



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

SOP N°: MHP/RPQ/PQT/VAX/PQS/005

Version n°: 01.06

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**HOW TO REVIEW AND REVISE A PQS PRODUCT VERIFICATION
PROTOCOL.**

	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
2nd edition: 06/04/2018 <i>Authorised by:</i> <i>Reviewed by:</i>	06/04/2018 I. Gobina P. Mallins	01/04/2020

Prequalification Team (PQT)



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1. Purpose

A PQS product [verification protocol](#) describes in detail how the performance of a class of immunization-related [products](#) will be tested or otherwise evaluated as part of the PQS product prequalification procedure. All immunization products in the following categories require a PQS product verification protocol, 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 product verification protocols are regularly reviewed and revised where necessary, so that they remain consistent with current technical standards and continue to meet WHO policy objectives.

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 product verification protocols 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: “*Prequalification 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)*² (at the direction or request of the PQS Secretariat):

- Documents the need for a revised verification protocol;
- May prepare draft design criteria for the required revision;
- 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 to inform the prioritization of protocol development; and
- Reviews draft protocol revision and provides input to TS.

The *PQS Secretariat (Secretariat)*³:

- Examines the proposal and, if satisfied of the need, directs that a new verification protocol be commissioned;
- Commissions a *Technical Specialist* to develop the draft verification protocol revision;
- Reviews draft verification protocol revision and provides input to TS;
- Requests WG review(s) of draft verification protocol revision;
- Arranges for as peer review and [manufacturer](#) review of draft verification protocol revision;
- Takes the decision for final approval of the revised protocol; and
- Publishes the final revised verification protocol 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 verification protocol revision in consultation with the WG; and
- Revises the protocol based on the WG, peer and manufacturer reviews and submits a final draft 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.



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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/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/006: *How to withdraw a PQS product verification protocol.*

5. Procedure

5.1 Introduction

A verification protocol 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.

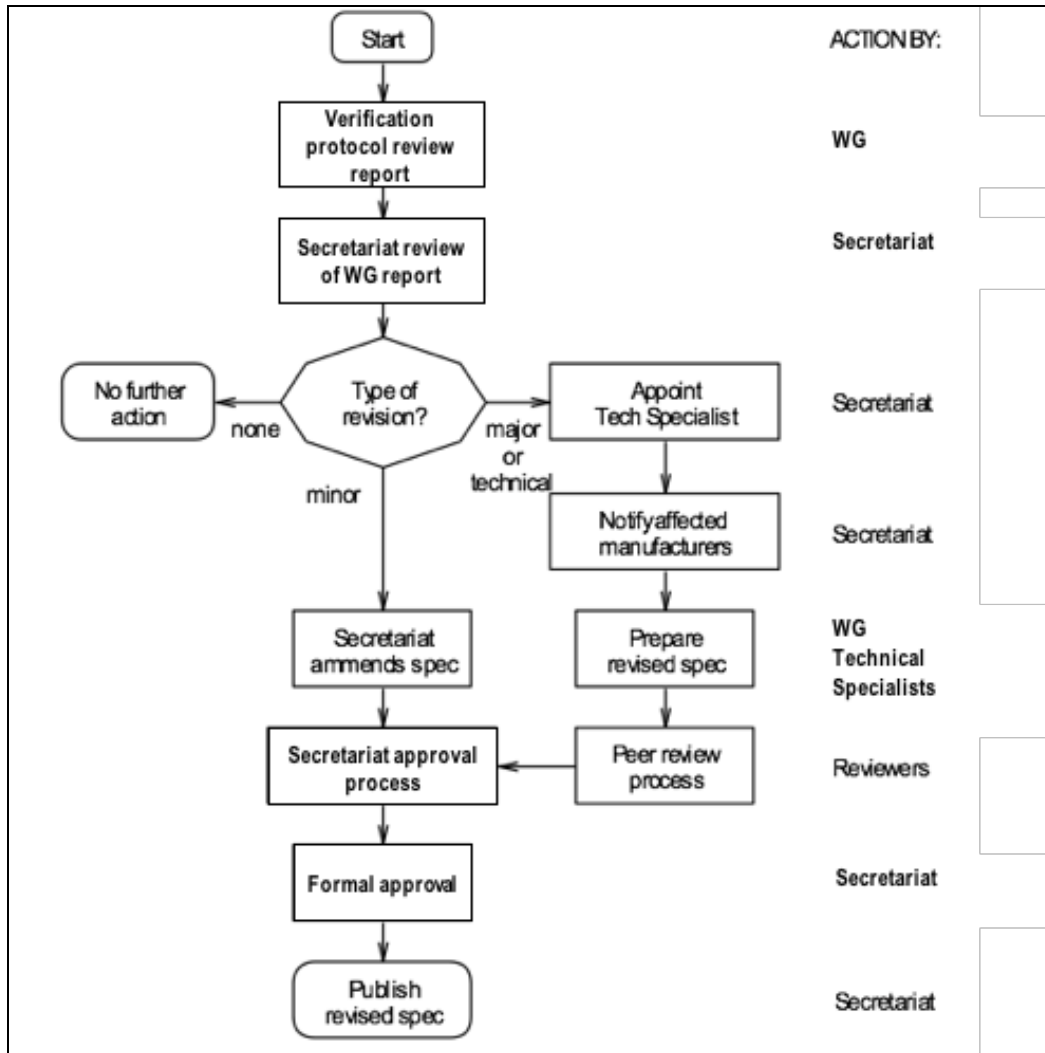
Figure 1 provides an overview of the various stages in the development of a verification protocol, which are described in more detail in the following paragraphs. Each of the task headings below includes (in brackets) a description of the person or group responsible for the task.

