixed location or during transit.</p> <p><b>Approach</b><br/>A disposable device that can be stored with vaccines and that – when exposed to temperatures below 0°C – provides a permanent indication of exposure to freezing.</p> <p><b>Target Performance Criteria</b></p> <ol style="list-style-type: none"> <li>1. The purpose of the device is to indicate clearly and permanently that vaccine has been exposed to freezing conditions.</li> <li>2. In 100% of instances during testing the indicator must be triggered by exposure to a temperature of <math>-0.4^{\circ}\text{C} \pm 0.1^{\circ}\text{C}</math> for a period of 60 minutes <math>\pm</math> 5 minutes.</li> <li>3. In 100% of instances during testing the indicator must NOT be triggered by exposure to a temperature of <math>+0.4^{\circ}\text{C} \pm 0.1^{\circ}\text{C}</math> for a period of 60 minutes <math>\pm</math> 5 minutes.</li> <li>4. The device must not require activation by the user.</li> <li>5. If the device requires a power source, this must be permanently embedded and the device must have a visible ‘active battery’ indicator.</li> <li>6. The device must have an operational life (including shelf life) of at least three years, starting from the time of delivery to the client.</li> </ol> |



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7. At all times, the indicator must clearly demonstrate one or other of two bi-polar states:
  - Freezing has NOT occurred.
  - Freezing HAS occurred.No transitional phase is acceptable.
8. The device will be stored at ambient conditions before it is deployed. During storage, it must remain fully functional at any temperature between +4°C and +43°C and at any relative humidity (RH) between 10% and 100%.
9. When the device is deployed it may encounter temperatures in the range of -20°C to +43°C.
10. Both indicator states must be legible to normally sighted individuals and those suffering from the four most common types of colour blindness: deuteranopic, protanopic, protanomalous and deuteranomalous.
11. Both indicator states must remain unaffected by the temperature or humidity of the environment in which the device is read.
12. The device must be unaffected by vibration of the type caused by a road vehicle traveling on rough roads.
13. The device must not be damaged by dropping onto a hard surface.
14. The dimensions of the device must not exceed 75 x 75 x 25mm.
15. The delivered price of the device must be less than US\$ 2.50 per unit.

#### 5.6 Conduct a market investigation

(TS, in consultation with WG and others)

The purpose of a market investigation (also called a ‘product landscape analysis’) is to establish whether potentially suitable products already exist. If they DO exist, then the *non-developmental* route can be followed. If they DO NOT exist, then either the design criteria will have to be changed or the *developmental* route will have to be followed. In some instances, [product innovators](#) may be involved initially in the developmental route.

A typical market investigation involves up to six steps:

- 1) *Summarise market surveillance*: Review what you already know. Provided you have a good general knowledge of the field, you should be able to hypothesise whether or not the design criteria are likely to be met by a commercially available product.
- 2) *Identify sources*: Find out which manufacturers are able to offer suitable products. If none are available, identify manufacturers and/or related product innovators who are best placed to develop a product that meets the design criteria.



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- 3) *Survey manufacturers:* Contact potential manufacturers and obtain the following information:
- Product data sheets, product test data and quality management registration details (e.g. ISO 9001);
  - Details of manufacturing capacity and, if required, details of the company's current customer base for reference-checking purposes.
- 4) *Check references:* Reference checking is a lengthy process – in most cases this exercise can be left until the prequalification stage. However, references should be checked in the following circumstances:
- Where the technology involved is novel and few manufacturers are in a position to supply the product;
  - Where manufacturers are being invited to modify an existing product to meet the agreed design criteria;
  - Where manufacturers are being asked to develop an entirely new product.

A maximum period of one month should be allowed for this process.

- 5) In each of these three cases outlined in point 4) above, it is essential to try to establish whether potential manufacturers have the relevant capabilities with regards to:
- Financial stability;
  - Research and development facilities;
  - Product quality;
  - Product performance and reliability;
  - Reliable delivery;
  - Production capacity;
  - Satisfactory after sales service.

