

 World Health Organization	REGULATION AND PREQUALIFICATION DEPARTMENT	
	VACCINES ASSESSMENT TEAM	
STANDARD OPERATION PROCEDURE		
REVIEWING AND REVISING AN IMD-PQS PRODUCT VERIFICATION PROTOCOL		
Doc No: IMD/SOP/05	Version No: 2	Revise before: 15 Jun 2027
Effective date: 15 Jun 2024	Replaces: 01.06	Page 1 of 11
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1. OBJECTIVE

- 1.1. This SOP provides the procedures for the [IMD-PQS Secretariat](#) (Secretariat), the [IMD-PQS Working Group](#) (WG) and by all *Technical Specialists* (TS) commissioned by the [Secretariat](#) to follow when reviewing and revising product [verification protocols](#).
- 1.2. 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.

2. SCOPE

- 2.1. This SOP is applicable to all [product verification protocols](#) prepared by the [IMD-PQS Secretariat](#), with the exception of syringes.
- 2.2. All immunization products in the following categories require an IMD-PQS [product verification protocol](#), 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 IMD-PQS system: Guidelines 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:	<ul style="list-style-type: none"> • IMD/TP/05a: Standard letter A -Notification of minor changes to verification protocol • IMD/TP/05b: Standard letter B -Notification of major changes to verification protocol

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Other QMS documents:	<ul style="list-style-type: none"> • IMD/SOP/01: How to review and revise an IMD-PQS product performance specification. • IMD/SOP/02: How to withdraw an IMD-PQS product performance specification. • IMD/SOP/03: How to withdraw an IMD-PQS product performance specification. • IMD/SOP/04: How to develop and publish an IMD-PQS product verification protocol. • IMD/SOP/06: How to withdraw an IMD-PQS product verification protocol.
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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 Working Group is comprised of the WHO (IMD-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

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	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	<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 their own name, regardless of whether these operations are carried out by that person themselves or on their behalf by a third party.</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>
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	An IMD-PQS product verification protocol describes in detail how the performance of an immunization-related products will be tested or otherwise evaluated as part of the IMD-PQS product prequalification procedure. See SOP No. IMD/SOP/04: <i>How to develop and publish an IMD-PQS product verification protocol</i> .

5. RESPONSIBILITIES

A Technical Specialist (TS)	<ul style="list-style-type: none"> Drafts the verification protocol in consultation with the WG; and
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	<ul style="list-style-type: none"> Revises the draft verification protocol based on the WG, peer and manufacturer reviews and submits a final draft to the Secretariat.
IMD-PQS Working Group (WG)	<ul style="list-style-type: none"> Documents the need for a new verification protocol; 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 to inform prioritisation of protocol development; and Reviews draft verification protocol and provides input to TS.
IMD-PQS Secretariat	<ul style="list-style-type: none"> 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 IMD-PQS website and circulates it to the relevant members of staff of WHO, UNICEF and manufacturers.



