 World Health Organization	REGULATION AND PREQUALIFICATION DEPARTMENT	
	VACCINES ASSESSMENT TEAM	
STANDARD OPERATION PROCEDURE		
Developing and publishing an IMD-PQS product performance specification		
Doc No: IMD/SOP/01	Version No: 2	Revise before: 15 June 2027
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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 for developing and publishing product [performance specifications](#).
- 1.2. 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.

2. SCOPE


- 2.1. This SOP is applicable to all [performance specification](#) 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: *“Prequalification of single-use injection devices under the IMD-PQS system: Guidelines for manufacturers”*. <https://apps.who.int/iris/handle/10665/69096>)

- 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

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Under this SOP:	<ul style="list-style-type: none"> • IMD/TP/01a: Standard format for a performance specification • IMD/TP/01b: Online Resources
Other QMS documents:	<ul style="list-style-type: none"> • IMD/SOP/02: Reviewing and revising 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 Working Group 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



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	<p>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</p>
Manufacturer	<p>In the context of this SOP, the word manufacturer includes both legal manufacturers and resellers.</p>
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	<p>In this document, where the word 'product' is used on its own, it includes device.</p>
Performance Specification	<p>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.</p>
Product innovator	<p>A person, company or organization from a related industry that introduces new methods, ideas or products to the IMD-PQS product development process.</p>



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Production-run product	“Samples” of the product submitted for IMD-PQS prequalification that are commercial-run / production-run products, NOT prototypes or models of products.
QA	Quality Assurance.
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	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/04: Developing and publishing an IMD-PQS product verification protocol.

5. RESPONSIBILITIES

A Technical Specialist (TS)	<ul style="list-style-type: none"> • Completes the proposed design criteria and drafts the performance specification in consultation with the WG; and • Revises the draft performance specifications 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"> • 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.

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IMD-PQS Secretariat	<ul style="list-style-type: none"> • Examines the proposal and, if satisfied of the need, directs that a new performance specification be commissioned; • Commissions a Technical Specialist to develop the draft specification; • Reviews draft specification and provides input to TS; • Requests WG to review(s) of the draft specification; • Arranges for peer review and manufacturer review of the draft specification; • Takes the decision for final approval of the document; and • Publishes the final specification to the IMD-PQS website and circulates it to the relevant members of staff of WHO, UNICEF and manufacturers.
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6. HIGH LEVEL FLOW CHART SUMMARY

