PERFORMANCE, QUALITY & SAFETY (PQS) STANDARD OPERATING PROCEDURE		
SOP N°: MHP/RPQ/PQT/VAX/PQS/012	**Version n°:** 01.06	**Page:** 1 of 17
HOW TO FIELD-TEST A PQS PRODUCT.		
	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	~~(none to date)~~01/04/2020
Prequalification Team (PQT)		

Contents

Commented [GH1]: I have added a revision history note for these updates – let me know if its ok. I've changed the edit date to today too.

1. Purpose

The purpose of PQS field studies is to ensure that devices and/or technologies perform according to the specifications when used in field settings, are acceptable to end-users and have no significant negative impacts on the health system.

Field testing will generally be mandatory for products with the following characteristics:

- Based on technology(ies) not previously employed in immunization or general health programmes in the developing world;
- Require creation of a new PQS equipment category;
- Consist of a new technology not previously PQS prequalified;
- Require a substantial PQS modification, such as a need for specific tests not covered in the current verification protocols;
- Require specific user training to be operated effectively;
- Risk being rejected by health workers or patients; and/or
- Product has an R&D history of technical failures.

In addition, field testing may also be justified for products which are safety-critical or which are used in very large quantities.

Field-testing provides manufacturers with information to improve product design and it can also help end-users to choose products that are best suited to their needs. However, if test results are to be useful, there must be a completely clear understanding of the purpose to which they will be put. This requires well-developed evaluation techniques and protocols based on standardised criteria. The aim must be to obtain the maximum amount of useful information on product performance at minimum cost and with minimum disruption to the working lives of health care staff.

This SOP outlines some field-testing methods, indicates which of these is suitable for testing the various categories of immunization-related equipment and gives guidance on the development of field-test protocols. It also establishes the administrative framework within which a PQS field-test should take place. This will require the active cooperation of national EPI programme managers, as well as the assistance of technical staff in WHO/UNICEF country and regional offices.

The procedures set out in this SOP will be followed by the *PQS Secretariat* (Secretariat), the *PQS Working Group* (WG), by all product manufacturers, implementing partners and Ministries of Health (MoH) involved in field testing a PQS product.

2. Scope

This SOP is applicable to all field-tests of products carried out under the PQS initiative.

3. Responsibility

PQS-required field studies are the responsibility of manufacturers. The *PQS Secretariat*[1] (Secretariat) and/or individual members of the *PQS Working Group*[2] (WG) may, in specific, exceptional circumstances, fund studies.

Commented [GH2]: Added exceptional here, to reflect Joanie's feedbacks. Ok or should we remove this last sentence altogether and just leave it that manufacturers fund? I would vote we DON'T remove it in the SOP, just because here we need to reflect the entirely of the possible scenarios / processes.

Responsibilities and tasks will be assigned as follows.

The *PQS Secretariat* (Secretariat):

Commented [GH3]: This appears to still be correct based compared to joanie's feedback.

- Maintains a prioritised list of product types which justify field-testing and recommends appropriate field-tests for each of these types;
- Determines, if a product requires field testing as part of the prequalification process including, if required consultation with the Working Group (WG);
- Approves a protocol and/or implementing partner;
- Reviews field studies proposals and field test reports;
- Examines the proposals in liaison with the Working Group (WG) if deemed appropriate and, if satisfied of the need, directs that a model field-testing protocol be commissioned; and
- Stores field test reports in the product dossier.

The *product manufacturer*:

Commented [GH4]: This appears to still be correct based compared to joanie's feedback.

- Commissions a field test protocol;
- Identifies implementing partner;
- Funds the field test; and
- Obtains country approvals for the field study.

[1] 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.

[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.

The *implementing partner(s)*:
- Remains independent and impartial.

Commented [GH5]: Do we want to add something about their role in supporting the manufacturer in gaining the relevant authorizations and ethical clearances from MoH?

The *Ministry of Health (MoH)*:
- Approves the field test protocol; and
- Provides required access for the implementing partner.

4. Associated reference documentation

- WHO/PQS/GENERIC/GUIDE.1.1: *Generic Guide for the field evaluation of new technologies for PQS prequalification.*
- SOP No MHP/RPQ/PQT/VAX/PQS/013: *How to obtain feedback on the performance of a PQS product.*
- 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/003: *How to develop and publish a PQS product verification protocol.*
- Product performance specification relating to the product(s) under test.
- Product verification protocol relating to the product(s) under test.

