



**PERFORMANCE, QUALITY & SAFETY (PQS)
STANDARD OPERATING PROCEDURE**

SOP N°: MHP/RPQ/PQT/VAX/PQS/003

Version n°: 01.06

Page: 1 of 9

**HOW TO WITHDRAW A PQS PRODUCT PERFORMANCE
SPECIFICATION**

	Effective date	Revision date
1st edition: 08/07/2004 <i>(For details see revision table)</i>	08/07/2004	06/01/2007; 27/01/2017
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Prequalification Team (PQT)



SOP No MHP/RPQ/PQT/VAX/PQS/003	Date of issue 2 nd edition: 06/04/2018	Revision date 2 nd edition: 01/04/2020
Version: 01.06	Effective date 2 nd edition: 06/04/2018	Page: 2 of 9

Title: How to withdraw a PQS product performance specification.

Contents

1. Purpose.....	3
2. Scope.....	3
3. Responsibility.....	4
4. Associated reference documentation	5
5. Procedure	5
5.1 Identify the need for withdrawal	5
5.2 Approval for withdrawal	6
5.3 Publication	6
6. Distribution.....	6
Annex 1: Standard letter A - Notification of specification withdrawal.....	7
Annex 2: Terms and definitions.....	8
Revision history	9



SOP No MHP/RPQ/PQT/VAX/PQS/003	Date of issue 2 nd edition: 06/04/2018	Revision date 2 nd edition: 01/04/2020
Version: 01.06	Effective date 2 nd edition: 06/04/2018	Page: 3 of 9
Title: How to withdraw a PQS product performance specification.		

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 syringes¹:

- 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](#)

It is essential that performance specifications are regularly reviewed. As soon as it becomes evident that the product type described in the specification is no longer required to help meet WHO policy objectives, the specification should be formally withdrawn.

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

Applicable to all performance specifications prepared under the PQS initiative, with the exception of syringes.

¹ 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*”.



SOP No MHP/RPQ/PQT/VAX/PQS/003	Date of issue 2 nd edition: 06/04/2018	Revision date 2 nd edition: 01/04/2020
Version: 01.06	Effective date 2 nd edition: 06/04/2018	Page: 4 of 9
Title: How to withdraw a PQS product performance specification.		

3. Responsibility

Responsibilities and tasks will be assigned as follows:

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

- Documents outdated performance specifications that should be withdrawn and informs the Secretariat;
- Sends the proposal to the *PQS Secretariat* (this may take place at any time); and
- Where requested by the Secretariat, solicits information and input from country EPI to that may inform prioritization of specification withdrawal.

The *PQS Secretariat (Secretariat)*³:

- Examines the proposal and, if satisfied of the need, directs that the withdrawal of the performance specification be commissioned;
- Commissions a *Technical Specialist* to review the specification that is commissioned for withdrawal;
- Requests WG review(s) of the specification commissioned for withdrawal;
- Arranges for peer review of the specification commissioned for withdrawal, and may also arrange for [manufacturer](#) review (at the discretion of the Secretariat);
- Takes the ultimate decision to approve the withdrawal of the specification; and
- Publishes the withdrawal of the specification to the PQS website and circulates it to the relevant members of staff of WHO, UNICEF and manufacturers.

A *Technical Specialist (TS)*:

- Reviews the need for withdrawal and makes recommendations to the Secretariat.

² 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.

³ 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.



SOP No MHP/RPQ/PQT/VAX/PQS/003	Date of issue 2 nd edition: 06/04/2018	Revision date 2 nd edition: 01/04/2020
Version: 01.06	Effective date 2 nd edition: 06/04/2018	Page: 5 of 9
Title: How to withdraw a PQS product performance specification.		

4. Associated reference documentation

- SOP No MHP/RPQ/PQT/VAX/PQS/001: *How to develop and publish a PQS product performance specification.*
- 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/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.*
- SOP No MHP/RPQ/PQT/VAX/PQS/011: *How to remove a pre-qualified product from the PQS database.*

5. Procedure

Each of the task headings below includes (in brackets) a description of the person or group responsible for the task.

5.1 Identify the need for withdrawal (WG)

The WG will advise the Secretariat of any performance specifications which may need to be withdrawn for any of the following reasons:

- Feedback from country EPI programmes;
- WHO and UNICEF immunization programme changes;
- Comments received from testing laboratories, technical specialists and manufacturers identifying fundamental technical shortcomings in the specification;
- Feedback reports from field monitoring activities highlighting fundamental specification-related problems; or
- Technical or other developments which may render a specification obsolete.

The WG will send its withdrawal proposals to the Secretariat for decision and approval. This can happen at any time but will usually occur at the next PQS WG quarterly meeting.



SOP No MHP/RPQ/PQT/VAX/PQS/003	Date of issue 2 nd edition: 06/04/2018	Revision date 2 nd edition: 01/04/2020
Version: 01.06	Effective date 2 nd edition: 06/04/2018	Page: 6 of 9

Title: How to withdraw a PQS product performance specification.

5.2 Approval for withdrawal

(Secretariat)

The Secretariat takes the final decision on withdrawal of a specification.

5.3 Publication

(Secretariat)

As soon as the withdrawal has been approved, the affected manufacturers should be notified of the intended action. Withdrawal notification and the associated timelines for manufacturer conformity must be reasonable, and may vary on a case-by-case basis depending on the reason for withdrawal. Standard letter A (Annex 1) can be used for this purpose.