Figure1: Developing a performance specification

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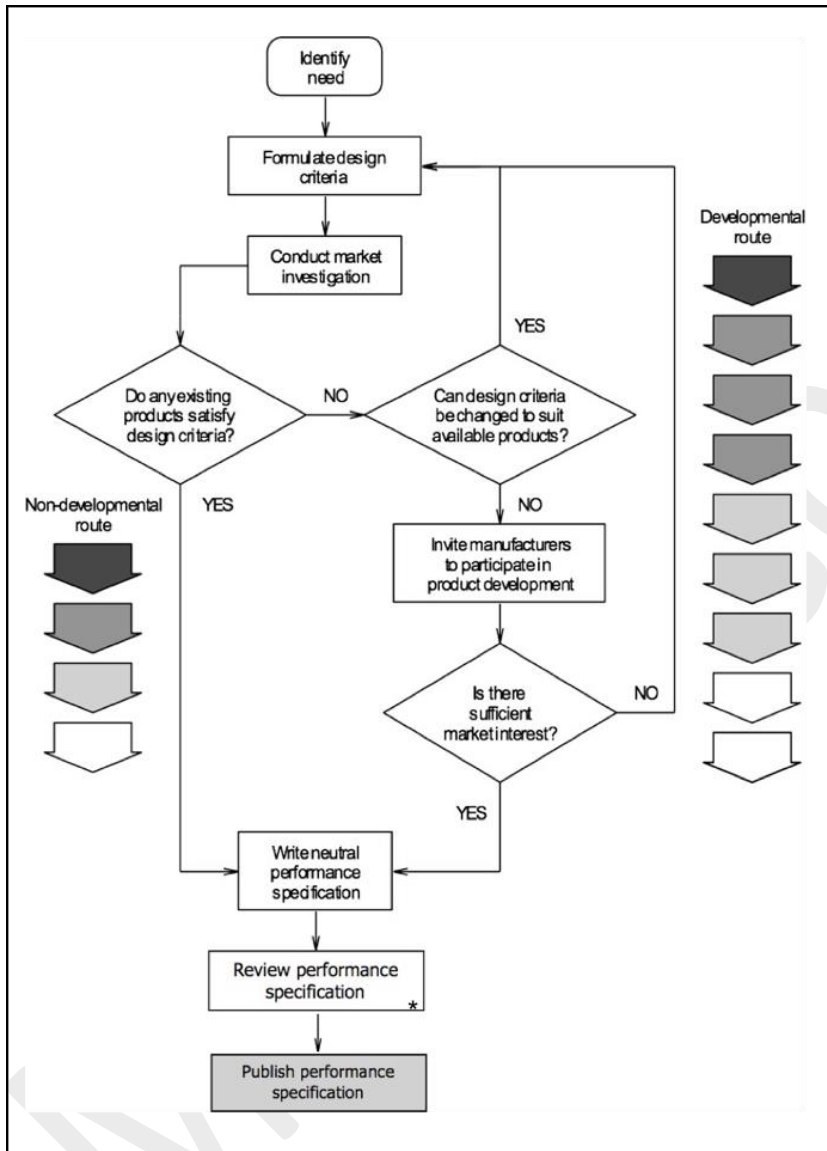
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* In consultation with relevant stakeholders

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](#)

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from a particular [manufacturer](#) (brand) 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 the development of a [performance specification](#), which are described in more detail in the following paragraphs. Each of the task headings below includes (in brackets) 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 are accurately recorded in the specification's *revision history form*.

7.2. Approaches to product prequalification (All responsible staff)

There are two approaches to [product](#) prequalification:

- i) The *non-developmental approach* invites [manufacturers](#) to offer compliant items from their existing [product](#) range;
- ii) The *developmental approach* identifies selected product [manufacturers](#) who are prepared to modify an existing [product](#) or to develop a new one.


7.2.1. The [Secretariat](#), WG and/or TS ensures that the list of [product manufacturers](#) contacted is as inclusive and wide as possible.

7.2.2. As a minimum, this list includes all prequalified [manufacturers](#), developers, inventors etc. known to IMD-PQS in the category.

7.2.3. A [performance specification](#) which targets commercially available [products](#) is likely to attract the widest and most economically competitive range of compliant [devices](#); this *non-developmental approach* must be the first choice.

7.2.4. The *developmental approach* is taken only when market investigation has established that no existing [products](#) can meet the design criteria and that the design criteria themselves cannot be

7.3. Maintain background market surveillance (All responsible staff)

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7.3.1. All staff responsible for preparing and/or reviewing [performance specifications](#) must keep themselves up to date with [product](#) information and technological developments relevant to their own area of expertise.

7.4. Identify need (WG)

- 7.4.1. A [performance specification](#) is developed in response to an identified need.
- 7.4.2. Understanding genuine EPI programme needs is the critical first step.
- 7.4.3. The WG ensures that all relevant stakeholders are consulted and that the relevance and extent of the needs they identify are assessed.
- 7.4.4. Most often these needs arise from the field; e.g. a requirement for low-temperature protection for refrigerators in cold climates, driven by field observation of freeze-sensitive vaccines subjected to temperatures below freezing.
- 7.4.5. In other instances, the need may be driven by broader programme development issues; e.g. the introduction of Hepatitis B vaccine triggers the need for more effective freeze indicator devices.
- 7.4.6. IMD-PQS maintains documented information about the need and/or interest of the country-level EPI for a new [product](#) before beginning work on the [performance specification](#). [Manufacturer](#) promotion is not enough to justify this work.