5. Procedure

Obtaining good quality information on product performance in the field is a challenge. There are two generic methods that can be used to field-test PQS products: field surveys and real-time instrumentation. In addition, there is a tailor-made field-survey based tool which has been specifically designed to evaluate the ease of use of AD syringes[3].

Figure 1 indicates the strengths and weaknesses of each of these three methods.

[3] See Gergonne, B., Grandesso, F., Pinoges, L., Construction and validation of a tool for the assessment of single use injection devices under field conditions MSF Epicentre 2004.

Figure 1 – Field-testing techniques

Method	Strengths	Weaknesses
Field-survey	• Can produce statistically reliable, quantitative results. • Able to capture multi-dimensional factors, including user behaviour.	• Can be time consuming and expensive to administer. • Dependent on skills and motivation of the survey team.
MSF/WHO tool for the assessment of single use injection devices [4]	• Well-researched product-specific tool. • Satisfactory internal consistency. • Can produce quantitative results.	• Does not yet ensure with certainty 'reproducibility over time'.
Real-time instrumentation	• Relatively cheap to administer. • Provides accurate and complete quantitative records. • Enables continuous monitoring to take place over extended time periods.	• Narrowly focused on a specific indicator. • Cannot directly capture user behaviour.

[4] *Ibid* p.14.

Figure 2 indicates which of the three techniques may be appropriate for the various categories of equipment on the PQS database. This model may not fit all future PQS categories

