



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

SOP N°: MHP/RPQ/PQT/VAX/PQS/004

Version n°: 01.06

Page: 1 of 23

**HOW TO DEVELOP AND PUBLISH 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
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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](#)

[Manufacturers](#) are free to offer products for assessment against the performance standards set out in the product verification protocol; products that satisfy these standards are deemed to be prequalified and will be included on the PQS database. This database provides a resource which 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 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: “*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)*² (at the direction or request of the *PQS Secretariat*):

- Documents the need for a new verification protocol;
- 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 to inform prioritisation of protocol development; and
- Reviews draft verification protocol 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;
- Reviews draft verification protocol and provides input to TS;
- Requests WG review(s) of draft verification protocol;
- Arranges for as peer review and [manufacturer](#) review of draft verification protocol;
- Takes the decision for final approval of the document; and
- Publishes the final verification protocol to the PQS website and circulates it to the relevant members of staff of WHO, UNICEF and manufacturers.

A *Technical Specialist (TS)*:

- Drafts the verification protocol in consultation with the WG; and
- Revises the draft verification 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/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 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.

Figures 1 to 5 in this document provide an overview of the various stages in the development of a verification protocol and other associated protocols in the process. These protocols 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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5.2 Product verification

(PQS Secretariat, WG and TS)

A product must be verified before it can be added to the list of prequalified products in the PQS database.

Verification establishes whether a specific product from a specific manufacturer satisfies the requirements of the relevant PQS performance specification. There are three distinct methods:

- Type-examination,
- Independent type-testing, and
- Full quality assurance.

Effective quality control (QC) throughout the manufacturing process is an essential prerequisite for consistent product quality. In the absence of effective QC procedures, laboratory testing (which relies on a limited number of samples) cannot provide the assurance that a product will perform satisfactorily in the field. Consequently, a key element of all three of the verification routes described below is an examination of the manufacturer's QC procedures. The distinction between the first two routes and the *Full quality assurance* route is that examination of QC in the latter case extends to on-site operations.

Type-examination verification involves the systematic inspection of product samples supplied by the product manufacturer who wishes to be prequalified. The technique is checklist-based. It is a suitable verification method for technologically simple items that are supplied in relatively small quantities. Where the risks⁴ associated with product failure⁵ are low, type-examination may also be a suitable method of verification for simple high-volume items as well as for more complex items that are supplied in small quantities. Type examination verification may also be justified where quality control standards in the relevant industry are uniformly high. Type examination can be carried out in-house by WHO and UNICEF or the work may be delegated to an independent inspecting organization. Alternatively, a *type examination certificate*, issued by a reputable independent body, may be an acceptable substitute.

Independent type-testing verification involves the physical testing of a number of product samples against a rigorously defined test verification protocol. This route is required for complex high value products and also for simple high-volume products where the issues

⁴ E.g. risks to life of patients, or major loss of vaccine potency.

⁵ Product failures should be reported and corrective actions taken by manufacturer; such as the replacement of goods, or correction of the manufacturing process. See SOP No MHP/RPQ/PQT/VAX/PQS/013: *How to obtain feedback on the performance of a PQS product*.



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that may arise from product failure⁶ are high-risk. Independent type testing must be carried out by an ISO/IEC 17025 accredited testing laboratory.

Full quality assurance verification is required for complex high value, low volume products which require an element of site-specific design as well as on-site assembly and commissioning work; cold rooms and standby generator installations are examples that fall into this category. Manufacturers or [approved installers](#) offering such products cannot be prequalified solely on the basis of type-examination or type-testing because every instance of the product will in some way be unique. Instead, prequalification must be based on a thorough assessment of technical specifications and quality control procedures, supported by references from other customers. To achieve full quality assurance, the manufacturer or approved installer must generally be ISO 9001-accredited; in most cases the completed installation will also be inspected and approved by an independent inspecting organization⁷. The fees for the independent inspection will be paid either by the donor agency that has paid for the equipment, or by the client government.