In addition to individual references, consumer organizations and user groups are sometimes able to provide this information. These criteria should not be used to inhibit potential innovative smaller suppliers. Potential manufacturers should be judged on a case by case basis.

- 6) *Document the results:* Every market investigation must be adequately documented. Good documentation provides an audit trail and a resource for future researchers. Prepare a table summarising the characteristics of each product relative to the principle design criteria (Figure 3 provides an example). File the manufacturers' data and other paperwork on the WHO PQS *sharedrive*



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**Figure 3 – Example of a market investigation summary table**

| <b>FREEZE INDICATOR DEVICE</b>                                    |                           |          |          |          |          |          |
|---|---------------------------|----------|----------|----------|----------|----------|
| <b>Item</b>   | <b>Product reference</b>  | <b>A</b> | <b>B</b> | <b>C</b> | <b>D</b> | <b>E</b> |
| 01  | Technology                | BV       | LQ       | LQ       |          |          |
| 02  | Triggered @-0.4°C?        | yes      | yes      | -0.5°C   |          |          |
| 03  | NOT triggered @+0.4°C?    | yes      | yes      | yes      |          |          |
| 04  | User activation required? | no       | no       | no       |          |          |
| 05  | Embedded power source?    | no       | yes      | yes      |          |          |
| 06  | Active battery indicator? | n/a      | yes      | no       |          |          |
| 07  | Shelf life (years)        | 3 yrs    | 3 yrs    | 2 yrs    |          |          |
| 08  | Bi-polar state?           | yes      | yes      | yes      |          |          |
| 09  | Storage temp (max °C)     | ?        | ?        | 35°C     |          |          |
| 10  | Storage RH (max %)        | ?        | ?        | 90%      |          |          |
| 11  | Legibility (normal sight) | good     | good     | fair     |          |          |
| 12  | Legibility (colour blind) | good     | good     | fair     |          |          |
| 13  | Resistance to vibration?  | good     | good     | good     |          |          |
| 14  | Impact resistance?        | good     | good     | poor     |          |          |
| 15  | Size (H x W x T)          | 60x40x10 | 50x30x10 | 70x40x12 |          |          |
| 16  | Unit price (US \$)        | 2.38     | 2.50     | 3.00     |          |          |
| <b>Key:</b><br>Technologies: BV = burst vial; LQ = liquid crystal |                           |          |          |          |          |          |

**5.7 Establish whether existing products meet the design criteria**  
(TS in consultation with WG)

If there are a reasonable number of suitable products, follow the *non-developmental* route. If no suitable products are available, take the following steps:

- a. Consider whether the design criteria can be altered to suit products that are commercially available.
- b. If the criteria cannot be changed, ask selected manufacturers if they can modify an existing product to achieve the desired performance.
- c. Only if there is no alternative should manufacturers and/or related product innovators be invited to develop an entirely new product line (and once a specification has been published).



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### 5.8 Write a performance specification (TS)

When the PQS Secretariat has decided to commission a new performance specification, the Secretariat then identifies a TS to write the performance specification document. The person or organization selected to be the TS must be a technical expert in the relevant field.

*Normative references:* Identify relevant existing normative references. ISO standards should be used wherever possible. If no suitable ISO standard exists then regional and national standards are acceptable. However, every effort must be made to avoid a regional or national bias in the specification. This can be avoided by referring to similar standards drawn from different parts of the world.

*Performance specifications based on a single normative reference:* In a few cases there may be a single standard which covers all aspects of an entire product category. Single use medical devices are a case in point – for example ISO/DIS/7886-3 has been drafted to cover any auto-disable syringe intended for fixed dose immunization. In such a case, the performance specification need only describe a specific instance of the type, e.g. ‘0.5 ml AD syringes with integrated needles to ISO/DIS/7886-3, supplied in blister strips’.