Figure 2 – Field-testing techniques for different categories of equipment

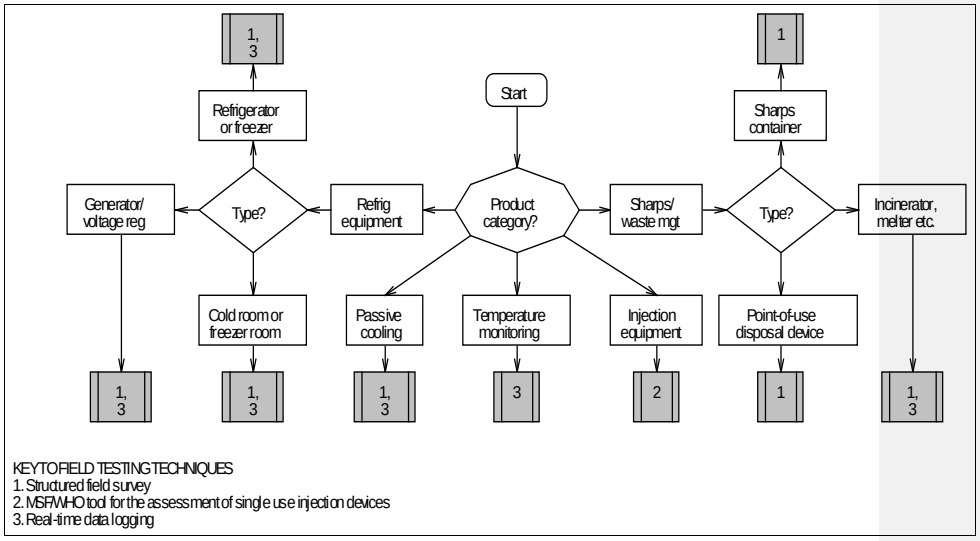

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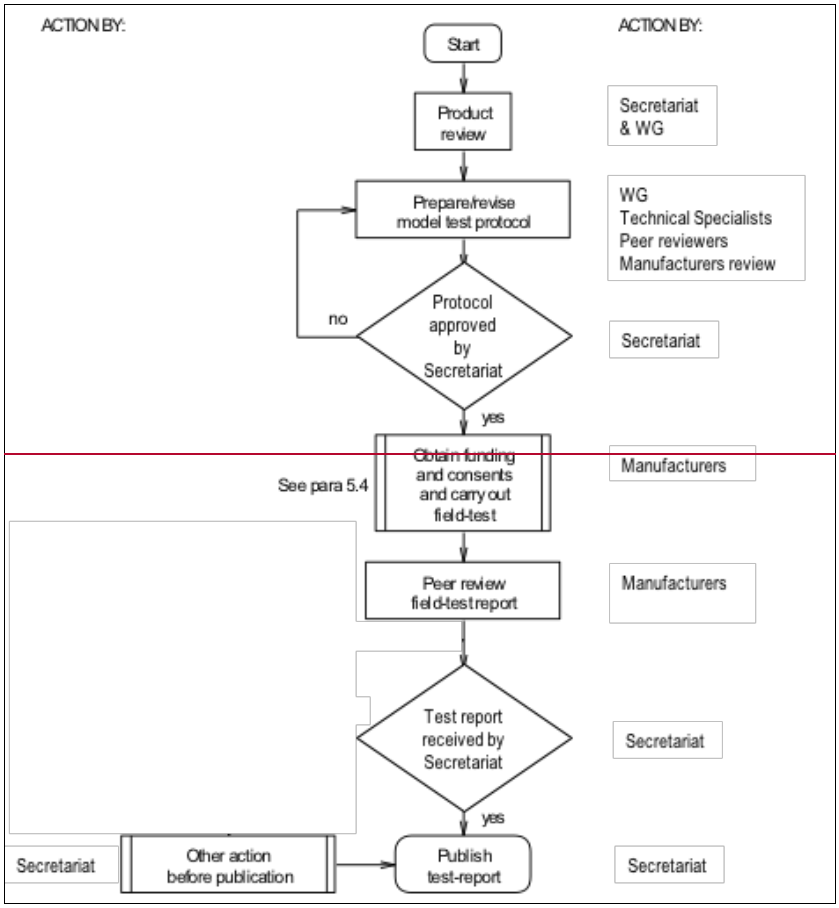
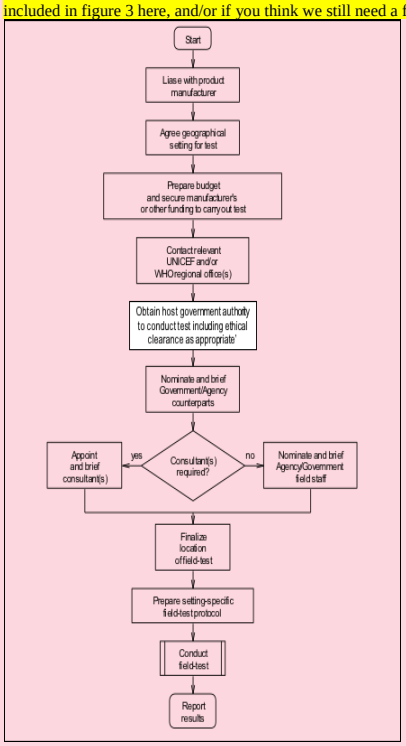
Figure 3 outlines the overall field-testing procedure which is described in more detail in Section 5.1 onwards.

Figure 3 – Developing a field-test protocol and implementing a field-test



Commented [GH6]: Alongside redrawing this one I have deleted figure 4 entirely that was below as it duplicated many of these steps and was now, its purpose was not clear. Here is figure 4 – let me know if there is anything from it that you think should be included in figure 3 here, and/or if you think we still need a figure 4?