5.3 Establish a verification protocol grouping (PQS Secretariat, TS, WG)

Every product performance specification must be associated with a compatible verification protocol. In some cases, a performance specification will have its own unique verification protocol. In other cases, a verification protocol will be common to a group of specifications. For example, all absorption cycle refrigerators may use the same verification protocol, even though there may be more than one performance specification for this category of equipment. The TS, in consultation with the WG, will agree this basic *verification protocol group*. Figure 1 outlines this process.

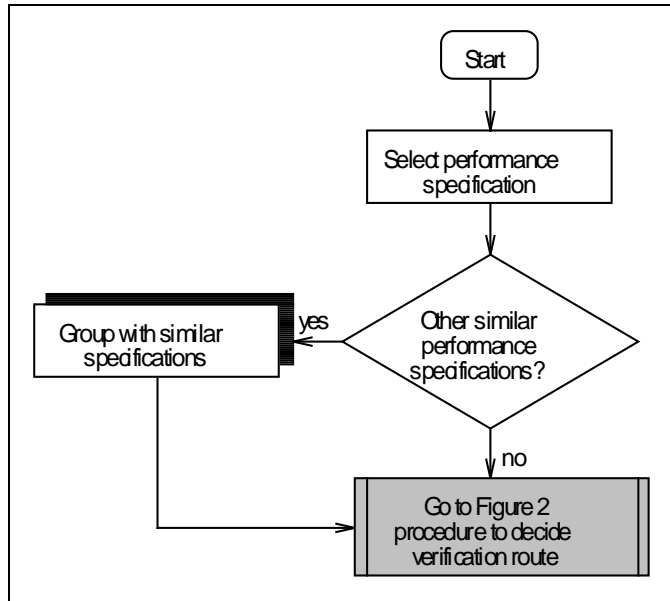
⁶ Product failures should be reported and corrective actions taken by manufacturer; such as the replacement of goods, or correction of the manufacturing process. See SOP No MHP/RPQ/PQT/VAX/PQS/013: *How to obtain feedback on the performance of a PQS product*.

⁷ See SOP No MHP/RPQ/PQT/VAX/PQS/001: *How to develop and publish a PQS product performance specification Annex 1*.



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Figure 1 – Define the verification protocol group



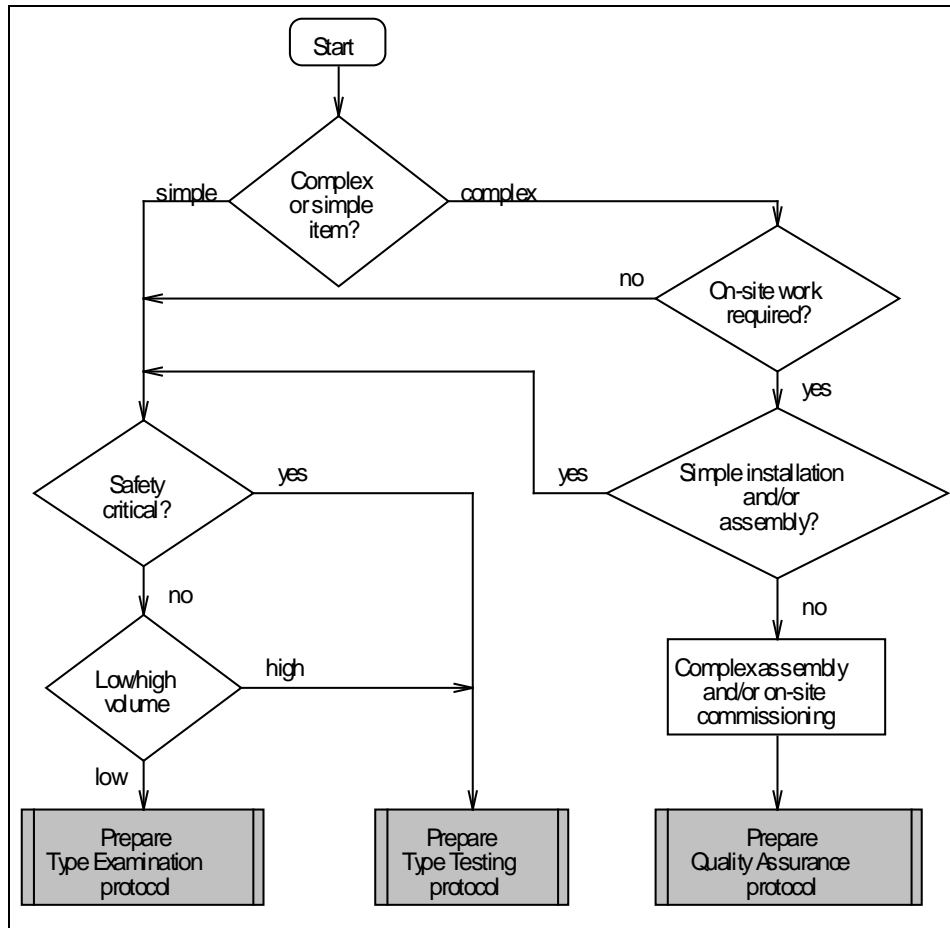
5.4 Agree a verification route for each grouping
(TS, WG)