*Specification format:* Annex 1 provides a model format for writing a performance specification and Annex 2 defines key terms used in Annex 1. Not all the sections outlined in the template will be required for every specification, and in other cases added “requirements” will need to be included (e.g. E003 appliance product specifications include numerous other requirements like “Electromagnetic compatibility” for devices with electronics). Specifications must be verifiable.

Avoid wording that is ambiguous or might allow for discretion (e.g. avoid “should” if the product “must” meet a requirement). Aspirational attributes should be clearly stated as such (e.g. a 10-year target life is the goal of this product, however no test presently exists to verify this product life).



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### 5.9 Review process

(Secretariat, WG, Manufacturers, TS)

The Secretariat will share the draft specification with the WG for review. The draft specification must go through at least one round of WG review, with the initial reviewing lasting approximately four to six weeks. The number of reviews is determined by the complexity of the specification and decided at the discretion of the Secretariat. Subsequent rounds of WG review will align (at the latest) with the WG quarterly meetings.

The Secretariat will determine when the draft specification is ready for manufacturer review.

The Secretariat will send the draft specification to manufacturers for review, via email and by posting to the PQS website. Manufacturers will be given one month to respond with comments.

The WG Lead/s and/or TS will collate all manufacturers' comments and prepare a revised draft with recommendations for the WG and Secretariat to review. WG and Secretariat comments will be incorporated into a revised draft. The Secretariat will determine if another round of manufacturer review is required.

Depending on the complexity and issues that may arise from the manufacturer review, there may need to be multiple manufacturer review cycles.

### 5.10 Documenting revisions

(TS, WG and/or Secretariat)

All changes will be clearly identified in the 'revisions' section of the specification that will:

- Give the date of the amendment;
- Identify the amendment; and
- Briefly describe the reason for the amendment.

Figure 4 provides an example.



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**Figure 4 – Example of a product verification protocol revision record**

| Revision history |   |   |          |
|------------------|---|---|----------|
| Date             | Change summary  | Reason for change   | Approved |
| 01.01.05         | <ul style="list-style-type: none"> <li>• Clause 6: Stable running test at -5°C added.</li> <li>• .....etc.</li> </ul> | <ul style="list-style-type: none"> <li>• To test performance of freeze-protection system.</li> <li>• .....etc.</li> </ul> | ABC      |
|                  |   |   |          |
|                  |   |   |          |

5.11 Approval  
(Secretariat)

The fully reviewed and corrected specification will be submitted to the Secretariat for formal approval. The decision on final approval rests solely with the Secretariat.

5.12 Publication  
(Secretariat)

Immediately after approval of the amended document, the Secretariat will publish it on the PQS website, in electronic (.pdf) format. In addition, notification of publication will be posted on the TechNet-21 website. All PQS manufacturers and related innovators will be informed of the publication by email. The previous edition will be archived.

**6. Distribution**  
(Secretariat)

This SOP is to be distributed to the following individuals and groups:

- PQS Secretariat,
- PQS WG,
- WHO Expanded Programme on Immunization (EPI),
- UNICEF Supply Division and UNICEF Programme Division,
- Each Technical Specialist commissioned to work on any aspect of a specification,
- All relevant manufacturers,
- PQS and TechNet-21 websites.



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### Annex 1: Standard format for a performance specification