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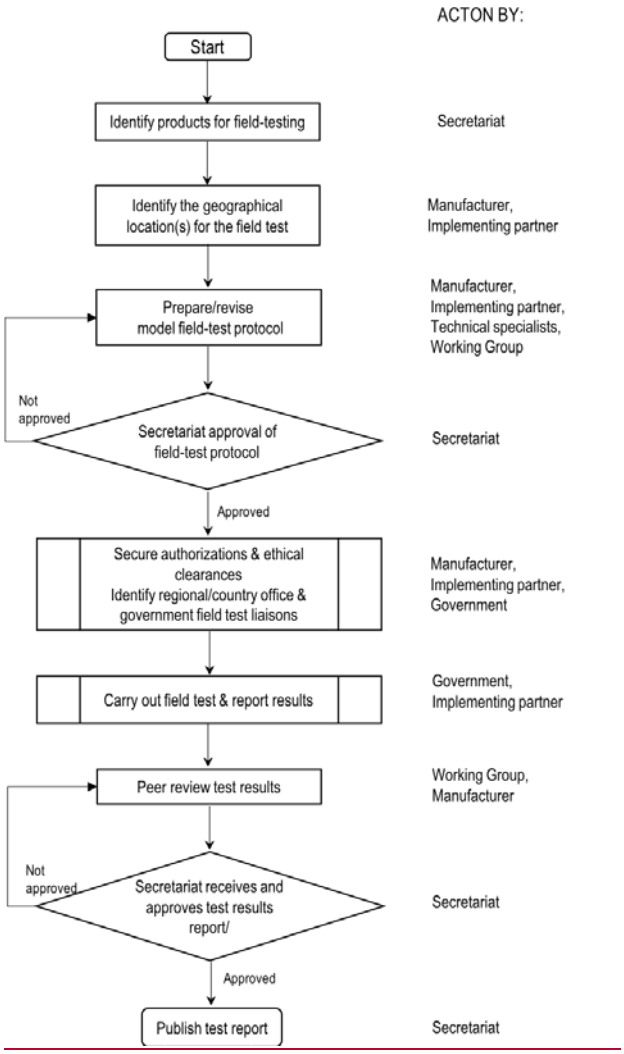
ACTON BY:
Start
Identify products for field-testing
Secretariat
Identify the geographical location(s) for the field test
Manufacturer, Implementing partner
Prepare/revise model field-test protocol
Manufacturer, Implementing partner, Technical specialists, Working Group
Not approved
Secretariat approval of field-test protocol
Secretariat
Approved
Secure authorizations & ethical clearances
Identify regional/country office & government field test liaisons
Manufacturer, Implementing partner, Government
Carry out field test & report results
Government, Implementing partner
Peer review test results
Working Group, Manufacturer
Not approved
Secretariat receives and approves test results report/
Secretariat
Approved
Publish test report
Secretariat

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

5.1 Identify products for field-testing

(Secretariat)

In the course of its liaison with the *Working Group* (WG) and *Technical Specialists* (TS) on new and revised PQS performance specifications and product verification procedures, the Secretariat will decide whether field-testing of a specified product is relevant or desirable[5].

Based on these discussions, the Secretariat will draw up and maintain a *field-testing list.* This list will prioritise product types for which field-testing is either mandatory or desirable and will specify the appropriate generic testing method for each product type (see Figure 1).

The Secretariat will also maintain a watching brief on the product feedback reports that are posted on the PQS website[6], and may subsequently amend the list to take account of evidence received from the field.

Field testing will generally be mandatory for products with the following characteristics:

- Based on technology(ies) not previously employed in immunization or general health programmes in the developing world;
- Require creation of a new PQS equipment category;
- Consist of a new technology not previously PQS prequalified;
- Require a substantial PQS modification, such as a need for specific tests not covered in the current verification protocols;
- Require specific user training to be operated effectively;
- Risk being rejected by health workers or patients; and/or
- Product has an R&D history of technical failures.

In addition, field testing may also be justified for products which are safety critical or which are used in very large quantities.

[5] See SOP No MHP/RPQ/PQT/VAX/PQS/001: *How to develop and publish a PQS product performance specification.* Annex 2, Clause 4.11.
[6] See SOP No MHP/RPQ/PQT/VAX/PQS/013: *How to obtain feedback on the performance of a PQS product.*

5.2 Identify the geographical location(s) for the field test

(Manufacturer, implementing partner)

With support from WHO PQS and possibly WHO and UNICEF regional offices, the manufacturer and implementing partner agree on a country or countries in which the field-test will be carried out.

~~5.2~~5.3 Prepare model field-test protocol

(Manufacturer, i~~I~~mplementing partner, ~~manufacturer~~)

Under normal circumstances the product manufacturer will fund the cost of the field-test. The manufacturer will proceed with the support of the implementing partner, and collaborating with the Ministry of Health in the selected location(s), to prepare the protocol. Specific testing sites are identified in this step of the process (details will be included in the test report).

A generic format for a protocol document is provided in the 'Generic Guide for Field Evaluation' (Section IV), which can be accessed at http://apps.who.int/immunization_standards/vaccine_quality/pqs_catalogue/catdocumentation.aspx?id_cat=17. Using the model field-test protocol as a basis, field staff will prepare a *setting-specific field-test protocol.* Changes to the model document will be confined to those aspects that have been left 'open' to suit test-setting conditions. NO changes will be made to the basic test design or to the method of data analysis without the agreement of the WG. A copy of this document will be annexed to the test report.

