PERFORMANCE, QUALITY & SAFETY (PQS) STANDARD OPERATING PROCEDURE		
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HOW TO REMOVE A PREQUALIFIED PRODUCT FROM THE PQS DATABASE.

	Effective date	**Revision date**
1st edition: 08/07/2004 *(For details see revision table)*	08/07/2004	06/01/2007; 27/01/2017
2nd edition: 06/04/2018 *Authorised by:* *Reviewed by:*	06/04/2018 I. Gobina P. Mallins	01/04/2020

Prequalification Team (PQT)

Contents

1. Purpose

All immunization-related products or devices in the following categories must *prequalified* before they can be added to the PQS database[1]:

- 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 product can only be prequalified if it complies with a PQS performance specification and with the related PQS product verification protocol.

Circumstances can subsequently arise which make it necessary to remove a prequalified product from the database. This SOP identifies these circumstances and describes the removal procedure.

The procedures set out in this SOP will be followed by the *PQS Secretariat* (Secretariat) and by the *PQS Working Group* (WG).

2. Scope

This SOP is applicable to all products prequalified through 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: "*Prequalification of single-use injection devices under the PQS system: Guidelines for manufacturers*"

3. Responsibility

Responsibilities and tasks will be assigned as follows.

The *PQS Working Group* (WG)[2] (at the direction of *PQS Secretariat*):

- Reviews products being considered for removal from the PQS database;
- Makes recommendations to Secretariat.

The *PQS* Secretariat (Secretariat)[3]:

- Establishes and maintains a register which records the performance of prequalified products and prequalified manufacturers;
- Takes the final decision to retain, suspend or remove a product's prequalified status;
- Removes all dependent prequalified products from the PQS database[4] if a PQS performance specification and/or a verification protocol is withdrawn; and
- Publishes withdrawal of a product's prequalified status on the PQS website and circulates it to the relevant members of staff of WHO, UNICEF and manufacturers.

4. Associated reference documentation

- SOP No MHP/RPQ/PQT/VAX/PQS/003: How to withdraw a PQS product performance specification.
- SOP No MHP/RPQ/PQT/VAX/PQS/006: How to withdraw a PQS product verification protocol.
- SOP No MHP/RPQ/PQT/VAX/PQS/009: How to review applications for prequalification of PQS products.
- SOP No MHP/RPQ/PQT/VAX/PQS/010: How to re-evaluate a prequalified PQS product.

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[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.

[4] See SOP No MHP/RPQ/PQT/VAX/PQS/003: *How to withdraw a PQS product performance specification* and SOP No MHP/RPQ/PQT/VAX/PQS/006: *How to withdraw a PQS product verification protocol*.

5. Procedure

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

5.1 Product Performance Register

(Secretariat)

The performance of each prequalified product and each prequalified manufacturer listed on the PQS database will be regularly monitored. The Secretariat will establish and maintain a register to record these data and will investigate complaints of unsatisfactory performance. The register will be organized according to the following hierarchy:

<PQS product category> : <manufacturer> : <product>

The Secretariat will obtain performance information from the following sources:

- UNICEF Supply Division Quality Assurance Centre (QAC) reports;
- Results of structured field performance monitoring;
- Performance feedback from governments and donor agencies;
- Manufacturers' *Change Notifications*[5];
- Manufacturers' *Product Defect Reports*[6];
- Questionnaires;
- Anecdotal reports from the field; and
- Relevant policy decisions.

5.2 Grounds for removing a product from the database

(Secretariat)

There are five principle reasons why a product or group of products may need to be removed from the database.

[5] See SOP No MHP/RPQ/PQT/VAX/PQS/001: *How to develop and publish a PQS product performance specification*. Annex 1.
[6] Ibid.

5.2.1 Unsatisfactory product

If a prequalified product fails to perform satisfactorily as per the relevant product specification, it should be removed from the PQS database. Grounds for taking this action include:

- If the manufacturer changes the product in way which is unacceptable as per the requirements of the relevant product performance specification;
- If the field performance is not in accordance with performance specification requirements;
- If product quality is poor or inconsistent;
- If there are product defects; or
- If the product reliability is poor.

In cases where a specific design or manufacturing fault is widely reported, the Secretariat will notify the manufacturer, allowing a six-month period in which to rectify the fault and (if necessary) to re-verify the product. In the meantime, the product will be suspended as described in SOP No MHP/RPQ/PQT/VAX/PQS/010: *How to re-evaluate a prequalified PQS product.*

5.2.2 Unsatisfactory manufacturer

If a manufacturer of prequalified products fails to perform satisfactorily, some or all of his products may have to be removed from the PQS database. Grounds for taking this action include:

- Bankruptcy, receivership, corruption or other financial irregularity;
- Poor production quality control (e.g. reported by UNICEF Supply Division QAC;
- Failure to meet agreed delivery schedules;
- Poor after-sales service (e.g. reported by end-users);
- An un-notified change of manufacturer or manufacturing site, resulting in one or more of the problems identified in Clauses 5.2.1 and 5.2.2.

5.2.3 Major revision to performance specification/verification protocol

Whenever there is a major revision to a performance specification or product verification protocol, a transitional period of at least one year[7] (determined on a case-by-case basis at the discretion of the Secretariat) will be allowed to enable manufacturers to re-verify their products. After a re-verification process, some products may no longer be compliant and these products will be removed from the PQS database.

