World Health Organization	REGULATION AND PREQUALIFICATION DEPARTMENT
	VACCINES ASSESSMENT TEAM

STANDARD OPERATION PROCEDURE

Reviewing and revising an IMD-PQS product performance specification

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Approved by:	TL-VAX, date: 8 May 2024	UH-PQT, date: 31 May 2024

1. OBJECTIVE

1.1. This SOP provides procedures which are followed by the IMD-PQS Secretariat (Secretariat), the IMD-PQS Working Group (WG) and by all *Technical Specialists* (TS) commissioned by the Secretariat to review and revise IMD-PQS product performance specifications.

1.2. It is essential that performance specifications are regularly reviewed and revised where necessary, so that they remain consistent with current technical standards and continue to meet WHO policy objectives.

2. SCOPE

2.1. Applicable to all performance specifications prepared by the WHO IMD-PQS Secretariat, with the exception of syringes.

2.2. All immunization products in the following categories require an IMD-PQS product performance specification, with the exception of syringes:

(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: A guideline for manufacturers)*

- 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

3. CROSS-REFERENCES

Relevant KPI(s):	Nil
Background:	https://extranet.who.int/pqweb/immunization-devices
Under this SOP:	• IMD-TP-02a - Standard letter A - Notification of minor specification changes • IMD-TP-02b -Standard letter B - Notification of major specification changes

Other QMS documents:	• IMD/SOP/01: Developing and publishing an IMD-PQS product performance specification. • IMD/SOP/03: Withdrawing an IMD-PQS product performance specification. • IMD/SOP/04: Developing and publishing an IMD-PQS product verification protocol. • IMD/SOP/05: Reviewing and revising an IMD-PQS product verification protocol. • IMD/SOP/06: Withdrawing an IMD-PQS product verification protocol.

4. 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.
IMD-PQS Secretariat	The WHO IMD-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 IMD-PQS process and takes all final IMD-PQS decisions, including the decision to award prequalified status to a product or device
IMD-PQS Working Group (WG)	The IMD-PQS WG is comprised of the WHO (IMD-PQS and Expanded Programme on Immunization (EPI)), 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.
Manufacturer	In the context of this SOP, the word manufacturer includes both legal manufacturers and resellers.
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 their own name, regardless of whether these operations are carried out by that person themself or on their behalf by a third party. 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.
Performance Specification	An IMD-PQS product performance specification is a published standard which sets out the detailed performance requirements for an immunization-related product. A performance specification defines the functional requirements of a product and describes the environment within which it must operate. It also describes any interface and inter-changeability requirements. Although it should set out clear verification criteria, it must not attempt to describe how the functional requirements are to be met. Rather, stimulating the device manufacturer to determine how the functional requirements may be best met creates room for innovation.
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 *Inclusive Design* or *Design for all.*
Verification protocol	Describes in detail how the performance of a product or device is tested or otherwise evaluated as part of the IMD-PQS product prequalification procedure. See SOP No. IMD/SOP/4: *How to develop and publish a IMD-PQS product verification protocol.*