~~5.3~~5.4 Peer review model field-test protocol

(Secretariat, WG)

The Secretariat will arrange for the field-test protocol to be reviewed by technical specialist and the PQS Working Group. Once a consensus has been reached between the TS and the other reviewers, the protocol will be submitted to the

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Commented [GH8]: Joanie's feedback was: Yet the original SOP text seems to imply the TS creates the protocol and the WG reviews it… However, we don't explicitly state the TS develops the protocol… So, my suggested text here to address these issues.

Secretariat for formal approval. The Secretariat will decide which products most urgently need to be tested and will prioritise their review by the WG.

~~5.4~~5.5 Organize ~~and carry out~~ field-test

(~~Government~~M~~, m~~anufacturer, implementing partner, Government).

The manufacturer and implementing partner work with the Ministry of Health to secure the relevant authorizations and ethical clearances for the field test and identify the relevant organizations to help carry out the testing.

Once the relevant country's(ies) authorisation (including ethical clearance as appropriate) has been obtained, the regional/country office(s) will nominate and brief counterparts who will liaise with field staff during the testing programme. In addition, the regional/country office(s) will provide the Secretariat with the names(s) of the government counterpart(s). *Standard letter D* can be used for this (Annex 5).

In the standard situation where the test is funded in whole by industry, a copy of the test protocol, the work programme and budget should be shared with Secretariat.

5.6 Carry out field-test

(Government, implementing partner)

In collaboration with implementing partners, Government field staff will conduct the field-test in accordance with the approved setting-specific field-test protocol. ~~The Secretariat will liaise with product manufacturer(s), member government(s), UNICEF and/or WHO regional offices, consultant(s) and to agree funding and set up the field test.~~

~~Figure 4 outlines the process.~~

Commented [GH9]: Organize and carry out are one step in Joanie's feedback but here I think it's better to separate – it's a bit clearer.

Commented [GH10]: Specifically, the secretariat has been removed from this step, as per Joanie's feedback.

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Commented [GH11]: Original SOP text mentioned the involvement of "UNICEF and/or WHO regional offices, consultant(s)"? This also wasn't in the original website draft text so no surprise it wasn't in Joanie's reedits ether. Should we keep it here then in the SOP?

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Commented [GH12]: I have moved this up here from a step below in line with Joanie's feedback (though it is not included in her redraft, I didn't want to lose the reference to the standard letter).

Commented [GH13]: I have removed figure 4 from this section (see comme,nt abouve on figure 3)

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Commented [GH15]: Are these the correct stakeholders for the carrying out of the test? On the website we say "field staff" but that doesn't exist in the list of stakeholders we describe above here in the SOP.

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Commented [GH16]: Is this correct (also in the figure 3)

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~~**Figure 4 – Finalise test protocol and carry out field test**~~

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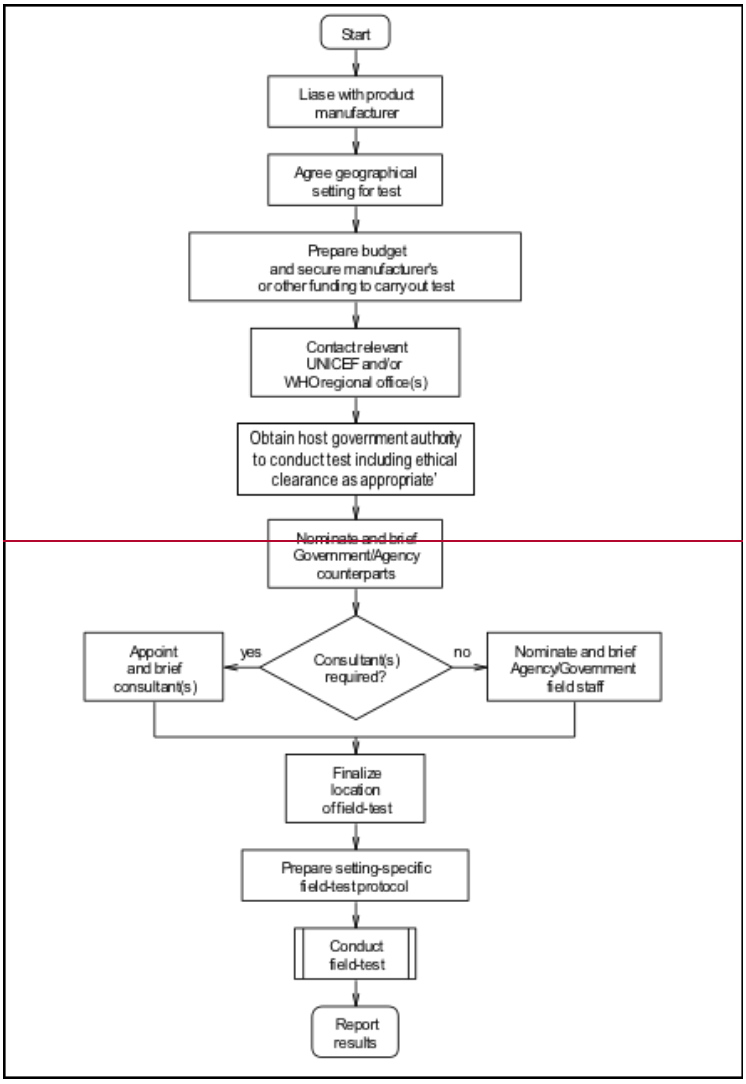

