



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

SOP N°: MHP/RPQ/PQT/VAX/PQS/010

Version n°: 01.06

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**HOW TO RE-EVALUATE A PREQUALIFIED PQS
PRODUCT.**

	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)



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1. Purpose

All immunization-related [products](#) or [devices](#) in the following categories must *prequalified* before they can be added to the PQS database¹:

- 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 the relevant PQS performance specification and with the related PQS product [verification protocol](#). Once a product has been prequalified it must be re-evaluated annually to ensure that it continues to be fit for purpose. This SOP describes the procedure for product re-evaluation.

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 any product or device prequalified through the PQS initiative, with the exception of syringes.

3. Responsibility

Responsibilities and tasks will be assigned as follows.

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

- Re-evaluates product dossiers;
- Makes recommendations to the Secretariat.

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*”

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.



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The *PQS Secretariat* (Secretariat)³:

- Ensures that every product on the database is re-evaluated annually;
- Receives dossiers from applicants, establishes and maintains a register that records the details of all applications for product prequalification;
- Convenes Working Group (WG) members and/or Technical Specialists to carry out annual review;
- Reviews product dossiers;
- Corresponds with applicants if any clarifications are required on product dossiers;
- Takes the final decision to retain, suspend or remove a product's prequalified status;
- Informs PQS product manufacturers of their decision; and
- Publishes re-evaluation status on the PQS website and circulates it to the relevant members of staff of WHO, UNICEF and manufacturers.

A *Technical Specialist* (TS):

- Re-evaluates dossiers as directed by the Secretariat; and
- Makes recommendations to Secretariat.

4. Associated reference documentation

- WHO/BCT/03.09: Procedure for assessing the acceptability, in principle, of single-use injection devices for procurement by United Nations agencies.
- SOP No MHP/RPQ/PQT/VAX/PQS/009: How to evaluate applications for the prequalification of PQS products.
- SOP No MHP/RPQ/PQT/VAX/PQS/011: How to remove a prequalified product from the PQS database.
- 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/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.

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.



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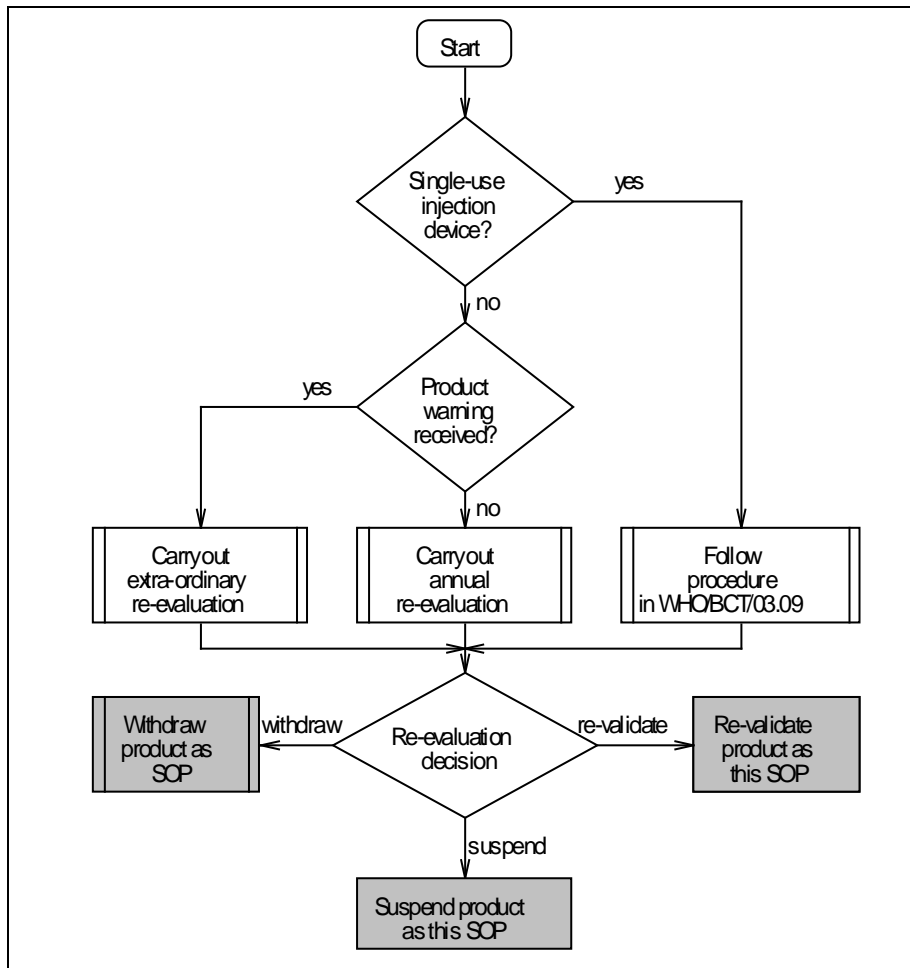
- SOP No MHP/RPQ/PQT/VAX/PQS/005: How to review and revise a PQS product verification protocol.
- SOP No MHP/RPQ/PQT/VAX/PQS/006: How to withdraw a PQS product verification protocol.