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|---|---|--|
|  WHO/XXX<br><b>PQS performance specification</b> |   | Original: English<br>Distribution: General |
| <b>TITLE:</b> <description>   |   |  |
| <i>Specification reference:</i>   | <PQS category>/<unique reference>   |  |
| <i>Product verification protocol:</i>   | <PQS category>/<unique reference>   |  |
| <i>Date of origin:</i>  | <dd.mm.yy>  |  |
| <i>Date of last revision:</i>   | <dd.mm.yy>  |  |
| <b>Contents:</b> <list the specification content down to level 1.1.1>   |   |  |
| <b>1.</b>   | <b>Scope:</b> <briefly describe what product(s) the specification covers>   |  |
| <b>2.</b>   | <b>Normative references:</b> < list ISO/IEC and other standards that apply to the specification, and list any relevant WHO product verification protocols; cross- refer to any other relevant performance specifications>   |  |
| <b>3.</b>   | <b>Terms and definitions:</b> <define any specific terms used in the specification, particularly terms which may not be widely understood>  |  |
| <b>4.</b>   | <b>Requirements:</b>  |  |
| 4.1   | <u>General:</u> <state <i>what</i> is generally required of the product, but <i>not how</i> this is to be achieved; briefly describe the context in which the product is to be used>  |  |
| 4.2   | <u>Performance:</u> <set out the specific performance characteristics required, including limits on energy consumption where relevant>  |  |
| 4.3   | <u>Environmental requirements:</u> <quantitatively define the operating environment in respect of temperature range, humidity, shock, vibration, etc.>  |  |
| 4.4   | <u>Physical characteristics:</u> <set out critical physical characteristics such as limits on weight, size etc., but only to the extent that these data are essential to satisfy human factors and/or interface requirements>   |  |
| 4.5   | <u>Interface requirements:</u> <describe form and fit requirements to the extent that these impact on other related products; e.g. size of icepacks to suit a specific range of cold boxes>   |  |
| 4.6   | <u>Human factors:</u> <describe ergonomic requirements, including percentile of users; ‘ <a href="#">universal design</a> ’ principles; health and safety issues etc.>  |  |
| 4.7   | <u>Materials:</u> <specify materials that are to be used or excluded only to the extent that this is absolutely necessary; e.g. to ensure adequate corrosion or wear resistance, to minimise toxicity, or to comply with international agreements (e.g. the Montreal Protocol)> |  |



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- 4.8 **Reliability:** <define reliability requirements in quantitative terms and define the conditions under which these requirements must be met>
- 4.9 **Servicing Provision:** <define the requirement and specify the terms>
- 4.10 **Maintenance:** <define maintenance issues in as quantitative manner as possible; for example, mean time between maintenance, level of maintenance skill needed, etc.>
- 4.11 **Disposal and recycling:** <state specific requirements relating to end-of-life disposal, including any requirements for recycling of materials or components>
- 4.12 **Instructions:** <if user and/or maintenance instructions are required, state in which languages they are to be supplied >
- 4.13 **Training:** <if user training is required, state who is to be trained and for what purpose>
- 4.14 **Verification:** <state how product performance is to be verified, by citing the relevant type-testing, type-examination or full quality-assurance protocol>
- 6. Packaging:** <state any specific requirements for packaging>
- 7. On-site installation:**<sup>4</sup> <where a product requires on-site installation (e.g. solar powered appliances and standby generator) clearly define who is to be responsible for each stage in the process, such as:
- designing the installation<sup>5</sup>;
  - identifying a suitable space or building to house the installation;
  - inspecting and approving the space or building;
  - making necessary physical changes to prepare for the installation;
  - inspecting and approving the changes;
  - carrying out the installation;
  - testing and commissioning the installation;
  - user training (when required at the time of installation)>
- 7. Product dossier:** <state what supporting information and/or samples the manufacturer ([legal manufacturer](#) or [reseller](#)) or the [approved installer](#) must provide when submitting a product for prequalification, including details of quality systems ([QA](#)) in place>
- 8. On-site maintenance:** <if on-site maintenance is required, state the desired performance criteria with regard to response rate etc.>

<sup>4</sup> This section may take the form of a guideline to the 'client' who will draw-up a site-specific specification. See, for example, WHO/V&B 02.33. *Equipment performance specifications and test procedures. E1: Cold rooms and freezer rooms.*

<sup>5</sup> This process includes establishing the required 'capacity' of the installation; for example, the kVA rating of a generator, the internal volume of a cold room, etc. In some cases, this may be entirely the responsibility of the installer. In other instances, responsibility may be split between the 'client' and the installer.