Subsequently the specification will be removed from the PQS website and replaced with a document describing the reason for the withdrawal. Generally speaking, this action should not take place until at least six months after the affected manufacturers have been notified. At the same time, notification of withdrawal will be posted on the PQS database/catalogue website and the TechNet-21 website. All PQS manufacturers affected by the specification withdrawal will be informed by email.

All products covered by the specification will be deleted from the database. Refer to SOP No MHP/RPQ/PQT/VAX/PQS/011 *How to remove a pre-qualified product from the PQS database* for details of this procedure.

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.



SOP No MHP/RPQ/PQT/VAX/PQS/003	Date of issue 2 nd edition: 06/04/2018	Revision date 2 nd edition: 01/04/2020
Version: 01.06	Effective date 2 nd edition: 06/04/2018	Page: 7 of 9

Title: How to withdraw a PQS product performance specification.

Annex 1: Standard letter A - Notification of specification withdrawal

Dear Sirs,

Proposed withdrawal of PQS performance specification

We refer to the WHO PQS performance specification <reference, title and date>. We write to advise you that it has been decided that this specification no longer meets the needs of the immunization programme. The principle reasons for this are as follows:

< reasons> (Example:)

Project Optimize reported that battery system failure accounted for the majority of first generation solar-powered vaccine appliance equipment failures. In response PQS established a category of for battery free solar direct drive appliances.

PQS RF06 relies on a battery to sustain acceptable vaccine storage temperatures. Technology has advanced since the initial publication of RF06 and demonstrates that an ancillary battery is not necessary for solar direct drive operation. Of the <insert number> solar direct drive appliances presently prequalified <insert number> are battery free and comply with the RF05 category with no ancillary battery.

The RF06 specification was revised and published on 15 September 2016. The revision informed the discontinuation plan for the specification stating: ‘The RF06 category will expire and no longer be prequalified after two years from the date of this revision.’

PQS E003 RF05.4 Refrigerator or combined refrigerator and water-pack freezer: Solar direct drive without battery storage remains in effect and allows the prequalification of solar direct drive appliances.

Your company currently has prequalified product(s) conforming to this specification listed on the PQS database. As a matter of courtesy we write to inform you that we intend formally to withdraw this specification in six months` time on <dd.mm.yy>⁴.

Yours faithfully,

⁴ When a specification is withdrawn the pre-qualified products to which the document relates will also be withdrawn. This process is covered by SOP No MHP/RPQ/PQT/VAX/PQS/011: *How to remove a pre-qualified product from the PQS database*. This letter is a pre-warning of withdrawal of pre-qualification status.



SOP No MHP/RPQ/PQT/VAX/PQS/003	Date of issue 2 nd edition: 06/04/2018	Revision date 2 nd edition: 01/04/2020
Version: 01.06	Effective date 2 nd edition: 06/04/2018	Page: 8 of 9

Title: How to withdraw a PQS product performance specification.

Annex 2: Terms and definitions

Device	A medical device such as a syringe or temperature monitor for example.
Legal manufacturer	<p>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 party⁵.</p> <p>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, or OEM.</p>
Manufacturer	In the context of this SOP, the word manufacturer includes both legal manufacturers and resellers.
Product	In this document, where the word 'product' is used on its own, it includes device.
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.
Verification protocol	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>

⁵ Definition derived from Article 1 2.(f) of the EU Medical Device Directives.



SOP No MHP/RPQ/PQT/VAX/PQS/003	Date of issue 2 nd edition: 06/04/2018	Revision date 2 nd edition: 01/04/2020
Version: 01.06	Effective date 2 nd edition: 06/04/2018	Page: 9 of 9
Title: How to withdraw a PQS product performance specification.		

Revision history

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

SOP Number:	MHP/RPQ/PQT/VAX/PQS/003	
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Revisions		
Date	Change and reason	Authorised by (Signature and Name)
06/01/2007	<ul style="list-style-type: none"> ATT team was changed to QSS team due to the reorganization in the IVB Department. The code VML was changed to PQS in the SOP No.s for easy reference. The person responsible for giving no- objection clearance for the specifications was identified as the QSS Coordinator. 	Drafted by O. Afsar Approved by U. Kartoğlu
27/01/2017	<ul style="list-style-type: none"> Hyperlink to each PQS category added in the 'Purpose' clause. Footnotes defining the PQS Working Group and the PQS Secretariat added in Clause 3. 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). 'Responsibilities' clause revised to separate out specific responsibilities of key actors and to remove process elements. Clause 6 'Distribution' edited to include complete group of stakeholders. 'Terms & definitions' moved to annex, revised, definitions updated in line with WG reviews of PQS glossary Feb 2018. Sub-clauses of 5 'Annual technical review' and 'Extraordinary technical review' removed as standalone sections. Concrete example of a reason for specification withdrawal added to Annex 1. 	Drafted by P. Mallins Approved by I. Gobina
01/04/2020	<ul style="list-style-type: none"> MVP/EMP/PQT is renamed MHP/RPQ/PQT/VAX throughout to reflect structural changes: (Vaccines & Immunization Devices Assessment Team (VAX), Prequalification Unit (PQT), Regulation & Prequalification Department (RPQ), Access to Medicines and Health Products Division (MHP) 	Drafted by P. Mallins Approved by I. Gobina