Figure 2 shows the decision tree for selecting the suitable product verification route, using criteria set out in Clause 5.1. The TS, in consultation with the WG, will follow this procedure and will decide which of the three verification routes should be chosen for a particular grouping of equipment or devices. For safety-critical items the default decision will generally be to adopt type-testing, unless the quality control standards of *all* prequalifying manufacturers are likely to be high.



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Figure 2 – Choose the product verification protocol type



5.5 Prepare a verification protocol

(TS, WG,)

Once a verification route has been chosen the TS will prepare the relevant protocol. The TS will consult with the WG and will consider controlled recommending the inclusion of field trials in the product verification process. The following sections describe how to prepare each type of verification protocol.

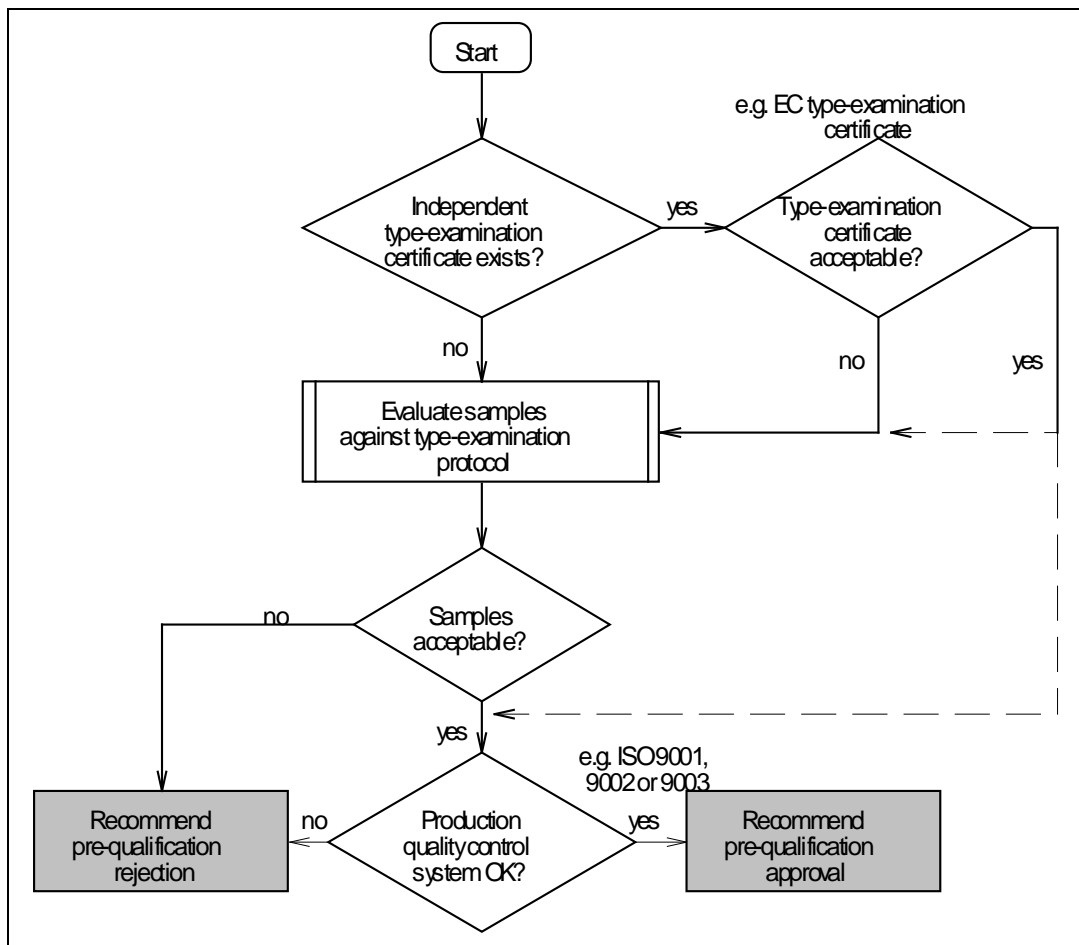


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5.5.1 Prepare a type-examination protocol

Figure 3 outlines the type-examination process.

Figure 3 – Type-examination protocol





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A *Type Examination Certificate* is evidence that the product conforms to certain minimum standards; it should only be accepted if it has been issued by a recognised independent body and if the standards certified are at least as stringent as those set out in the product performance specification. If this is the case, then it may not be necessary to evaluate samples against the assessment checklist. However, if there is any doubt about quality or suitability then these additional checks will also be carried out.

No products will be prequalified unless the manufacturer can show that he has a satisfactory production *Quality Control* system in place. Ideally the system should be certified or audited by a *Notified body* in accordance with the ISO 9000 series standard(s) appropriate to the industry. If there is any doubt about the standard of quality control, an on-site inspection of the production facilities must be carried out.⁸ If the manufacturer subsequently modifies a prequalified product, he is required to notify WHO of the alteration(s) under the change notification procedure set out in the relevant PQS performance specification.⁹

Annex 2 provides a model format for a type-examination checklist.

⁸ The UNICEF Quality Assurance Centre also inspects the premises and Quality Control systems of many of its manufacturers as part of its normal procurement procedures.

⁹ See SOP No MHP/RPQ/PQT/VAX/PQS/001: How to develop and publish a PQS product performance specification Annex 1.