~~In the normal situation where the test is funded in whole by industry, a copy of the test protocol, the work programme and budget should be shared with Secretariat.~~

~~*5.4.1 Nominate and brief counterparts*~~

~~(Manufacturer, implementing partner)~~

~~Once the relevant country's authorisation (including ethical clearance as appropriate) has been obtained, the Secretariat will ask the regional/country office(s) to nominate and brief the counterparts who will liaise with field staff during the testing programme. In addition, the regional/country office(s) will provide the Secretariat with the names(s) of the government counterpart(s). *Standard letter D* can be used for this (Annex 5).~~

~~*5.4.2 Finalise test locations*~~

~~(Manufacturer, implementing partner):~~

~~The appointed field staff will liaise with government and agency counterparts and, where relevant, with manufacturer(s) to finalise the test locations. Details will be included in the test report.~~

~~*5.4.3 Prepare setting-specific field test protocol*~~

~~(Field staff, WG, manufacturer)~~

~~Using the model field test protocol as a basis, field staff will prepare a *setting-specific field test protocol*. Changes to the model document will be confined to those aspects that have been left 'open' to suit test-setting conditions. NO changes will be made to the basic test design or to the method of data analysis without the agreement of the WG. A copy of this document will be annexed to the test report.~~

~~*5.4.4 Conduct the field test*~~

~~(Field staff)~~

~~Field staff will conduct the field test in accordance with the setting-specific field test protocol.~~

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~~5.4.5~~5.7 Report results

(~~Field staff~~Government, implementing partners)

In collaboration with implementing partners, Government f~~F~~ield ~~staff~~ staff will prepare a test report and submit it to the Secretariat for peer-review within ~~two weeks~~one month of leaving the field. The layout of the report will be as specified in the model field-test protocol.

~~5.5~~5.8 Peer review

(WG, manufacturer~~, Secretariat~~)

The test report will be sent to the WG and the product manufacturer(s) for peer review, before it is submitted to the Secretariat for the final approval process. A minimum of two reviewers will be members of the WG. All review comments will be documented.

~~5.6~~5.9 Approval

(Secretariat~~, WG~~)

PQS is responsible for the review of a device or product that has been submitted for prequalification and the Secretariat (alone) is responsible for its approval.

(Note: there may be cases where a field-test report raises important policy-related issues. In such circumstances, the Secretariat may require further corroborative testing or may instruct other action before the test report can be published. On the other hand, if only minor changes are required, the Secretariat will arrange for these to be made.)

~~5.7~~5.10 Publication

(Secretariat)

Test reports will be published electronically in .pdf format on the PQS website. A copy of the final report will also be sent to the product manufacturer(s).

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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: 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	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[7]. 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.*

[7] 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/012
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	• 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-clause 5.4 'Organize and carry out a field-test' simplified: notably the field-	Drafted by P. Mallins Approved by I. Gobina

	test preparation phases. Field-test is responsibility of manufacturer. Replaced with references to 'Generic Guide to Field-testing' where relevant. • All 'Standard Letter' annexes removed. References to 'Generic Guide to Field-testing' added in text where relevant.	
0~~1~~5/0~~4~~3/2020	• 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
01/04/2020	• Edits to the field test process steps to reflect current practice and stakeholder responsibilities.	Drafted by P. Mallins Approved by I. Gobina