7.5. Formulate design criteria (WG, TS)

- 7.5.1. After a need has been identified by relevant stakeholders, and assessed together with the WG, formulate a brief description of the proposed design criteria that are required to meet it.
- 7.5.2. This document begins with a statement of the need and also lists desired performance criteria for the proposed [product](#).
- 7.5.3. The document may outline possible approaches to meet the need, but this is not its main purpose; given that the core principle of IMD-PQS [performance specification](#) is to define the 'what' and not the 'how' of new [product](#) needs.
- 7.5.4. Overall, the design criteria document provides a focused brief for the initial market investigation phase, and it is very likely that it will be further changed by this process.

Figure 2 provides an example.


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Figure 2 - Sample design criteria

<p>FREEZE INDICATOR DEVICE</p> <p>Need A device to enable store staff and health workers to see whether vaccines have been exposed to temperatures below 0°C, during storage in a fixed location or during transit.</p> <p>Approach A disposable device that can be stored with vaccines and that – when exposed to temperatures below 0°C – provides a permanent indication of exposure to freezing.</p> <p>Target Performance Criteria</p> <ol style="list-style-type: none"> 1. The purpose of the device is to indicate clearly and permanently that vaccine has been exposed to freezing conditions. 2. In 100% of instances during testing the indicator must be triggered by exposure to a temperature of $-0.4^{\circ}\text{C} \pm 0.1^{\circ}\text{C}$ for a period of 60 minutes ± 5 minutes. 3. In 100% of instances during testing the indicator must NOT be triggered by exposure to a temperature of $+0.4^{\circ}\text{C} \pm 0.1^{\circ}\text{C}$ for a period of 60 minutes ± 5 minutes. 4. The device must not require activation by the user. 5. If the device requires a power source, this must be permanently embedded and the device must have a visible ‘active battery’ indicator. 6. The device must have an operational life (including shelf life) of at least three years, starting from the time of delivery to the client. 7. At all times, the indicator must clearly demonstrate one or other of two bi-polar states: <ul style="list-style-type: none"> • Freezing has NOT occurred. • Freezing HAS occurred. No transitional phase is acceptable. 8. The device will be stored at ambient conditions before it is deployed. During storage, it must remain fully functional at any temperature between $+4^{\circ}\text{C}$ and $+43^{\circ}\text{C}$ and at any relative humidity (RH) between 10% and 100%. 9. When the device is deployed it may encounter temperatures in the



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range of - 20°C to +43°C.


10. Both indicator states must be legible to normally sighted individuals and those suffering from the four most common types of colour blindness: deutanopic, protanopic, protanomalous and deuteranomalous.
11. Both indicator states must remain unaffected by the temperature or humidity of the environment in which the device is read.
12. The device must be unaffected by vibration of the type caused by a road vehicle traveling on rough roads.
13. The device must not be damaged by dropping onto a hard surface.
14. The dimensions of the device must not exceed 75 x 75 x 25mm.
15. The delivered price of the device must be less than US\$ 2.50 per unit.

7.6. Conduct a market investigation (TS, in consultation with WG and others)

7.6.1. The purpose of a market investigation (also called a '[product](#) landscape analysis') is to establish whether potentially suitable [products](#) already exist. If they DO exist, then the non-developmental route can be followed. If they DO NOT exist, then either the design criteria will have to be changed or the developmental route will have to be followed. In some instances, [product innovators](#) may be involved initially in the developmental route.

7.6.2. A typical market investigation involves up to six steps:

- (1) Summarise market surveillance: Review what you already know. Provided you have a good general knowledge of the field, you should be able to hypothesise whether or not the design criteria are likely to be met by a commercially available [product](#).
- (2) Identify sources: Find out which [product manufacturers](#) are able to offer suitable [products](#). If none are available, identify [manufacturers](#) and/or related [product](#) innovators who are best placed to develop a [product](#) that meets the design criteria.
- (3) Survey [manufacturers](#): Contact potential [product manufacturers](#) and obtain the following information:
 - [Product](#) data sheets, [product](#) test data and quality management registration details (e.g. ISO 9001);
 - Details of manufacturing capacity and, if required, details of the company's current customer base for reference-checking purposes.