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**9. Change notification:** <state that the manufacturer or approved installer is to report future changes in product specification, manufacturing location and manufacturing methods to WHO/UNICEF; define the conditions under which re-testing may be required>

**10. Defect reporting:** <state that the manufacturer or approved installer is to notify purchasers, end-users and WHO/UNICEF in the event of safety-related product recalls, component defects and other similar events>

**Annexes:** <special symbols and other supporting information, as required>

**Revision history:**

| Date     | Change summary            | Reason for change               | Approved |
|----------|---------------------------|---------------------------------|----------|
| dd.mm.yy | < change item><br>< etc.> | < reason for change><br>< etc.> | <name>   |
|          |                           |                                 |          |
|          |                           |                                 |          |
|          |                           |                                 |          |

**Annex 2: Terms and definitions**

|                                    |   |
|------------------------------------|---|
| <a href="#">Approved installer</a> | A person or organization approved by the legal manufacturer or reseller as a competent installer of the system components and who has been appointed by the Employer to carry out the installation of the System.   |
| <a href="#">Device</a>             | A medical device such as a syringe or temperature monitor.  |
| <a href="#">Manufacturer</a>       | In the context of this SOP, the word manufacturer includes both legal manufacturers and resellers.  |
| <a href="#">Legal manufacturer</a> | 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 <sup>6</sup> .<br><br>A legal manufacturer may commonly contract another company to manufacture products or devices sold under the legal manufacturer's name. A manufacturer that is contracted in this way is typically known as an Original Equipment Manufacturer, |

<sup>6</sup> Definition derived from Article 1 2.(f) of the EU Medical Device Directives.



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|                                       |  |
|---------------------------------------|--|
|                                       | or OEM.  |
| <a href="#">Product</a>               | In this document, where the word ‘product’ is used on its own, it includes device.   |
| <a href="#">Product innovator</a>     | A person, company or organization from a related industry that introduces new methods, ideas or products to the PQS product development process.   |
| <a href="#">QA</a>                    | Quality Assurance.   |
| <a href="#">Reseller</a>              | 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.  |
| <a href="#">Universal design</a>      | The design of products and services that address the needs of the widest possible audience, irrespective of age or ability. Also called <i>Inclusive Design</i> or <i>Design for all</i> .   |
| <a href="#">Verification protocol</a> | Describes in detail how the performance of a product or device will be tested or otherwise evaluated as part of the PQS product prequalification procedure. See SOP No. MHP/RPQ/PQT/VAX/PQS/004: <i>How to develop and publish a PQS product verification protocol</i> . |

### Annex 3: Online resources

The following list gives some sources of useful online information.

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| <b>Guidance on writing performance specifications:</b>  |
| <i>SD-15: Performance Specification Guide</i> . Office of the Assistant Secretary of Defence for Economic Security. Washington D.C., 1995. <a href="http://www.dsp.dla.mil/documents/sds.htm">http://www.dsp.dla.mil/documents/sds.htm</a>  |
| Story, M.F., Mueller, J.L. Mace, R.L., <i>The Universal Design File: Designing for People of All Ages and Abilities</i> . NC State University, Center for Universal Design. <a href="http://www.design.ncsu.edu:8120/cud/pubs/center/books/ud_file/toc3b14.htm">http://www.design.ncsu.edu:8120/cud/pubs/center/books/ud_file/toc3b14.htm</a> |
| <b>International agency resources:</b>  |
| Inter-Agency Procurement Services Office (IAPSO). <a href="http://www.iapso.org/supplying/">http://www.iapso.org/supplying/</a> Online catalogue.   |
| UNICEF Supply Division. <a href="http://www.supply.unicef.dk/Catalogue/">http://www.supply.unicef.dk/Catalogue/</a> Online catalogue.   |