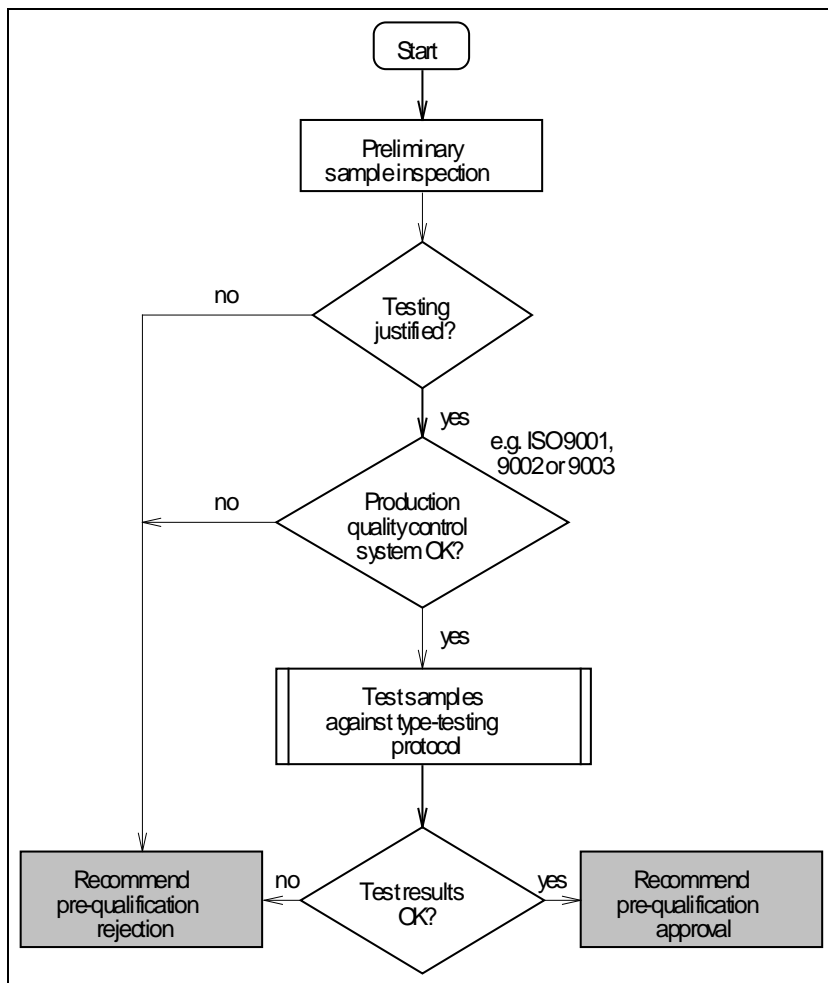


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5.5.2 *Prepare a type-testing protocol*

Figure 4 outlines the independent type-testing protocol.

Figure 4 – Independent type-testing protocol