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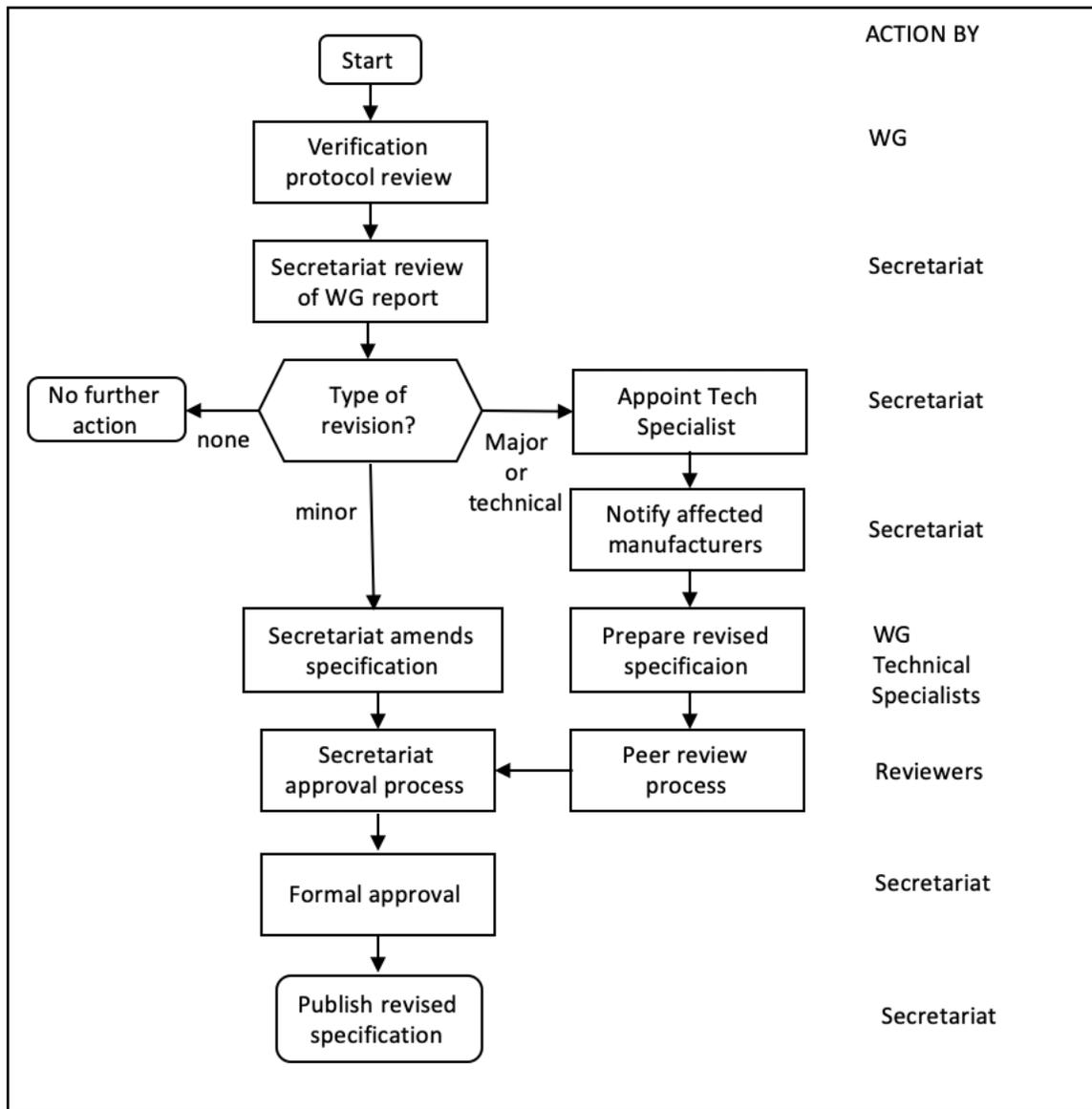
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6. HIGH LEVEL FLOW CHART SUMMARY

Figure 1 – Verification protocol revision procedure



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7. PROCESS STEPS

7.1. Introduction

- 7.1.1. A [verification protocol](#) is 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 cites any relevant ISO or other published normative references that are directly applicable to the specified [product](#) or to its component parts.
- 7.1.3. Finally, it complies fully with WHO immunization policies and guidelines current at the time of publication.
- 7.1.4. Figures 1 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.
- 7.1.5. Each of the task headings below includes (in brackets) a description of the person or group responsible for the task.
- 7.1.6. the [IMD-PQS Secretariat](#) reviews and signs off a [verification protocol](#) and all its subsequent revisions. All revisions are accurately recorded in the protocol's *revision history form*.

7.2. Identify the need for revision (WG)

- 7.2.1. The [WG](#) advises the [Secretariat](#) of any [product verification protocols](#) which may require amendment for any of the following reasons:
 - 7.2.1.1. Feedback from country EPI programmes.
 - 7.2.1.2. WHO and UNICEF immunization programme changes which may affect the status or content of a protocol.
 - 7.2.1.3. Introduction of new or revised international standards that are relevant to EPI;
 - 7.2.1.4. Other changes in programme requirements, such as the introduction of new vaccines;
 - 7.2.1.5. Comments received from testing laboratories, technical specialists and [manufacturers](#) which identify technical shortcomings in the protocol;
 - 7.2.1.6. Feedback reports from field monitoring activities; or
 - 7.2.1.7. Technical or other developments which may render a protocol obsolete.

7.2.2. No revisions

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7.2.2.1. If the [WG](#) advises that no revisions are necessary, this will be noted in its report to the [IMD-PQS Secretariat](#). No further action is required.

7.2.3. Minor revisions

7.2.3.1. The [WG](#) identifies 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 IMD-PQS database/catalogue.

7.2.3.2. Such revisions may include, but are not limited to, updated references to published (relevant) international standards and typographical corrections.