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- (4) Check references: Reference checking is a lengthy process – in most cases this exercise can be left until the prequalification stage. However, references should be checked in the following circumstances:

- Where the technology involved is novel and few [manufacturers](#) are in a position to supply the [product](#);
- Where [manufacturers](#) are being invited to modify an existing product to meet the agreed design criteria;
- Where [manufacturers](#) are being asked to develop an entirely new [product](#).

A maximum period of one month should be allowed for this process.

- (5) In each of these three cases outlined in point 4) above, it is essential to try to establish whether potential [manufacturers](#) have the relevant capabilities with regards to:

- Financial stability;
- Research and development facilities;
- Product quality;
- Product performance and reliability;
- Reliable delivery;
- Production capacity;
- Satisfactory after sales service.

In addition to individual references, consumer organizations and user groups are sometimes able to provide this information. These criteria are not used to inhibit potential innovative smaller suppliers. [Manufacturers](#) are judged on a case-by-case basis.

- (6) *Document the results:* Every market investigation must be adequately documented. Good documentation provides an audit trail and a resource for future researchers. Prepare a table summarising the characteristics of each [product](#) relative to the principal design criteria (Figure 3 provides an example). File the [manufacturers'](#) data and other paperwork on WHO ePQS (Box).

Figure 3 – Example of a market investigation summary table

FREEZE INDICATOR DEVICE						
Item	Product reference	A	B	C	D	E
01	Technology	BV	LQ	LQ		
02	Triggered @-0.4°C?	yes	yes	-0.5°C		



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03	NOT triggered @+0.4°C?	yes	yes	yes
04	User activation required?	no	no	no
05	Embedded power source?	no	yes	yes
06	Active battery indicator?	n/a	yes	no
07	Shelf life (years)	3 yrs	3 yrs	2 yrs
08	Bi-polar state?	yes	yes	yes
09	Storage temp (max °C)	?	?	35°C
10	Storage RH (max %)	?	?	90%
11	Legibility (normal sight)	good	good	fair
12	Legibility (colour blind)	good	good	fair
13	Resistance to vibration?	good	good	good
14	Impact resistance?	good	good	poor
15	Size (H x W x T)	60x40x10	50x30x10	70x40x12
16	Unit price (US \$)	2.38	2.50	3.00

Key:
Technologies: BV = burst vial; LQ = liquid crystal


7.7. Establish whether existing products meet the design criteria (TS in consultation with WG)

7.7.1. If there are a reasonable number of suitable products, follow the non-developmental route. If no suitable products are available, take the following steps:

- a) Consider whether the design criteria can be altered to suit products that are commercially available.
- b) If the criteria cannot be changed, ask selected manufacturers if they can modify an existing product to achieve the desired performance.
- c) Only if there is no alternative should product manufacturers and/or related product innovators be invited to develop an entirely new product line (and once a specification has been published).

7.8. Write a performance specification (TS)

7.8.1. When the IMD-PQS Secretariat has decided to commission a new performance specification the Secretariat then identifies a TS to write the performance specification

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[specification](#) document. The person or organization selected to be the TS must be a technical expert in the relevant field.

7.8.2. *Normative references*: Identify relevant existing normative references. ISO standards are used wherever possible. If no suitable ISO standard exists then regional and national standards are acceptable. However, every effort must be made to avoid a regional or national bias in the specification. This can be avoided by referring to similar standards drawn from different parts of the world.

7.8.3. *Performance specifications based on a single normative reference*: In a few cases there may be a single standard which covers all aspects of an entire product category. Single use medical devices are a case in point – for example ISO/DIS/7886-3 has been drafted to cover any auto-disable syringe intended for fixed dose immunization. In such a case, the [performance specification](#) need only describe a specific instance of the type, e.g. ‘0.5 ml AD syringes with integrated needles to ISO/DIS/7886-3, supplied in blister strips’.