Annex 3 provides a model format for an independent type-testing protocol.

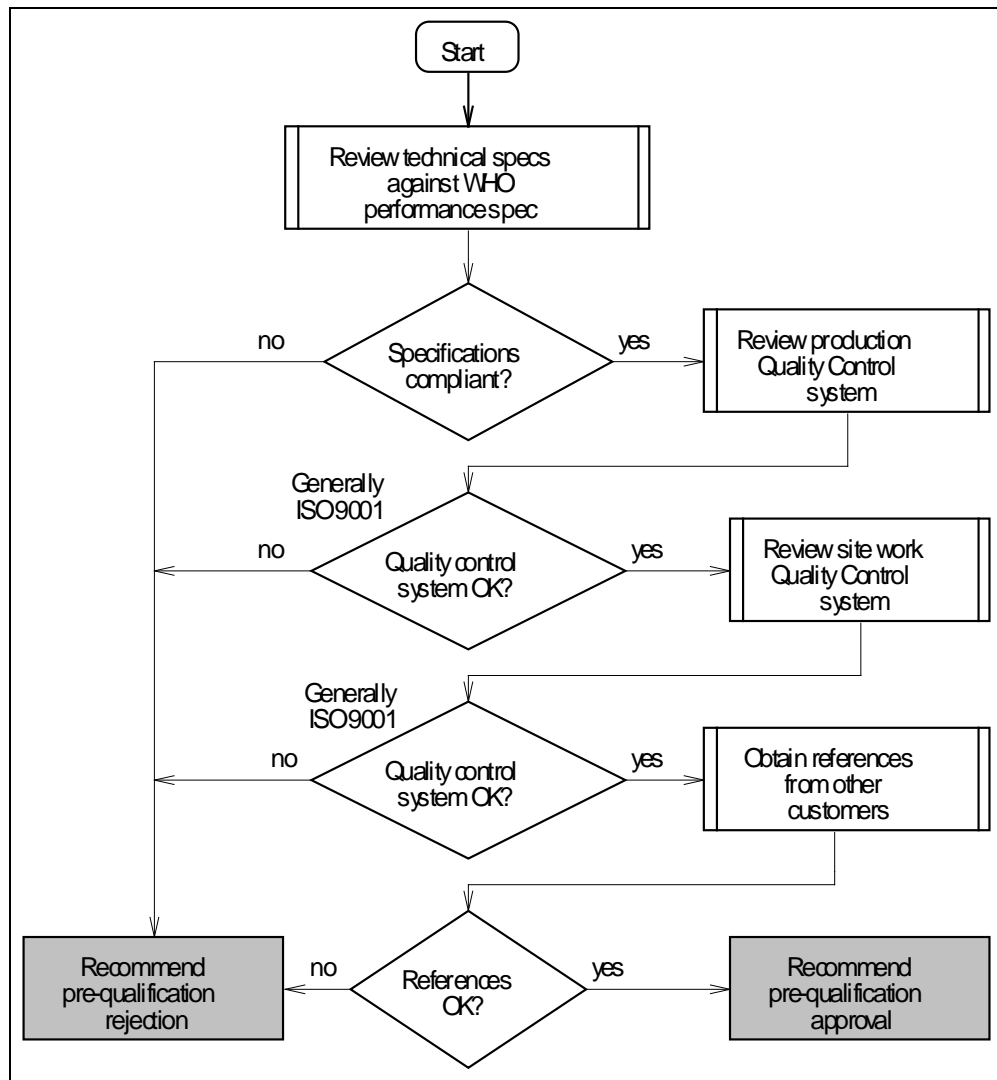


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5.5.3 *Prepare a quality assurance protocol*

Figure 5 outlines the quality assurance protocol.