5. Procedure

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

Figure 1 summarizes the pre-evaluation process.

Figure 1 – Re-evaluation process





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5.1 Identifying the need for withdrawal of a specification

(WG)

The WG will identify 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 formal approval. This can happen at any time but will usually occur at the next PQS WG quarterly meeting.

5.2 Re-evaluation for single-use injection devices

(Secretariat)

All re-evaluations relating to single-use injection devices will be processed strictly in accordance with the procedure described in document WHO/BCT/03.09: *Procedure for assessing the acceptability, in principle, of single-use injection devices for procurement by United Nations agencies*. As with other PQS products, the decisions of the Secretariat will be filed in the PQS product register.

5.3 Re-evaluation for all other products

(Secretariat)

The Secretariat is responsible for the re-evaluation process. Normally this will be carried out on an annual basis. However, there are circumstances when it may be necessary to carry out an extraordinary re-evaluation.



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A re-evaluation exercise will consider the following:

- UNICEF Supply Division Quality Assurance Centre (QAC) reports;
- Results of structured field performance monitoring;
- Performance feedback from governments and donor agencies;
- Manufacturers' *Change Notifications*⁴;
- Manufacturers' *Product Defect Reports*⁵;
- Questionnaires;
- Anecdotal reports from the field; and
- Relevant policy decisions.

5.3.1 Annual re-evaluation

The normal annual re-evaluation exercise will take place on an agreed date each year. It will cover all products on the PQS database irrespective of the original date of acceptance of the product onto the database. Thus, in the first year following prequalification, a product may be re-evaluated less than 12 months after its acceptance.

5.3.2 Extraordinary re-evaluation

An extraordinary re-evaluation is justified under the following circumstances:

- If and when major changes have been made to the product;
- If there has been a failure on the part of the manufacturer to notify WHO of complaints received about the product;
- If UN agencies or organizations have reported receiving non-compliant products; and/or
- If complaint investigations have indicated significant quality or safety defects.

If such circumstances arise, the product must be re-evaluated *immediately*.

⁴ See SOP No MHP/RPQ/PQT/VAX/PQS/001: How to develop and publish a PQS product performance specification. Annex 1.

⁵ Ibid.



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5.3.3 *Courses of action*

Where minor concerns regarding quality or performance have come to light, the manufacturer should be notified and asked to comment. *Standard letter A* (Annex 1) can be used for this purpose.

Where major concerns arise, it may be necessary to suspend a product's prequalification status; for example, a product change has resulted in a material reduction in performance, or a change in manufacturing site has resulted in a noticeable loss of quality. In these circumstances, *Standard letter B* (Annex 2) may be used to notify the manufacturer, who is given the following options:

1. In the case of *quality concerns*: To satisfy the Secretariat that quality issues have been addressed;
2. In the case of *performance concerns*: To re-test against the current verification protocol; or
3. To withdraw the product voluntarily.

Action by the manufacturer must place within six months of the date of notification.