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| <b>Standards:</b>  |
| American National Standards Institute. <a href="http://www.nssn.org/">http://www.nssn.org/</a> The National Standards System Network provides a wide range of standards information from ANSI, other U.S. private sector standards organizations, government agencies and international standards organizations.   |
| British Standards Institute. <a href="http://www.bsonline.techindex.co.uk/">http://www.bsonline.techindex.co.uk/</a> Lists British and international standards, which can be purchased online.   |
| European Community. <i>Guide to the implementation of directives based on the New Approach and the Global Approach</i> . Office for Official Publications of the European Communities Luxembourg, 2000. ISBN 92-828-7500-8. Also at <a href="http://europa.eu.int/comm/enterprise/newapproach/">http://europa.eu.int/comm/enterprise/newapproach/</a> Document outlining the New Approach to technical harmonization and the Global Approach to conformity assessment used within the EC to achieve the granting of a 'CE' mark. |
| International Standards Organization. <a href="http://www.iso.org">http://www.iso.org</a> Lists ISO standards, which can be purchased online.  |
| World Standards Services Network. (WSSN). <a href="http://www.wssn.net/WSSN/print/listings/worldmap.html">http://www.wssn.net/WSSN/print/listings/worldmap.html</a> lists links to national and international standards organizations worldwide.   |
| 1stNclass.com. <i>Quality Glossary – 250+ common Quality Management acronyms and terms</i> . <a href="http://www.1stnclass.com/quality_glossary.htm">http://www.1stnclass.com/quality_glossary.htm</a>   |
| <b>Market investigation resources:</b>   |
| <i>SD-5: Market Research – gathering information about commercial products and services</i> . Office of the Assistant Secretary of Defence for Economic Security. Washington D.C., 1997. <a href="http://www.dsp.dla.mil/documents/sds.htm">http://www.dsp.dla.mil/documents/sds.htm</a>   |
| ECRI. A non-profit organization specialising in information about medical devices and equipment <a href="http://www.ecri.org/">http://www.ecri.org/</a>  |



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### Revision history

(form number MHP/RPQ/PQT/VAX/PQS/GEN/F002)

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|--|---|---|
| SOP Number:                            | MHP/RPQ/PQT/VAX/PQS/001   |   |
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| Date of issue 2 <sup>nd</sup> edition: | 06/04/2018  |   |
| <b>Revisions</b>                       |   |   |
| <b>Date</b>                            | <b>Change and reason</b>  | <b>Authorised by (Signature and Name)</b>               |
| 06/01/2007                             | <ul style="list-style-type: none"> <li>ATT team was changed to QSS team due to the reorganization in the IVB Department.</li> <li>The code VML was changed to PQS in the SOP No.s for easy reference.</li> <li>The person responsible for giving no- objection clearance for the specifications was identified as the QSS Coordinator.</li> </ul>   | Drafted by<br>O. Afsar<br>Approved by<br>U.<br>Kartoğlu |
| 27/01/2017                             | <ul style="list-style-type: none"> <li>Hyperlink to each PQS category added in the 'Purpose' clause.</li> <li>Footnotes defining the PQS Working Group and the PQS Secretariat added in Clause 3.</li> <li>PQS system structure simplified, removing FMWG, Steering Group. IVB/QSS is also renamed EMP/PQT. Revisions to this SOP reflect these changes (text and figures).</li> <li>'Responsibilities' clause revised to separate out specific responsibilities of key actors and to remove process elements.</li> <li>Clause 6 'Distribution' edited to include complete group of stakeholders.</li> <li>'Terms &amp; definitions' moved to annex, revised, definitions updated in line with WG reviews of PQS glossary Feb 2018.</li> <li>Clause 5.10 'Documenting revisions' added.</li> <li>Annex 1, sub-clause 4.9 'Servicing provision' added.</li> <li>Annex 3 'Online resources' added.</li> </ul> | Drafted by<br>P. Mallins<br>Approved by<br>I. Gobina    |
| 01/04/2020                             | <ul style="list-style-type: none"> <li>MVP/EMP/PQT is renamed MHP/RPQ/PQT/VAX throughout to reflect structural changes: (Vaccines &amp; Immunization Devices Assessment Team (VAX), Prequalification Unit (PQT), Regulation &amp; Prequalification Department (RPQ), Access to Medicines and Health Products Division (MHP).</li> </ul>   | Drafted by<br>P. Mallins<br>Approved by<br>I. Gobina    |