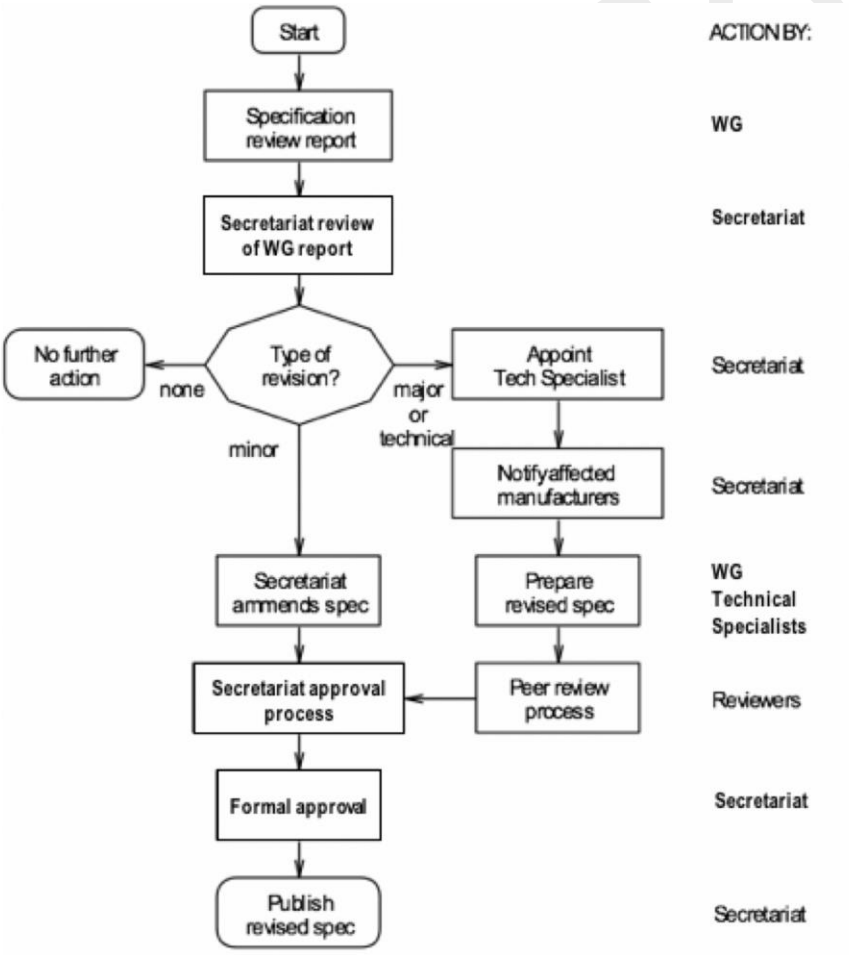
5. RESPONSIBILITIES

A Technical Specialist (TS)	• Completes the proposed design criteria and drafts the performance specification revision in consultation with the WG; and • Revises specifications based on the WG, peer and manufacturer reviews and submits a final draft to the Secretariat.
IMD-PQS Working Group (WG)	• Gathers and documents programme needs that are identified by national immunization programmes to incorporate into new performance specifications; • May prepare draft design criteria for the required product or device; • Sends the proposal to the IMD-PQS Secretariat (this may take place at any time); • Where requested by the Secretariat, solicits information and input from country EPI that may inform the prioritisation of specification development; and • Reviews draft specification and provides input to TS.
IMD-PQS Secretariat	• Examines the proposal and, if satisfied of the need, directs that a new directs that a new performance specification be commissioned; • Commissions a Technical Specialist to develop the draft specification revision; • Reviews draft specification revision and provides input to TS; • Requests WG review(s) of the draft specification revision; • Arranges for peer review and manufacturer review of the draft specification revision;

	• Takes the decision for final approval of the revised specification; and • Publishes the final revised specification to the IMD-PQS website and circulates it to the relevant members of staff of WHO, UNICEF and manufacturers.

6. HIGH LEVEL FLOW CHART SUMMARY

Figure 1 – Performance specification revision procedure



7. PROCESS STEPS

7.1. Introduction

7.1.1. A performance specification 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.

7.1.2. 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.

7.1.3. Figure 1 provides an overview of the various stages in a revision of a performance specification, which are described in more detail in this SOP. The responsibility section includes a description of the person or group responsible for the task.

7.1.4. The IMD-PQS Secretariat reviews and signs off a performance specification and all its subsequent revisions. All revisions must be accurately recorded in the revision history form (found at the end of this document).

7.2. Identify the need for revision (WG)

7.2.1. The WG advises the Secretariat of any amendments that may be required to performance specifications for any of the following reasons:

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

7.2.2. No revisions

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

7.2.3. Minor revisions

a) The WG may identify revisions which do not significantly affect the technical content of the performance specification, and which do not affect the prequalification status of existing products listed on the IMD-PQS database/catalogue. Such revisions may include, but are not limited to, updated references to published (relevant) international standards and typographical corrections.

b) A member of the Secretariat checks and sings off the amended performance specification which doesn't require a formal review. Typographical corrections are generally carried out by the Secretariat.

c) The TS commissioned to carry out the work generally makes the technical corrections. As a matter of courtesy, existing Prequalification Holders are provided with a copy of the amended document when it is published.

d) **IMD/TP/02a - Standard letter A** may be used for this purpose.

7.2.4. Major revisions

a) The WG may identify revisions that significantly affect the technical content of the performance specification. In this situation, the WG makes a recommendation to the Secretariat that it commissions a TS to prepare a revised specification which is reviewed *as though it were a new document*.

b) The proposed changes are evaluated to establish how they will impact existing prequalified products.

c) As part of this process, the Secretariat informs the manufacturers of **all** the prequalified products that are affected by the proposed changes of the intended amendments and invited to comment on the intended amendments at the draft stage.

d) **IMD/TP/02b - Standard letter B** may be used for this purpose.

e) The period for submitting comments is generally not less than two months.

f) Existing manufacturers of prequalified products are accorded a grace period before they must conform to the new specification. The grace period is for a minimum of one year after publication of the revised document[4].

