World Health Organization	REGULATION AND PREQUALIFICATION DEPARTMENT
	VACCINES ASSESSMENT TEAM

STANDARD OPERATION PROCEDURE		
WITHDRAWING AN IMD-PQS PRODUCT VERIFICATION PROTOCOL		
Doc No: IMD/SOP/06	Version No: 2	Revise before: 15 Jun 2027
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Approved by:	TL-VAX, date: 10 Jun 2024	UH-PQT, date: 13 Jun 2024
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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 *Technical Specialists* (TS) commissioned by the Secretariat to follow when withdrawing a product verification protocol.

1.2. It is essential that product verification protocols are regularly reviewed. As soon as it becomes evident that a product verification protocol is no longer required it should be formally withdrawn.

2. SCOPE

2.1. This SOP is applicable to all product verification protocols prepared buy 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:	IMD/TP/06a: Standard letter A - Notification verification protocol withdrawal
Other QMS documents:	• IMD/SOP/01: Development and publishing an IMD-PQS product performance specification.

	• IMD/SOP/02: Reviewing and revising an IMD-PQS product performance specification. • IMD/SOP/03: Withdrawing a IMD-PQS product performance specification. • IMD/SOP/04: Development and publishing an IMD-PQS product verification protocol. • IMD/SOP/05: Reviewing and revising an IMD-PQS product verification protocol. • IMD/SOP/11: Removing a prequalified product from the IMD-PQS database.

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 IMPQS WG 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

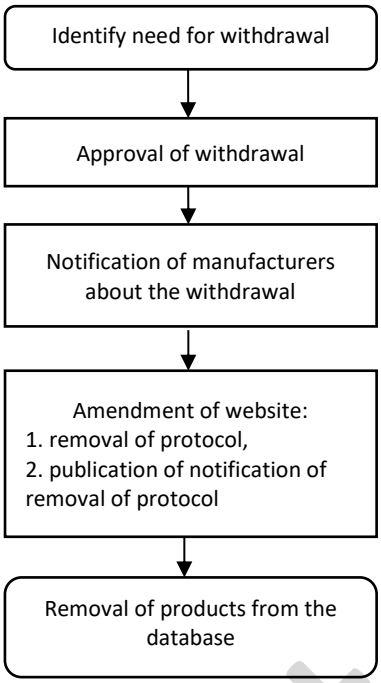
	offer a wide range of programmatic and technical expertise that supports the development, introduction and advancement of technologies that will meet countries' EPI needs for high-quality cold chain equipment and devices
Manufacturer	In the context of this SOP, the word manufacturer includes both legal 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.
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	An IMD-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 IMD-PQS product prequalification procedure. See SOP No. IMD/SOP/04: *How to develop and publish an IMD-PQS product verification protocol.*

5. RESPONSIBILITIES

A Technical Specialist (TS)	• Reviews the need for withdrawal and makes recommendations to the Secretariat.

IMD-PQS Working Group (WG)	• Documents the need for a new verification protocol; • Identifies outdated verification protocols that should be withdrawn and informs the Secretariat; • Sends the proposal to the IMD-PQS Secretariat (this may take place at any time); and • Where requested by the Secretariat, solicits information and input from country EPI to inform prioritisation of protocol withdrawal.
IMD-PQS Secretariat	• Examines the proposal and, if satisfied of the need, directs that the withdrawal of the verification protocol be commissioned; • Commissions a Technical Specialist to review the protocol that is commissioned for withdrawal; • Requests WG review(s) of the protocol commissioned for withdrawal; • Arranges for peer review of the specification commissioned for withdrawal, and may also arrange for manufacturer review (at the discretion of the Secretariat); • Takes the ultimate decision to approve the withdrawal of the protocol; and • Publishes the withdrawal of the protocol 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



7. PROCES STEPS

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

7.2. Identify the need for withdrawal (WG)

7.2.1. The WG advises the Secretariat of any verification protocol which may need to be withdrawn 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;

7.2.1.3. Comments received from testing laboratories, technical specialists and manufacturers identifying fundamental technical shortcomings in the protocol;

7.2.1.4. Feedback reports from field monitoring activities highlighting fundamental protocol-related problems; or

7.2.1.5. Technical or other developments which may render a protocol obsolete.

7.2.1.6. The WG sends its withdrawal proposals to the Secretariat for formal approval. This can happen at any time but will usually occur at the next IMD-PQS WG quarterly meeting.

7.3. Approval for withdrawal (Secretariat)

7.3.1. The Secretariat takes the final decision on withdrawal of a verification protocol.

7.4. Publication (Secretariat)

7.4.1. As soon as the withdrawal has been approved, the Secretariat notifies the affected manufacturers of the intended action.

7.4.2. Withdrawal notification and the associated timelines for manufacturer conformity must be reasonable and may vary on a case-by-case basis depending on the reason for withdrawal. Standard letter (IMD/TP/06a) can be used for this purpose.

7.4.3. Subsequently, the Secretariate removes the verification protocol the IMD-PQS website and replaces it with a document describing the reason for the withdrawal.

7.4.4. This action does not take place until at least six months after the affected manufacturers have been notified.

7.4.5. At the same time, the Secretariate posts the notification of withdrawal on the IMD-PQS database/catalogue and TechNet-21 website.

7.4.6. The Secretariate informs by email all IMD-PQS manufacturers affected by the verification protocol withdrawal.

7.4.7. The Secretariate deletes all products covered by the verification protocol from the database. Refer to IMD/SOP/11 *Removing a prequalified product from the IMD-PQS database* for details of this procedure.

7.5. Distribution (Secretariat)

This SOP is 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 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 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 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 Clause 5. 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). 4. 'Responsibilities' clause revised to separate out specific responsibilities of key actors and to remove process elements. 5. Clause 7.5 '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.	Drafted by P. Mallins Approved by I. Gobina	27/01/2017

	7. Sub-clauses of 7 'Annual technical review' and the 'Extraordinary technical review' 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	0/2024