7.8.4. *Specification format*: Use **IMD/TP/01a – Standard format for a performance specification** as a starting format for writing a [performance specification](#). Key terms used in **IMD/TP/01** are defined in **IMD/TP/01b – Online resources**. Not all the sections outlined in the template will be required for every [specification](#), and in other cases added “requirements” will need to be included (e.g. E003 appliance product specifications include numerous other requirements like “Electromagnetic compatibility” for devices with electronics). Specifications must be verifiable.


7.8.5. Avoid wording that is ambiguous or might allow for discretion (e.g. avoid “should” if the [product](#) “must” meet a requirement). Aspirational attributes should be clearly stated as such (e.g. a 10-year target life is the goal of this [product](#), however no test presently exists to verify this product life).

7.9. Review process (Secretariat, WG, Manufacturers, TS)

7.9.1. The Secretariat shares the draft [specification](#) with the WG for review.

7.9.2. The draft [performance specification](#) goes through at least one round of WG review, with the initial reviewing lasting approximately four to six weeks.

7.9.3. The number of reviews is determined by the complexity of the [performance specification](#) and decided at the discretion of the [Secretariat](#). Subsequent rounds of WG review align (at the latest) with the WG quarterly meetings.

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7.9.4. The [Secretariat](#) determines when the draft specification is ready for [manufacturer](#) review.

7.9.5. 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.

7.9.6. 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.

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

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

7.10.1. 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 4 provides an example.

Figure 4 – Example of a product specification protocol revision record

Revision history			
Date	Change summary	Reason for change	Approved
01.01.05	<ul style="list-style-type: none"> • Clause 6: Stable running test at -5°C added. •etc. 	<ul style="list-style-type: none"> • To test performance of freeze-protection system. •etc. 	ABC

7.11. Approval (Secretariat)

The secretariat approves the fully reviewed and corrected [performance specification](#). The decision on final approval rests solely with the [Secretariat](#).

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7.12. Publication (Secretariat)

Immediately after approval of the amended document, the [Secretariat](#) publishes it on the IMD-PQS website, in electronic (.pdf) format. In addition, notification of publication is posted on the TechNet-21 website. The [Secretariat](#) informs all IMD-PQS [manufacturers](#) and related [innovators](#) of the publication by email. The previous edition is archived.


7.13. 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 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".

 World Health Organization	REGULATION AND PREQUALIFICATION DEPARTMENT	
	VACCINES ASSESSMENT TEAM	
STANDARD OPERATION PROCEDURE		
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9. REVISION HISTORY

Version	Reason for revision	Author	Drafted
	<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 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. 	<p>Drafted by O. Afsar</p> <p>Approved by U. Kartoğlu</p>	06/01/2007
01	<ol style="list-style-type: none"> 4) Hyperlink to each IMD-PQS category added in the 'Purpose' clause. 5) Footnotes defining the IMD-PQS Working Group and the IMD-PQS Secretariat added in Clause 5 Responsibilities. 6) 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). 7) 'Responsibilities' clause revised to separate out specific responsibilities of key actors and to remove process elements. 8) Clause 7.13 'Distribution' edited to include complete group of stakeholders. 9) 'Terms & definitions' moved to annex, revised, definitions updated in line with WG reviews of IMD-PQS glossary Feb 2018. 10) Clause 7.10 'Documenting revisions' added. 11) Annex 1a, sub-clause 4.9 'Servicing provision' added. 12) Annex 1b 'Online resources' added. 	<p>Drafted by P. Mallins</p> <p>Approved by I. Gobina</p>	27/01/2017
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 	<p>Approved by I. Gobina</p>	01/2024



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	<ul style="list-style-type: none"> 4) Assignment of IMD as code for the product stream on PQ of immunization devices and equipment 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) 		
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