5.2.4 Withdrawal of performance specification/verification protocol

When a performance specification or verification protocol is withdrawn, all prequalified products conforming to that package are to be removed from the PQS database. Manufacturers will have been notified of the withdrawal in accordance with the relevant SOPs[8].

5.2.5 WHO policy change

From time to time, changes in WHO policy will make an entire group of products obsolete. A recent example of this is the decision no longer to recommend the use of reusable syringes. When such a policy decision comes into force, all prequalified products affected by the policy decision must be removed from the PQS database. Generally, there will be a transitional period of months or even years leading up to the removal.

5.2.6 Nonpayment of prequalification or annual review fee

The Secretariat will suspend and eventually remove a product if fees are not paid.

- After two months of non-payment from invoice date a product will be suspended.
- After four months of non-payment from invoice date a product will have PQS status removed.

[7] See SOP No MHP/RPQ/PQT/VAX/PQS/002: *How to review and revise a PQS product performance specification* and SOP No MHP/RPQ/PQT/VAX/PQS/005: *How to review and revise a PQS product verification protocol*. Manufacturers will have been invited to comment on the draft revision, so the effective transitional period is likely to be 15 to 18 months.

[8] See SOP No MHP/RPQ/PQT/VAX/PQS/003: *How to withdraw a PQS product performance specification* and SOP No MHP/RPQ/PQT/VAX/PQS/006: *How to withdraw a PQS product verification protocol*.

5.3 Recommendation to remove a product

(WG)

Upon the request of the Secretariat, the WG is responsible for delivering recommendations concerning the removal of an unsatisfactory or obsolete product. Before doing so, it may need to consult with WHO EPI, UNICEF Programme Division and Supply Division and relevant experts on policy matters and technical issues. A written case for removing the product will then be prepared by the WG and submitted to the Secretariat.

5.4 Approval process

(Secretariat)

The Secretariat will review the written case for product removal and take the final decision to either to remove or to retain the product. Final decision for removal of a product rests with the Secretariat.

5.5 Publication

(Secretariat)

As soon as removal has been approved, the product manufacturer will be notified of the decision using the general format of *Standard letter A* (Annex 1).

Notification is to be by letter, fax or by email. A copy must be filed in the Performance Register.

The relevant PQS database website entry will be overwritten with the words:

PRODUCT WITHDRAWN ON <DD.MM.YY>

The overwritten entry will remain on the website for a minimum period of six months, after which it will be deleted. Notification of the withdrawal will also be posted on the TechNet-21 forum.

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 the product prequalification process,
- All relevant manufacturers,
- PQS and TechNet-21 websites.

Annex 1: Standard letter A - Notification of product removal

Dear Sirs,

Notification of loss of prequalification status for a product or device listed on the PQS database.
Your reference:

We refer to <product/device description> which is currently listed on the PQS database. We regret to inform you that a decision has been made to remove the product from the database for the following reasons:

EITHER (ref 5.2.1 - unsatisfactory product):
<briefly list principle reasons>

You are free to re-submit a new or modified product/device at any time in the future provided it complies fully with the requirements set out in the PQS performance specification and PQS verification protocol current at the time of re-submission.

OR (ref 5.2.2 – unsatisfactory manufacturer):
<briefly list principle reasons>

OR (ref 5.2.3 – major revision to specification or verification protocol):
The reason for this decision is that WHO have revised the PQS performance specification/verification protocol relating to this class of products and we do not consider that <product/device description> complies with the revised document(s). Accordingly the product will be withdrawn from the database on <dd.mm.yy>. You are free to re-submit a new or modified product/device before that date, or at any time in the future, provided it complies fully with the requirements set out in the revised performance specification/ revised verification protocol, a copy of which we enclose.

OR (ref 5.2.4, 5.2.5 – specification/verification protocol withdrawal/policy change):
The reason for this decision is that WHO have now withdrawn the performance specification relating to this class of products <give reasons if necessary, e.g. policy change>.

AND:
We regret that we are unable to enter into any correspondence on this matter.

Yours faithfully,

Annex 2: Terms and definitions

Correspondence	Includes mail, fax and email.
Device	A medical device such as a syringe or temperature monitor for example.
Evaluator	An individual or organization (including a testing laboratory) responsible for evaluating the suitability of the components and services described in this specification for inclusion in the register of PQS prequalified products.
In writing	Communication by letter, fax or email. A hard copy will be kept on file.
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[9]. 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.
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: *How to develop and publish a PQS product verification protocol.*

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

Revision history

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

SOP Number:	MHP/RPQ/PQT/VAX/PQS/011	
Date of issue 1st edition:	08/07/2004	
Date of issue 2nd edition:	06/04/2018	
Revisions		
Date	**Change and reason**	**Authorised by (Signature and Name)**
06/01/2007	• 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	• 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. • Added sub-clause 5.2.6 'Nonpayment of prequalification or annual review fee'.	Drafted by P. Mallins Approved by I. Gobina
01/04/2020	• MVP/EMP/PQT is renamed MHP/RPQ/PQT/VAX throughout to reflect structural changes: (Vaccines &	Drafted by P. Mallins Approved by I. Gobina

	Immunization Devices Assessment Team (VAX), Prequalification Unit (PQT), Regulation and Prequalification Department (RPQ), Access to Medicines and Health Products Division (MHP)	