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

7.3. Peer review of major revisions (Secretariat, WG, Manufacturers, TS)

7.3.1. The Secretariat shares the draft performance specification with the WG for review.

7.3.2. The draft specification goes through at least one round of WG review, with the initial reviewing lasting approximately four to six weeks.

7.3.3. The number of reviews is determined by the complexity of the performance specification and decided at the discretion of the Secretariat.

7.3.4. Subsequent rounds of WG review are aligned (at the latest) with the WG quarterly meetings.

7.3.5. The Secretariat determines when the draft specification is ready for manufacturer review.

7.3.6. The Secretariat sends the draft performance specification to manufacturers for review, via email and by posting to the IMD-PQS website. Manufacturers are given one month to respond with comments.

7.3.7. The WG Lead/s and/or TS collate all manufacturers' comments and prepare a revised draft with recommendations for the WG and Secretariat to review. WG and Secretariat comments are incorporated into a revised draft. The Secretariat determines if another round of manufacturer review is required.

7.3.8. Depending on the complexity and any issues that may arise from the manufacturer review, there may need to be multiple manufacturer review cycles.

7.4. Documenting revisions (TS, WG and/or Secretariat)

7.4.1. All changes are clearly identified in the 'revisions' section of the specification that:

- Gives the date of the amendment;
- Identifies the amendment; and
- Briefly describes the reason for the amendment.

Figure 2 provides an example.

Figure 2 – Example of a product specification revision record

Revision history			
Date	**Change summary**	**Reason for change**	**Approved**
01.01.05	• 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 requirements • ……etc.	ABC

7.5. Time allowance

All performance specification changes identified by the Secretariat are implemented, reviewed as necessary and approved within two months of the Secretariat meeting.

7.6. Approval (Secretariat)

The fully reviewed and corrected performance specifications are submitted to the Secretariat for formal approval. Final decision for approval rests with the Secretariat.

7.7. Publication (Secretariat)

7.7.1. Immediately after approval of the amended document, the Secretariat publishes it on the IMD-PQS website, in electronic (.pdf) format.

7.7.2. In addition, notification of publication is posted on the TechNet-21 website.

7.7.3. The Secretariate informs all IMD-PQS manufacturers and related innovators of the publication by email. The previous edition is archived.

7.8. Distribution (Secretariat)

This SOP is to be distributed to the following individuals and groups:

- IMD-PQS Secretariat,
- IMD-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 performance specification,
- All relevant manufacturers,
- IMD-PQS and TechNet-21 websites.

8. RECORDS

8.1. The Secretariat saves product specifications in WHO ePQS-Box / Sharepoint: Folder "Specs, VPs & PQS Guides".

8.2. The Secretariat saves verification Protocols in WHO ePQS-Box / Sharepoint: Folder "Specs, VPs & PQS Guides".

8.3. IMD Product Catalogue - WHO IMD Prequalification Website: "WHO Catalogue of Prequalified Immunization Devices".

9. REVISION HISTORY

Version	Reason for revision	Author	Drafted
01	1) ATT team was changed to QSS team due to the reorganization in the IVB Department. 2) The code VML was changed to IMD-PQS in the SOP No.s for easy reference. 3) 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	06/01/2007
01	1) Hyperlink to each IMD-PQS category added in the 'Purpose' clause. 2) Footnotes defining the IMD-PQS Working Group and the IMD-PQS Secretariat added in *Responsibilities*. 3) IMD-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).	Drafted by P. Mallins Approved by I. Gobina	27/01/2017

	4) 'Responsibilities' clause revised to separate out specific responsibilities of key actors and to remove process elements. 5) Clause 7.8 'Distribution' edited to include complete group of stakeholders. 6) 'Terms & definitions' moved to annex, revised, definitions updated in line with WG reviews of IMD-PQS glossary Feb 2018. 7) In Clause 7 'Procedure' an introduction has been added (sub-clause 7.1). 8) Sub-clauses of 7 'Annual technical review' and the 'Extraordinary technical review' 9) removed as standalone sections.		
02	1) Updating to new RPQ format 2) New department, unit and team names 3) Changed supervisors name from Group Lead to Team Lead 4) Assignment of IMD as code for the product stream on PQ of immunization devices and equipment and used for numbering of QMS documents 5) Inclusion of KPIs and their targets where applicable 6) Transforming some annexes into templates related to the SOP 7) PQS updated to IMD-PQS (Immunization Devices Performance, Quality and Safety)	Approved by I. Gobina	01/2024