5.4 Re-evaluation report

(Secretariat)

In the case of an extraordinary re-evaluation, -the Secretariat will prepare a special re-evaluation report for circulation to the WG.

In the case of the annual re-evaluation, the Secretariat will prepare a report covering all products on the database. Reports will follow the format set out in Annex 3.

5.5 Approval process

(Secretariat)

The Secretariat, will review the recommendations in the re-evaluation report and take the final decision to either to re-validate, to suspend or to withdraw a product.



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5.6 Subsequent action

(Secretariat)

The decisions of the Secretariat will be filed in the PQS product register.

Products that are directed to be withdrawn will be processed in accordance with SOP No MHP/RPQ/PQT/VAX/PQS/011: *How to remove a prequalified product from the PQS database.*

Products that are suspended will be followed up to ensure that the manufacturer responds adequately. The suspension will not be lifted until the manufacturer has responded effectively.

In addition, the relevant PQS website entry will be overwritten with the words:

PRODUCT SUSPENDED ON <DD.MM.YY>

UNICEF Supply Division will also be notified of the notice of suspension.

No further action will be required for products that are to be re-validated.

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.



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Annex 1: Standard letter A - Notification of problems identified during product re-evaluation

Dear Sirs,

Notification of problems identified during product re-evaluation.

Your reference:

We refer to <product/device description> which is currently listed on the PQS database.

We write to advise you that at the recent

EITHER:

<annual product review >

OR:

<extraordinary product review>

a number of concerns regarding this item of equipment came to light. These concerns are as follows:

- <list concerns>

At present, the PQS prequalification status for this product will be maintained. However, we would be grateful if you would comment on the problems we have identified and provide us with a timetable for their resolution.

Meanwhile, if you have any queries, please contact the writer.

Yours faithfully,



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Annex 2: Standard letter B - Notice of suspension of prequalification status

Dear Sirs,

Notification of suspension of 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 write to advise you that at the recent

EITHER:

<annual product review>

OR:

<extraordinary product review>

it was decided to suspend the prequalification status for this item of equipment. This means that, for the time being, UN purchasing agencies will no longer procure the product from your company. The reasons for this decision are as follows:

<list reasons>

EITHER: (quality control concerns)

If you wish us to reinstate your prequalified status you must satisfy us by <dd/mm/yy> that the quality control problems that we have identified have been adequately addressed.

AND/OR: (performance concerns)

If you wish to reinstate your prequalified status you must re-test the product by <dd/mm/yy>. We enclose a copy of the relevant verification protocol <state reference, title and date>, current at the date of this letter.

If you wish to withdraw the product permanently from the PQS database, please confirm this in writing. Meanwhile, if you have any queries, please contact the writer.

Yours faithfully,



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Annex 3: Model format for product re-evaluation report

PQS product re-evaluation report		Date: <dd.mm.yy>
PQS reference: <ref>		Prequalification date: <dd.mm.yy>
<product description>		
1.	UNICEF Supply Division Quality Assurance Centre (QAC) reports: <brief description>	
2.	Results of structured field performance monitoring: <brief description>	
3.	Performance feedback from governments and donor agencies: <brief description>	
4.	Manufacturers' <i>Change Notifications</i>: <brief description>	
5.	Manufacturers' <i>Product Defect Reports</i>: <brief description>	
6.	Questionnaires: <brief description>	
7.	Anecdotal reports from the field: <brief description>	
8.	Relevant policy decisions: <brief description>	
9.	Recommendation: <brief description>	
Re-validate product: <input type="checkbox"/> Suspend product: <input type="checkbox"/> Remove product: <input type="checkbox"/>		
Date of suspension notification: <dd.mm.yy>		



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Annex 4: Terms and definitions

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	<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 party⁶.</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>

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



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Revision history

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

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Date of issue 1 st edition:	08/07/2004	
Date of issue 2 nd edition:	06/04/2018	
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. Added sub-clause 5.1 'Identifying the need for withdrawal of a specification.' 	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 & 	Drafted by P. Mallins Approved by I. Gobina



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