Figure 5 – Quality assurance protocol



Annex 4 provides a model format for a quality assurance protocol.



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5.6 Review process

(Secretariat, WG, Manufacturers, TS)

The Secretariat will request the WG to review the draft verification protocol. The draft protocol 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 protocol 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 protocol is ready for manufacturer review.

The Secretariat will send the draft protocol 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.

5.7 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.

5.8 Approval

(Secretariat)

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



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5.9 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 format for a type-examination protocol



WHO/XXX
PQS Type-examination protocol
 English
 Distribution: General

Original:

TITLE: <Description>

Product verification protocol: <PQS category>/<unique reference>

Applies to specification ref(s): <PQS category>/<unique reference>

Date of origin: <Date>

Date of last revision: <Date>

Contents: <list the content down to level 1.1.1>

1. **Scope:** <briefly describe the purpose of the type examination protocol>
2. **Normative references:** < list ISO/IEC and other standards that apply to the protocol and list any other relevant WHO product verification protocols>
3. **Terms and definitions:** <define any specific terms used in the protocol, particularly terms which may not be widely understood>
4. **Applicability:** <state who will carry out the sample examination and state who will carry out on-site inspection of the manufacturer's production facilities (where relevant)>
5. **Sample-examination checklist:**
 - 5.1 Type examination certificates: < list acceptable type-examination certifiers and state the form in which evidence of type-examination is to be provided >
 - 5.2 Number of samples: <state minimum number of samples to be evaluated>
 - 5.3 Sample checklist: <list product features that are to be examined and describe how each item in the list is to be evaluated, including ergonomic, health and safety and 'universal design' features>
 - 5.4 Criteria for qualification: <state the minimum requirements for prequalification>
6. **Quality control checklist:**
 - 6.1 Quality control standards: < list acceptable quality control standards (e.g. ISO 9001) and state the form in which evidence of conformity is to be provided>
 - 6.2 Quality control checklist: <list the production quality control features that are to be examined in the course of the on-site inspection (if applicable)>
 - 6.3 Criteria for qualification: <state the minimum requirements for prequalification>



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7. **Prequalification evaluation:** <state the overall minimum requirements for prequalification taking account of results from Clauses 5.4 and 6.3 and including any weighting system that may be needed >
 8. **Modified products:** <describe the procedure for re-checking products that are already prequalified, but which have subsequently been modified by the manufacturer. This procedure may not involve full re-verification.>
- Annexes:** < as required>

Revision history

Date	Change summary	Reason for change	Approved
ddmmy y	< change item> < etc.>	< reason for change> < etc.>	<name>

Annex 2: Standard format for a type-testing protocol



WHO/XXX
PQS Independent type-testing protocol
 Distribution: General

Original: English

TITLE: <Description>

Product verification protocol: <PQS category>/<unique reference>

Applies to specification ref(s): <PQS category>/<unique reference>

Date of origin: <Date>

Date of last revision: <Date>

- **Contents:** <list the content down to level 1.1.1>

1. **Scope:** <briefly describe the purpose of the independent type-testing protocol>
2. **Normative references:** < list ISO/IEC and other standards that apply to the protocol and list any other relevant WHO product verification protocol>
3. **Terms and definitions:** <define any specific terms used in the protocol, particularly terms which may not be widely understood>
4. **Applicability:** <state who will carry out the type-testing and state who will carry out on-site inspection of the manufacturer's production facilities (where relevant)>
5. **Type-testing procedure**
 - 5.1 Number of samples: <state minimum number of samples to be evaluated>
 - 5.2 Test procedure: <set out the technical details of the test procedure, including testing ergonomic, health and safety and 'universal design' features>



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5.3 Test criteria for qualification: <state the minimum requirements for qualification>

6. Quality control checklist

6.1 Quality control standards: < list acceptable quality control standards (e.g. ISO 9001) and state the form in which evidence of conformity is to be provided>