7.2.3.3. The amended protocol does not require formal review, but it is checked and signed off by a member of the [Secretariat](#).

7.2.3.4. The [Secretariat](#) generally carries out typographical corrections .

7.2.3.5. The TS, commissioned to carry out the work, generally makes technical corrections .

7.2.3.6. As a matter of courtesy, the [Secretariate](#) provides a copy of the amended document when it is published to existing prequalified [manufacturers](#) .

7.2.3.7. Standard letter A (provided in IMD/TP/05a) may be used for this purpose.

7.2.4. Major revisions

7.2.4.1. The [WG](#) identifies revisions that significantly affect the technical content of the protocol.

7.2.4.2. In this situation, the [WG](#) makes a recommendation to the [Secretariat](#) that it commissions a TS to prepare a revised protocol which is reviewed as *though it were a new document*.

7.2.4.3. The [Secretariate](#) evaluates the proposed changes to establish how they will impact existing prequalified [products](#).

7.2.4.4. As part of this process, the [Secretariate](#) informs the [manufacturers](#) of **all** the prequalified [products](#) that will be affected by the proposed changes/intended amendments and invites comments on them at the draft stage.

7.2.4.5. Standard letter B (provided in IMD/TP/05b) may be used for this purpose.

7.2.4.6. The period for submitting comments is generally two months.

7.2.4.7. Existing [manufacturers](#) of prequalified [products](#) are accorded a grace period before they must conform to the new protocol.

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7.2.4.8. The grace period is a minimum of one year after publication of the revised document. This may be subject to negotiation with the affected [manufacturers](#). The timeframe must be reasonable and fair.

7.2.4.9. 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

7.3.1. The [Secretariat](#) shares the draft [verification protocol](#) with the [WG](#) for review.

7.3.2. The draft protocol goes through at least one round of [WG](#) review.

7.3.3. The number of reviews is determined by the complexity of the protocol and decided at the discretion of the [Secretariat](#).

7.3.4. The [Secretariat](#) determines when the draft protocol is ready for review by [manufacturers](#).

7.3.5. The [Secretariat](#) sends the draft protocol to [manufacturers](#) for review, via email and by posting it to the IMD-PQS website.

7.3.6. [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.

7.3.8. [WG](#) and [Secretariat](#) comments are incorporated into a revised draft.

7.3.9. The [Secretariat](#) determines if another round of review by [manufacturers](#) is required.

7.3.10. Depending on the complexity and issues that may arise from the review by [manufacturers](#), there may need to be multiple review cycles by [manufacturers](#).

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

7.4.1. The TS, WG and/or Secretariat clearly identify all changes in the 'revisions' section of the protocol.

7.4.2. The Secretariat is responsible for approving all revisions.

7.4.3. The revision section of the protocol also:

7.4.3.1. Gives the date of the amendment;

7.4.3.2. Identifies the amendment; and

7.4.3.3. Briefly describes the reason for the amendment.

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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

7.5. Time allowance

7.5.1. All [product verification protocol](#) changes identified by the [Secretariat](#) are implemented, reviewed as necessary and approved within two months of the [Secretariat](#) meeting.

7.6. Approval (Secretariat)

7.6.1. The fully reviewed and corrected protocol is 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, the secretariate posts a notification of publication on the TechNet-21 website.

7.7.3. The Secretariat informs all IMD-PQS [manufacturers](#) and related innovators of the publication by email.

7.7.4. The Secretariat archives the previous edition.

7.8. DISTRIBUTION (Secretariat)

This SOP is distributed to the following individuals and groups:



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- [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 [verification protocol](#),
- 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 - 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	<ol style="list-style-type: none"> 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	<ol style="list-style-type: none"> 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 Clause5. 3. IMD-PQS system structure simplified, removing FMWG, Steering Group. IVB/QSS is also renamed EMP/PQT. Revisions to this 	Drafted by P. Mallins Approved by I. Gobina	27/01/2017



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	<p>SOP reflect these changes (text and figures).</p> <ol style="list-style-type: none"> 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 5.1). 8. Sub-clauses of 7 'Annual technical review' and the 'Extraordinary technical review' removed as standalone sections. 9. Clause 7.3 'Peer review of major revisions' expanded including timelines. 		
02	<ol style="list-style-type: none"> 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