1. OBJECTIVE

1.1. This SOP provides the 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 withdraw performance specifications.

1.2. It is essential that each performance specification is regularly reviewed. As soon as it becomes evident that the product type described in the specification is no longer required to help meet WHO policy objectives, the specification is formally withdrawn.

2. SCOPE

2.1. Applicable to all performance specifications prepared under the IMD-PQS initiative, 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 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/03a: Standard letter A - Notification of specification withdrawal
Other QMS documents:	• MD/SOP/01: Developing and publishing an IMD-PQS product performance specification • IMD/SOP/02: Reviewing and revising 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. • IMD/SOP/11: Removing a pre-qualified 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)	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 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

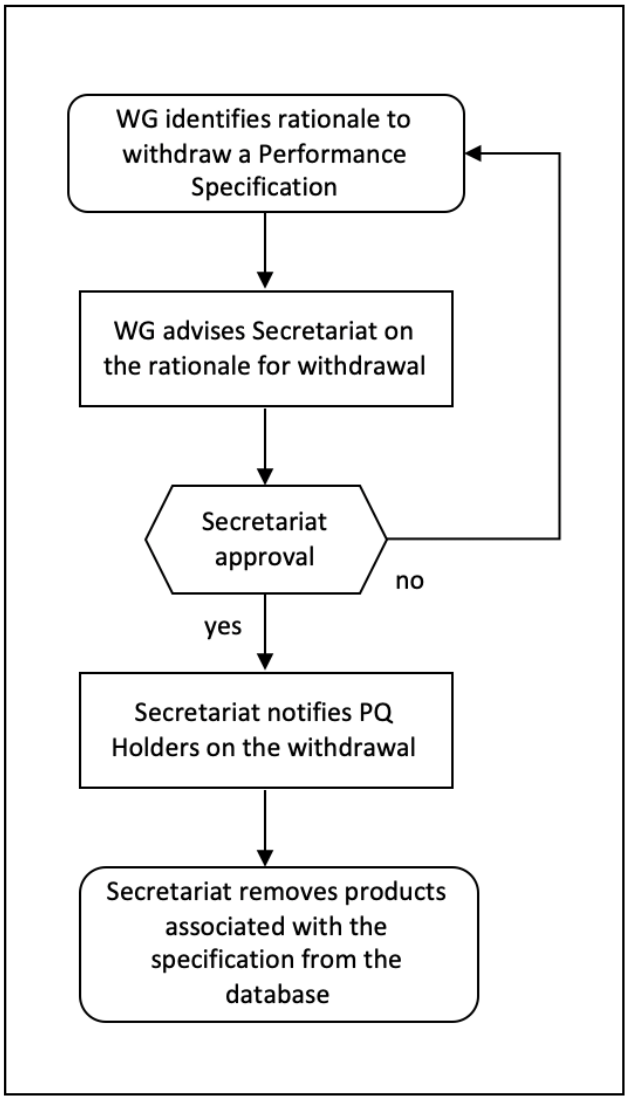
	responsibilities no less onerous than those carried by the legal manufacturer
Universal design	The design of products and services that address the needs of the widest possible audience, irrespective of age or ability. Also called *Inclusive Design* or *Design for all.*
Verification protocol	Describes 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 IMD/SOP/4: *Developing and publishing 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 outdated performance specifications 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 that may inform prioritization of specification withdrawal.
IMD-PQS Secretariat	• Examines the proposal and, if satisfied of the need, directs that the withdrawal of the performance specification be commissioned; • Commissions a Technical Specialist to review the specification that is commissioned for withdrawal; • Requests WG review(s) of the specification 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 specification; and

	• Publishes the withdrawal of the 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



7. PROCESS STEPS

7.1. Identify the need for withdrawal (WG)

7.1.1. The WG advises the Secretariat of any performance specification which may need to be withdrawn for any of the following reasons:

- Feedback from country EPI programmes;
- WHO and UNICEF immunization programme changes;
- Comments received from testing laboratories, technical specialists and manufacturers identifying fundamental technical shortcomings in the specification;
- Feedback reports from field monitoring activities highlighting fundamental specification-related problems; or
- Technical or other developments which may render a performance specification obsolete.

The WG sends its withdrawal proposals to the Secretariat for decision and approval. This can happen at any time but usually occurs at the next IMD-PQS WG quarterly meeting.

7.2. Approval for withdrawal (Secretariat)

7.2.1. The Secretariat takes the final decision on withdrawal of a performance specification.

7.3. Publication (Secretariat)

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

7.3.2. 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.

7.3.3. Standard letter A (IMD/TP/3a) can be used for this purpose.

7.3.4. Subsequently the performance specification is removed from the IMD-PQS website and replaced with a document describing the reason for the withdrawal.

7.3.5. Generally speaking, this action does not take place until at least six months after the affected manufacturers have been notified.

7.3.6. At the same time, notification of withdrawal is posted on the IMD-PQS database/catalogue website and the TechNet-21 website.

7.3.7. The Secretariat informs by email all manufacturers of IMD-PQS prequalified products affected by the performance specification withdrawal.

7.3.8. The Secretariat deletes all products covered by the performance specification from the database.

7.3.9. Refer to IMD/SOP/11 *Removing a prequalified product from the IMD-PQS database* for details of this procedure.

7.4. 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 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
01.06	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	Drafted by O. Afsar Approved by U. Kartoğlu	06/01/2007

	specifications 4. was identified as the QSS Coordinator.		
01.06	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 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). 4. 'Responsibilities' clause revised to separate out specific responsibilities of key actors and to remove process elements. 5. Clause 7.4 '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. Sub-clauses of 7'Annual technical review' and 'Extraordinary technical review' removed as standalone sections. 8. Concrete example of a reason for specification withdrawal added to IMD-TP-3a	Drafted by P. Mallins Approved by I. Gobina	27/01/2017
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	Approved by I. Gobina	01/2024

	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)		