6.2 Quality control checklist: <list the production quality control features that are to be examined in the course of the on-site inspection (if applicable)>

6.3 Quality control evaluation: <state how the quality control checklists are to be evaluated>

7. Prequalification evaluation: <state the minimum criteria for prequalification taking account of results from Clauses 5.3 and 6.3 and including any weighting system that may be needed >

8. Modified products: <describe the procedure for re-checking products that are already prequalified, but which have subsequently been modified by the manufacturer This procedure may not involve full re-verification.>

Annexes: < as required>

Revision history

Date	Change summary	Reason for change	Approved
ddmmy y	< change item> < etc.>	< reason for change> < etc.>	<name>



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Annex 3: Standard format for a quality assurance protocol



WHO/XXX
PQS Quality assurance protocol
 English
 Distribution: General

Original:

TITLE: <Description>	
<i>Product verification protocol:</i>	<PQS category>/<unique reference>
<i>Applies to specification ref(s):</i>	<PQS category>/<unique reference>
<i>Date of origin:</i>	<Date>
<i>Date of last revision:</i>	<Date>
-	Contents: <list the content down to level 1.1.1>
1.	Scope: <briefly describe the purpose of the quality assurance protocol>
2.	Normative references: < list ISO/IEC and other standards that apply to the protocol and list any other relevant WHO product verification protocols>
3.	Terms and definitions: <define any specific terms used in the protocol, particularly terms which may not be widely understood>
4.	Applicability: <state who will carry out the quality assurance assessment and (where relevant) state who will carry out on-site inspection of the manufacturer’s production facilities and site work>
5.	Specification checklist
5.1	<u>Specification requirements:</u> <list the performance specification requirements against which manufacturers’ own specifications are to be checked>
5.2	<u>Criteria for qualification:</u> <state the minimum requirements for prequalification>
6.	Quality control checklist
6.1	<u>Quality control standards:</u> < list acceptable quality control standards (e.g. ISO 9001) and state the form in which evidence of conformity is to be provided>
6.2	<u>Manufacturing quality control checklist:</u> <list the production quality control features that are to be checked. State whether on-site inspection of the production facility is required>
6.3	<u>Site work quality control checklist:</u> <list the site work quality control features that are to be checked. State whether on-site inspection of an assembly site(s) is required. Including ergonomic, health and safety and ‘universal design’ features>
6.4	<u>Criteria for qualification:</u> <state the minimum requirements for prequalification, including provision of evidence of ‘approved installer’ status>



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7. Customer reference checklist

- 7.1 Number of references: <specify the minimum number of customer references that are required>
- 7.2 Reference questionnaire: <draw up the questionnaire to be circulated to selected customers>
- 7.3 Questionnaire evaluation: <state how questionnaire results are to be evaluated>

8. Prequalification evaluation: <state the overall minimum criteria for prequalification taking account of results from Clauses 5.2, 6.4 and 7.3 and including any weighting system that may be needed >

9. Modified products: <describe the procedure for re-checking manufacturers that are already prequalified, but who have subsequently modified their product. This procedure may not involve full re-verification.>

Annexes: < as required>

Revision history

Date	Change summary	Reason for change	Approved
ddmmy y	< change item> < etc.>	< reason for change> < etc.>	<name>

Annex 4: Terms and definitions

Approved installer	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.
Device	A medical device such as a syringe or temperature monitor.
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 ¹⁰ . A legal manufacturer may commonly contract another company to manufacture products or devices sold under the legal manufacturer's

¹⁰ Definition derived from Article 1 2.(f) of the EU Medical Device Directives.



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	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.
Universal design	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> .
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.



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Revision history

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SOP Number:	MHP/RPQ/PQT/VAX/PQS/004	
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. Footnotes added to sub-clause 5.2 to define product failure and describe its risks. 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-clause of 5 'Prepare a memorandum for the PQS-SG' removed as standalone sections reflecting the changes to the PQS system. Clause 5.7 'Documenting revisions' added. Clause 5.6 expanded to cover full 'Review 	Drafted by P. Mallins Approved by I. Gobina



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	process' and timelines.	
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