A verification protocol 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 – Verification protocol revision procedure





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5.2 Identify the need for revision

(WG)

The WG will advise the Secretariat of any product verification protocols which may require amendment for any of the following reasons:

- Feedback from country EPI programmes;
- WHO and UNICEF immunization programme changes which may affect the status or content of a protocol;
- Introduction of new or revised international standards that are relevant to EPI;
- Other changes in programme requirements, such as the introduction of new vaccines;
- Comments received from testing laboratories, technical specialists and manufacturers which identify technical shortcomings in the protocol;
- Feedback reports from field monitoring activities; or
- Technical or other developments which may render a protocol obsolete.

5.2.1 *No revisions*

If the WG wishes to advise that no revisions are necessary this will be noted in its report to the PQS Secretariat. No further action is required.

5.2.2 *Minor revisions*

The WG may identify revisions which do not significantly affect the technical content of the protocol and which do not affect the prequalification status of existing products listed on the PQS database/catalogue. Such revisions may include, but are not limited to, updated references to published (relevant) international standards and typographical corrections. The amended protocol will not require formal review, but it must be checked and signed off by a member of the Secretariat. Typographical corrections will generally be carried out by the Secretariat. Technical corrections should, in general, be made by the TS, commissioned to carry out the work. As a matter of courtesy, existing prequalified manufacturers should be provided with a copy of the amended document when it is published. Standard letter A (provided in Annex 1) may be used for this purpose.

5.2.3 *Major revisions*

The WG may identify revisions that significantly affect the technical content of the protocol. In this situation, the WG will make a recommendation to the Secretariat that it commissions a TS to prepare a revised protocol which will be reviewed *as though it were a new document*. The proposed changes should be evaluated to establish how they will impact existing prequalified products. As part of this process, the manufacturers of **all** the prequalified products that will be affected by the proposed changes must be informed of



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the intended amendments and invited to comment on them at the draft stage. Standard letter B (provided in Annex 2) may be used for this purpose. The period for submitting comments should generally be two months. Existing manufacturers of prequalified products are accorded a grace period before they must conform to the new protocol. The grace period should be a minimum of one year after publication of the revised document⁴.

The WG will send its revision proposals to the Secretariat for formal approval, either at its next annual technical review, at quarterly PQS WG meetings, bi-monthly teleconferences or at an extraordinary technical review.

5.3 Peer review of major revisions

The Secretariat will share the verification protocol with the WG for review. The draft protocol must go through at least one round of WG review. The number of reviews is determined by the complexity of the specification and decided at the discretion of the Secretariat.

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.

⁴ This may be subject to negotiation with the affected manufacturers. The timeframe must be reasonable and fair.



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5.4 Documenting revisions

(TS, WG and/or Secretariat)

All changes will be clearly identified in the ‘revisions’ section of the protocol. The Secretariat is responsible for approving all revisions.

The revision section of the protocol will also:

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

Figure 2 provides an example.

Figure 2 – Example of a verification protocol revision record

Revision history:			
Date	Change summary	Reason for change	Approved
01.01.05	<ul style="list-style-type: none"> • Clause 4.2.1: Temperature range changed to +2°C to +10°C. • Clause 4.2.10: Pen recorder option omitted. •etc. 	New directive on storage temperatures. To comply with EVSM requirementsetc.	ABC

5.5 Time allowance

All product verification protocol changes identified by the Secretariat must be implemented, reviewed as necessary and approved within two months of the Secretariat meeting.

5.6 Approval

(Secretariat)

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



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5.7 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 verification protocol,
- All relevant manufacturers,
- PQS and TechNet-21 websites.



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Annex 1: Standard letter A -Notification of minor changes to verification protocol

Dear Sirs,

Amendments to PQS product verification protocol

We refer to the WHO PQS product verification protocol <reference, title and date>.

Your company currently has prequalified product(s) conforming to this protocol listed on the PQS database. As a matter of courtesy, we write to inform you that we have made some minor amendments to this document. The nature and purpose of these amendments is summarised below:

Amendment

<list>

Reason for amendment

<list>

These alterations do not affect the prequalification status of your existing product(s). However, you should take them into account if and when you request prequalification of additional products and whenever you make changes to your existing product line(s) which justify re-verification.

If you have any comments, please contact the writer by post, fax or email.

Yours faithfully,



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Annex 2: Standard letter B -Notification of major changes to verification protocol

Dear Sirs,

Proposed changes to PQS product verification protocol

We refer to the WHO PQS product verification protocol <reference, title and date>.

Your company currently has prequalified product(s) conforming to this protocol listed on the PQS database. As a matter of courtesy, we write to inform you that we intend to make significant changes to the document. The nature and purpose of these changes is summarised below:

Proposed change
<list>

Reason for change
<list>

If you have any comments on the proposed alterations please contact the writer by post, fax or email no later than <dd.mm.yy>⁵. In preparing the revised document we will take full account of your comments and those of other prequalified manufacturers and we may wish to discuss them with you in detail before finalising the revisions.

Our intention is to publish the revised verification protocol in <mm.yy> and we will expect all existing prequalified manufacturers to re-verify their products in accordance with the new requirements by no later than <mm.yy>⁶.

Yours faithfully,

⁵ Allow a minimum of two months.

⁶ Allow a minimum of one year after the publication date in the first instance.



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Annex 3: 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 party⁷.</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>

⁷ 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	
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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.• In Clause 5 'Procedure' an introduction has been added (sub-clause 5.1).• Sub-clauses of 5 'Annual technical review' and the 'Extraordinary technical review' removed as standalone sections.• Clause 5.3 'Peer review of major revisions' expanded including timelines.	Drafted by P. Mallins Approved by I. Gobina



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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 and Prequalification Department (RPQ), Access to Medicines and Health Products Division (MHP))	Drafted by P. Mallins Approved by I. Gobina
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